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Background documentation for Day 1

This file contains the slides that were shown by the presenters during Day 1 of the meeting as well the background documentation shared with MPAG members ahead of the meeting.

Monday, 30 October 2023			
	Session 1	**Open**	
11:45 – 11:50	Opening remarks by the Assistant Director-General, WHO/UCN	Dr Jérôme Salomon, Assistant Director-General, UCN	**For information**
11:50 – 12:00	Welcome by the Chairperson, MPAG	Professor Dyann Wirth MPAG Chairperson	
12:00 – 12:45	Report from the Director, GMP Presentation	Dr Daniel Ngamije M. Director, Global Malaria Programme	
	Session 2	**Open**	
12:45 – 13:15	Malaria Operational Strategy 2024-2030 Background | Presentation	Dr Daniel Ngamije M. Director, Global Malaria Programme	**For information**
	Session 3	**Open**	
13:15 – 14:00	Update on malaria vaccines • R21/Matrix-M update • RTS,S/AS01 and MVIP update • Status of malaria vaccine roll-out Background | Presentation	Dr Lindsey Wu Technical Officer, Diagnostics, Medicines & Resistance Dr Mary Hamel Senior Technical Officer, Product & Delivery Research Ms Eliane Furrer Technical Officer, Product & Delivery Research	**For information**
	Session 4	**Open**	
14:30 – 15:30	Guiding principles for prioritizing malaria interventions in resource constrained settings to achieve maximal impact Background | Presentation	Dr Andrea Bosman Unit Head, Diagnostics, Medicines & Resistance	**For decision**
15:30 – 16:30	Update on subnational tailoring: progress and challenges Background | Presentation	Dr Beatriz Galatas Epidemiologist, Strategic Information for Response	**For information**

WHO/UCN/GMP/MPAG/2023.04

Report from the WHO Global Malaria Programme

Malaria Policy Advisory Group
Geneva, Switzerland

Dr Daniel Ngamije, Director

World Health Organization

GMP vision and mission

Vision: A world free of malaria

– inspired by the broader WHO vision of a world in which all people attain the highest possible level of health

Mission:

- to support all Member States in implementing the *Global technical strategy for malaria 2016–2030*
- to promote effective partnerships with malaria stakeholders

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GMP core functions

- To play a leadership role in malaria, effectively supporting Member States and rallying partners to reach UHC and achieve the goals and targets of the GTS 2016-2030
- To shape the research agenda and promote the generation of evidence to support global guidance for new tools and strategies to achieve impact
- To develop ethical and evidence-based global guidance on malaria, with effective dissemination, to support adoption and implementation by national malaria programmes and other relevant stakeholders
- To monitor and respond to global malaria trends and threats

** To support all functions of the department, ensuring the optimal use of human and financial resources through effective planning, budgeting and reporting (internal function to ensure GMP is able to deliver on all areas of work)*

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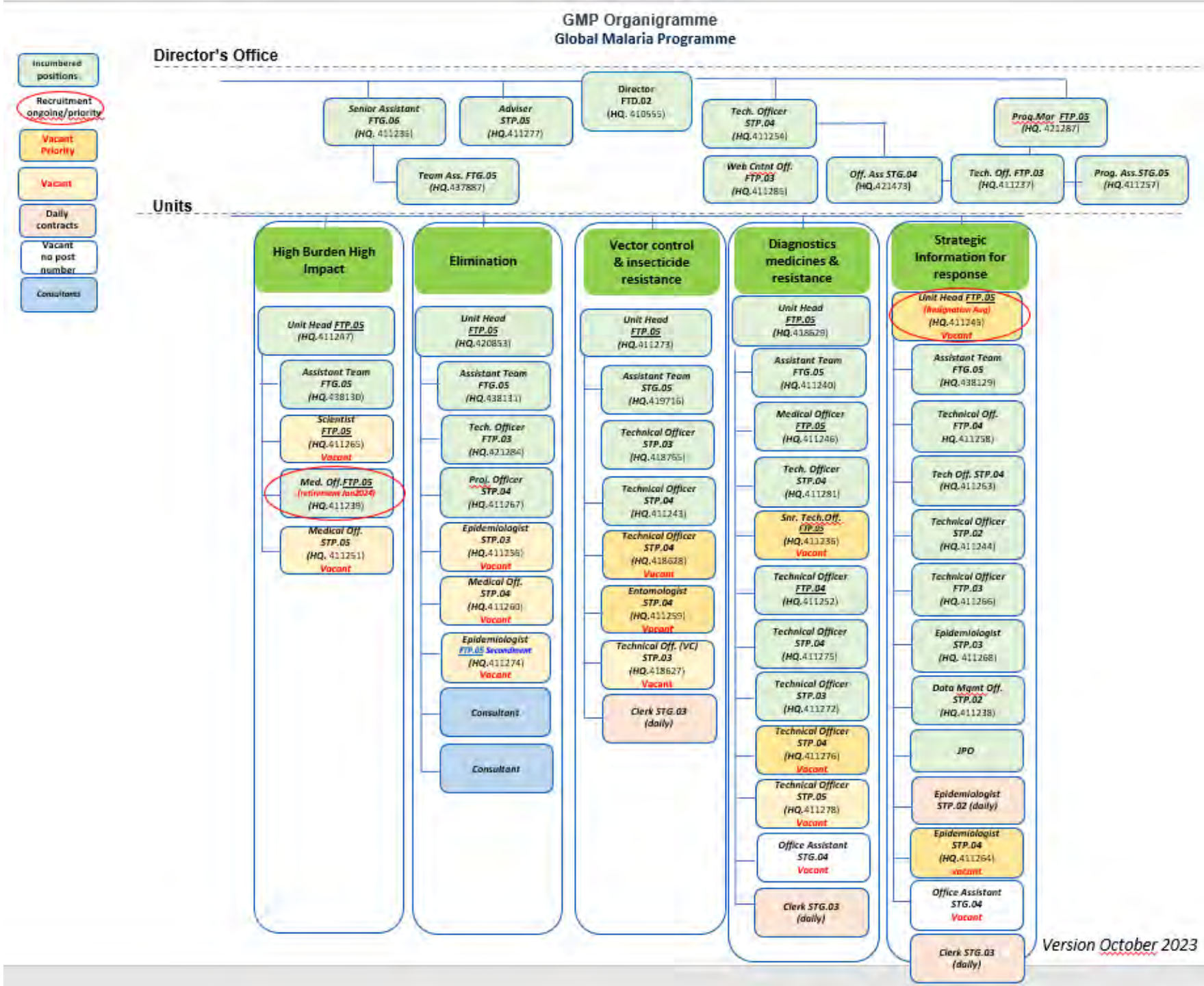
New GMP structure

- New structure approved by the WHO Director-General in July 2023
- 5 technical units:
  - High burden high impact
  - Elimination
  - Vector control & insecticide resistance
  - Diagnostics, medicines and resistance
  - Strategic information for impact



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Key achievements: the first 100 days

COMPLETED

- New GMP structure approved
- Unit Heads of DMR & HBHI appointed
- Programme manager recruited
- Alliances established within the 3 levels of WHO
- Key existing and new stakeholders engaged
- Alignment achieved on key technical issues *(comparative effectiveness for vector control, response to drug resistance in Africa)*

UNDER WAY

- BMGF bridging & multi-year grants and other resource mobilization
- SIR unit head recruitment
- Submission and approval of GMP operational strategy 2024-2030, M&E plan and resource mobilization strategy
- Two-year operational plans
- Guiding principles for prioritizing malaria interventions in resource constrained country context to achieve maximal impact

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Other updates since our last meeting…

- WHO certifies Belize as malaria-free
- WHO recommends a 2nd malaria vaccine
- GMP operational strategy 2024-2030
- Normative guidance – latest updates
- Meeting reports
- Technical updates

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Malaria-free certification of Belize

- Belize awarded the WHO certification after a 70-year effort to stamp out the disease
- 42 countries and 1 territory now certified by WHO as malaria-free, including 11 in the Region of the Americas
- Belize's success underpinned by strong malaria surveillance, access to diagnosis and effective vector control.
- Trained community health workers played a vital role in timely diagnosis and treatment.

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WHO recommends a 2nd malaria vaccine

- 2 October 2023: R21/Matrix-M recommended as a safe and effective malaria vaccine for children
- Recommendation follows evidence review by WHO's top advisory bodies on immunization and malaria
- A two-vaccine market (R21, RTS,S) is expected to lower costs and substantially ramp up supply
- Impact of the vaccines can be maximized by combining them with other recommended prevention tools

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“As a malaria researcher, I used to dream of the day we would have a safe and effective vaccine against malaria. Now we have two. Demand for the RTS,S vaccine far exceeds supply, so this second vaccine is a vital additional tool to protect more children faster, and to bring us closer to our vision of a malaria-free future.”

Dr TedrosAdhanom Ghebreyesus, WHO Director-General

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GMP operational strategy 2024-2030

- Six-year strategy anchored in the GTS and consistent with the ambitions of WHO's General Programme of Work (GPW)
- Closely integrated with UHC/PHC, MNCH, GER and climate agendas
- Candid and anonymous feedback sought from 50+ stakeholders, with the support of the Boston Consulting Group
- 4 strategic objectives: (1) Norms and standards; (2) New tools and innovations; (3) Strategic information for impact; (4) Leadership
- A 5th transversal pillar, context-based country support, completes the objectives.
- Annexes to the strategy will include resource mobilization and M&E plans

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Process and timeline for developing the operational strategy, July – December 2023

July	August	September	October	November	December
Development of draft strategy by GMP	50+ stakeholder interviews, supported by BCG	Strategy refinement & identification of KPIs	Presentation of strategy to WHO DG and Malaria Policy Advisory Group	Publication of strategy (target date: 15 November)	Socialization of strategy and resource mobilization

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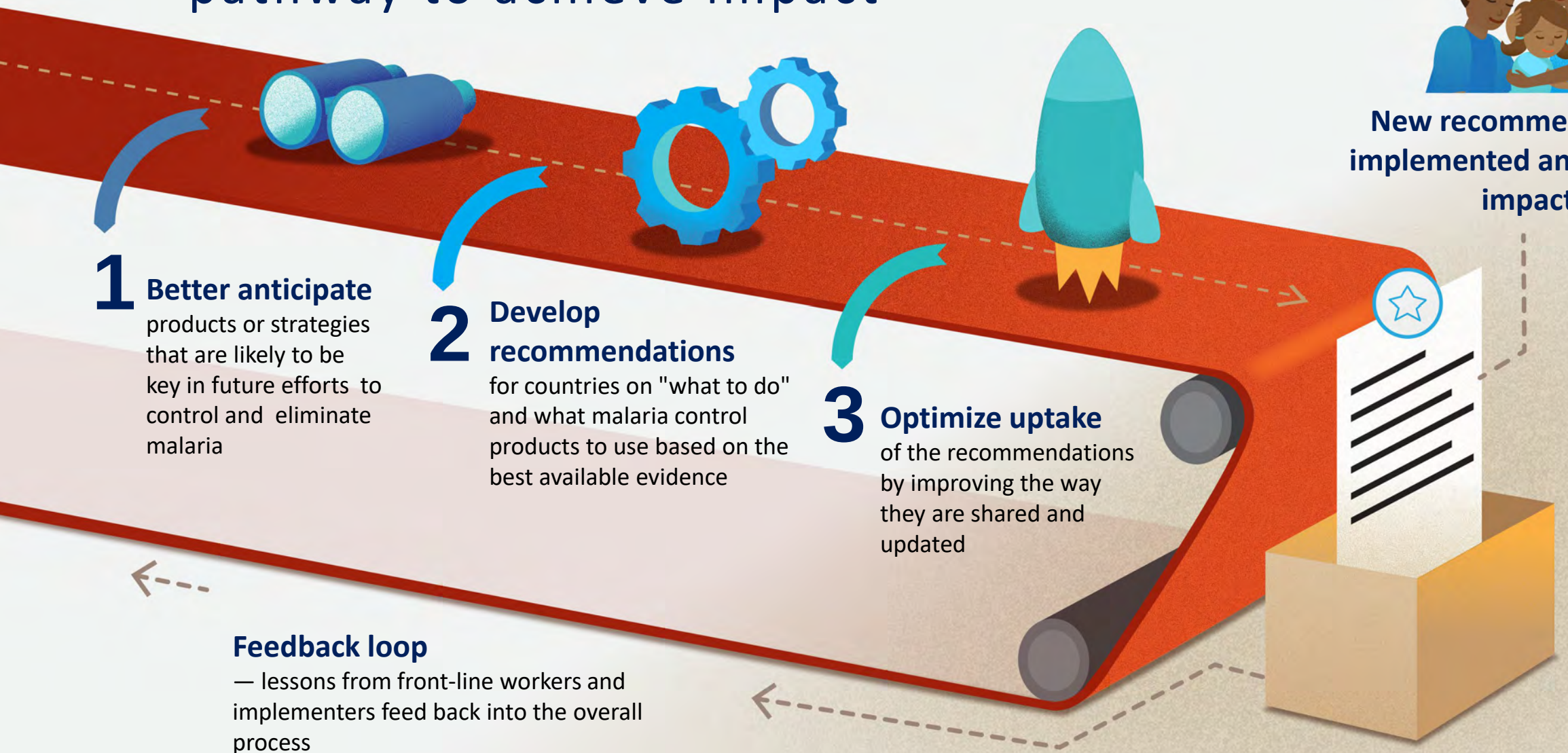
Normative guidance: 3 steps in GMP's pathway to achieve impact



1 Better anticipate
products or strategies that are likely to be key in future efforts to control and eliminate malaria

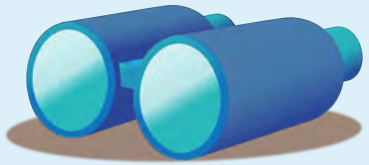
2 Develop recommendations
for countries on "what to do" and what malaria control products to use based on the best available evidence

3 Optimize uptake
of the recommendations by improving the way they are shared and updated

New recommendations implemented and achieve impact

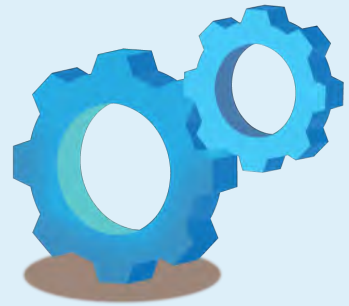
Feedback loop
— lessons from front-line workers and implementers feed back into the overall process

Normative guidance – latest updates



Step 1 – Better anticipate

- **November 2023:** Anticipated release of preferred product characteristics (PPCs) for diagnostic tests detecting the risk of *P. vivax* relapses (point of contact and population-based)



Step 2 – Develop recommendations

- **October 2023**: publication of new vector control recommendations on:
  - Indoor residual spraying
  - Topical repellents

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Normative guidance – latest updates

Step 3 – Optimize uptake

- **WHO "Malaria Toolkit" mobile app:** French-language version expected in Q4 2023
- **Animated videos:** release of 3 new videos (July 2023) focused on:
  - spread of the *Anopheles stephensi* in Africa
  - global response to malaria in urban settings
  - recommendations on new types of insecticide-treated nets

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Technical updates

- Vector control and insecticide resistance
- Vaccines
- Diagnostics, medicines & resistance
- Strategic information for response
- High burden to high impact
- Elimination

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Meeting reports

- Technical consultation to review the effectiveness of rectal artesunate used as pre-referral treatment of severe malaria in children (June)
- Partners convening: a regional response to the invasion of *Anopheles stephensi* in Africa (June)
- Eighteenth meeting of the WHO Vector Control Advisory Group (August)
- Report of the first and second meetings of the technical advisory group on malaria elimination and certification (August)
- Technical consultation to assess comparative efficacy of vector control products (September)

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Vector control and insecticide resistance

2023 progress to date

- 2 guidelines updates published *(14 Mar, 16 Oct)*
- *An. stephensi* partners convening held in Addis Ababa
- Technical consultation to assess comparative efficacy held and respective report published
- PPCs on outdoor transmission published
- Participated in EMRO entomology training in Oman
- Two VCAG meetings convened

Priorities for next quarter

- Conduct deep dive on successes and failures of *An. stephensi* control (Iran, Sri Lanka, India)
- Publish updated IRS manual
- Publish updated comparative efficacy study protocol
- Finalize review of vector control evaluation process procedures and integration of comparative efficacy
- Review feedback from public consultation on quality of WHO test kits and papers

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Vaccines

2023 progress to date

- Supported the review of 2nd malaria vaccine, R21/Matrix-M, recommended for use in October 2023
- Updated WHO recommendation for malaria vaccine use
- Continued to provide technical leadership and coordinate the Malaria Vaccine Implementation Programme (MVIP)
  - 46-month surveillance completed
  - Analysis completed, showing high impact (22% reduction in hospitalized severe malaria and 13% reduction in mortality in children age-eligible for vaccination)
  - Many lessons learned from MVIP incorporated into introduction guide and training materials
- Support country development of Gavi applications
  - To-date 19 applications approved for 18 countries (Ghana has 2 applications approved)

Priorities for next quarter

- Close MVIP and disseminate results, including through country and regional presentations and publications
- Continue to support expansion in MVIP countries, increased uptake of dose 4
- Support decision making regarding where to introduce / new vaccine introduction of RTS,S/AS01 or R21 in additional countries
- Review evidence on fractional dosing of RTS,S
- Continue to monitor pipeline and support development of new vaccines – blood stage, transmission blocking, multi-stage and mRNA – and of monoclonal antibodies

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Diagnostics, medicines & resistance

2023 progress to date

- RAS a pre-referral treatment for severe *falciparum* malaria – 2023 information note update
- Field guides finalized on:
  - SMC with SPAQ in children
  - Pre-referral treatment with RAS
  - Community deployment of IPTp-SP
- Technical consultation on EQA expansion to include molecular markers of drug resistance
- Technical consultation to scope the update of the chemotherapy sections of the WHO malaria guidelines
- Technical support to UNITAID PLUS and PAVE projects as part of enabler grant

Priorities for next quarter

- Guidelines Development Group meetings
  - Tafenoquine and primaquine
  - G6PD near patient tests
- Regional meeting on drug resistance in Africa
- Subregional network East African and HANMAT
- Release of new publications
  - PPC on tests to identify risk of *P. vivax* relapses
  - Updated HRP2 deletions surveillance protocol and global response plan
- Technical support to countries on:
  - Drug resistance response plan
  - Therapeutic efficacy studies
  - HRP2 deletions surveillance and response

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Strategic information for impact

2023 progress to date

- 2 guidance documents updated:
  - Surveillance, monitoring & evaluation (SME) manual
  - Malaria surveillance assessment toolkit: implementation reference guide
- Country support:
  - Subnational tailoring in 13 countries
  - 2 epidemiological stratification workshops held – 22 countries trained
  - Surveillance assessments in 7 countries
- Malaria Strategic Information Technical Advisory Group inaugural meeting, July 2023
- RTS,S allocation process to inform Gavi applications
- Launch of new version of Malaria Threats Map

