

Sharing the experience of developing a Framework for allocation of limited malaria vaccine supply

12 October 2022 – GTFCC Working Group on Oral Cholera Vaccine

WHO recommendation for use of the first malaria vaccine (October 2021)

WHO recommends the RTS,S/AS01 malaria vaccine be used for the prevention of *P. falciparum* malaria in children living in regions with moderate to high transmission.



- Schedule of 4 doses, starting in children from 5 months of age*
- Injectable vaccine (intramuscular)
- Storage temperature between +2°C and +8°C.

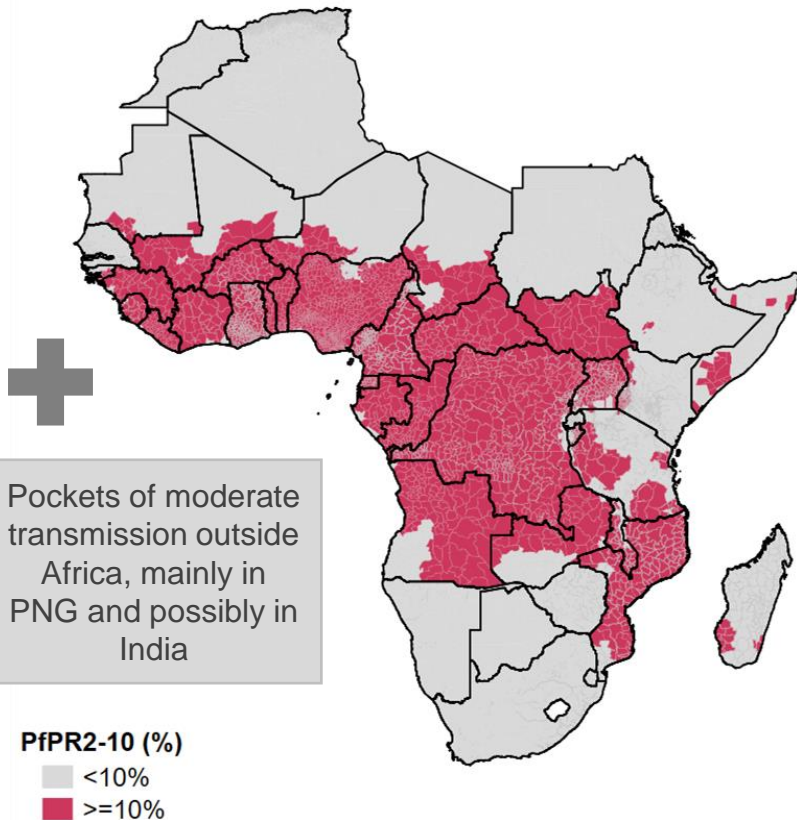
Source: WHO malaria vaccine position paper:

<https://www.who.int/publications/i/item/who-wer9709-61%E2%80%93380>

*In settings with highly seasonal malaria transmission or perennial malaria transmission with seasonal peaks, countries may consider a seasonal delivery strategy with a 5 dose schedule

Vaccine supply expected to be insufficient to meet demand in initial years

P. falciparum parasite prevalence
(PfPR₂₋₁₀) estimates, 2019. Source: MAP 2019



Demand

- Over 25 million children are born each year in regions with medium to high malaria transmission
- Potentially > 80 - 100 million doses needed per year at peak
- > 20 countries already expressed interest in introducing

Supply

- Currently only 1 product, 1 manufacturer
- Committed to provide 18 million doses over 2023 - 2025
- ~1/3 of this needed to continue vaccination services in areas of Ghana, Kenya and Malawi where the vaccine is implemented as part of pilot since 2019

Some key differences to keep in mind for the purpose of this discussion...

