GLOBAL TASK FORCE ON CHOLERA CONTROL

Preventative Campaign: Oral Cholera Vaccine Supply Allocation Framework

Guidance Document

2024

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Acknowledgements

Acknowledgement is given to the members of the Preventative Campaign OCV Supply Allocation Framework sub-working group of the Global Taskforce on Cholera Control (GTFCC), experts and partners who have participated in the development of this guidance document.

Acronyms

AIG	Allocation Implementation Group	**Gavi**	Global Alliance for Vaccine and Immunisation
GTFCC	Global Task Force for Cholera Control	**ICG**	International Coordinating Group
IRC	Independent Review Committee	**MYPOA**	Multi-year plan of action
NCP	National Cholera Plan	**OCV**	Oral Cholera Vaccine
PAMIs	Priority Area for multisectoral interventions	**RACI**	Responsible, Accountable, Consulted Informed
SAF	Supply Allocation Framework	**UNICEF PD/SD**	United Nationals International Children's Emergency Fund: Programme Division, Supply Division
WHO	World Health Organisation		

1. Background

The Global Roadmap to End Cholera by 2030 calls for a multisectoral approach for cholera control or elimination targeted to priority areas for multisectoral interventions (PAMIs, sometimes referred to as "hotspots"). The strategy consists of a package of measures to control cholera, consisting of:

- Water, sanitation and hygiene
- Leadership and coordination
- Strengthening healthcare systems
- Surveillance and reporting
- Oral cholera vaccine (OCV)
- Community Engagement

Cholera vaccination is a cholera prevention and control measure that can be implemented in the short to medium term, while complementary interventions focused on expanding sustainable access to other primary prevention measures, including safe water and sanitation, are put in place. In 2013, a global stockpile for OCV doses was created to facilitate access to OCV to help control cholera epidemics. This global stockpile is comprised of an emergency response component that is managed by the International Coordinating Group (ICG) and a non-emergency reserve, which is used to vaccinate preventatively in cholera PAMI areas. Despite the current and forecasted steady increase in the global OCV supply, present demand for OCV remains greater than the available supply resulting in a tightly constrained supply environment. While supply is constrained, a delicate balance must be met between responding to immediate outbreaks and conducting preventative campaigns. Effective coordination across stakeholders will ensure that constrained OCV supply is allocated strategically, ultimately supporting the overarching goal set out in the Global Roadmap to End Cholera by 2030.

After the important first step of apportioning OCV doses for preventative use, the next step is to allocate these apportioned OCV doses for preventative use amongst countries that have been approved for preventative campaign support**. The development of this framework ensures that the global cholera community is prepared and ready to allocate OCV doses for preventive campaigns once OCV supply is apportioned for preventative campaign use.** This guidance document was developed to enable efficiency, and the standardization of criteria and the process to allocate the preventative campaign OCV doses to countries that have been approved for OCV preventative campaign support.

> This Framework is intended to be dynamic to support allocation decisions for preventative campaign OCV doses over the coming years as OCV supply increases and until supply constraints are resolved. Annual reviews and updates will ensure that the Framework remains useful and appropriate.

Since January 2023, Gavi has embedded the OCV preventive campaigns into its portfolio. Countries eligible to be included in the allocation framework described here will have been approved for preventative campaign support by Gavi. The GTFCC is heavily engaged in the process leading up to the Gavi approval, providing comprehensive support through global guidance, tools and technical assistance in the areas of surveillance, the identification of PAMIs, prioritization of PAMIs for OCV, and development and review of the multi-year preventive OCV application (Figure 1).

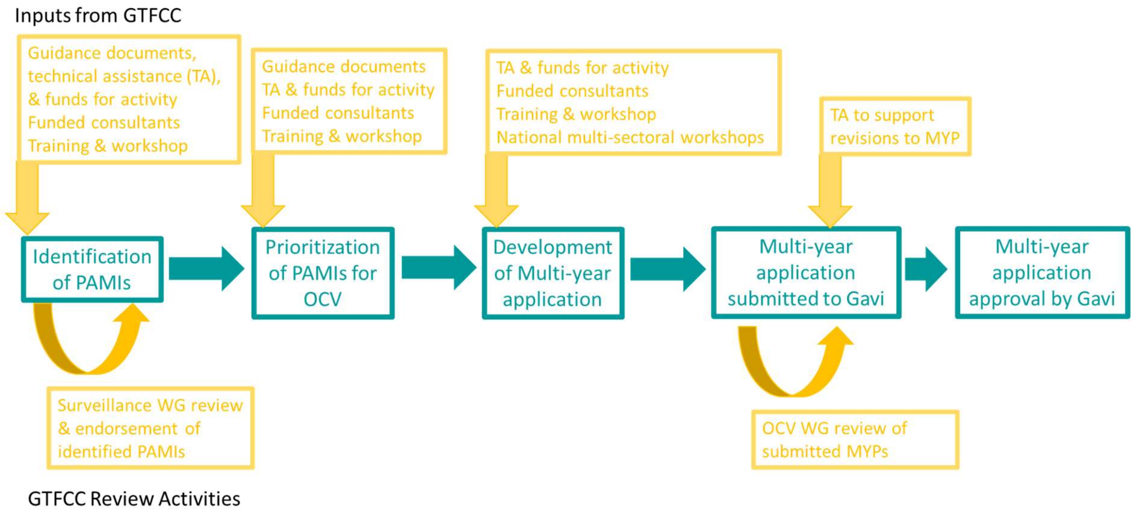


Figure 1: The Global Task Force on Cholera Control engagement in the development of the multiyear plan of action for preventive oral cholera vaccine requests