Priorities for next quarter

- Surveillance assessment toolkit & webpage piloting
- Subnational tailoring implementation manual
- Analysis and use of health facility data
- WHO academy: Online training in analysis of health facility data
- Update of Malaria Threats Map datasets
- Epidemiological stratification workshops for 14 additional countries scheduled in Dec. 2023

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High burden to high impact (HBHI)

2023 progress to date

- HBHI country updates
- Supported countries in developing NSPs, MPRs, MTRs and GF proposals
- Supported countries in responding to epidemics and emergencies
- HBHI evaluation
- Malaria control in emergencies manual
- Implementation of 1,7-malaria reactive community-based testing and response (1,7-mRCTR) operational research (funded by UNPDF)

Priorities for next quarter

- Stakeholders' review meeting for finalization of malaria control in emergencies manual (5-8 Dec, 2023)
- Finalization of 1,7-mRCTR operational research in 3 countries (Senegal, Zambia and Tanzania)
- Requesting no-cost extension for Burkina Faso (due to conflict)
- Revision of epidemic preparedness and response (within surveillance manual)

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Elimination

2023 progress to date

- 3 countries certified malaria-free and 2 countries supported to prepare for certification
  - Malaria-free certification assessment of Cabo Verde underway
- 17 countries supported to accelerate towards malaria elimination
- Development of new guidance documents initiated:
  - Framework for malaria elimination, 2nd edition
  - Preparing for certification of malaria elimination, 3rd edition
  - Global guidance on prevention of re-establishment of malaria transmission

Priorities for next quarter

- Malaria-free certification of Egypt, Georgia, Timor-Leste and Turkey
- Acceleration of malaria elimination in selected countries to meet 2025 milestones of the GTS 2016-2035
- Launch of three guidance documents
- Malaria elimination in areas with zoonotic malaria

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Coming soon

- Technical publications expected in Q4 2023
- World Malaria Report 2023
- HBHI ministerial meeting in Cameroon

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Technical publications expected in Q4 2023

- New field implementation manual on rectal artesunate as pre-referral treatment of severe malaria in children
- New field implementation manual on community-based intermittent preventive treatment of malaria in pregnancy
- Analysis and use of health facility data: guidance for malaria programme managers
- Report of WHO technical consultation to update the global *pfhrp2/3* response plan
- 2nd edition of ”Data requirements and protocol for determining non-inferiority of insecticide-treated net and indoor residual spraying products within an established WHO intervention class”

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Technical publications expected in Q4 2023

- Indoor residual spraying to control vectors of malaria, leishmaniases, Chagas disease, lymphatic filariasis and *Aedes*-borne diseases: an operational manual
- Safety of artemisinin and non-artemisinin antimalarials in the first trimester of pregnancy: review of evidence
- Updated global *pfhrp2/3* response plan
- Updated *pfhrp2/3* gene deletion surveillance template protocols
- 2nd edition of *Malaria surveillance assessment toolkit – implementation reference guide 2023*
- 2nd edition of the Framework for malaria elimination

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World Malaria Report 2023

- This year's report launch planned at the COP28 meeting in Dubai on 5 December 2023
- Report to include, for the first time, a dedicated chapter focused on the intersection between climate and malaria
- WHO messaging to focus on the expected direct and indirect effects of climate change on the global malaria response
- WHO to convene a Technical Expert Group on climate change and malaria in 2024 to review available evidence and recommend an official position for WHO on the impact of climate change on malaria and on mitigation approaches

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HBHI ministerial meeting in Cameroon

- Twelve countries, mainly in Africa, carry over 70% of the global malaria burden.
  - In 2021, there were about 171 million malaria cases and 446 000 deaths in these countries
- With available resources and tools, African countries can dramatically reduce malaria mortality.
- In March 2024, WHO will host a high-level meeting of Ministers of Health and Finance to strengthen political and financial commitments for accelerated malaria responses in HBHI countries
- Four specific objectives:
  - Review progress and challenges in meeting the GTS malaria targets;
  - Discuss mitigation strategies and funding for malaria;
  - Agree on effective strategies and responses for accelerated malaria mortality reduction in Africa;
  - Establish a roadmap for increased political commitment and societal engagement in malaria control, with a clear accountability mechanism.

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Thank you

For more on the Malaria Policy Advisory Group, visit:
https://www.who.int/groups/malaria-policy-advisory-group

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Malaria Policy Advisory Group Meeting

30 October–1 November 2023, Geneva, Switzerland
Background document for Session 2

Global Malaria Programme operational strategy 2024–2030

Dr Daniel Ngamije

Introduction and context

This presentation contains a summary of the Global Malaria Programme (GMP) operational strategy for 2024–2030. The document is aligned with latest drafts of the World Health Organization Global Programme of Work (WHO GPW) 14. It is also aligned with the WHO *Global technical strategy for malaria 2016–2030* (GTS) and incorporates input from partners, countries and the three layers of Organization. Input was collected by interviewing more than 50 stakeholders. The GMP operational strategy has no vocation to replace the GTS as a guide for the entire malaria ecosystem to work towards, but will rather set the direction for GMP's contributions towards supporting countries and partners to reach targets that have been laid out in the GTS.

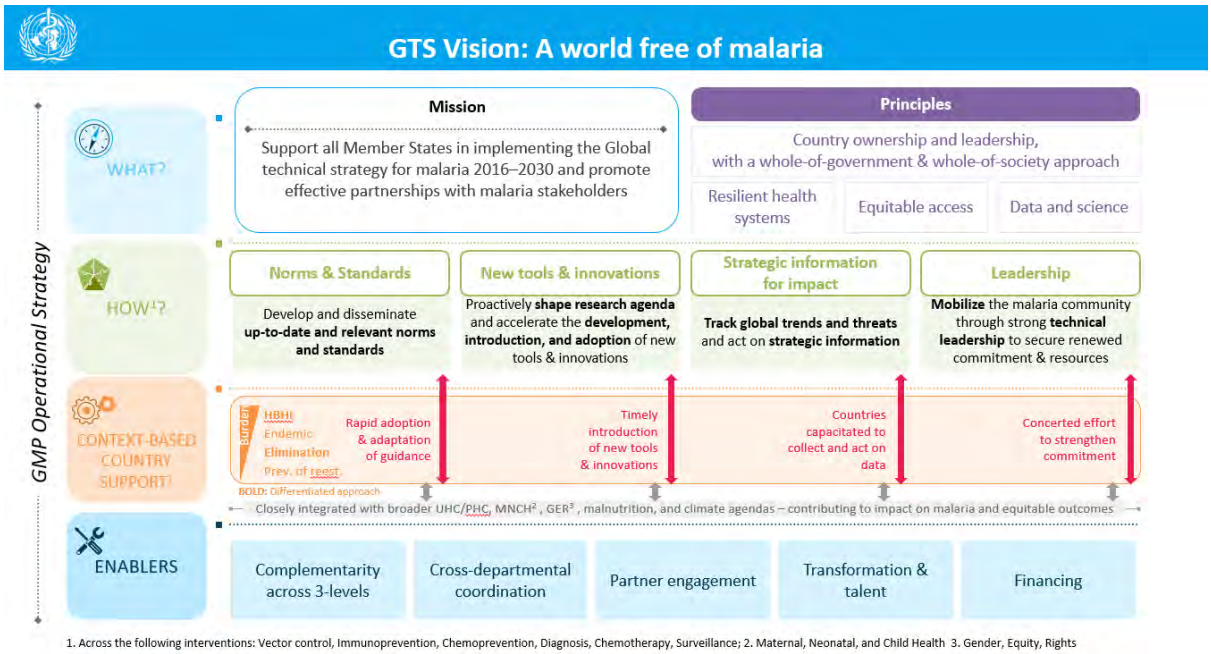
Context. Malaria remains a severe global health issue disproportionately affecting the most marginalized. Historic successes in the control of malaria were realised between 2000–2015, underpinned by robust investments in research & development (R&D) for new tools, deployment of commodities, capacity building. The GTS, updated in 2021, sets ambitious targets for the response by 2030. WHO/GMP is responsible for coordinating global efforts to control and eliminate malaria and supporting Member States in implementing the GTS.

Case for change. The world is off track to meet the GTS 2030 targets and the context for the malaria response has changed dramatically. The increased pace of technological and scientific change, the tight funding environment and the evolving health ecosystem are contributing factors. Emerging biological threats and environmental and demographic changes are new challenges. A "business as usual", vertical approach to malaria is no longer sufficient. A concerted effort across the ecosystem is needed to put the response back on track. Success will require alignment with the broader Universal Health Coverage/Primary Health Care (UHC/PHC) agenda and other growing priorities, including the interplay between climate and health.

Root cause analysis. A high-level review of the root causes of stalled progress has been undertaken. This showed the ecosystem faces challenges along the continuum of maximizing the impact of interventions (e.g., availability, accessibility, acceptability, contact and effectiveness/quality, based on the Tanahashi framework) to the millions of people in need. These are compounded by the heavily resource-constrained environment, with an increasing number of players needing coordination.

Shift in response needed. A shift in the global malaria response is urgently needed to prevent avoidable deaths. This shift should seek to answer the root causes identified and be centered around efficiency, sustainability, equity and integration. GMP must drive this turnaround in the rapidly changing global health context of the post-pandemic era. The entire ecosystem of partners may also need to adapt their respective approaches.

The GMP operational strategy



Strategic objectives. The principles underpinning the strategic framework are: country ownership and leadership, with a whole-of-government and whole-of-society approach; resilient health systems to underpin the success of the malaria response; equity in access to quality health services; and the integration of data and science into decisions, recommendations and action plans. At the heart of the framework are four strategic functional objectives: norms & standards; new tools & innovation; strategic information for impact; and leadership. A fifth cross-cutting pillar, context-based country support completes the objectives. The full cost of these objectives will be estimated.

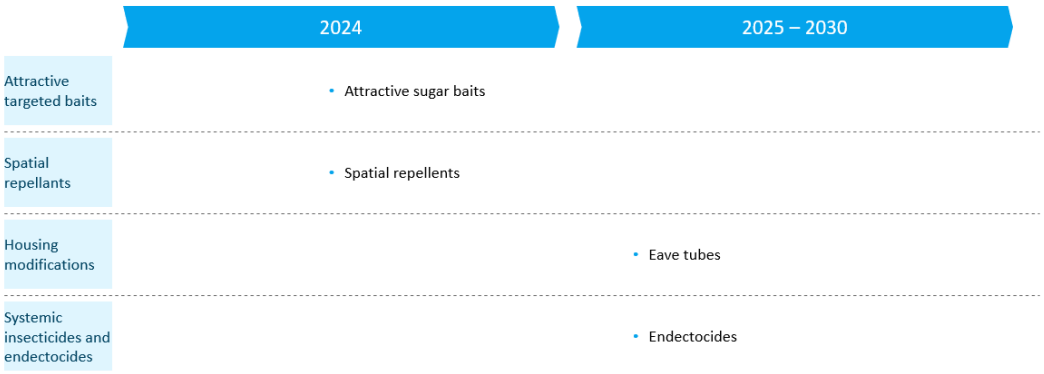
Core activities and transformative initiatives within strategic objectives and proof points within strategic objectives. Across all strategic objectives, GMP will strengthen core activities to meet the needs of countries and the broader malaria ecosystem. These include up-to-date consolidated guidance that is disseminated quickly and clearly; end-to-end support for introduction of new products underpinned by unified and streamlined processes; tracking of trends and threats to facilitate data-driven decision-making; alignment of stakeholders around a common technical agenda; and stratification of support to countries based on need. Three transformative initiatives have been identified to amplify GMP's impact on the response. Firstly, GMP will introduce International Programme Officers (IPOs) in High Burden to High Impact (HBHI) countries to multiply the impact of partners' investments at country levels through better coordination from a position of neutrality. Within 12 months of the launch of the strategy, GMP aims to pilot the IPO approach in two African countries. Secondly, GMP will expedite elimination efforts through technical assistance to bring attention to an area that has limited focus where GMP is the sole actor providing guidance and support to countries on the brink of elimination. Within 12 months of the launch of the strategy, GMP aims to certify malaria-free status in Georgia and Timor-Leste. Thirdly, GMP will bolster the response to resistance by proactively addressing new and emerging threats using the reach and knowledge accumulated by GMP. Within 12 months of the launch of the strategy, GMP aims to launch and convene therapeutic efficacy studies (TES) networks in East Africa and the Horn of Africa, Central Africa, and Southern Africa. The timely implementation of these initiatives is conditional on adequate funding for GMP.

Technical products. Central to the GMP operational strategy is maintaining, and further strengthening GMP's role as the technical leader of the global malaria response. WHO is the only organization that

has the authority to publish norms and standards that guide countries and partners to execute activities. Driven by an increased emphasis on transparency, predictability and early engagement with the ecosystem – a detailed list of technical deliverables have been included in the strategy. The timelines for reviewing data for new interventions have been included for vector control and drugs and medicines below. Note, all timelines and products are highly preliminary and subject to change based on availability of data. These timelines also constitute timelines for technical review of data and do not imply that recommendations will be issued. GMP will continuously maintain, develop and share this view over time as the pipeline of products change.

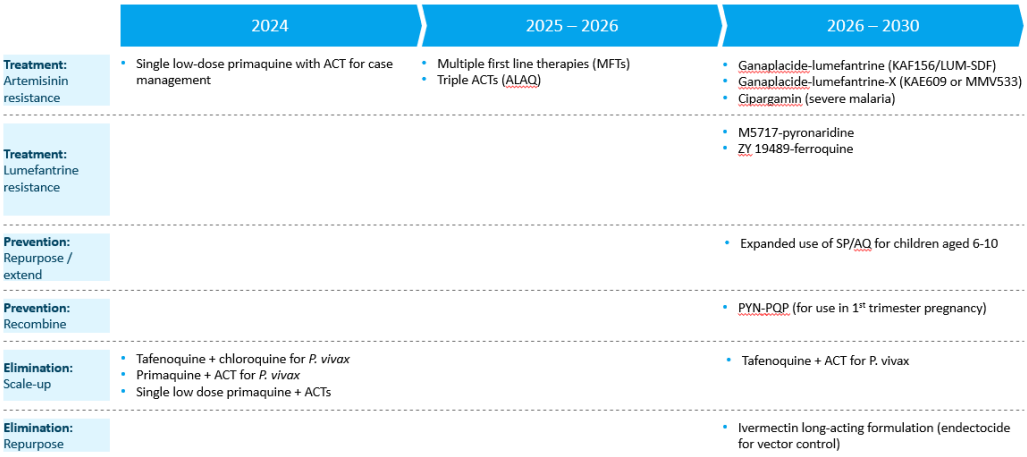
Highly preliminary – subject to change

Vector control | Expected data review timelines for new interventions



Highly preliminary – subject to change

Drugs and medicines | Expected data review timeline for new interventions



Enablers. The cross-cutting enablers include 1) complementarity between the three levels of WHO, 2) closer collaboration with other WHO departments and malaria partners to leverage WHO's unique position, and 3) enable GMP to work better with partners. Other enablers include: 4) an internal transformation of GMP to strengthen its performance management and value proposition for talent, and 5) a new focus on resource mobilization for sustainable funding.

Results framework. Detailed operational plans outlining specific activities will be prepared and maintained. Progress on these activities will be monitored via a Theory of Change. A summarized Theory of Change is included below.

Additional background information

GTS targets at risk. The world is off track to meet the 2030 GTS targets for reducing global malaria i) mortality and ii) morbidity by at least 40% from 2015 levels. Based on current trends, interim milestones and the 2030 targets are out of reach. "Business as usual" will lead to continued deaths from this preventable and curable disease.

Feedback from partners highlights the need for a refined GMP strategy. GMP has reached out to more than 40 key malaria stakeholders (e.g., countries, academia, funders, civil society organizations, etc.) for feedback. Partners acknowledged recent accomplishments by GMP (e.g., consolidated guidelines), but recommended that GMP needs to strengthen its capacity to deliver the "basics" (e.g., norms and standards) and sharpen its strategic focus to speak with "one voice" (e.g., on new tools & innovation, context-based country support). GMP risks losing its leadership in normative and strategic guidance.

Methodology for strategy development. The strategy development process rests on three pillars: 1) a listening tour which includes feedback on GMP's unique role in the malaria ecosystem, and solicits feedback on key elements of the strategy in development (e.g., HBHI); 2) Bi-weekly workshops with GMP's Senior Management Team (SMT) as Steering Committee for detailed guidance, further refined in 1:1 meetings with SMT members; 3) a high level root cause analysis.

Additional deliverables – M&E framework and resources mobilization narrative: A detailed monitoring & evaluation (M&E) framework will include a Theory of Change that will outline specific outputs of the activities. The M&E framework will also be supported by a list of key performance indicators to create accountability for the activities and enable performance management and progress tracking. RM narratives that can be used to drive fundraising conversations with diverse funders will also be prepared. This RM narrative will be aligned with the broader WHO IR model and cover a deep dive into the funding of other malaria-focused organizations, and an outlook on the preferences of some of the largest potential funders.

WHO GMP| Operational Strategy 2024-2030

Presentation to the Malaria Policy Advisory Group (MPAG)

30th October 2023

Global **Malaria** Programme

World Health Organization

Objectives for today

- Review background to why a new GMP strategy is needed
- Present the key strategic objectives for GMP until 2030
- Outline proof points to signal change is happening at GMP
- Discuss a preliminary list of deliverables in GMP strategy
- Collect feedback and lay out what GMP needs from MPAG

Agenda

Draft 2024-2030 Operational Strategy 30 min

- Context & purpose
- Methodology & strategy development process
- Structure of the strategy document
- Expected deliverables of technical products
- Impact of the strategy

Next steps and Q&A 30 min

Agenda

Draft 2024-2030 Operational Strategy 30 min

- Context & purpose
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- Impact of the strategy

Next steps and Q&A 30 min

The global malaria response is off track

Source: World Malaria Report 2022; Note: historical data available until 2021

GMP has made good progress but feedback from partners is clear, GMP must evolve…

Good progress has been made

I appreciate that they **progressed towards consolidated guidelines**. That was something all the **partners have been requesting**

- Implementer

GMP's work in **supporting the development of the malaria vaccine has been exemplary**. It's a monumental step in the right direction

- Advocacy & RM

But there is a need to evolve

Insanity is **doing the same thing over and over** and expecting different results. **The time for GMP to evolve is now**

- Technical Partner

They [GMP] have a **list of areas to address** and a lot of them end up **not being addressed**

- Country

… or risk losing its abili-ty to lead the response

GMP's role and influence have declined over time […] **compelling countries to seek alternative sources of guidance**

- Funder

We are facing challenges in translating GMP's guidance into operations… **If GMP does not provide** [timely and adequate] **guidance, partners may step in** to fill in the void.