Malaria vaccine

- Delivery via **routine** programme (i.e. recurrent need, once started)
- Start with single age cohort (e.g. 5 mos old)
- 4 doses, 4-weeks apart for initial three doses, fourth dose 12-18 months after 3rd dose
- Malaria burden is regionally concentrated - primarily Sub-Saharan Africa
- No stockpile; no outbreak response use
- No herd protection, nor reduction of transmission

Cholera vaccine

- Delivery via **campaigns** (once off, but potential need to repeat)
- Multi-age cohort (e.g. **from XX to XX olds**)
- 2 doses, 2-weeks apart
- Endemic cholera burden in large parts of sub-Saharan Africa, south and south-east Asia, as well as Haiti.
- Stockpile for outbreak response - > related uncertainty regarding residual supply
- Considerable herd protection

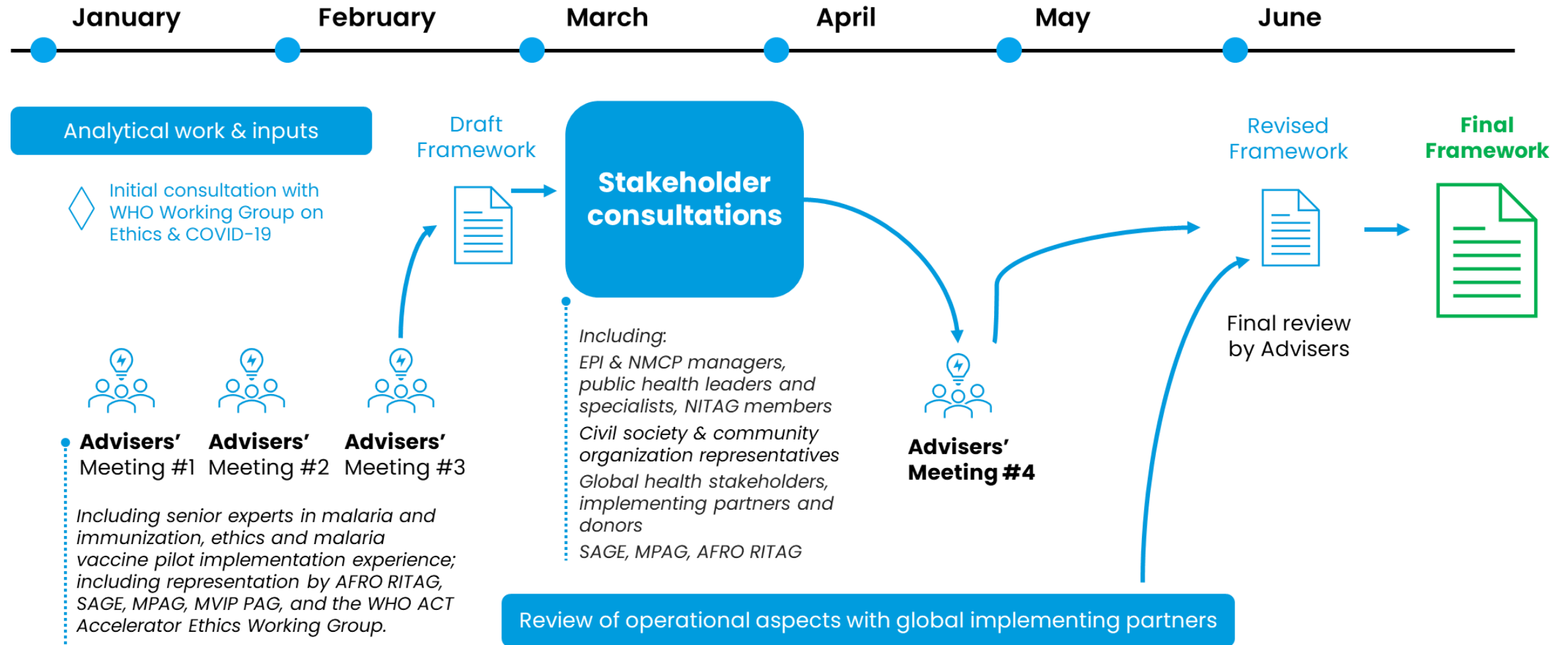
Learning from COVID-19 experience and from available guidance



*Out of the many ways that we might choose to allocate scarce resources, this choice represents the objective that is being **valued** most... Science and/or evidence alone cannot tell us which choice or aim is 'correct' or which aim society should value most. This requires a value judgement, which is the domain of ethics... Consequently, the first step in developing a framework for the allocation of scarce resources requires explicit consideration and clarification of ethical values—values that technical considerations and mechanisms should subsequently operationalize.*

Extract from: Ethical foundations of a global vaccine allocation framework for COVID-19: high-level overview - Considerations from WHO Working Group on Ethics and COVID-19