2. Purpose

The purpose of defining and developing the Preventative Campaign OCV Supply Allocation Framework (SAF) is to ensure transparent and streamlined decision making. The framework will govern the allocation of preventative OCV doses between countries that have been approved for Gavi OCV preventative campaign support. The preventative OCV doses allocated using the SAF are intended to be used in accordance with Gavi programming requirements of its financial support. The framework is to be used when global OCV supply constraints[1] exist and there are multiple countries that have been approved for Gavi OCV preventative campaign support for which the demand for preventative doses is greater than the preventative OCV supply available. The SAF is a pre-agreed mechanism that has been endorsed by the GTFCC Steering Committee.

The SAF consists of:

1. Global Guidance Document
2. Excel based calculation tool

[1] Supply constraints defined as a situation where the supply availability of oral cholera vaccine is limited or insufficient to meet the demand for the vaccine.

The SAF is not intended to address the allocation of OCV doses between reactive and preventative use. As discussed in the background section above, a delicate balance must be met between responding to immediate outbreaks and conducting preventative campaigns. This framework will and can only be used once OCV doses have been apportioned for preventative use.

Similarly, the SAF is not intended to address the allocation of preventative OCV doses within a country. This is assumed to be informed by the country's National Cholera Plan and its multi-year plan of action included in its approved Gavi application for preventative campaign support. The further allocation by a country of preventative OCV doses within its borders is assumed to be informed by the country's own ethical framework that aligns with the spirit of the governing principles stipulated in this global framework.

3. Why a preventative campaign supply allocation framework is needed

In an OCV supply-constrained environment, a SAF is needed for the following reasons:

- **Equity of outcome**: Preventative campaign OCV doses will be distributed according to the needs of each country approved for preventative campaign support in order to achieve more equitable outcomes.
- **Fairness in access:** All countries with planned approved preventative campaigns will have a fair & transparent opportunity to access limited preventative OCV doses based on pre-defined allocation criteria.
- **Efficiency of OCV dose utilization**: OCV doses are limited and must be used as efficiently as possible.
- **Stability & predictability**: A clear allocated mechanism helps maintain stability & predictability in the ecosystem, allowing countries & OCV manufacturers the ability to plan to the maximum extent possible.

4. The process for developing the Framework

As part of the preparedness exercise to ensure a framework is in place and ready to use once OCV supply is apportioned for preventative campaign use, the OCV Working Group prioritized the creation of this framework as part of its 2023 workplan. Members within the GTFCC were invited to be a part of the preventative campaign sub-group, based on his/her expertise & experience in Cholera. The intention was to have representation across the GTFCC partners and from the global, regional and country perspectives. The terms of reference for the sub-group were to discuss & develop guidance on how to allocate preventative OCV doses between countries for preventative campaign use in a situation where demand for preventative OCV doses is greater than available preventative OCV supply. A smaller design team within the sub-group was created to facilitate the process. The preventative campaign SAF sub-group virtual meetings were run as interactive sessions and members were active participants to ideate and discuss. In conjunction with the sub-group discussions, extensive consultations were held with a diverse array of key stakeholders from the global, regional and country level and the 50+ consultations were conducted over the period of May 2023 – October 2024. The consultations also included a session with two global ethicists and their feedback has been incorporated into the final guidance document. These consultations have incorporated a breadth of perspectives and insights, ensuring a comprehensive and inclusive approach to designing the OCV SAF for use in preventative OCV campaigns. The framework development and process have been presented throughout 2023 & 2024 in various forums including the annual GTFCC meetings, the annual OCV Working Group meetings and multi-country OCV training events. The framework development process also leveraged the learnings from past vaccine allocation frameworks, in particular the Malaria and Yellow Fever framework. Following the comprehensive design and consultation process, the framework was put forward for final endorsement by the GTFCC Steering Committee.

5. Components of the Framework

The SAF has three main components:

a) **Governing Principles**: The broad overarching values that guide the SAF and provides a moral compass for its design and use.
b) **Calculation Process and Indicators**: The mathematical formula used to calculate the allocation of preventative OCV doses, based on a set of pre-defined indicators and scoring table.
c) **Governance and Decision-Making Process**: The process to govern the SAF use and roles & responsibilities of key stakeholders.

a) Governing Principles

The purpose of governing principles for the framework is to guide the decision-making process and ensure fairness, efficiency, and effectiveness in the allocation of limited preventative OCV resources. By providing clear guidelines and standards, the governing principles enable cholera decision-makers to make informed choices. The framework's governing principles play a crucial role in promoting equitable resource allocation, optimizing health outcomes, and fostering trust and collaboration among cholera stakeholders involved in the preventative OCV allocation process. **With this role in mind, through its governing principles this framework aims to maximize health impact, promote equity in outcomes, and have a process that is accountable and transparent and is evidence-based in its decision making.** These five governing principles are strengthened by **stakeholder solidarity** to agree to and stand by these principles under the common goal to implement the Global Roadmap to End Cholera by 2030.