- Technical Partner

2015-2020 Transformation Roadmap

Context

Developed toward the end of "Golden era[1]" of malaria control with introduction of GTS and arrival of Dr Pedro Alonso

Focus

Improve GMP's ways of working while strengthening its activities and resources to cover critical technical fields

1. World Malaria Report 2020

2024-2030 Operational Strategy

Developed after **years of stalled progress** and the **post COVID-19 tightening funding environment**

Crystallize **GMP's unique value proposition** in the ecosystem and ensure coherence under a publicly available **Operational Strategy**

GMP's Operational Strategy will be fully aligned with the GTS & GPW14 priorities

Agenda

Draft 2024-2030 Operational Strategy 30 min

- Context & purpose
- Methodology & strategy development process
- Structure of the strategy document
- Expected deliverables of technical products
- Impact of the strategy

Next steps and Q&A 30 min

Three stages of the strategy development process

Strategy draft

~7 weeks

- GMP drafted the operational strategy, an M&E framework and high-level RM narrative in August and September

Strategy refinement

~5 weeks

- Refine the Operational Strategy with input from WHO DG, GMP technical teams, and partners in October

Strategy socialization

We are concluding the **validation and refinement of the strategy while finalizing the M&E framework and RM narrative**

~2 weeks

- Validate and endorse strategy with MPAG in October
- Circulate and socialize strategy in November

The strategy development combined research with extensive internal & external stakeholder engagement

Literature review to identify potential **root causes**

Listening tour with 40+ interviews, inc. WHO three-layers, NMCPs, countries & partners

Close engagement with GMP through weekly working sessions

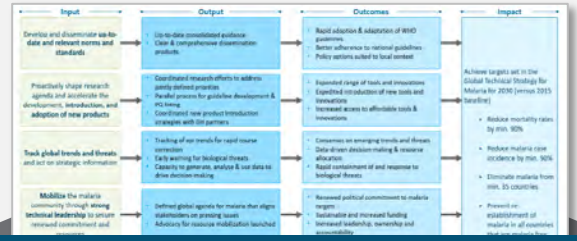
3 key deliverables are to be developed during the project

GMP 2024-2030 Operational Strategy

Define strategy for GMP to help countries develop and implement NSPs in alignment with the GTS

No intention to replace GTS

Monitoring & evaluation framework



Lay out how the strategy will be translated into operations for tangible impact

Resource mobilization strategy

In line with broader WHO efforts, develop GMP's contribution to fundraising

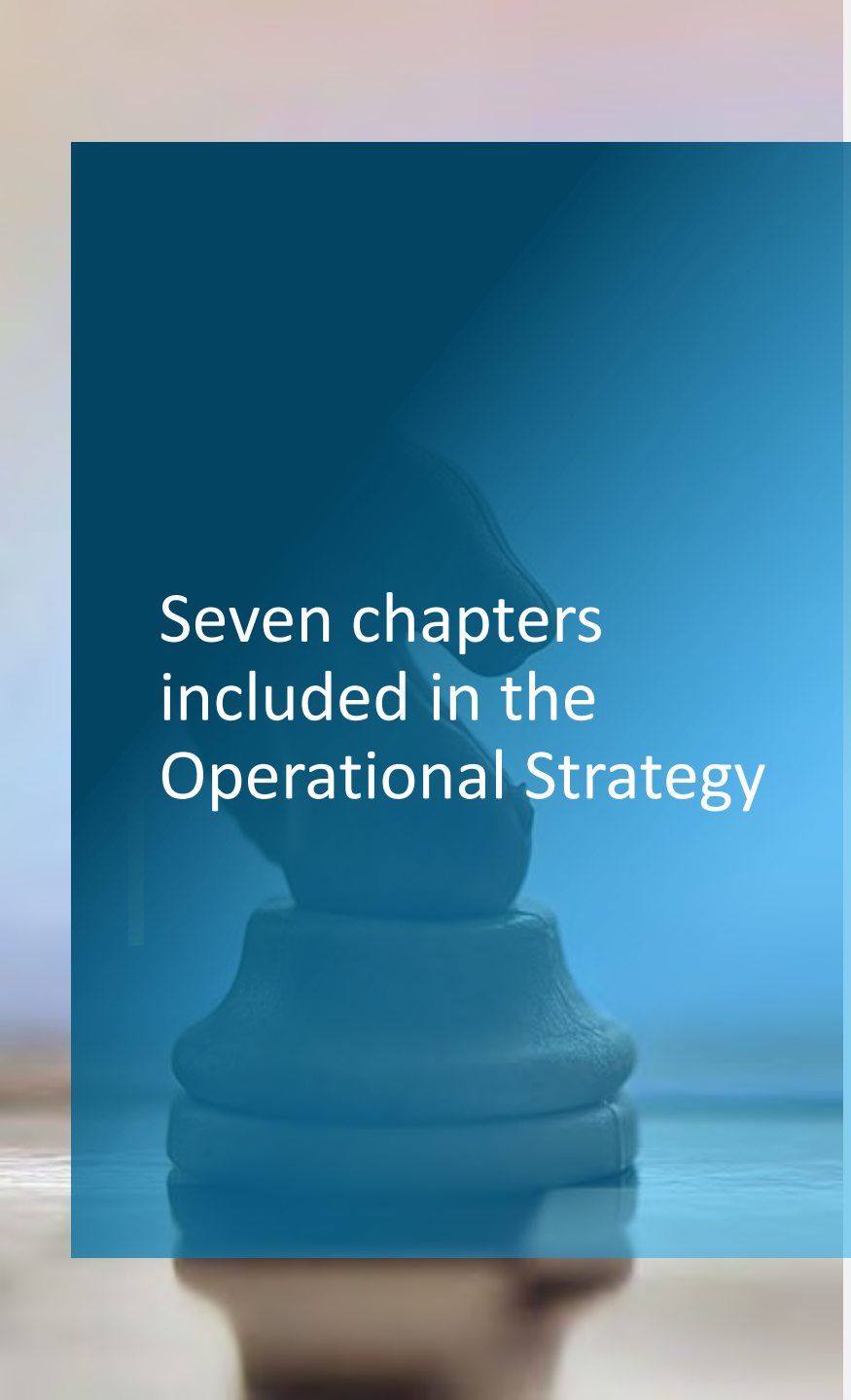
Part of coherent WHO RM narrative

Agenda

Draft 2024-2030 Operational Strategy 60 min

- Context & purpose
- Methodology & strategy development process
- Structure of the strategy document
- Expected deliverables of technical products
- Impact of the strategy

Next steps and Q&A 30 min



Seven chapters included in the Operational Strategy

		Primary focus of section
1	**Context**	Provide broader context of the disease burden, and introduce GTS and GMP
2	**Case for change**	Unpack stalled global response in dynamic environment
3	**Root causes**	Summarize on challenges that hamper the malaria response
4	**Shift in response needed**	Outline what is needed to get the response back on track
5	**GMP strategic objectives**	Explain the new operational strategy for GMP in detail
6	**Enablers**	List elements, resources, conditions required to execute the strategy
7	**Results framework**	Describe expected impact via ToC, incl. a M&E plan to measure progress

GTS targets are at-risk, and the global health & malaria landscape is evolving

- Historic gains are being eroded due to challenges such as, biological threats and a changing ecology & demography
- Some promising innovations are on the horizon, with COVID-19 setting a new benchmark for rapid product introduction
- Existing global health architecture is competing for limited funding, making increased efficiency and better coordination necessary
- A concerted effort is needed, alongside progress on and integration with the broader UHC/PHC, MNCH[1], GER[2], malnutrition, and climate agendas
- Recent changes in the leadership of key malaria actors, while WHO is gearing up for a strong GPW14, represent window of opportunity

1. Maternal, Neonatal, and Child Health 2. Gender, Equity, Rights

Now is the time for GMP to refine its strategy to lead the technical aspects of the global malaria response

The root causes underscore the challenges the ecosystem faces in delivering interventions that maximize coverage

Broader determinants of the malaria response

- Broad range of biological, technical, financial, socio-economic, political, and environmental factors – many of which evolve over time

Challenges around coverage w/ Tanahashi framework

- Coverage issues:
  - Availability (e.g., insuff. facilities & tools)
  - Accessibility (e.g., distance constraints)
  - Acceptability (e.g., lack of cultural fit)
  - Contact (e.g., expensive)
- Issues with effectiveness (e.g., less efficacious products)

Challenges related to funding and the ecosystem

- Resource-constrained domestic + international funding environment ($7bn required p.a. – only ~50% available)
- Fragmented ecosystem

Source: BCG analysis

GTS Vision: A world free of malaria

GMP Operational Strategy

WHAT?

Mission

Support all Member States in implementing the Global technical strategy for malaria 2016–2030 and promote effective partnerships with malaria stakeholders

Principles

Country ownership and leadership, with a whole-of-government & whole-of-society approach

- Resilient health systems
- Equitable access
- Data and science

HOW[1]?

Norms & Standards	New tools & innovations	Strategic information for impact	Leadership
Develop and disseminate **up-to-date and relevant norms and standards**	Proactively **shape research agenda** and accelerate the **development, introduction, and adoption** of new tools & innovations	**Track global trends and threats** and act on **strategic information**	**Mobilize** the malaria community through strong **technical leadership** to secure renewed commitment & resources

CONTEXT-BASED COUNTRY SUPPORT[1]

Burden

HBHI
Endemic
Elimination
Prev. of reest.

- Rapid adoption & adaptation of guidance
- Timely introduction of new tools & innovations
- Countries capacitated to collect and act on data
- Concerted effort to strengthen commitment

BOLD: Differentiated approach

Closely integrated with broader UHC/PHC, MNCH[2] , GER[3] , malnutrition, and climate agendas – contributing to impact on malaria and equitable outcomes

ENABLERS

- Complementarity across 3-levels
- Cross-departmental coordination
- Partner engagement
- Transformation & talent
- Financing

1. Across the following interventions: Vector control, Immunoprevention, Chemoprevention, Diagnosis, Chemotherapy, Surveillance; 2. Maternal, Neonatal, and Child Health 3. Gender, Equity, Rights

GMP's strategy to contribute towards the global response is built on 4 strategic objectives and context-based country support

Aligned with GTS and GPW 14 core functions

HOW[1]?

Norms & standards
- Living guidelines
- Dissemination products

New tools & innovations
- Research agenda (incl. TPPs / PPCs) & view of pipeline
- Coordinated market-shaping
- Introduction & validation of new tools & innovations

Strategic information for impact
- Updates on global trends (incl. WMR)
- Updates on global threats (biological and others)
- Feedback mechanism for evidence-to-action

Leadership
- Convening technical forums and malaria stakeholders
- Buy-in & funding for malaria
- Malaria in the broader context of PHC, UHC & SDGs
- Partnerships, including with communities
- Malaria-free certification

Rapid adoption & adaptation of guidance

Timely introduction of new tools & innovations

Countries capacitated to collect and act on data

Concerted effort to strengthen commitment

CONTEXT-BASED COUNTRY SUPPORT[1]

Burden

HBHI
Endemic settings
Elimination
Prev. of reest.

Capacity building

- Policy adaptation & adoption
- Strategic support
- Technical assistance

BOLD: Differentiated approach

Closely integrated with broader UHC/PHC, MNCH[2] , GER[3] , malnutrition and climate agendas

Global Malaria Programme

1. Across the following interventions: Vector control, Immunoprevention, Chemoprevention, Diagnosis, Chemotherapy, Surveillance; 2. Maternal, Neonatal, and Child Health 3. Gender, Equity, Rights

World Health Organization

GMP will strengthen core activities to meet the needs of countries and partners

Norms & Standards

Up-to-date consolidated guidance, **disseminated quickly and clearly**

New Tools & Innovation

Product introductions **supported end-to-end**, with a parallel process for guideline development and PQ listing

Strategic info for impact

Tracking of trends, threats and other **data to drive decision making**

Leadership

Stakeholders aligned behind **common agenda** addressing the most pressing issues of malaria response

Context-based country support

Stratified approach to country support based on needs

Note: Detailed proof points and 2024 deliverables available

To demonstrate progress, GMP has identified proof points which will be delivered within 12 months of strategy launch

Norms & standards

- Published guidance on tafenoquine (+ G6PD test) and SLD primaquine[1], larval source management
- Convened technical forum and published report on MFT[2]
- Began data review for novel vector control tools[3]

New tools & innovation

- Published view of expected data review timelines for upcoming recommendations
- Revised norms and standards procedure document
- Published website for consolidated data on comparative efficacy of vector control tools

Strategic info for impact

- Shared interim updates to WMR
- Published manual for subnational tailoring
- ☆ Convened first meeting in Africa to address resistance
- ☆ Mapped gaps in TES support where GMP is needed

Leadership

- MoH of high burden countries signed a declaration to end malaria deaths
- Convened Technical Expert Group on climate and malaria
- ☆ Certified malaria elimination in Georgia and Timor-Leste

Context-based country supp.

- ☆ Launched pilot of IPOs in 2 HBHI countries and established feedback mechanism to capture learnings
- Refined HBHI approach based on evaluation

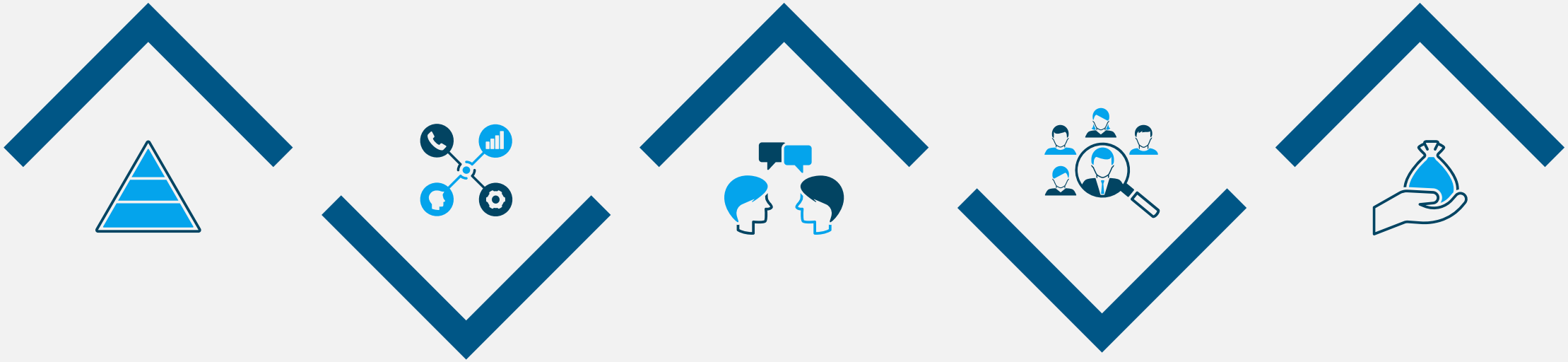
☆ Transformative idea related

1. Single low dose primaquine in areas of artemisinin partial resistance 2. Multiple first line therapies 3. Including spatial repellents, ATSBs, eave tubes, pyrethroid paints

Transformative initiatives will amplify GMP's impact on response

	Introduce IPOs in HBHI countries	Expedite efforts for elimination	Bolster response for resistance
Vision	Countries supported to optimize interventions and tools, mobilize for and address challenges	10 more countries certified as malaria-free	Up-to-date understanding of emerging resistance threats and how to combat them
Outputs	IPOs piloted in at least 4 HBHI countries by 2026 (potentially DRC, Mozambique, Ghana, Tanzania), and fully operational by 2030	GMP providing technical support to at least 5 countries on the brink of elimination by 2026 and at least 10 countries by 2030	3 TES networks in Africa convened by 2026, 5 networks by 2030. AFRO secretariat launched by 2026, ramped up by 2030
Value add	Multiply impact of partners' investments at country levels through better coordination from a position of neutrality	Bring attention to area that has limited focus – GMP sole actor that can help in elim. settings, and needs resources to do so	Proactively address new and emerging threats using reach and knowledge accumulated by GMP

Five transversal enablers are needed at all levels to drive impact



Complementarity across 3-levels

Ensures greater impact combining unique presence of WHO

Cross- dept. coordination

Ensures better alignment with PQ and technical teams & integration across diseases & priorities

Partner engagement

Ensures GMP is seen as collaborative partner helping alignment

Transformation & talent

Ensures vacancies are filled, and employees are empowered to execute their role

Predictable financing

Ensures upfront planning and prioritization of new activities

ToC has been defined to help turn strategy into action

Input	Output	Outcomes	Impact
Norms & Standards	Up-to-date consolidated guidance, disseminated quickly and clearly	Guidance adopted and adhered to	Achieve targets set in the Global Technical Strategy for Malaria for 2030 (versus 2015 baseline)
New Tools & Innovation	Product introductions supported end-to-end, with a parallel process for guideline development and PQ listing	Increased, rapid access to new tools and innovations	
Strategic info for impact	Tracking of trends, threats and other data to drive decision making	Fast understanding of threats & trends, decisions driven by data, customized for sub-national context	
Leadership	Stakeholders aligned behind common agenda addressing the most pressing issues of malaria response	Renewed commitment to fight malaria, with funding increased	
Context-based country support	Stratified approach to country support based on needs	Countries well supported with NMCPs/NSPs	

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GMP will identify and work towards achieving deliverables along the continuum of care

Driven by an increased emphasis on **transparency, predictability, and early engagement with the ecosystem** – a detailed list of deliverables will be included in the strategy

	Vector control	Immunization prevention	Chemo-prevention	Diagnosis	Chemotherapy	Surveillance
Norms & standards	• Published technical recommendations for new products in the pipeline • Published updates of current recommendations, where necessary, given emerging data • Published operational guidance to accompany recommendations					
New tools & innovations	• Prioritized research agenda across all commodities/interventions • Published PPCs for next-gen products and interventions					
Strategic information for impact	• Disseminated regular updates on current/emerging malaria trends and threats affecting malaria • Strengthened in-country surveillance of trends and threats					
Leadership	• Convened technical experts and malaria stakeholders • Strengthened advocacy for coordinated technical dialogue • Published guiding principles for prioritizing malaria interventions in resource-constrained settings					
Country support	• Held regular engagement via HBHI taskforce meetings, E2025 partnership, and other forums • Conducted capacity building to strengthen regional and country-level response • Monitored adaptation and adoption of normative guidelines at country level					

Focus next page

Highly preliminary – subject to change

Drugs and medicines | Expected data review timeline for new interventions

	2024	2025 – 2026	2026 – 2030
Treatment: Artemisinin resistance	• Single low-dose primaquine with ACT for case management	• Multiple first line therapies (MFTs) • Triple ACTs (ALAQ)	• Ganaplacide-lumefantrine (KAF156/LUM-SDF) • Ganaplacide-lumefantrine-X (KAE609 or MMV533) • Cipargamin (severe malaria)
Treatment: Lumefantrine resistance			• M5717-pyronaridine • ZY 19489-ferroquine
Prevention: Repurpose / extend			• Expanded use of SP/AQ for children aged 6-10
Prevention: Recombine			• PYN-PQP (for use in 1st trimester pregnancy)
Elimination: Scale-up	• Tafenoquine + chloroquine for *P. vivax* • Primaquine + ACT for *P. vivax* • Single low dose primaquine + ACTs		• Tafenoquine + ACT for P. vivax
Elimination: Repurpose			• Ivermectin long-acting formulation (endectocide for vector control)