Process to develop the Framework for allocation of malaria vaccines



Framework for the allocation of limited malaria vaccine supply

Available on [WHO website](#)

Governance principles

Transparency

Inclusiveness & participation

Accountability

Ethical principles for allocation

First priority principle: Greatest need

Allocate the vaccine to countries with areas of greatest need, where the malaria disease burden in children and the risk of death are highest

Second priority principle: Maximize health impact

Allocate the vaccine to countries for use in areas where the expected health impact is greatest

Third priority principle: Equity (Equal Respect)

Prioritize countries that commit to fairness and addressing the needs of marginalized individuals and communities in their malaria vaccination programmes

Fourth priority principle: Fair benefit sharing

If everything else is equal, the country with a prior contribution to the vaccine's development should get priority

Additional key considerations



Honour commitments to MVIP countries: MVIP areas continue to get priority access to vaccine



Ensure continuity / sustainability of access to vaccine once a programme has started



Minimize risk of vaccine wastage and delayed use of available doses



Allocation should not perpetuate pre-existing structural injustices

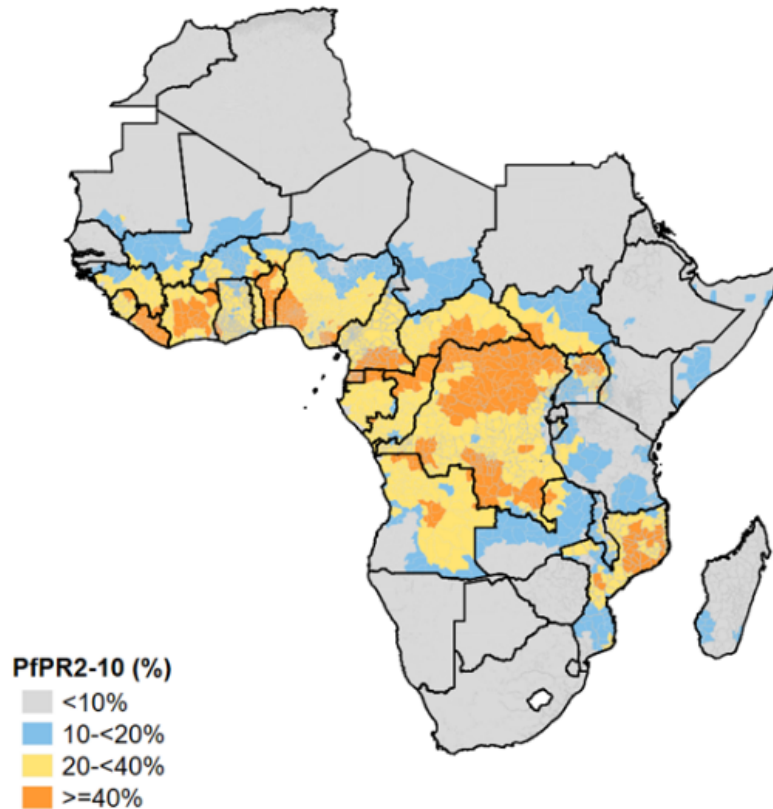
Foundational value: solidarity

Thinking as a community and standing in solidarity with those most in need:

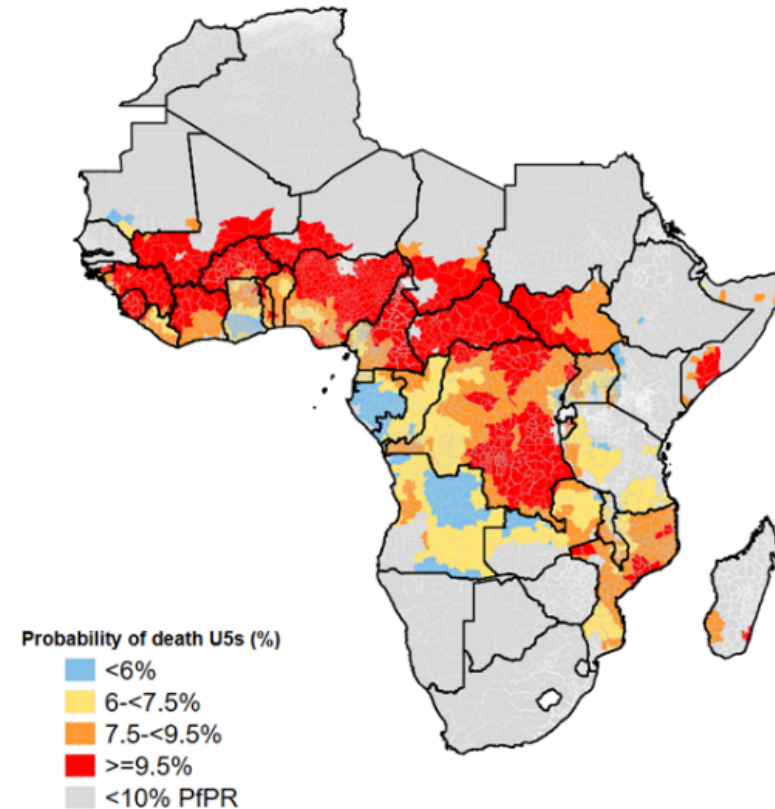
Initially, if there are unmet vaccine requests for greatest need (category 1) areas across multiple countries, no single country should receive more than 20% of the total available supply