Foundational Governing Principles: Maximizing Health Impact & Equity in Outcome

The foundational governing principle of **aiming to maximize health impact** revolves around prioritizing interventions that yield the greatest gains in terms of lives saved and reducing the spread of disruptive cholera outbreaks. Through this principle the framework focuses on the allocation of preventative OCV doses that could have the highest potential to make a significant positive impact on public health in terms of reducing cholera-related morbidity and mortality. In choosing this foundational principle, we recognize the importance of tailoring preventative OCV use to specific contexts and considering the unique circumstances of different cholera endemic regions and populations. We additionally recognize the challenges and limitations of allocating preventative OCV doses based on trying to maximize health impact when each country setting is extremely variable, including diverse surveillance systems and data quality. The preventative OCV allocation framework prioritizes a needs-based approach, ensuring that resources are allocated based on the highest priority needs defined through disease burden indicators and the size of the population at risk. The foundational governing principle of **equity of outcome** aims to address and minimalize inequities in health outcomes by allocating scarce resources (e.g. preventative OCV doses), amongst countries that have been approved for preventative campaign support, using a needs-based approach. This allocation is based on the highest priority needs defined through disease burden indicators and the size of the population at risk.   Independent and neutral decision-making processes guided by public health priorities are integral to this principle. Overall, equity serves as a foundational governing principle to promote equity in health-related outcome, considering various factors and ensuring that resources are allocated appropriately to address the most pressing needs. By using a needs-based approach, the governing principle of equity of outcome is **complementary** to the governing principle of aiming to maximize health impact.

Process-related principles: Accountability, Transparency, Evidence-Based Decision Making

Working within the two foundational governing principles are three process related principles. The first is the governing principle of **accountability** which is rooted in ensuring there is a transparent and responsible decision-making regarding the allocation process and that the allocation is consistently based upon the agreed principles and criteria. The principle emphasizes that the SAF decisions should be based solely on clear and transparent allocation criteria, promoting fairness and objectivity and conversely that countries that are allocated doses are accountable for utilizing preventative OCV doses in accordance with the highest need (as informed by their endorsed PAMI analysis). This principle highlights the importance of ensuring that preventative OCV doses are directed towards those with the greatest need and where maximal public health impact could be attained, particularly amongst communities identified as PAMIs. By establishing an accountability process, this governing principle ensures that SAF decisions are made in a transparent manner, and countries are held accountable for the utilization of scarce resources, ultimately striving for equitable distribution and efficient utilization of available preventative OCV supply.

The governing principle of **transparency** is centered on ensuring clarity and open communication throughout the framework decision-making process. It emphasizes that the framework process to allocate preventative OCV doses should be clearly understood by countries, decision-makers, and relevant cholera stakeholders. Transparency promotes an environment where information flows freely, allowing for active communication and feedback. The principle encourages the sharing of knowledge, best practices, and lessons learned, facilitating collaborative problem-solving and fostering a culture of continuous improvement. The governing principle of transparency serves as a foundation for trust amongst all cholera stakeholders, fostering a transparent and inclusive decision-making process that ultimately leads to more effective and informed actions.

The governing principle of **evidence-based decision-making** is grounded on utilizing the best available data and adhering to global guidance on OCV use to inform the preventative OCV allocation

It is acknowledged that the quality of surveillance data will vary by and within countries and that this may impact the preventative OCV allocation decision-making since disease burden indicators are used to determine the highest priority need. This framework is based on the assumption that countries' cholera surveillance is aligned with the GTFCC surveillance guidance to the best extent possible and are of similar quality, which is recognized as a limitation. As there is not an alternative data source available and fully respecting a countries' sovereignty in its decision-making processes, the framework will rely on the information submitted by countries in its Gavi application for preventative campaigns to summarize the disease burden. Countries engaging in its national cholera control plans will need to analyse and review their surveillance data to identify PAMIs. Preventive OCV campaigns are targeted to PAMIs so determining PAMIs is a critical essential first step. Since the GTFCC is heavily engaged in supporting countries with the identification of PAMIs and development of the preventative OCV application, any concerns about the quality of the available surveillance data and its potential impact on the allocation process will be raised to the Allocation Implementation Group for their awareness and consideration. Furthermore, countries should evaluate their cholera surveillance system, identify gaps, consider using Gavi supported RDTs to improve their surveillance data.

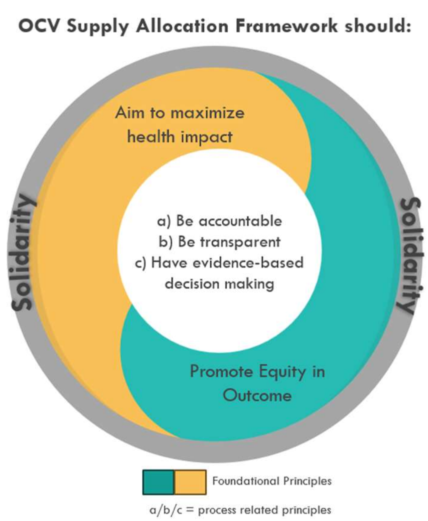
process. This principle emphasizes the importance of using reliable and up-to-date information to determine highest priority needs for preventative OCV allocation. By basing decisions on the best available evidence and incorporating global guidance, this governing principle seeks to promote effective OCV use, enhancing the overall impact and success of cholera control efforts.