Note: Timelines are indicative and subject to change based on data availability from clinical trials and other studies; Timelines indicate expected dates for data review – this does not imply that recommendations for products will be issued; The above list may not be fully exhaustive and will be continuously updated to reflect any new products on the pipeline

Highly preliminary – subject to change

Vector control | Expected data review timelines for new interventions

	2024	2025 – 2030
Attractive targeted baits	• Attractive sugar baits	
Spatial repellants	• Spatial repellents	
Housing modifications		• Eave tubes
Systemic insecticides and endectocides		• Endectocides

Note: Timelines are indicative and subject to change based on data availability from clinical trials and other studies; Timelines indicate expected dates for data review – this does not imply that recommendations for products will be issued; The above list may not be fully exhaustive and will be continuously updated to reflect any new products on the pipeline

Agenda

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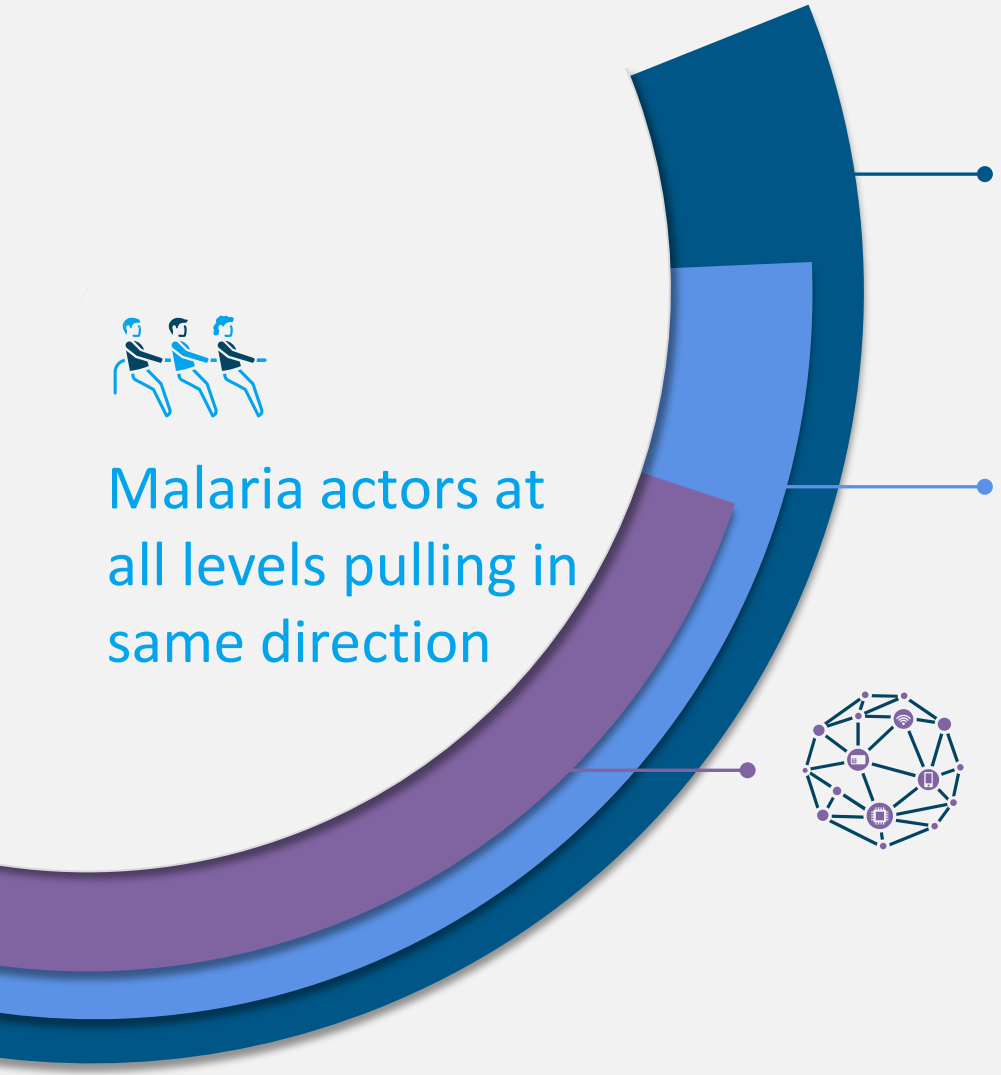
Next steps and Q&A 30 min

The strategy will have an impact on partners and all levels of WHO, maximizing the efficiency of the ecosystem



Malaria actors at all levels pulling in same direction

Fixed 'basics' to enhance partner trust, renewed strategic focus to lead the ecosystem & **alignment behind 'one voice'**

Better coordination within WHO **at all three levels**, strengthening WHO internally and externally for sustainable impact

Better **clarity on GMP's role and potential linkages with the whole ecosystem** (especially countries and partners), setting the foundation for a **more synergistic approach** to combatting malaria

Agenda

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- Context & purpose
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Next steps and Q&A 30 min

Next steps

1. Continue refinement of GMP's Operational Strategy based on your guidance
2. Finalize M&E framework for GMP, inc. full costing to ope-rationalize the strategy
3. Finalize & test GMP's resource mobilization narrative, in line with broader WHO efforts
4. Finalize stakeholder engagement in the malaria ecosystem to provide feedback on the draft strategy

Thank You

Global **Malaria** Programme

World Health Organization

Malaria Policy Advisory Group Meeting
30 October–1 November 2023, Geneva, Switzerland
Background document for Session 3

Update on malaria vaccines

October 2023

Background

In October 2021, the World Health Organization (WHO) recommended the first malaria vaccine (RTS,S/AS01) to be used for the prevention of *Plasmodium falciparum* malaria in children *(1)*. The WHO position was informed by findings from the ongoing Malaria Vaccine Implementation Programme (MVIP) in Ghana, Kenya and Malawi, which started in 2019 and demonstrated the feasibility, safety and substantial impact of the vaccine in routine use. Demand for the malaria vaccine is high and, to date, 18 countries have been approved by Gavi, the Vaccine Alliance, to receive support for introduction. Supply capacity for the RTS,S/AS01 vaccine is limited and insufficient to meet demand. A *Framework for the allocation of limited malaria vaccine supply (2)* was developed and operationalized to determine allocation of the 18 million doses of RTS,S/AS01 available for 2023–2025 *(3)*. Subnational introductions, prioritizing areas where malaria burden and death are highest, are expected to start in a limited number of countries in early 2024.

Update of WHO recommendation to include the R21/Matrix-M malaria vaccine

In a joint session on 27 September 2023, the Strategic Advisory Group of Experts on Immunization (SAGE) and the Malaria Policy Advisory Group (MPAG) were presented with clinical data on the safety, efficacy, public health impact and cost-effectiveness of the R21/Matrix-M malaria vaccine *(4,5)*.

R21/Matrix-M is a pre-erythrocytic stage vaccine that targets the circumsporozoite protein (the same target as RTS,S/AS01) and is formulated with the saponin-based adjuvant Matrix-M. A Phase 3 multi-centre randomized controlled trial has been ongoing since January 2021 to evaluate the vaccine's efficacy against clinical malaria in African children. The trial is evaluating a four-dose vaccine regimen with two vaccine administration strategies (age-based administration and seasonal administration) in five sites in Burkina Faso, Kenya, Mali and the United Republic of Tanzania, with a total of 4800 participants. The primary end-point of vaccine efficacy against clinical malaria 12 months after a primary series of three monthly doses has been met. At the time the SAGE and MPAG joint session, data had been evaluated during the 18 months following dose 3 for both vaccine administration strategies (including six months of follow-up after dose 4).

The two advisory bodies, SAGE and MPAG, concluded that R21/Matrix-M should be added as a WHO recommended malaria vaccine (together with the RTS,S/AS01 vaccine, which was recommended by WHO in October 2021) for the prevention of *P. falciparum* malaria in children living in malaria-endemic areas, prioritizing areas of moderate and high transmission. Both vaccines should be provided in a four-dose schedule to children starting at around 5 months of age. A fifth dose, given one year after dose 4, may be considered in areas where there is a significant malaria risk remaining amongst children one year after receiving dose 4. In areas with highly seasonal malaria or areas with perennial malaria transmission with seasonal peaks, countries may provide the malaria vaccines using an age-based or seasonal strategy, or a hybrid of these approaches.

Countries should prioritize vaccination in areas of moderate and high transmission, but may also consider providing the vaccine in low transmission settings. Decisions on expanding to low transmission settings should be considered at country level, based on the overall malaria control strategy, cost-effectiveness, affordability and programmatic considerations, such as whether it would simplify delivery to include such areas.

Vaccine introduction should be considered in the context of comprehensive malaria control plans.

The recommendation for the R21/Matrix-M vaccine was based largely on results from clinical trials showing high vaccine efficacy and no major safety concerns. The R21/Matrix-M vaccine is similar to the RTS,S/AS01 malaria vaccine in terms of indication for use, target population, schedule, route of administration and delivery strategies. There is no evidence that one vaccine performs better than the other, and decisions regarding product choice should be based on programmatic characteristics, vaccine supply and vaccine affordability.

Reviews by an R21/Matrix-M vaccine safety working group and the Global Advisory Committee on Vaccine Safety identified no major safety concerns that should delay introduction. No imbalances in serious adverse events were noted between study arms. There was a higher number and clustering of febrile convulsions within three days of vaccination among children in the R21/Matrix-M arm compared to children in the control arm, with an attributable risk in the same range as with some other childhood vaccines. Although there were very few deaths in the trial, an imbalance was observed, with more deaths in the R21/Matrix-M arm than in the control arm. The imbalance was not statistically significant and there was no pattern among deaths in relation to the timing of vaccination and no observed patterns or consistency in causes of death.

The R21/Matrix-M vaccine reduced clinical malaria cases by 75% during the 12 months following the three-dose primary series when provided seasonally just prior to the high transmission season. This high vaccine efficacy was maintained during the six months following the administration of dose 4, given prior to the transmission season and 12 months after dose 3.

Likewise, there was high vaccine efficacy when the vaccine was given in an age-based schedule to children living in areas of low to moderate malaria transmission, reducing clinical malaria cases by 66% for 12 months following dose 3. This vaccine efficacy was sustained for six months following the administration of dose 4, which was administered 12 months after dose 3. Efficacy declined slowly over the 12 months following dose 3 in both seasonal and standard administration sites.

There are no data on the vaccine efficacy of R21/Matrix-M in high perennial transmission settings. However, given the similarity to RTS,S/AS01, which has been shown to be efficacious in areas of high, moderate and low malaria transmission and in highly seasonal settings, the R21/Matrix-M will likely also be efficacious in all malaria-endemic settings.

The feasibility of delivering the R21/Matrix-M vaccine in routine immunization programmes is likely to be similar to that of RTS,S/AS01, as demonstrated through the MVIP, due to similarities between the two vaccines with regards to indication, target population, schedule, route of administration and delivery strategies.

Trial data and mathematical modelling predictions indicate a significant public health impact across a wide range of settings, including lower transmission areas. Cost-effectiveness estimates are comparable to other malaria interventions, other childhood vaccines and other widely deployed control measures.

SAGE and MPAG also recommended additional high-priority research on R21/Matrix-M to be conducted, including post-licensure assessment of vaccine effectiveness in high perennial transmission settings, vaccine co-administration studies, and monitoring for the risk of malaria rebound. Research partners and funding organizations are encouraged to support other priority research, including post-licensure monitoring of vaccine safety, vaccine efficacy against severe malaria,

vaccine impact on mortality using available systems, and interchangeability studies on heterologous schedules with RTS,S/AS01 and R21/Matrix-M. SAGE and MPAG recommended that WHO lead the prioritization and coordination of these priority research studies and the development of relevant generic research protocols for country adaptation. Implementation of these studies should not delay programmatic roll-out.

The WHO Director-General endorsed the advice from SAGE and MPAG, and the updated malaria vaccine recommendations were publicly announced on 2 October 2023 *(6)*. Next steps for the second recommended malaria vaccine, R21/Matrix-M, include completing the ongoing WHO prequalification, which would enable international procurement of the vaccine for broader roll-out.

The Malaria Vaccine Implementation Programme

From the start of RTS,S/AS01 malaria vaccine implementation in Ghana, Kenya and Malawi in 2019 until October 2023, over 6 million doses have been administered and over 2 million children reached. All three countries successfully expanded vaccine delivery to MVIP comparator areas between November 2022 and March 2023. Demand and uptake continue to be high in all three countries, despite the challenges brought about by external factors, including the coronavirus disease (COVID-19) global pandemic. While there was variation in performance observed, according to administrative data for the first 8 months of 2023 (January to August), the estimated coverage of the first dose of RTS,S/AS01 was 81% in Ghana (third dose: 79%; fourth dose: 81%), 86% in Kenya (third dose: 78%; fourth dose: 51%) and 85% in Malawi (third dose: 74%; fourth dose: 46%). In Ghana, since late February 2023, there has been a change in schedule for the fourth RTS,S /AS01 dose to be provided at 18 months of age (instead of 24 months) to coincide with the administration of the meningococcal A conjugate vaccine and the second dose of measles-rubella containing vaccine. This change has resulted in a significant increase in uptake.

All three countries have secured support from Gavi to continue vaccine implementation following the end of the MVIP in December 2023.

The 46-month community mortality and sentinel hospital surveillance as part of the malaria vaccine pilot evaluation was completed in Ghana and Malawi in February 2023 and in Kenya in July 2023. Data cleaning and analysis are ongoing. The final results of the MVIP will be presented at the Annual Meeting of the American Society of Tropical Medicine and Hygiene in late October and at the International Conference on Public Health in Africa hosted by the Africa Centres for Disease Control and Prevention in November. The results will be presented to MPAG during the October meeting. The MVIP will be completed in December 2023. The many lessons learned through the pilot implementations and findings from the malaria vaccine pilot evaluation are being documented and disseminated through publications, reports and presentations and are informing guidance for vaccine roll-out.

High demand for malaria vaccine roll-out

Demand for malaria vaccines continues to be high on the part of governments in malaria-endemic countries. Since Gavi opened a funding window in mid-2022, over 20 applications have been submitted and 18 countries have been approved to receive support for malaria vaccine introduction.

Given the initial constrained vaccine supply for RTS,S/AS01, the Gavi application guidelines directed countries to present a stratification analysis and outline a phased introduction approach that would prioritize initial vaccine implementation in the areas of greatest need, in line with the *Framework for the allocation of limited malaria vaccine supply (2)*. In July 2023, Gavi, the United Nations Children's Fund (UNICEF) and WHO finalized the first vaccine allocation based on the principles of the framework, allocating the 18 million doses of RTS,S/AS01 vaccine available for 2023–2025 to 12 countries for subnational introduction in areas where the need is greatest *(3)*. The first doses of the vaccine are

expected to arrive in non-MVIP countries during the last quarter of 2023, with new introductions expected as early as Q1 2024.

Because the R21/Matrix-M malaria vaccine is now recommended for use by WHO, following WHO prequalification, Gavi will be able to include this second vaccine in its support programme. The manufacturer of R21/Matrix-M, Serum Institute of India Pvt Ltd, has publicly stated that the vaccine can be manufactured at mass scale and modest cost. The supply agreement for 2024-2028 between the manufacturer and UNICEF, as Gavi's procurement partner, was finalized in October 2023 *(7)*. UNICEF expects to begin delivering the R21/Matrix-M vaccine in mid-2024, with immunizations beginning in the same period. As a result, beginning in 2024, the cumulative supply availability of the two WHO-recommended malaria vaccines is expected to meet the high demand. This will enable more countries to introduce and scale up the vaccine more quickly to benefit children living in areas where malaria is a public health risk.

References

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Contact

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Update on malaria vaccine

Malaria Policy Advisory Group (MPAG) Meeting
30 October 2023, 13:15-14:00 CET

Mary Hamel, Lindsey Wu, Eliane Furrer

World Health Organization

Credit: WHO/F.Combrink

MPAG October 2023 meeting

Session 5: Malaria Vaccines – FOR INFORMATION

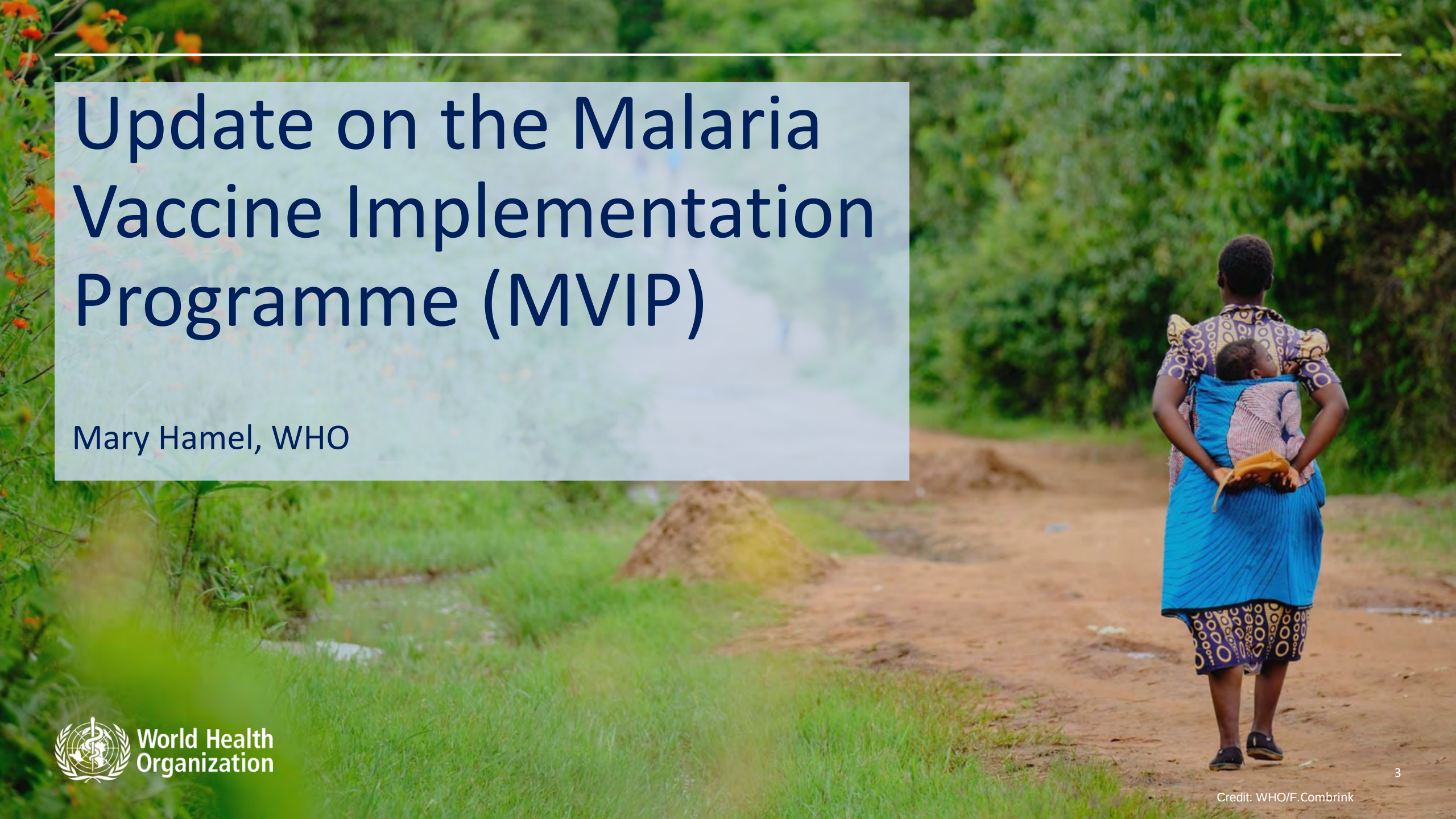
- Update on the Malaria Vaccine Implementation Programme (MVIP)
- WHO recommendation of R21/Matrix-M malaria vaccine
- Update on WHO Malaria Vaccines Recommendation
- Status of malaria vaccine roll-out