Illustration of “need” classification

Estimated prevalence of *P. falciparum* infections in children aged 2-10 years

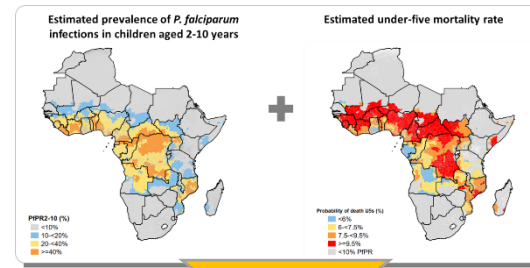


Estimated under-five mortality rate



Sources:
District level mean estimates of PfPR in 2-10 year old children in 2019 (Malaria Atlas Project)
District level mean estimates probabilities of death from all-causes before the age of 5 in 2015 (IHME)

Illustration of “need” classification



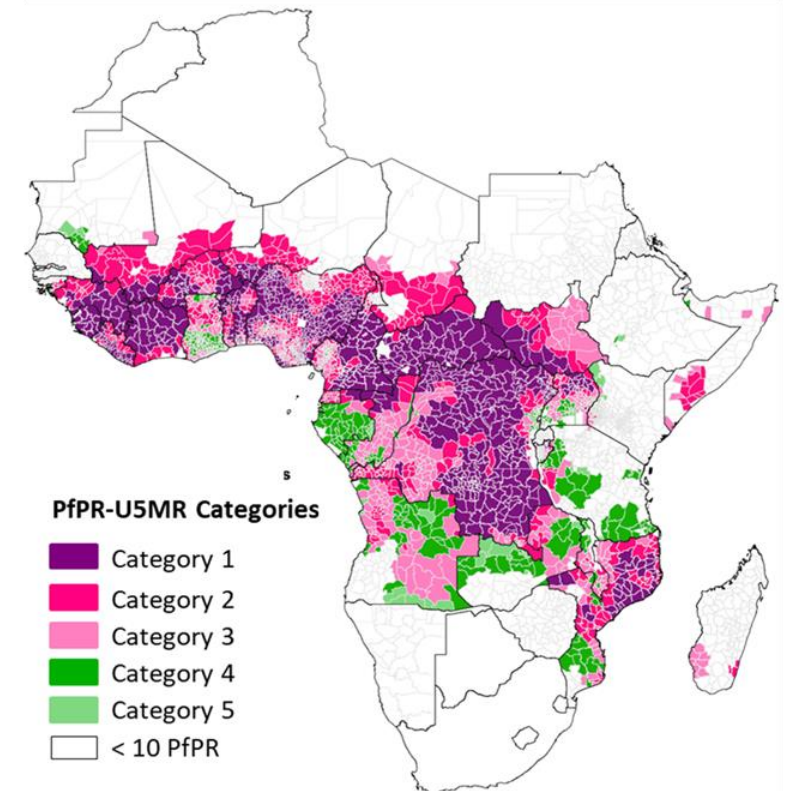
Composite classification of malaria prevalence and all-cause under-five mortality as proxy for “need”

Indicative.
Countries will present their own data

Maps are illustrative based on global estimates. Countries will identify areas of highest burden and need within its own borders based on best available local evidence and the broader context of sub-national tailoring of malaria interventions