Overarching Principle: Solidarity

The practice of solidarity often requires the limitation of one's own immediate interests for the interests of others where more good could be done and where needs are more pressing[2]. The successful implementation of this framework and operationalization of the framework's output (e.g. the allocation of OCV doses) will be dependent on the solidarity amongst all stakeholders to abide by the five governing principles and broader cholera control strategies as described in the Global Cholera Roadmap. The endorsement of this framework and its correct use is in itself a sign of solidarity.

Other Factors Considered

Several additional factors were considered in the development of the SAF, although they were not ultimately selected as governing principles. One such factor is sustainability. While sustainability remains an important aspect to consider in the cholera context, it does not provide specific guidelines for scarce resource allocation decisions. Similarly, contributing to OCV market health, although significant, is not the primary goal of the framework. However, the governing principles that were selected will indirectly contribute to one component of OCV market health by addressing the supply and demand dynamics. The proposed principle of reducing the likelihood of OCV wastage, while crucial, is considered an outcome of the chosen governing principles rather than a standalone principle in itself. The framework prioritizes a needs-based approach, ensuring that OCV resources are allocated based on the highest priority needs. Finally, the proposed principles of generating and strengthening OCV demand are important considerations, they were not chosen as governing principles as they are intricately tied to the selected principles of transparency, evidence-based decision-making, and maximizing health impact. By adhering to these selected governing principles, the framework indirectly addresses OCV demand generation and promotes overall demand.



[2] Framework for the allocation of limited malaria vaccine supply-July 2022

Figure 1: OCV Preventative Campaign Supply Allocation Framework Governing Principles

b) SAF Indicators and Annual Calculation Process

SAF Indicators and Scoring Table

Mapped to the governing principles, a fixed set of four allocation indicators were identified to be used in the annual calculation (Table 1). The indicators are transparent, informative and already collected and therefore will not create any additional data reporting burden on countries since the information can be retrieved from the country-endorsed results of the PAMI identification tool and its' approved Gavi preventative OCV application. In the annual preventative OCV allocation process, each country with an approved Gavi application would be included and scored for each indicator, following a set scoring table (Table 2). The indicator scores are then weighted and added together to provide a country with an overall SAF score, which is then compared to the other countries' SAF scores to determine the % of doses to be allocated to each country.

> It is important to remember the number of approved doses for each country within their Gavi application reflects both their epidemiological data indicated burden and the local knowledge and experience of the country with cholera. In other words, countries are including all areas they deem to be at risk of cholera which they want to prioritize for preventive interventions, including areas where they know surveillance is not reliable. The framework calculation will not alter the number of approved doses, it is an operational tool to help allocate preventative OCV doses that are available each year across countries with approved requests in a supply constrained environment. The intention is that over the time frame of a country's approved multi-year plan of action, it will receive all of its Gavi-approved doses.

Two main indicator categories were identified, with specific indicators subsumed under each category: (1) epidemiologic and (2) population at risk targeted for preventative OCV use. The multi-indicator approach spreads the risk of relying on a single indicator, and using the same indicators as described in the GTFCC PAMI methodology ensures the calculation of the indicators is comparable across countries.

For the epidemiologic category, there are three indicators: (1) incidence (2) mortality and (3) persistence %. The data for these indicators is included in each countries' endorsed PAMI analysis, which is undertaken following GTFCC guidance and is included in its approved Gavi preventative campaign support application. The SAF calculation will compute the median incidence, mortality and persistence data across all the PAMIs included in the country's Gavi approved preventative campaign support application. The individual country medians will then be compared to the overall SAF median incidence, mortality and persistence to determine the country's SAF weighted score. The overall SAF medians are calculated across all PAMIs from all countries included in the allocation calculation.

For the population at risk targeted category, there is one indicator which compares a country's total population targeted for preventative vaccination included in the approved Gavi application to the total population targeted for preventative vaccination by all countries included in the SAF calculation. The scoring of this indicator reflects the relative size of a country's population at risk when compared to the total population at risk among all countries in the SAF calculation.