World Health Organization

Update on the Malaria Vaccine Implementation Programme (MVIP)

Mary Hamel, WHO

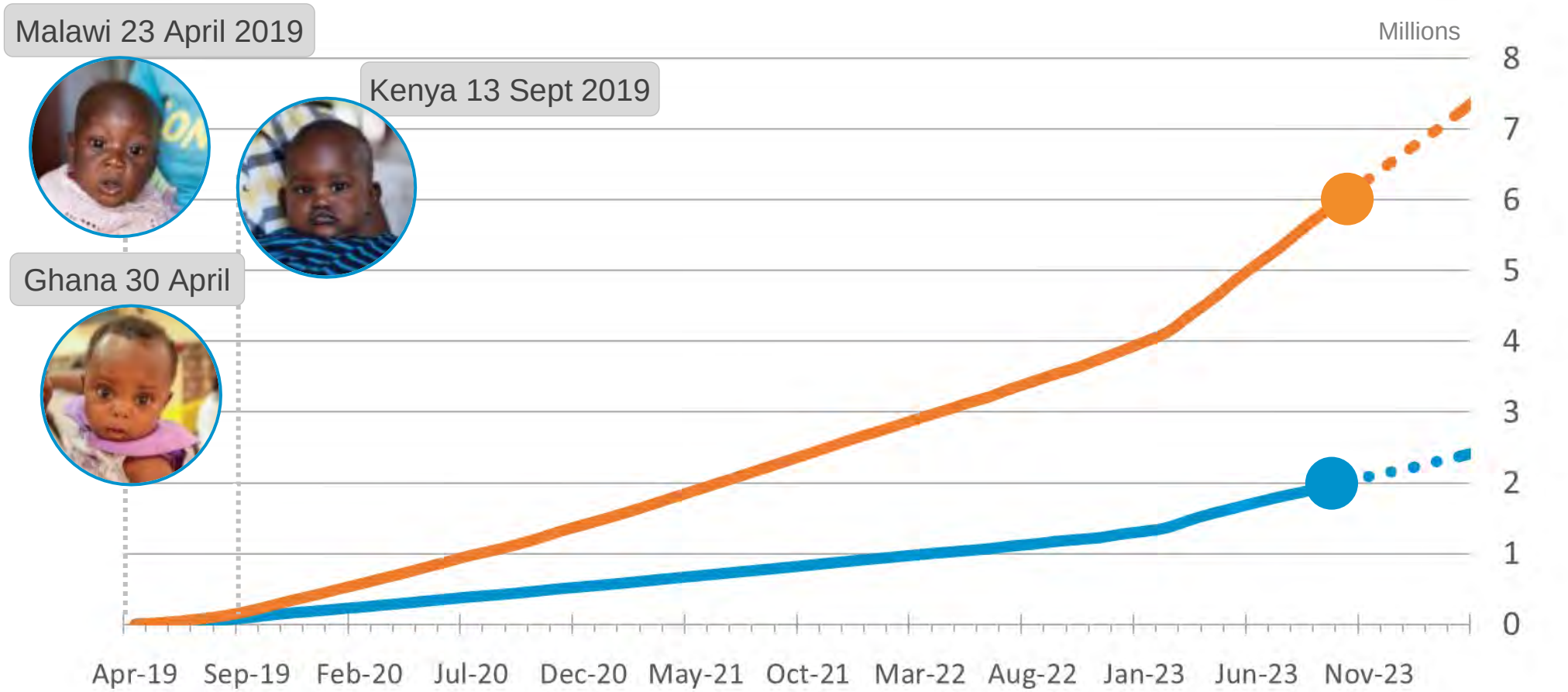
World Health Organization



Credit: WHO/F.Combrink

Malaria Vaccine Implementation Programme progressing well since 2019; MVIP end, Dec 2023

As of October 2023



> 6.0 million vaccine doses **administered**

> 2.0 million children received **at least one dose**

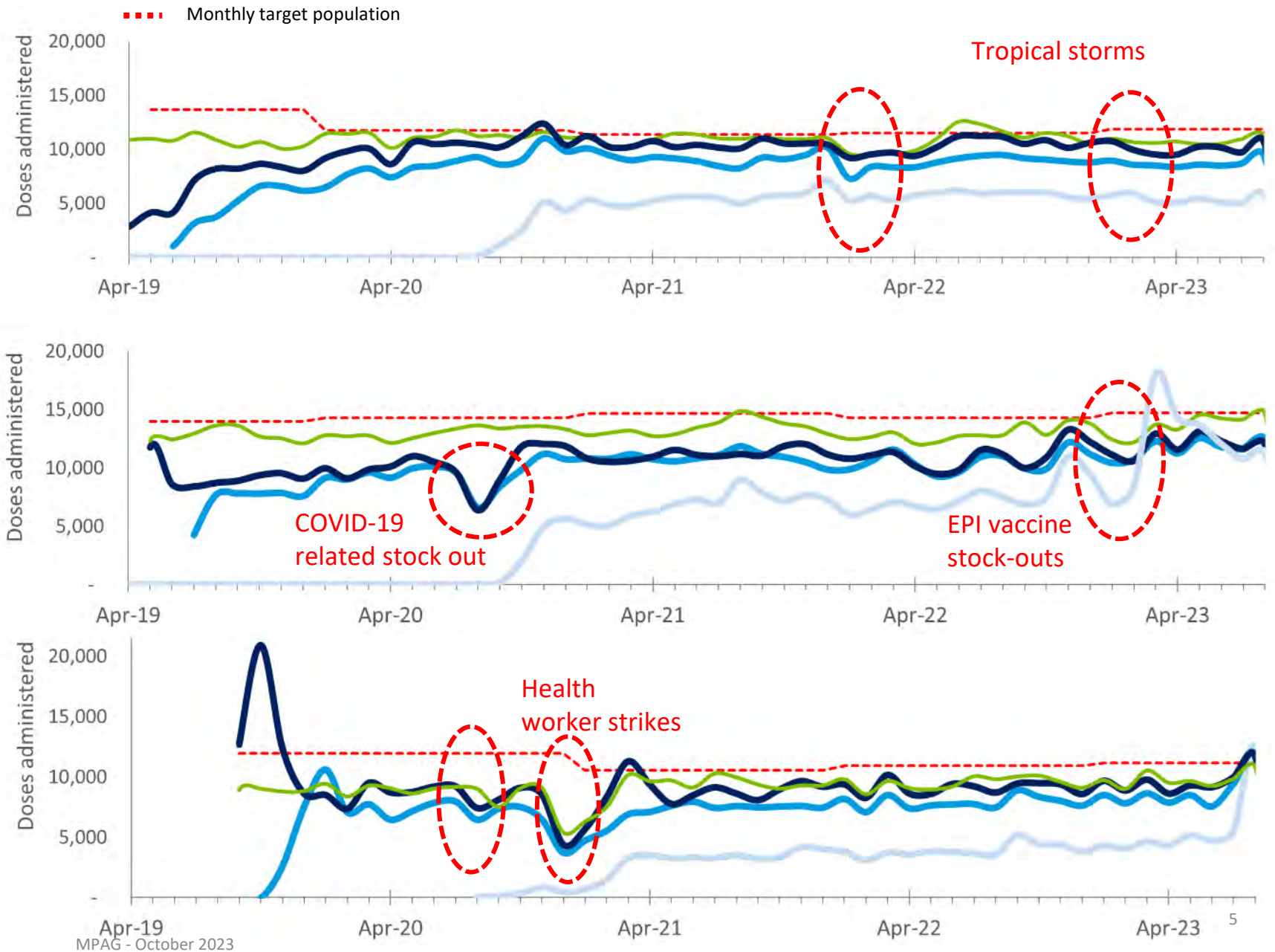
Estimates as of October 2023 - based on monthly MOH/EPI administrative data reports until Aug 2023 and MVIP team projections for subsequent months

Immunization coverage: monthly administrative data reports (through Aug 2023)

Malawi	2020	2021	2022	Jan-Aug 2023
Penta-3	95%	97%	95%	91%
RTS,S -1	88%	93%	90%	85%
RTS,S -3	73%	81%	76%	74%
RTS,S-4	--	49%	50%	46%

Ghana	2020	2021	2022	Jan-Aug 2023
Penta-3	92%	92%	91%	93%
RTS,S -1	71%	76%	77%	81%
RTS,S -3	66%	74%	74%	79%
RTS,S-4		47%	53%	81%

Kenya	2020	2021	2022	Jan-Aug 2023
Penta-3	72%	87%	87%	88%
RTS,S -1	69%	82%	83%	86%
RTS,S -3	60%	67%	72%	78%
RTS,S-4		29%	36%	51%



Expansion of vaccination to MVIP comparator areas

Using RTS,S/AS01 vaccine doses donated by GSK & funding from US-based Open Philanthropy to PATH

MVIP initial vaccinating district

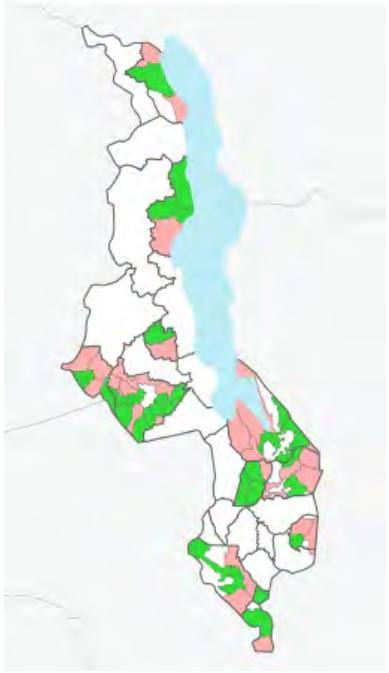
MVIP comparator district

Non MVIP district

Malawi

First introduced: 23 April 2019

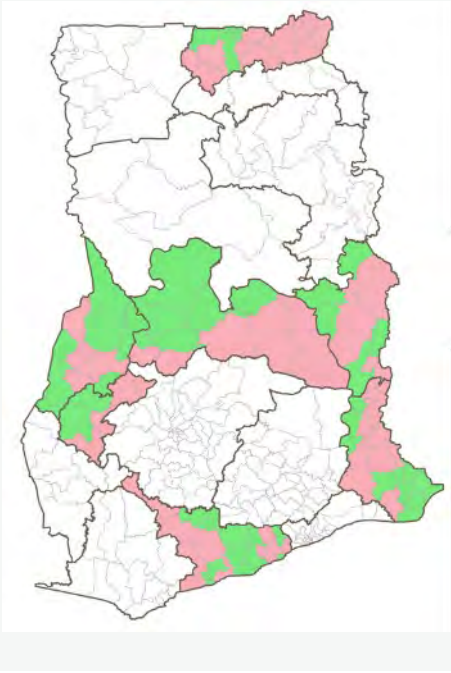
Expanded: 29 Nov 2022



Ghana

First introduced: 30 April 2019

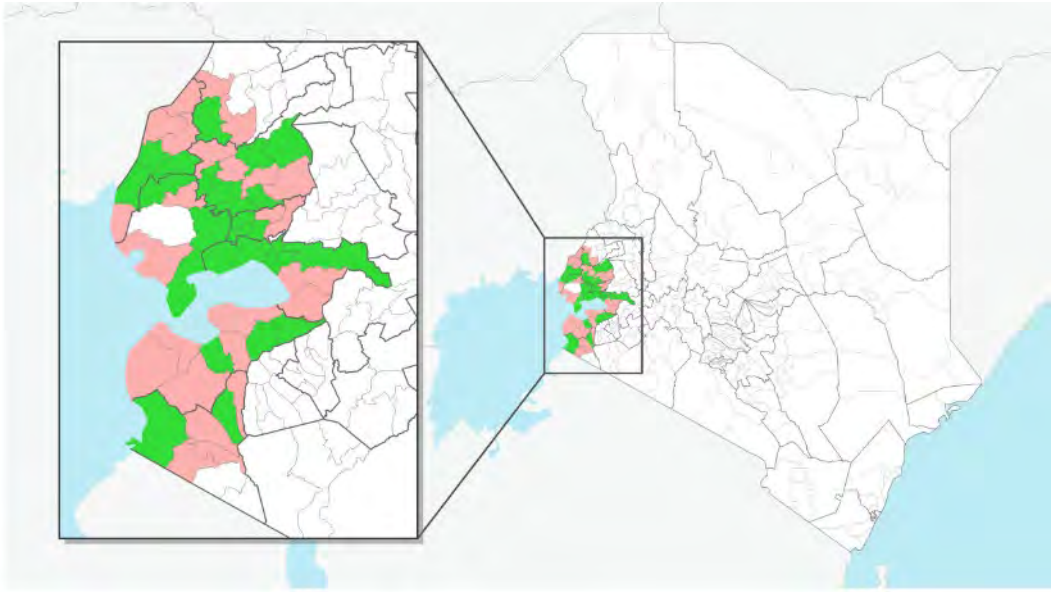
Expanded: 20 Feb 2023



Kenya

First introduced: 13 Sept 2019

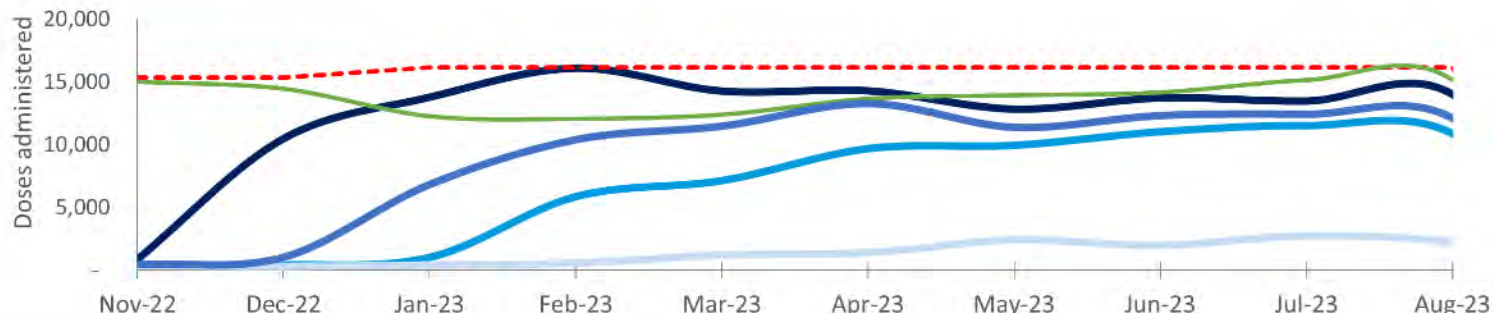
Expanded: 7 March 2023



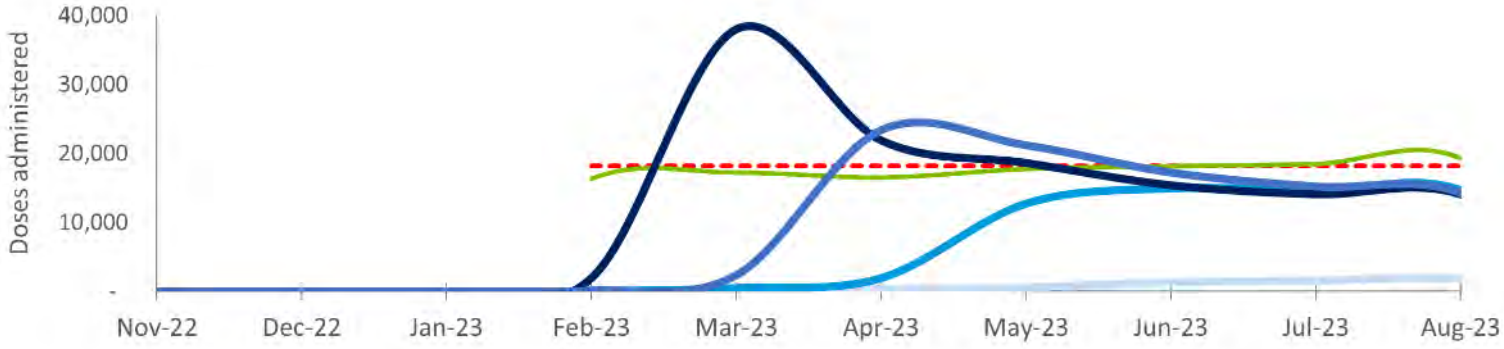
World Health Organization

Expansion to comparator areas: monthly administrative data reports (through Aug 2023)