Composite classification of malaria prevalence and all-cause under-five mortality as proxy for “need”

Category	Possible combinations	
	Malaria prevalence	All-cause under-five mortality
1 Greatest need	PfPR 20-<40%	& U5MR >=9.5%
	PfPR >=40%	& U5MR >=9.5%
	PfPR >=40%	& U5MR 7.5-<9.5%
2	PfPR 10-<20%	& U5MR >=9.5%
	PfPR 20-<40%	& U5MR 7.5-<9.5%
	PfPR >=40%	& U5MR 6-<7.5%
3	PfPR 10-<20%	& U5MR 7.5-<9.5%
	PfPR 20-<40%	& U5MR 6-<7.5%
	PfPR >=40%	& U5MR <6%
4	PfPR 10-<20%	& U5MR 6-<7.5%
	PfPR 20-<40%	& U5MR <6%
5	PfPR 10-<20%	& U5MR <6%



New births estimated for 2023 by need category in sub-Saharan African countries with moderate to high malaria transmission*



Highest need

	Cat 1	Cat 2	Cat 3	Cat 4	Cat 5	Total Cat 1-5	<10% PfPR
Angola	-	86,000	255,000	224,000	351,000	916,000	297,000
Benin	205,000	102,000	108,000	43,000	-	458,000	-
Burkina Faso	266,000	385,000	163,000	-	-	814,000	-
Burundi	111,000	80,000	100,000	24,000	-	315,000	208,000
Cameroon	190,000	213,000	318,000	104,000	32,000	857,000	91,000
Central African Republic	168,000	11,000	-	-	-	179,000	-
Chad	-	376,000	78,000	-	-	454,000	263,000
Congo	4,000	4,000	48,000	66,000	55,000	177,000	-
Côte d'Ivoire	567,000	328,000	-	-	-	895,000	-
Democratic Republic of the Congo	1,987,000	535,000	641,000	130,000	369,000	3,662,000	180,000
Equatorial Guinea	-	20,000	5,000	-	-	25,000	-
Ethiopia	-	-	-	7,000	19,000	26,000	3,620,000
Gabon	1,000	5,000	2,000	49,000	1,000	58,000	-
Ghana	10,000	75,000	70,000	247,000	147,000	549,000	96,000
Guinea	291,000	141,000	17,000	-	77,000	526,000	-
Guinea-Bissau	-	9,000	5,000	3,000	-	17,000	54,000
Kenya	-	4,000	4,000	11,000	93,000	112,000	1,097,000
Liberia	48,000	75,000	49,000	-	-	172,000	-
Madagascar	-	32,000	32,000	12,000	-	76,000	827,000
Malawi	-	19,000	240,000	136,000	-	395,000	13,000
Mali	171,000	458,000	11,000	-	-	640,000	244,000
Mauritania	-	-	3,000	26,000	44,000	73,000	86,000
Mozambique	337,000	406,000	183,000	77,000	-	1,003,000	237,000
Niger	192,000	628,000	100,000	-	-	920,000	281,000
Nigeria	2,830,000	1,188,000	890,000	301,000	-	7,209,000	788,000
Sierra Leone	178,000	-	37,000	-	-	215,000	-
Somalia	-	80,000	30,000	16,000	-	126,000	412,000
South Sudan	129,000	199,000	164,000	-	-	492,000	13,000
Togo	61,000	73,000	78,000	-	67,000	279,000	-
Uganda	181,000	192,000	650,000	327,000	243,000	1,593,000	163,000
United Republic of Tanzania	-	33,000	77,000	385,000	41,000	536,000	1,783,000
Zambia	15,000	33,000	113,000	160,000	88,000	409,000	312,000
TOTAL	7,942,000	7,790,000	4,471,000	2,348,000	1,627,000	24,178,000	11,065,000

 **Indicative.**
Countries will present their own data

Numbers in the table reflect indicative estimates based on globally available modelled estimates. Countries are encouraged to use their best available local evidence to assess the annual target population falling into the different categories of need in line with the definitions provided above. Estimates of new births by need category using country level data are likely to differ from global estimates.

* Additional countries may identify areas of need

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DRC
1,987,000
Children in
Cat. 1 areas

Solidarity cap:
Initially, if there are unmet vaccine requests for greatest need areas across multiple countries, no single country should receive more than 20% of total available supply.