Category	**SAF Indicator**	**Definition of Indicator**	**Information Source**
A. Epidemiologic indicators[3]	A1. Median incidence rate across all PAMIs	An incidence rate is calculated for each PAMI by: *Dividing:* *- the total number of cholera cases (including suspected cases and cases tested positive) reported in the unit over the analysis period* *by* *- the cumulative person-time (i.e., the sum of population of the geographic unit for each year over the analysis period), then multiplied by 100,000.* A PAMI's incidence rate represents the number of cholera cases reported per 100,000 person-years over the PAMI analysis period.	Country endorsed PAMI analysis included in Gavi application for OCV preventative campaign support
	A2. Median mortality rate across all PAMIs	A mortality rate is calculated for each PAMI by: *Dividing:* *- the total number of deaths attributed to cholera reported in the unit over the analysis period* *by* *- the cumulative person-time (i.e., the sum of the annual population over the period), then multiplied by 100,000.* A PAMI's mortality rate represents the number of deaths attributed to cholera reported per 100,000 person-years in the PAMI over the analysis period.	Country endorsed PAMI analysis included in Gavi application for OCV preventative campaign support
	A3. Median persistence % across all PAMIs	A persistence % is calculated for each PAMI by: *Dividing:* *- the number of weeks with at least one reported suspected cholera case over the analysis period* *by* *- the total number of weeks over the analysis period* A PAMI's persistence % represents the percentage of weeks with at least one reported suspected cholera case in the PAMI over the period of interest	Country endorsed PAMI analysis included in Gavi application for OCV preventative campaign support
B. Total Population at Risk Targeted	B. % targeted population at risk	The total population at risk targeted for preventative vaccination for the full period in Gavi application per country as % of total population at risk targeted for preventative vaccination for all countries included in the SAF calculation	Approved Gavi application for OCV preventative campaign support

[3] As defined in GTFCC Guidance Document: Identification of Priority Areas for Multisectoral Interventions (PAMIs) for cholera control (2023)

Table 1: Preventative Campaign OCV Supply Allocation Framework Indicators

For the SAF indicator scoring, a scoring range from 1-5 is attributed to each of the epidemiologic indicators while for the population at risk indicator, 10 points is distributed across included countries in accordance with the percent of the total SAF population at risk (Table 2). Consistent with the GTFCC Guidance Document for the Identification of Priority Areas for Multisectoral Interventions, the epidemiologic indicators scoring range is based on the 50% (median) and the 80th percentiles of their distributions.

	SAF Pool = All country PAMIs in calculation		Scoring Table*			
	Weighting	Indicator	1	3	5	Logic
Epidemiologic	60%	A1. Incidence Rate – country PAMI median A2. Mortality Rate – country PAMI median A3. Persistence % – country PAMI median	>0 < SAF pool median	=SAF pool median <SAF pool 80% percentile	= or > 80% SAF pool percentile	• High score = have **highest burden relative** to other countries in SAF calculation
Total Population at Risk Targeted	40%	B1. Country population at risk as % of total SAF population at risk	10 points allocated across countries in accordance with % of total population at risk			• High score = larger population at risk requiring vaccination in selected PAMIs

Table 2: Preventative Campaign OCV Supply Allocation Framework Indicators Scoring

Annual Calculation Process: See Annex 2 for illustrative example

On an annual basis, once global OCV supply has apportioned the annual number of doses for preventative OCV use, this number of preventative OCV doses will be communicated to the Allocation Implementation Group (AIG - described in Governance section c below) and triggers the start of the annual SAF calculation as described in the steps below.

Step 1: Data input into SAF excel tool:

The SAF calculation requires two key areas of information: (1) The total annual amount of preventative OCV doses for allocation (2) Country-specific data to calculate the SAF indicator score for each country. For (1), this information is communicated to the AIG by UNICEF SD and triggers the start of the SAF calculation. For (2), this information will come from the country's approved application for preventative campaign support. Once all the data are gathered, they are input directly into the SAF excel tool.

Step 2: SAF Calculation is performed:

2.1 Determine the countries to be included in the SAF calculation: All countries that have received Gavi approval for their application for OCV preventative campaign support are eligible to be included in the SAF calculation. Gavi approval will be communicated to countries through a decision letter from the Gavi Secretariat. Any country that is eligible and included in the SAF calculation will remain in all subsequent annual SAF calculations until all approved OCV doses have been received. In the SAF calculation, the group of countries included are referred to as the "SAF Pool".

2.2 Calculate the epidemiologic medians: Using data from the country's approved Gavi OCV preventative campaign application, calculate the incidence, mortality and persistence % median across all of the country's PAMIs included in the SAF calculation. Note: the SAF excel tool will automatically perform this calculation once data is imported into the tool in step 2.1.

2.3 Calculate the epidemiologic median & 80th percentile for the SAF Pool: From all the countries' PAMIs included in SAF calculation (step 2.1), calculate the median & 80th percentile for the SAF Pool for incidence, mortality and persistence %. The SAF medians and 80th percentile must then be updated in the SAF scoring table for the epidemiologic indicators. Note: the SAF excel tool will automatically perform this calculation once data is imported into the tool in step 2.1.

2.4 Input other key data points for each country in SAF calculation: From the country's approved Gavi OCV preventative campaign support application, enter in the number of PAMIs included in the calculation, the programmatic years included in the calculation, the total preventative OCV doses requested over these programmatic years, and the total population at risk targeted over these programmatic years.

2.5 Determine the scoring table: Based on the data points calculated in steps 2.3, populate the SAF Scoring table. Note: the SAF excel tool will automatically perform this calculation once data is imported into the tool in step 2.1.

2.6 Score each indicator for each country: Based on the data points and the SAF scoring table, assign each country a score for each of the four indicators based on the SAF scoring table scale.

2.7 Generate the SAF weighted score for each country: This is the sum of the individual indicators scored in step 2.6, which are automatically weighted in the SAF excel tool with 60% weight assigned to the epidemiologic indicators and 40% weight assigned to the population at risk. Note: the SAF excel tool will automatically perform this calculation.