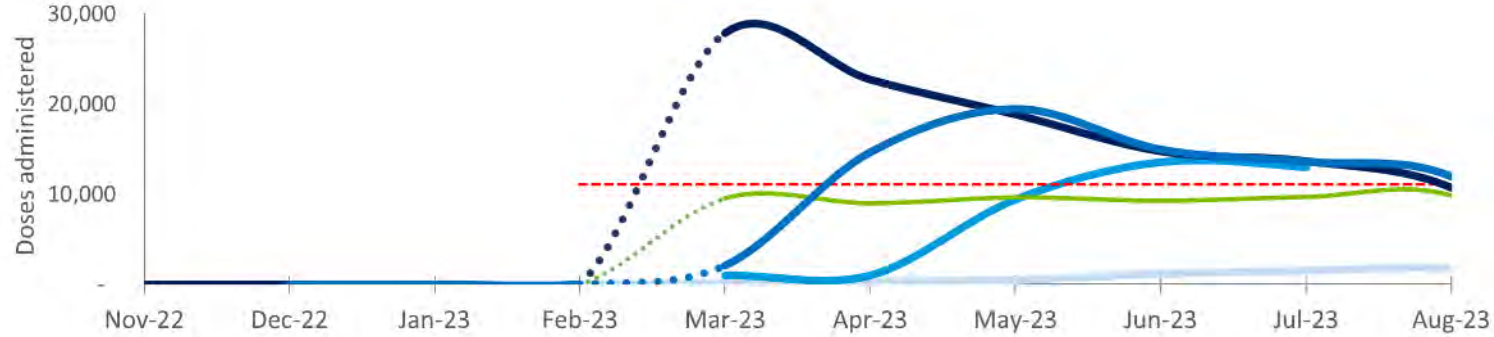
Malawi
29 Nov 2022

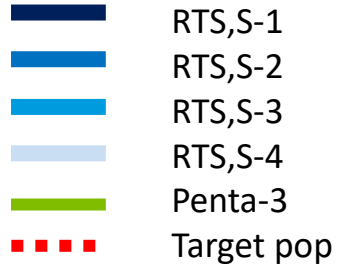


Ghana
20 Feb 2023



Kenya
7 March 2023





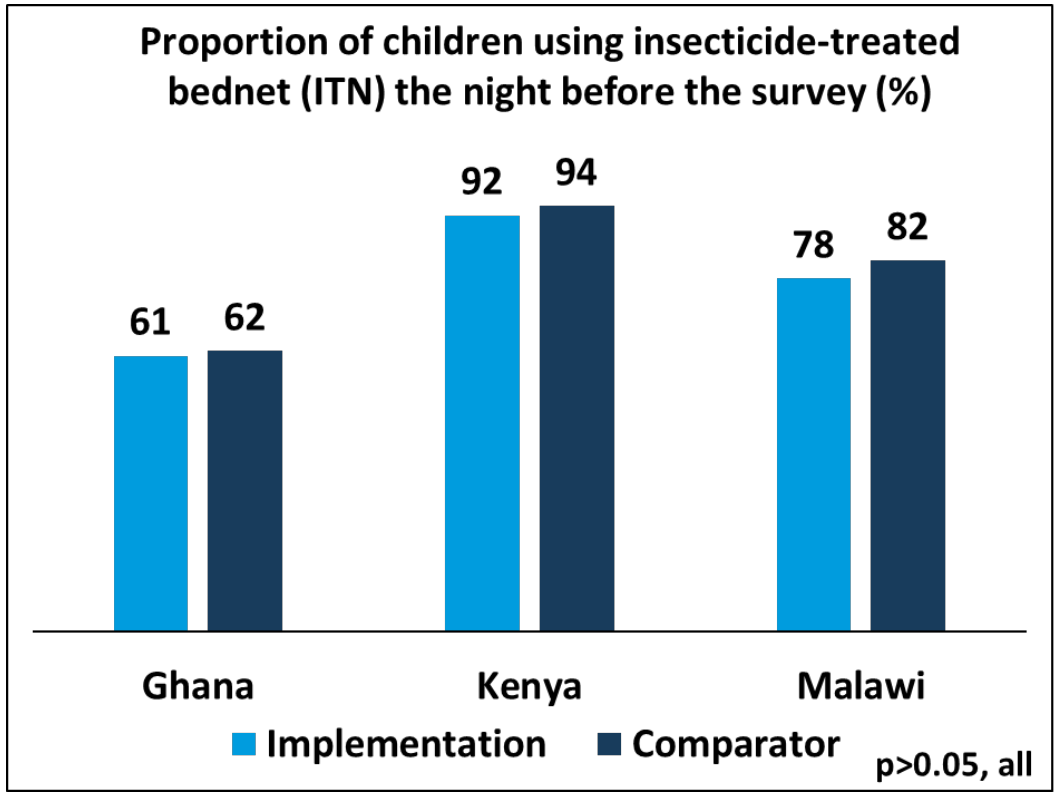
Note: Extended age-eligibility for vaccine access at the time of launch (i.e. children 6-11 months old in Ghana; 6-24 months old in Kenya; and 5-11 months old in Malawi)

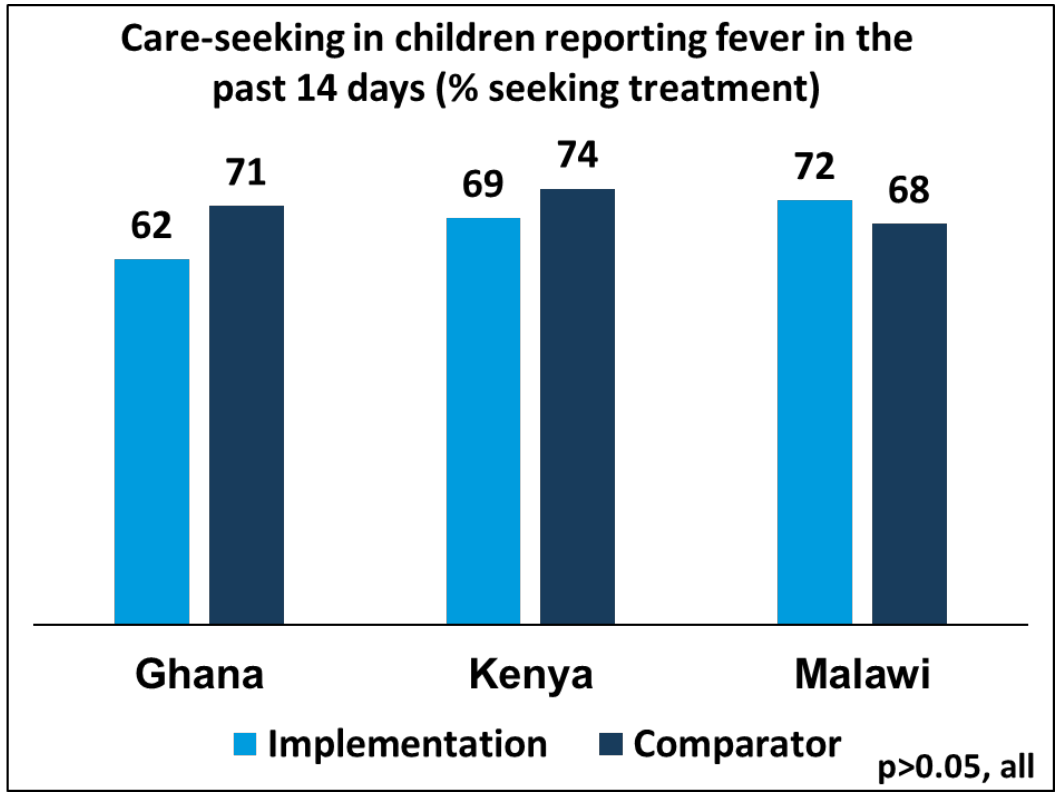
World Health Organization

RTS,S/AS01 pilot evaluation endline household surveys

(~30 months post introduction)

Malaria-related behaviours by implementation vs. comparator areas



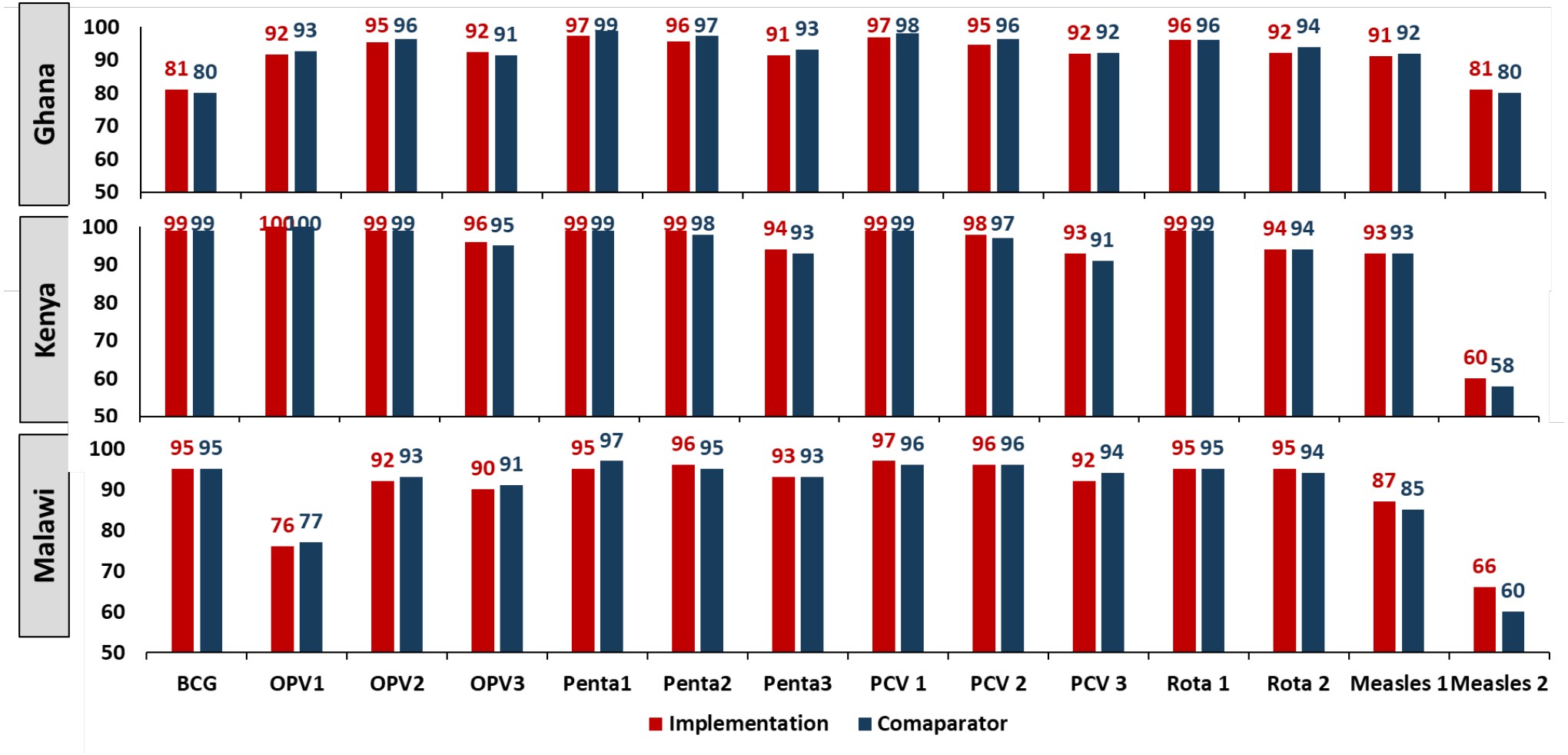


No changes in ITN use post RTS,S introduction, by study area or over time (except Malawi – changes in ownership and use post ITN campaign, but similar in implementation and control areas). **No differences by arm or over time in care-seeking among children reporting fever in past 14 days.**

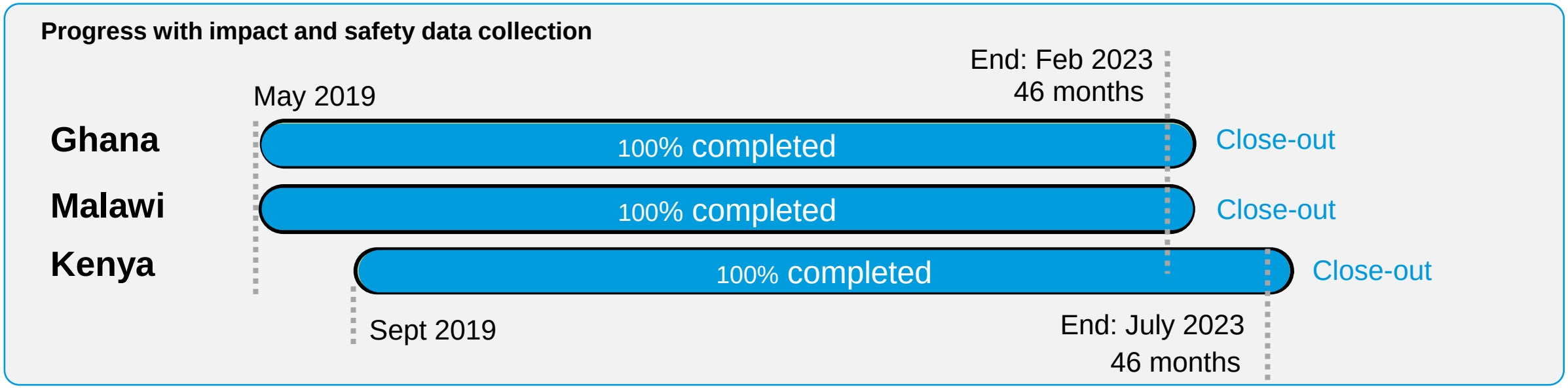
RTS,S/AS01 pilot evaluation endline household surveys

(~30 months post introduction)

No changes in vaccine coverage by study area or over time



Malaria vaccine pilot evaluation (MVPE)

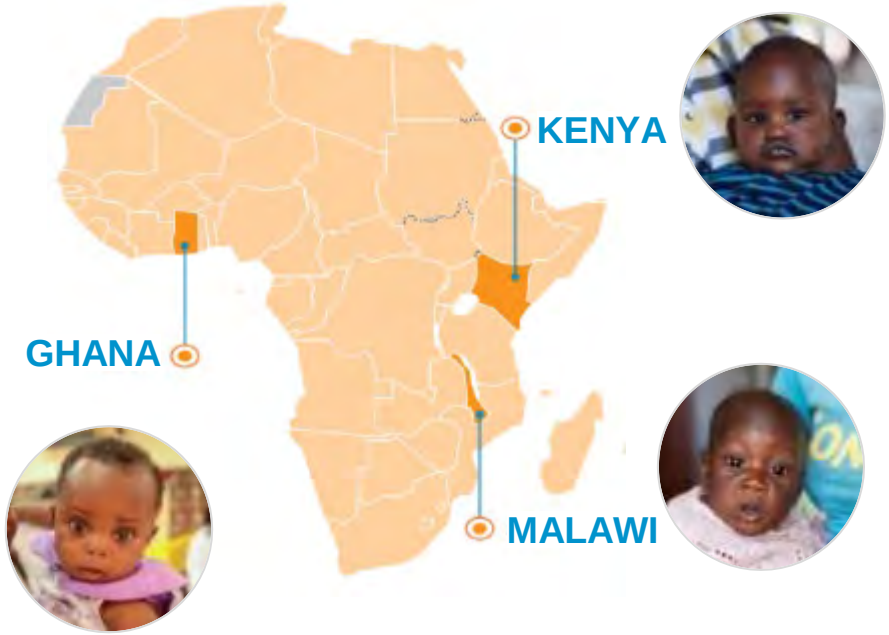


- 46 months of MVPE data collection ended in all 3 countries (Feb 2023 in Ghana and Malawi; and Jul 2023 in Kenya)
  - Data lock: Ghana (July); Kenya and Malawi (end Sep 2023)
  - Final review by the MVIP DSMB, 11-12 Oct 2023
  - Final review by SAGE/MPAG Working Group on Malaria Vaccines, 14-16 Nov 2023
  - MVIP end Dec 2023
  - DSMB to provide review for EDCTP-supported, nested case-control study around mid-2024

World Health Organization

Summary findings from the Malaria Vaccine Implementation Programme (RTS,S/AS01 implementation since 2019) showing good safety profile, **high impact**

Since 2019, over 2 million children vaccinated with RTS,S/AS01, over 6 million doses administered



Source: MOH monthly administrative data and MVIP projections, April 2019 to October 2023

- **Vaccine confirmed to be safe** with no increased risk of safety signals in Phase 3 trial, and no new safety signals
- **High impact during 46 months of vaccine introduction:**
  - **13% reduction in all cause mortality** excluding injury [0.87 (95% CI: 0.78, 0.98)]
  - **22% reduction** in hospitalized severe malaria [0.78 (95%CI: 0.64, 0.96)]
  - **17%** (95% CI: 6%, 27%) reduction in hospitalization with positive malaria test

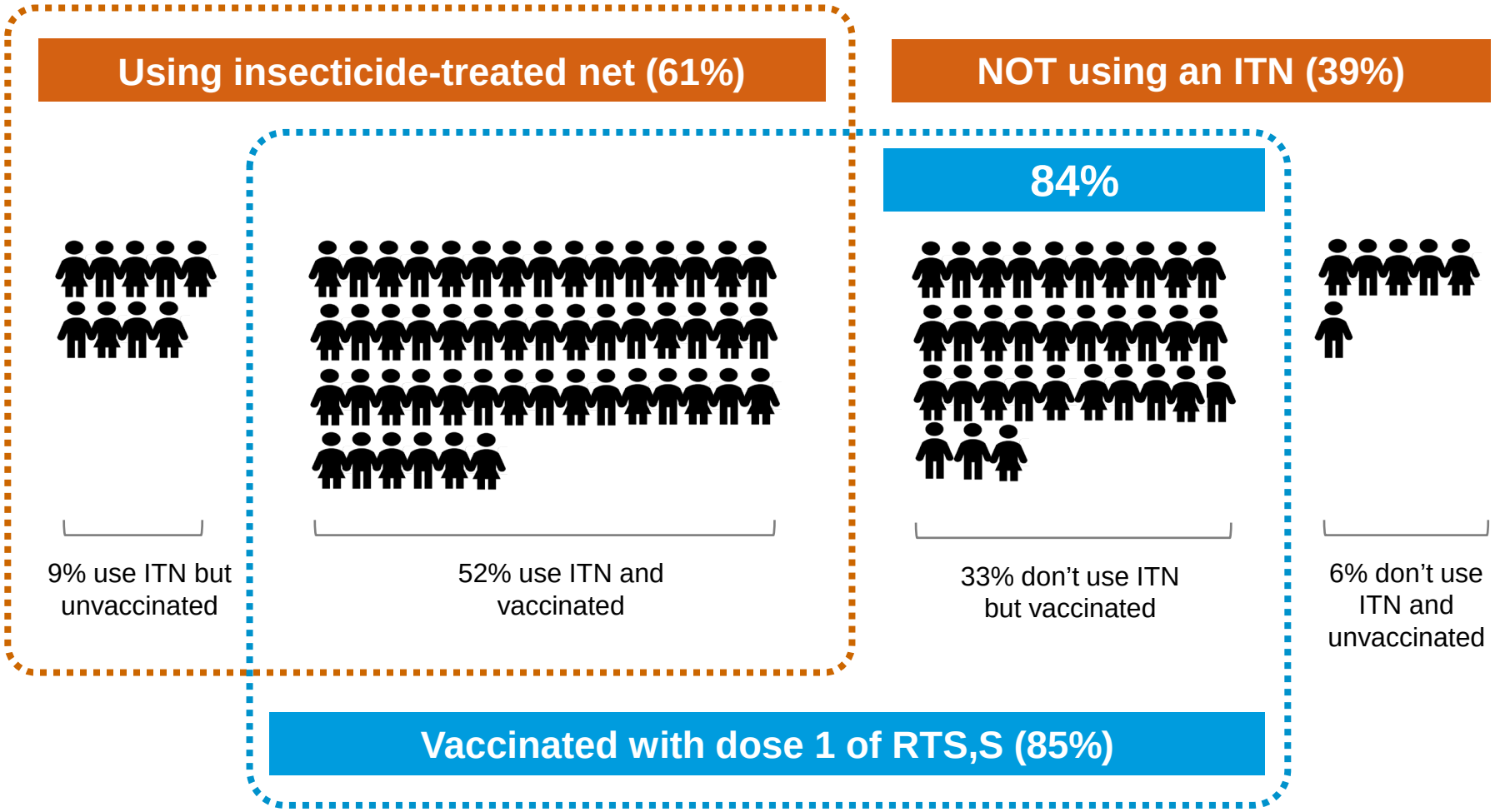
  Impact measured in children age-eligible to receive the vaccine (~64-74% dose 3 coverage, <50% dose 4 coverage)
- **Feasible to introduce with high uptake**
- **High demand** by community and acceptability by health workers
- **Equity:** Vaccine delivery equitable by gender or SES and is reaching children who are not using other forms of prevention