Initial cap is 1 million doses per year

* Additional countries may identify areas of need

Key implications for countries

- No country is excluded by the Framework (no *a priori* list of eligible countries).
- All countries will have to consider a phased approach to vaccine implementation, starting in areas with highest need, with expansion after supply increases.
- The Framework clarifies the allocation principles, but doesn't remove all uncertainties, e.g.:
 - There are no fixed vaccine quantities set aside for each country
 - Stratification of need based on country-specific data
 - Review of application by Gavi's Independent Review Committee (as for any other new vaccine support request) as first step
 - Interest by other countries?
 - Uncertainty about timing of supply increase
- To help manage expectations and support decision-making and planning, countries will be informed through a dialogue about the potential initial allocation quantities.

In conclusion

- There is no “single best” or “true” solution, the **process** through which the prioritization mechanism is developed is as important as the final mechanism
- Acceptance and **adherence by all key stakeholders** is key to success: affected countries / communities, manufacturer(s), funders (Gavi, etc.), implementing partners, etc.
- Design a **dynamic** mechanism that can deal with changes of supply / demand dynamics over time
- **Transparency & communication**

Merci beaucoup!



Temporary Advisers

Drawing expertise from the AFRO Regional Immunization Technical Advisory Group (RITAG), the Strategic Advisory Group of Experts on Immunization (SAGE), the Malaria Policy Advisory Group (MPAG), the Malaria Vaccine Implementation Programme Advisory Group (MVIP PAG), the WHO ACT Accelerator Ethics Working Group, CSOs and pilot implementation countries

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Professor Richard Adegbola	Member of AFRO RITAG & Research Professor & Consultant, Nigerian Institute of Medical Research
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Dr Eusebio Macete	Co-Chair of MIVP Programme Advisory Group (PAG) & Director, Farmácias de Moçambique SA, Mozambique
Professor Keymanthri Moodley	Distinguished Professor in Department of Medicine and Director of the Centre for Medical Ethics and Law, Stellenbosch University, South Africa and Adjunct Professor, Department of Social Medicine, University of North Carolina- Chapel Hill, USA

Purpose

- The Framework aims to offer guidance globally on the allocation of RTS,S/AS01, and other malaria vaccines as they become available, between countries, and to offer guidance on prioritization of areas for vaccination within countries until supply constraints can be resolved.
- The intended audience are policy makers in malaria-endemic countries, the manufacturer(s), Gavi, the Vaccine Alliance and other funding, implementing and technical partners.
- Details of in-country deployment should respect sovereign decision-making and align with the High Burden to High Impact (HBHI) approach to sub-national tailoring of malaria interventions.
- This Framework is intended to be dynamic to support prioritization decisions at the start of vaccine roll-out and over the coming years as supply ramps up, until supply constraints are fully resolved.

UNICEF announces contract award that secures supply for further roll-out, 16 August 2022

Short term (2023-2025)

Availability:

- From Q4-2023, however in very limited quantities: 4 M doses available in 2023, 6 M doses in 2024, 8 M doses in 2025 (18 million doses in total)
- All commercial supply: Offered by manufacturer to UNICEF only.

Price:

- Low volumes result in initial high cost: **EUR 9.30/dose**
- EUR 9.30/dose will remain ceiling price in 2024-2025 and subject to downward adjustment if cost of production decrease

Allocation

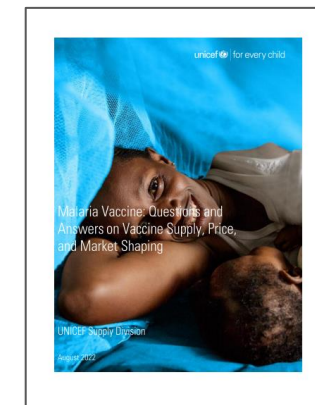
- Access based on the Allocation Framework

Useful links



UNICEF news release

<https://www.unicef.org/press-releases/millions-more-children-benefit-malaria-vaccine-unicef-secures-supply>



UNICEF Q&A on malaria vaccines supply, price and market-shaping efforts

<https://www.unicef.org/supply/documents/malaria-vaccine-questions-and-answers-august-2022>