2.8 Generate the total SAF score: This is the sum of the individual countries score in step 2.7. Note: the SAF excel tool will automatically perform this calculation.

2.9 Allocate the OCV supply: Based on step 2.7 & 2.8, determine the SAF indicator allocation % for each country by dividing the individual country score by the total SAF score. This percentage for each country is then multiplied against the total preventative OCV supply number. Note: the SAF excel tool will automatically perform this calculation.

2.10 Calculate the adjusted OCV supply allocation: For each country, compare the results of step 2.9 to the average annual programme year dose demand for the country. If the allocated OCV supply from step 2.9 is greater than the country's average annual dose demand, the allocated OCV doses is adjusted to equal the countries average annual demand (e.g. the number of doses allocated from the SAF is capped at the country's average annual demand in its approved Gavi application). The excess allocated doses would be put back into the available supply pool and re-allocated in step 2.11 for the remaining countries in the calculation. Note: the SAF excel tool will automatically perform this calculation.

2.11 Re-allocate remaining supply to remaining countries: For the remaining countries where the allocated preventative OCV supply is less than average annual demand, re-generate their step 2.9 allocation % and apply to the remaining supply.

2.12 Repeat steps 2.10 & 2.11 until supply = 0: The results of step 2.9-2.11 will be a single number of allocated doses for each country from the SAF calculation.

<u>Step 3: SAF Results Endorsement</u>

Once step 2 is completed, the AIG will review and discuss the results together. The finalized SAF results will then be presented by the AIG to the SAF endorsement body.

<u>Step 4: SAF Endorsed Results are communicated</u>

The AIG, in conjunction with the cholera implementation partners will coordinate the communication of the results of the SAF annual calculation process to countries and key cholera stakeholders. The AIG will be responsible for developing the communication plan and for building in flexibility into the allocation to review with countries the feasibility and impact of the allocated doses. For instance, in relation to the size of a specific administrative area if not all or a small additional number of doses are needed to vaccinate the targeted population, e.g., a complete district.

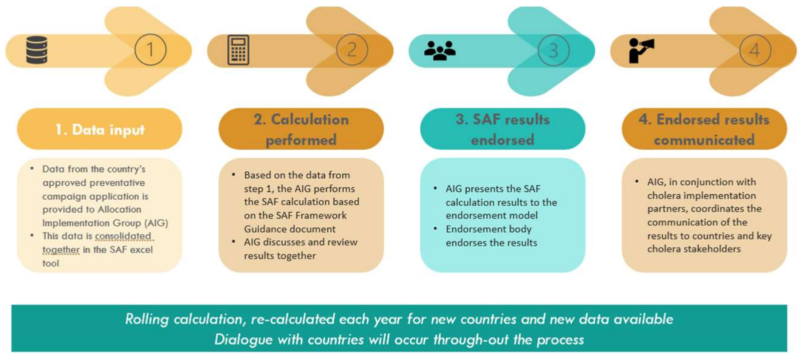


Figure 3: OCV Preventative Campaign Supply Allocation Framework Process

c) Governance and Decision-Making Process

The endorsed guidance document will govern the implementation and on-going utilization of the framework. Similar to past and existing supply allocation frameworks for other vaccines, the OCV SAF calculation will be run annually, and it is proposed to be done in Q2 of each year. This will ensure proper visibility is provided for programmatic planning, including procurement decisions. All countries that have been approved by Gavi to receive funding support for OCV preventative campaigns will be eligible to be included in the SAF calculation until the entirety of their approved doses have been received.

The calculation will be performed by a small multi-stakeholder group consisting of technical staff members from the WHO, Gavi Secretariat, UNICEF PD, the GTFCC OCV Working Group Chair and representatives with immunization programme expertise. Additional members with technical expertise can be added from other cholera partner organisations as deemed appropriate. This Allocation Implementation Group (AIG) will be responsible for performing the annual SAF calculation in accordance with the SAF Framework Guidance document and presenting the results to the endorsement body for annual endorsement. Once the annual SAF calculation results are endorsed, the AIG is responsible to coordinate the communication of the SAF results with relevant stakeholders.