Impact and 4th dose uptake

- **13% reduction in mortality measured in children age eligible for vaccination**
  - Population-based estimate with coverage of 3 doses ~ 64-74%. Coverage of 4 doses < 50%
  - Observed in areas with good ITN use, good access to care
  - Potentially even higher impact where preventive and curative services are less reliable
- Impact when most children have received only 3 vaccine doses implies that high impact can be gained by preventing malaria early when children most vulnerable of death
  - Added benefit of 4th dose may be limited (as suggested by modeling, Penny *et al,* 2015)
  - If rebound present, the effect is not of a magnitude that would overcome gains made
- Ongoing case control study embedded in MVIP will measure added benefit of 4th dose extent of rebound, if any

World Health Organization

Ghana Endline Feasibility Survey: ITN use and RTS,S, children 12-23 months



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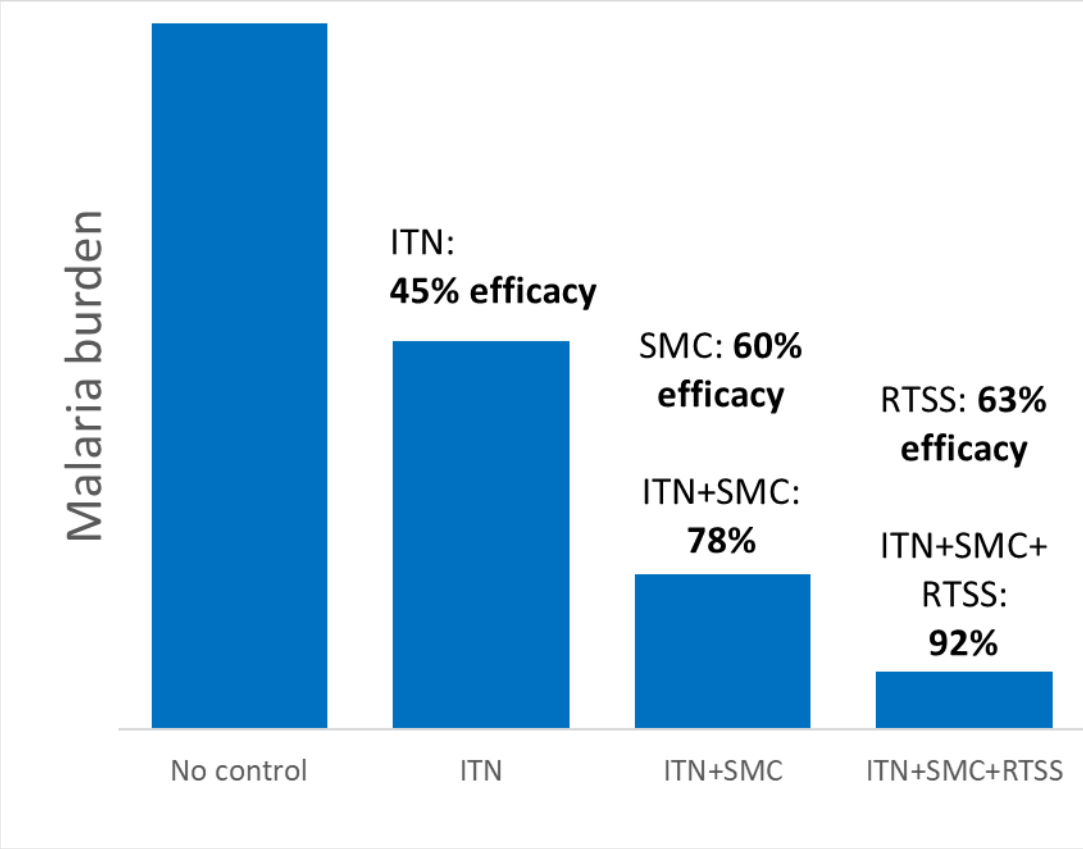
Highest impact achieved when malaria interventions strategically used together

Reduction in malaria burden when interventions are strategically used together



Insecticide Treated Net (ITN) efficacy: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000363.pub3/full

Seasonal Malaria Chemoprevention (SMC) efficacy: **85% per month**, case control studies in 5 countries, https://journals.plos.org/plosmedicine/article/authors?id=10.1371/journal.pmed.1003727
(SMC for 5 months covering 70% of annual burden)

RTS,S/AS01 efficacy of seasonal vaccination **39% efficacious over 3 years** https://www.nejm.org/doi/full/10.1056/NEJMoa2026330

World Health Organization

Prof Paul Milligan, LSHTM

Other MVIP priorities and next steps

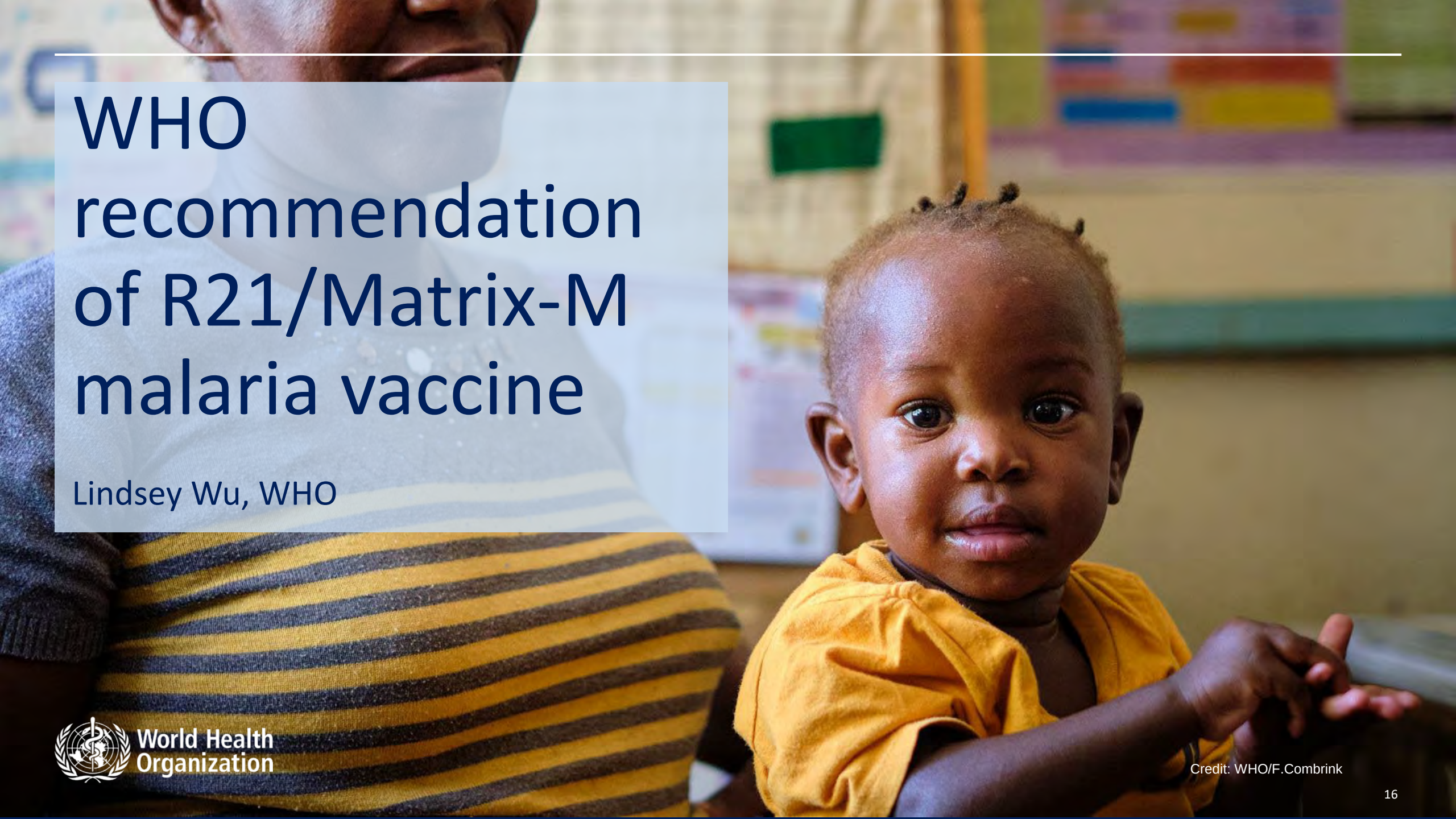
- **Support pilot countries as they continue implementation in comparison areas, scale up more broadly with either RTS,S or R21**
- **Document and share MVIP results and lessons**, including in forthcoming malaria vaccine introduction guide, 24-month analysis publication (in review), endline household survey reports, and final 46-month analysis dissemination (ASTMH and International Conference on Public Health in Africa)
- **Disseminate final findings to MoH and other stakeholders** through presentations, reports, publications, supplement

Thank you to MPAG, Gavi, Global Fund and UNITAID, for supporting the MVIP, which became a pathfinder for future malaria vaccines

World Health Organization

WHO recommendation of R21/Matrix-M malaria vaccine

Lindsey Wu, WHO



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Credit: WHO/F.Combrink

WHO press briefing on SAGE meeting outcomes, 2 October 2023

"As a malaria researcher, I used to dream of the day we had a safe and effective vaccine against malaria. Now we have two."

WHO Director-General's opening remarks

WHO Press release: https://www.who.int/news/item/02-10-2023-who-recommends-r21-matrix-m-vaccine-for-malaria-prevention-in-updated-advice-on-immunization

World Health Organization

R21/Matrix-M malaria vaccine background

- **Second malaria vaccine to be reviewed by WHO for recommendation**
- **Similar to RTS,S/AS01 with regards to:**
  - **Mechanism of action and indication**
    - Pre-erythrocytic stage vaccine for reduction of *P. falciparum* clinical malaria in infants and young children
  - **Vaccine construct and adjuvant**
    - Virus-like particle platform - fusion of circumsporozoite (CSP) and hepatitis B surface antigen (HBsAg)
    - Formulated with Matrix-M adjuvant, saponin extract (similar to AS01)
  - **Schedule:** 3 dose primary series (given 1 month apart); 4th dose given 12 months after dose 3, either seasonally or age-based (latter similar to schedule used in the large RTS,S/AS01 Phase 3 trial)
- **Developed by University of Oxford and manufactured by Serum Institute of India**

World Health Organization

R21/Matrix-M evidence review process

Groups involved	Key dates
SAGE/MPAG Working Group on Malaria Vaccines	Initial evidence review (7-8 March 2023) Full evidence review (25-27 July 2023) Additional teleconference (21 Sept 2023)
R21/Matrix-M Safety Working Group	Safety evidence review (20 June 2023)
African Advisory Committee on Vaccine Safety (AACVS)	Briefed by WHO Secretariat (May 2023)
Global Advisory Committee on Vaccine Safety (GACVS) • Received input from R21/Matrix-M Safety Working Group • Included representation from AACVS and R21/Matrix-M DSMB	Safety evidence review (30 June 2023)
SAGE and MPAG in joint session (following SAGE processes)	Technical briefing (5 Sept 2023) Joint session (27 Sept 2023)
WHO Prequalification (PQ)	Dossier accepted Q1 2023; review ongoing as per ordinary PQ processes

World Health Organization

WHO evidence review based on Phase 3 clinical trial data

Phase 3 trial design:

Seasonal administration (n=2,400), ages 5-36 months at first vaccination

- 2 sites: Nanoro, Burkina Faso and Bougouni, Mali

Age-based (“standard”) administration (n=2,400), ages 5-36 months at first vaccination

- 3 sites: Dande, Burkina Faso; Kilifi, Kenya and Bagamoyo, Tanzania

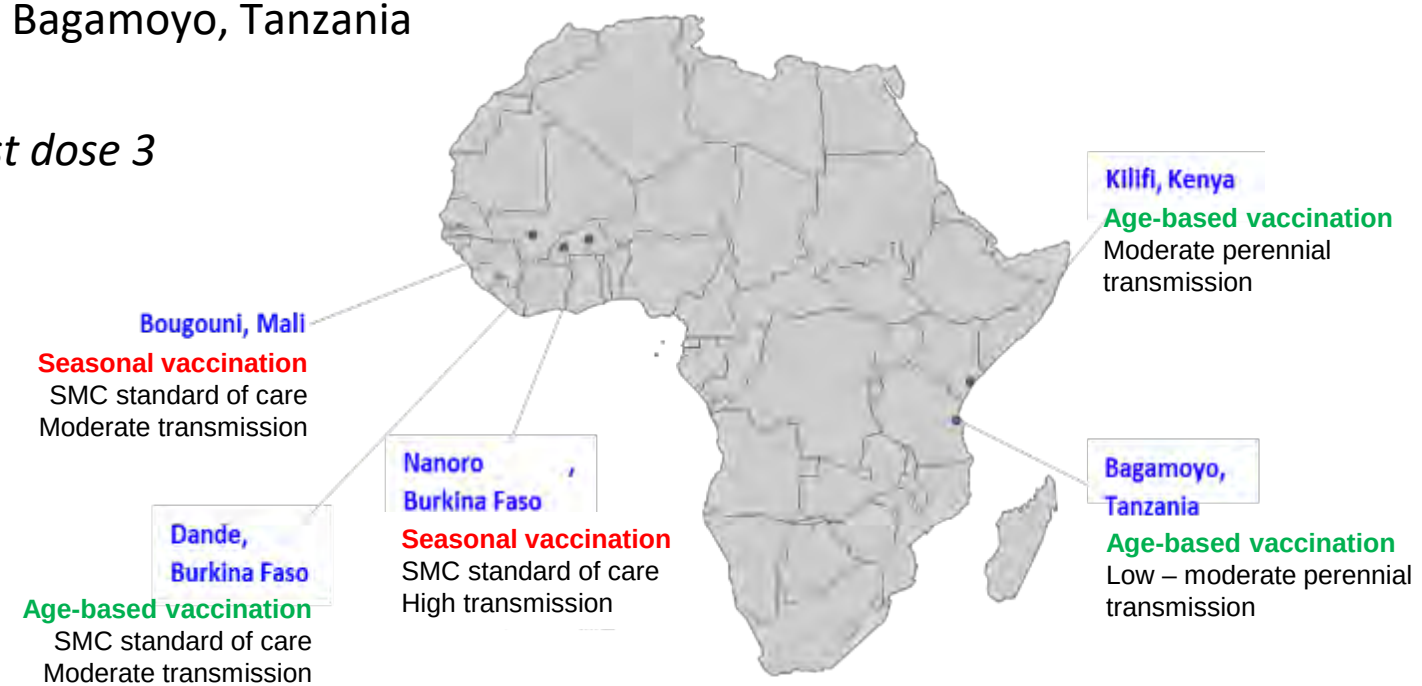
Primary endpoint: 12 months post dose-3

Data available through 18-months follow-up post dose 3

Seasonal malaria chemoprevention (SMC) administered as per standard of care in areas of highly seasonal malaria in West Africa

Insecticide-treated net (ITN) for every participant at the start of the trial

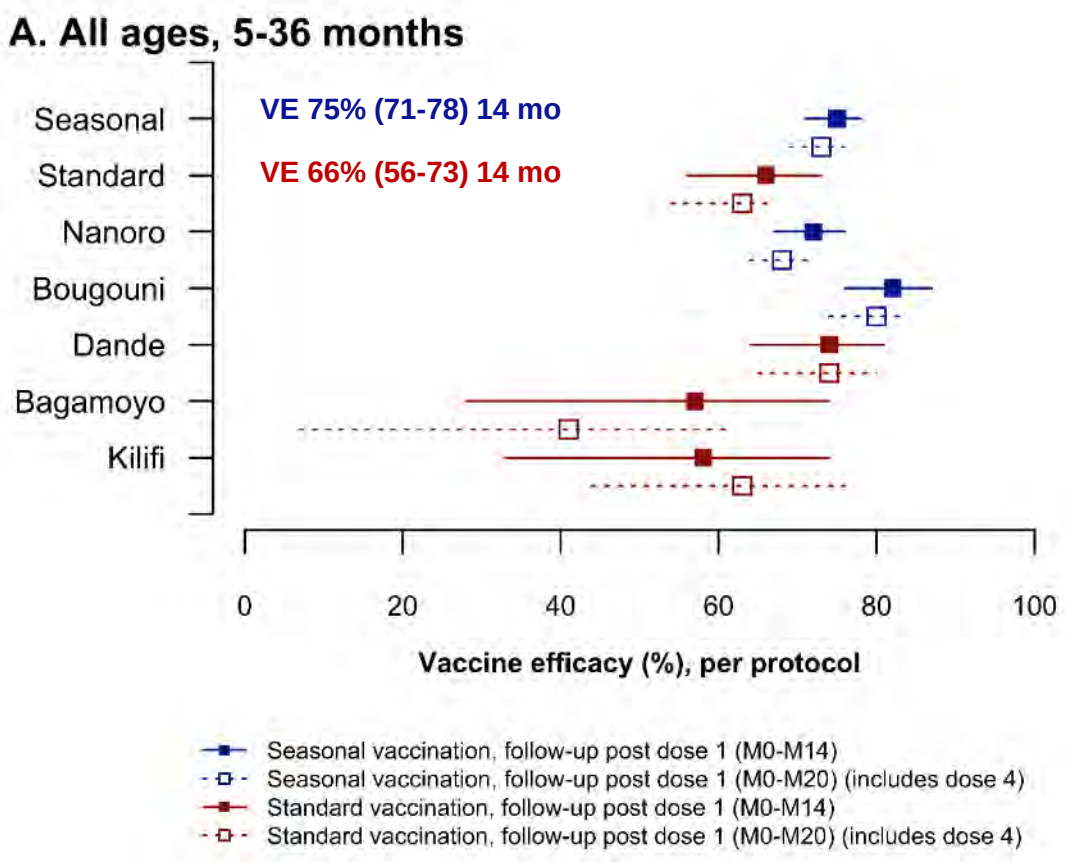
No assessment of vaccine efficacy or duration of protection in areas of high perennial transmission



World Health Organization

Vaccine efficacy against all episodes of clinical malaria, *per protocol*

Seasonal sites, 14- and 20-month follow-up post dose 1 (blue); Standard sites, 14-month follow-up post dose 1 (red)



- VE similar during 12 months after primary series and during 18 months after primary series with a 4th dose
- VE lower in East African sites (standard group)
- No significant differences in VE by sex
- VE for the younger 5-17 month age group slightly lower than 18-36 month age group, but with overlapping 95%CIs
- VE similar according to the number of rounds of SMC received, but limitations to data*

*study not designed to measure SMC effect, SMC provided through MOH with varying coverage, ascertainment of SMC through home health cards, no written documentation of SMC given on health card interpreted as zero SMC received

VE for modified intention to treat (mITT) population did not differ statistically from per protocol (PP)

Evidence on R21/Matrix-M (R21) malaria vaccine

- **High efficacy when given just before the high transmission season in areas with highly seasonal malaria transmission**
  - R21/Matrix-M vaccine reduces symptomatic cases of malaria by **75% (95% CI 71 - 78)** during the 12 months following a 3-dose series when provided with SMC. A fourth dose given a year after the third maintained efficacy
  - **This high efficacy is similar to the efficacy demonstrated when RTS,S is given seasonally with SMC (72%, 95% CI 64 - 78)** during 12 months following a 3-dose series*****
- **Good efficacy when given in an age-based schedule:** The vaccine showed good efficacy **[66% (95%CI 56-73)]** during the 12 months following the first 3 doses in moderate to low perennial transmission settings. A fourth dose a year after the third maintained efficacy
  - Although it has not been tested in areas of high perennial transmission, R21 expected have similar high impact as that seen with RTS,S
  - The two vaccines have not been tested in a head-to-head trial, and there is no evidence that one vaccine performs better than the other

World Health Organization

*Table 1, Year 1 protective efficacy combined vaccine and chemoprevention. Chandramohan N Engl J Med 2021: https://www.nejm.org/doi/pdf/10.1056/NEJMoa2026330?articleTools=true

Evidence on R21/Matrix-M (R21) malaria vaccine

- **High impact:** Mathematical modelling estimates indicate the public health impact of the R21 vaccine is expected to be high in a wide range of malaria transmission settings
- **Cost effectiveness:** At a price range assumption of US$ 2 – US$ 4 per dose, the cost-effectiveness of the R21 vaccine would be comparable with other recommended malaria interventions and other childhood vaccines
- **Safety:** No major safety concerns were noted that would warrant a delay in recommendation of R21 malaria vaccine for public health use
- **Similarity of R21 and RTS,S vaccines:** The R21 vaccine is similar to RTS,S in construct, target population, and delivery strategy. There is no evidence that one vaccine performs better than the other
- **Price:** The initial price of R21/Matrix-M vaccine has been announced at US$ 3.90 per dose, considerably lower than the initial price for RTS,S/AS01 (EUR 9.30 per dose)

World Health Organization

WHO updated recommendation for malaria vaccines

Mary Hamel

World Health Organization

Credit: WHO/Neil Thomas.