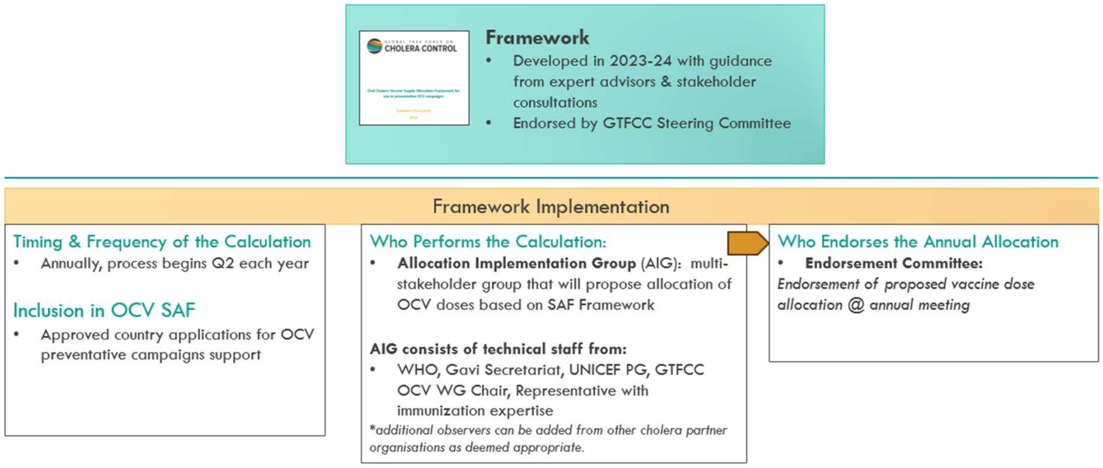


Figure 4: Preventative Campaign OCV Supply Allocation Framework Governance & Decision-Making Process

Responsibilities (RACI Framework)

	Allocation Implementation Group (AIG)	GTFCC Secretariat	Gavi Secretariat	UNICEF SD	Endorsement Body
1.Comunicate the annual OCV supply available for preventative campaigns for SAF calculation	I	I	I	R	
2.Provide AIG with country application documents	I	R	R		
3. Perform SAF calculation	A,R	C	C		
4. Present SAF results for endorsement	A,R				
5. Reviews and endorse SAF results					A,R
6. Informs stakeholders of SAF allocation decision	A,R	I	I	I	
7.Documents SAF results in the annual SAF report	A,R	C	C		I

R = Responsible: Performs the activity/task and is responsible for their execution
A = Accountable: Reviews the activity/task to deem it complete (ultimately accountable).
C = Consulted: Is asked to provide feedback or advice on the activity/task.
I = Informed: Is informed in the interim about the decisions, progress and results achieved on activity/task progress.

6. Periodic reviews of the Framework

Recognizing the dynamic nature of the OCV supply and demand environment, periodic reviews will take place to assess implementation of the Framework and whether it is achieving its intended purpose. Revisions to the approach or its operationalisation may be needed based on the findings and evolving supply sitaution. It is proposed that the first formal review take place one calendar year after the first calculation to take into account learnings from the first year of operationalisation and adapt the frameork, where possible, for the programmatic and logistic realities. A monitoring plan will be developed to guide this review.

Annex 1: OCV SAF Sub-Group Composition

Role	Member Name & Affiliation (in alphabetical order)
Co-Chairs*	Abhishek Rimal, CSP (IFRC) Amanda Tiffany, CDC
Member	BMGF • Duncan Steele, BMGF • Tanya Shewchuk, BMGF CDC: Lucy Breakwell, CDC* DRC: Placide Okitayemba, Head of National Cholera Control Programme – DRC GTFCC Secretariat • Malika Bouhenia, GTFCC Secretariat* • Philippe Barboza, GTFCC Secretariat • Vincent Mendiboure, GTFCC Secretariat Gavi, the Vaccine Alliance • Allyson Russell, Gavi • Beth Evans, Gavi • Olivia Bullock, Gavi Harvard University: Louise Ivers IFRC: Catherine Makwe JHU • David Sack • Andrew Azman UNICEF • Antonia Naydenov, UNICEF SD • Sanjay Bhardwaj, UNICEF PG WHO IVB: Eliane Furrer, WHO IVB

**Also, a member of the smaller design team*

The OCV SAF sub-group was supported by MMGH Consulting with project lead Minzi Lam Meier.

Annex 2: Illustrative Example

CAVEAT: The data points used in the annex are purely illustrative to demonstrate the steps of the calculation.

Annual preventative campaign OCV supply to be allocated: 20,000,000

Data from country approved Gavi preventative campaign application				
	Country A	**Country B**	**Country C**	**Total**
Time period in approved Gavi Preventative Campaign Application)	2024-2026	2024-2026	2024-2025	
Total Population at Risk Targeted approved Gavi Preventative Campaign Application)	25,000,000	17,500,000	8,500,000	51,000,000
Average annual dose demand in approved Gavi Preventative Campaign Application)	9,000,000	12,000,000	6,000,000	35,000,000
# of PAMIs in approved Gavi Preventative Campaign Application)	50	40	25	
SAF Calculation results: Step 2.2				
	Country A	**Country B**	**Country C**	
Country median persistence	444.8	0.8	76%	
Country median mortality	72.4	1.1	33%	
Country median persistence %	64.2	0.312	8%	
SAF Calculation results: Step 2.3				
	SAF Pool: Incidence Rate	**SAF Pool: Mortality Rate**	**SAF Pool: Persistence %**	
Calculation Step 2.4: SAF Pool median	168.1	0.7	35.4%	
SAF Pool 80% percentile	471.3	1.7	80%	

Step 1: Data input into the SAF excel tool

- Manually enter in the following data points into SAF excel tool tab. B1 Data input
    - Total annual supply preventative OCV doses
    - Country name
    - # PAMIs in application
    - Time period

- Average annual doses in application

- Import the PAMI incidence, mortality and persistence % from the countries PAMI excel files into the SAF excel tool tab B1.Country PAMI calculations

Step 2.1: Determine the countries to be included in the calculation

- In this example, 3 countries (country A, B, C) have received Gavi approval for their application for OCV preventative campaign.

Step 2.2: Calculate the epidemiologic median for each country in the calculation

- Once the data is manually imported in step 1, the SAF excel tool tab B1 will automatically calculate the median for each country. It is important to double-check that the formulas remain correct after the data import in step 1.

Step 2.3: Calculate the epidemiologic median & 80th percentile for the SAF Pool

- Once the data is manually imported in step 1, the SAF excel tool tab B1 will automatically calculate the SAF pool median and 80th percentile.

Step 2.4: Input other key data points for each country in calculation

- Manually enter in the following data points into SAF excel tool tab. B1 Data input
    - Total population at risk targeted for OCV preventative campaign vaccination

Step 2.5: Determine the scoring table

- In SAF excel tool tab A.Scoring table, the SAF scoring table is automatically generated based on the calculations performed in Step 2.2 & 2.3 on tab A.Scoring Table. It is important to double-check the excel formulas in the scoring table to ensure the data points have populated correctly.

	Preventative Campaign SAF Scoring Table				
score	1		3		5
	Between		Between		Greater than
A1. Incidence Rate	-	168.1	168.1	471.3	471.3
A2. Mortality Rate	-	0.64	0.65	1.73	1.74
A3. Persistance %	0%	34%	35%	79%	80%
B1. Total Population at risk targeted	10 points allocated across countries in accordance with % of total population at risk				

Step 2.6: Score each indicator for each country using the scoring table

- In SAF excel tool tab A.Scoring table, the Country Data Table is automatically populated from Step 2.2.
- Manually compare the Country Data Table to the SAF Scoring table and enter in a score based on the scoring scale for each country for A1-A3 indicator (A. Epidemiologic Indicators)
- B1. Indicator will be automatically populated based on the data entered in step 2.4. It is important to double-check the excel formulas for accuracy.

Country Data Table	A1. Incidence Rate	A2. Mortality Rate	A3. Persistance %	B1. Total Population at risk targeted
	Median	Median	Median	% of SAF Target Population
Country 1	445	0.5	76%	49%
Country 2	72	1.1	33%	34%
Country 3	64	0.3	8%	17%

Input values

	60%			40%
	A. Epidemiologic Indicators			B. Scale Indicator
	A1. Incidence Rate	A2. Mortality Rate	A3. Persistance %	B1. Total Population at risk targeted
Country 1	3	1	3	4.9
Country 2	1	3	1	3.4
Country 3	1	1	1	1.7

Step 2.7: Generate the SAF weighted score for each country
Step 2.8: Generate the Total SAF score

- In SAF excel tool tab A.Scoring table, steps 2.7 & 2.8 are automatically calculated (column Weighted score & SAF Indicator allocation %). It is important to double-check the excel formulas for accuracy.

	60%			40%		(c)
	A. Epidemiologic Indicators			B. Scale Indicator		
	A1. Incidence Rate	A2. Mortality Rate	A3. Persistance %	B1. Total Population at risk targeted	SAF Weighted Score	SAF Indicator Allocation %
Country 1	3	1	3	4.9	6.2	47%
Country 2	1	3	1	3.4	4.4	34%
Country 3	1	1	1	1.7	2.5	19%
				Total SAF Score	13.0	100%

Step 2.9: Allocate the OCV supply
Step 2.10: Calculate the adjusted OCV supply allocation
Step 2.11: Re-allocate remaining supply to remaining countries
Step 2.12: Repeat steps 2.9 & 2.10 until supply = 0

- In SAF excel tool tab A.Scoring table, steps 2.9 to 2.12 are automatically calculated. It is important to double-check the excel formulas for accuracy.

Compare SAF Allocated Doses to Annual Country Demand

supply of preventative OCV doses	*20,000,000*	(a)
Doses to be re-allocated	*478,130*	(e)

	(b) SAF Indicator Allocation %	(c) = a x b SAF Allocated Doses - round 1	(d) Avg annual demand	e = c - d Allocated doses > Annual Demand	g = country (b) / (all SAF Indicator % remaining) SAF Indicator Allocation %	h = g x e Additional re-allocated doses-round 2	j = c (capped at annual demand) + h Total SAF allocated doses after round 2	
Country 1	47%	9,478,130	9,000,000	478,130		-	9,000,000	100%
Country 2	34%	6,726,998	12,000,000	-	64%	305,685	7,032,683	59%
Country 3	19%	3,794,872	6,000,000	-	36%	172,445	3,967,317	66%
	100%	**20,000,000**	**27,000,000**	**478,130**	**100%**	**478,130**	**20,000,000**	

Results of the Calculation: in SAF excel tab. SAF Results

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Total preventative OCV supply	***20,000,000***
Total preventative OCV demand*	***27,000,000***

	Avg annual doses per application	Preventative Campaign SAF Allocated OCV doses	Allocated supply %	Allocated supply as % of demand
Country 1	9,000,000	9,000,000	45%	100%
Country 2	12,000,000	7,032,683	35%	59%
Country 3	6,000,000	3,967,317	20%	66%
		20,000,000	**100%**	

*For each country, the total dose requirement is divided by the time period of the SAF calculation to calculate an annual amount. This annual amount is then summed up for all countries in the SAF calculation.