WHO recommendation: malaria vaccines

WHO recommends the programmatic use of malaria vaccines for the prevention of *P. falciparum* malaria in children living in malaria endemic areas, prioritizing areas of moderate and high transmission

- The malaria vaccine should be provided in a schedule of 4 doses in children from around 5 months of age[1] for the reduction of malaria disease and burden
- A 5th dose, given one year after dose 4, may be considered in areas where there is a significant malaria risk remaining in children a year after receiving dose 4
- Countries may consider providing the vaccine using an age-based, seasonal, or a hybrid of these approaches in areas with highly seasonal malaria or areas with perennial malaria transmission with seasonal peaks
- Countries should prioritize vaccination in areas of moderate and high transmission, but may also consider providing the vaccine in low transmission settings
- Vaccine introduction should be considered in the context of comprehensive national malaria control plans

This recommendation now includes <u>two</u> malaria vaccines:

- **RTS,S/AS01**
  WHO pre-qualified in 2022
- **R21/Matrix-M**
  WHO pre-qualification review ongoing

[1] Vaccination programmes may choose to give the first dose at a later or earlier age based on operational considerations. Studies with RTS,S/AS01 indicated lower efficacy if first dose was given around 6 weeks of age. However, it seems unlikely that efficacy would be substantially reduced if some children received the first dose at 4 rather than 5 months, and providing vaccination at an age younger than 5 months may increase coverage or impact

World Health Organization

WHO recommendation: malaria vaccine dose schedule and delivery

- **In areas of perennial malaria transmission, the malaria vaccine should be provided as a 3-dose primary series, starting from around 5 months of age, with a minimal interval of 4 weeks between doses**
- **The fourth dose should be given to prolong protection. There can be flexibility to optimize delivery for dose 4:**
  - Alignment with other vaccines in the second year of life
  - Administration prior to seasonal peaks to optimize efficacy
  - The optimal interval between dose 3 and 4 has not been established
- If malaria remains a significant public health problem in children a year after the fourth dose, then a fifth dose might be considered, depending on a local assessment of feasibility and cost-effectiveness

Product Choice: There is no evidence that one vaccine performs better than the other. Country decisions on which vaccine to introduce should be made on programmatic characteristics, such as affordability and supply to scale-up

This recommendation now includes two malaria vaccines:

- **RTS,S/AS01**
  WHO pre-qualified in 2022
- **R21/Matrix-M**
  WHO pre-qualification review ongoing

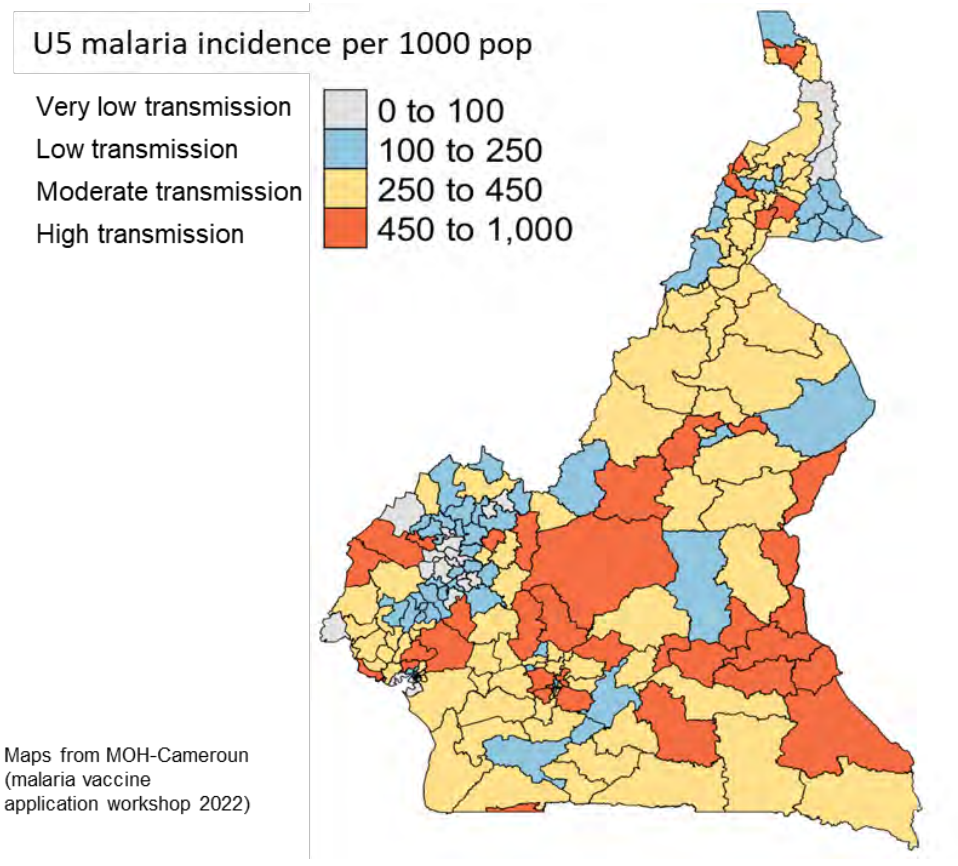
World Health Organization

Malaria vaccines in low transmission setting:

Permissive recommendation:

Potential to improve feasibility of delivery if lower transmission areas are next to higher transmission areas

Illustrated by the stratification of malaria burden for vaccine introduction in Cameroun below



Maps from MOH-Cameroun (malaria vaccine application workshop 2022)

Both R21/Matrix-M and RTS,S/AS01 are efficacious in areas of low malaria transmission, and clinical trial data and mathematical modelling estimate considerable impact, including in areas of low malaria transmission

Decisions on expanding to low transmission settings should be considered at a country level, considering:

- overall malaria control strategy
- cost-effectiveness, affordability
- programmatic considerations, such as whether including such areas would simplify delivery
- Should be considered as part of comprehensive malaria control plans

High priority M&E and research recommendations

- Immunological **co-administration studies** with other relevant infant vaccines such as pneumococcal conjugate vaccines, rotavirus, pentavalent vaccines (DTP-HepB-Hib), IPV, typhoid conjugate vaccine, meningococcal vaccine, hexavalent (DTwP-HepB-IPV-Hib) vaccine, measles vaccine, and observational studies for the occurrence of febrile seizures
- **Post-licensure evaluation studies should be conducted on vaccine effectiveness** in high perennial transmission settings, which are not represented in the Phase 3 trial
- **Monitoring for risk of malaria rebound** and collecting **further data on severe malaria and mortality** as part of the ongoing Phase 3 trial and 4 years of follow-up (already planned by the developer)

World Health Organization

High priority M&E and research recommendations

- **Post-licensure monitoring of R21/Matrix-M safety in infants and young children**, including the occurrence of febrile seizures and mortality. Monitoring mortality may be most easily achieved in areas where there is a demographic surveillance system in place
- **Evaluation of vaccine efficacy against severe malaria** (e.g., case-control study)
- **Evaluation of vaccine impact on mortality using available systems** – e.g. HDSS, community mortality surveillance, case-control study
- **Interchangeability studies on heterologous schedules with RTS,S/AS01 and R21/Matrix-M**

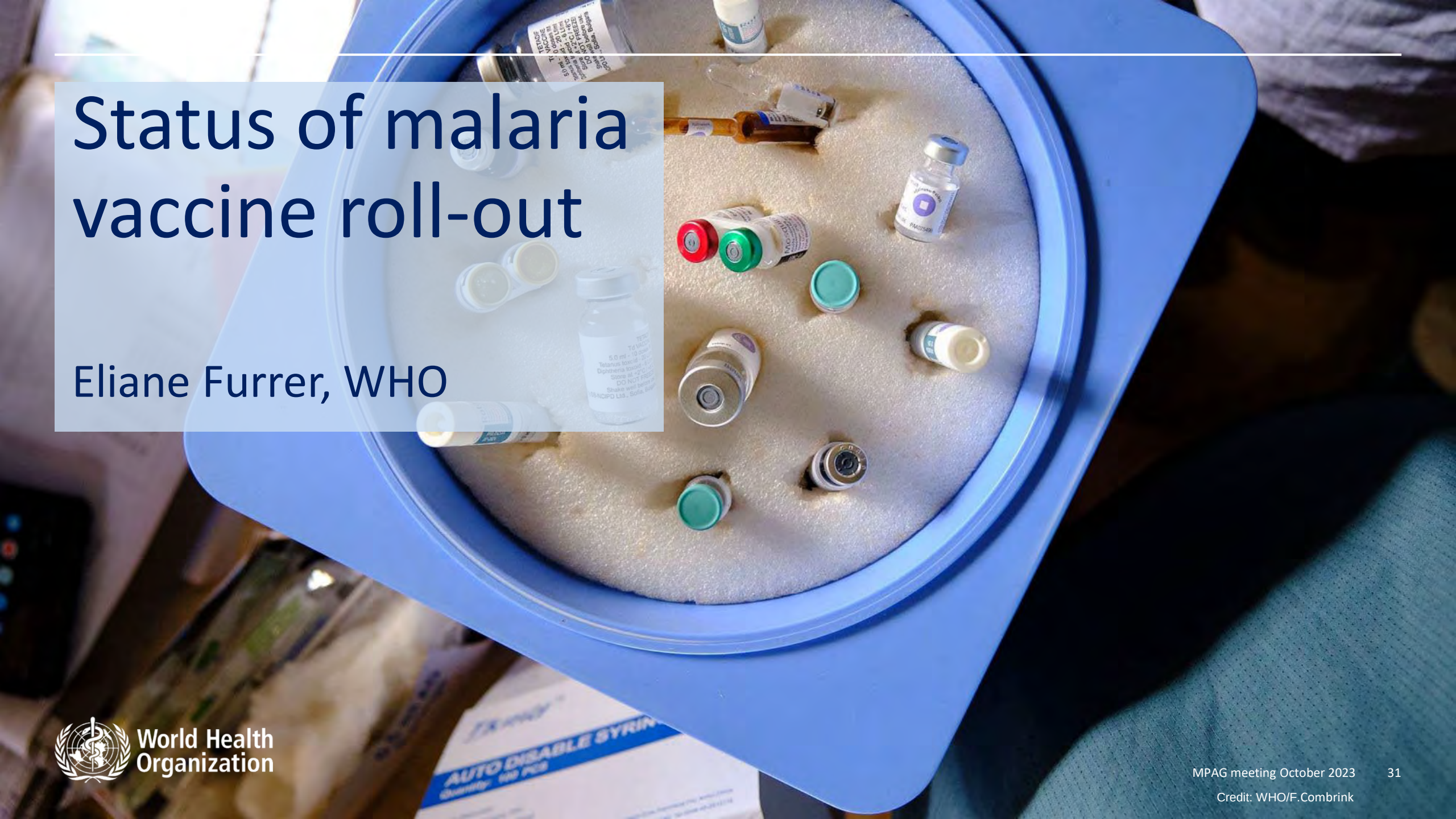
World Health Organization

IVB and GMP team to prioritize and monitor implementation and results of high priority research

- SAGE and MPAG recommended a cross-department team (IVB and GMP) to prioritize, coordinate and monitor identified high priority research activities
- Suggestion for development of generic protocols to guide study designs
- ToR for the cross-department team under development

Status of malaria vaccine roll-out

Eliane Furrer, WHO



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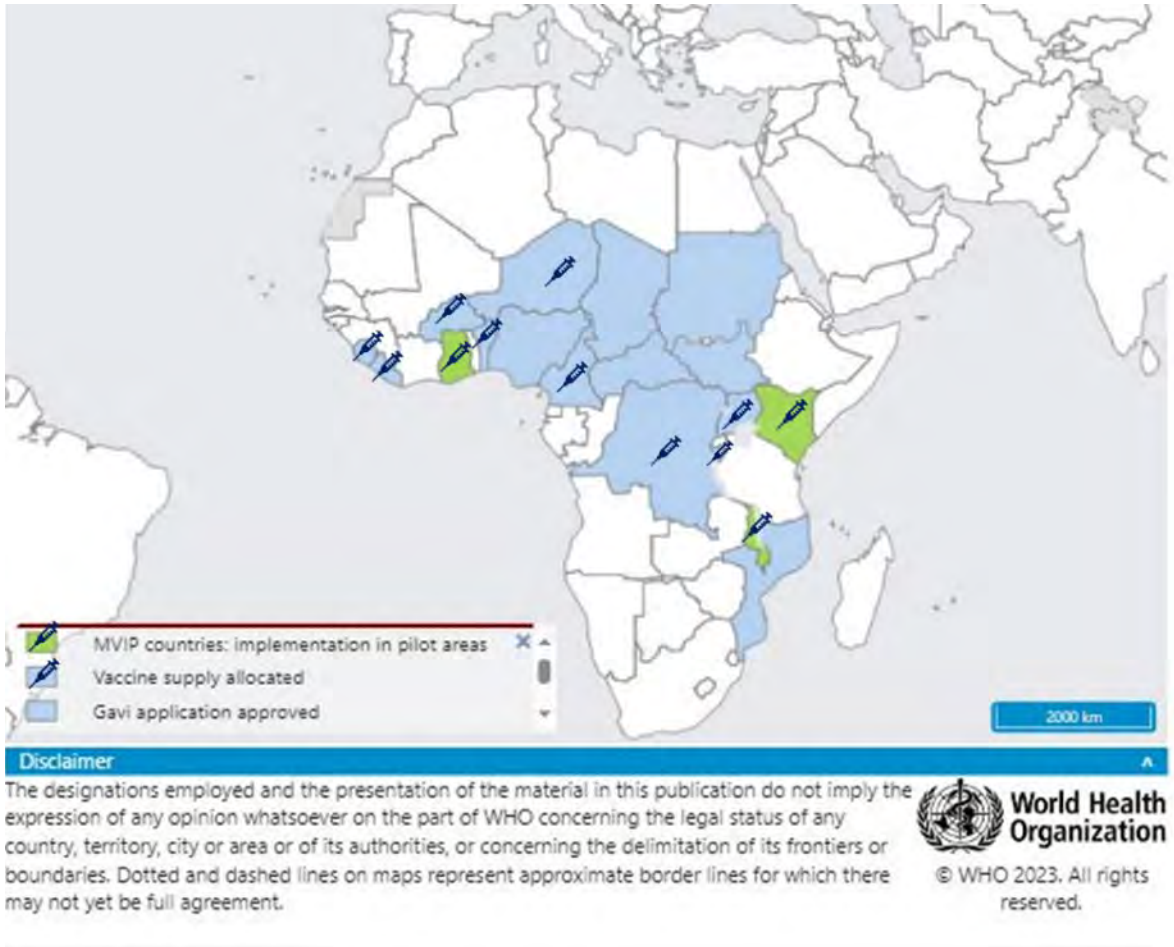
Credit: WHO/F.Combrink

Countries' Gavi application status for malaria vaccines - as of 30 Oct 2023

- **At least 28 countries** in Africa expressed interest in introducing a malaria vaccine
- Since opening the funding window in mid-2022, Gavi approved applications from 18 countries to introduce vaccine in routine immunization programmes:

  Benin, **Burkina Faso**, **Burundi**, **Cameroon,** Central African Republic, Chad, **DR Congo**, **Ghana, Kenya, Malawi, Niger**, Nigeria, **Liberia**, Mozambique, **Sierra Leone**, South Sudan, Sudan, **Uganda**

- In July 2023, first supply allocations confirmed for 12 countries (**in bold**) for introduction in Phase 1 (greatest need) areas[1]



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1 WHO/UNICEF/Gavi Joint News Release https://www.who.int/news/item/05-07-2023-18-million-doses-of-first-ever-malaria-vaccine-allocated-to-12-african-countries-for-2023-2025--gavi--who-and-unicef

Limited RTS,S supply required prioritization of moderate to high transmission areas based on the principles of the Framework for allocation of limited malaria vaccine supply

Framework

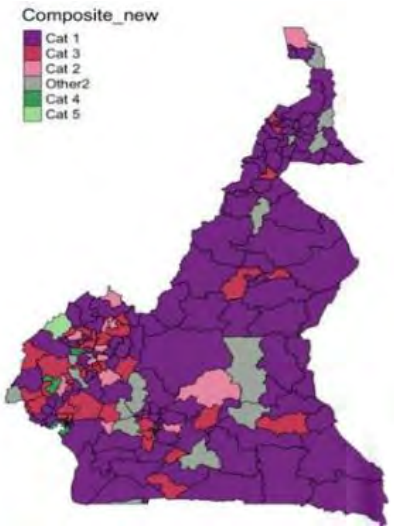
- First allocate to areas of greatest need, where the malaria disease burden in children and risk of death are highest
- Solidarity principle: no country to receive more than 1 million doses per year

Category of need	Malaria transmission intensity		All-cause under 5 mortality
	Either: Prevalence	OR: U5 Incidence	
Category 1 Greatest need	>=40%	>=450	>=9.5%
	>=40%	>=450	7.5-9.5%
	20-<40%	350-<450	>=9.5%
Category 2	10-<20%	250-<350	>=9.5%
	20-<40%	350-<450	7.5-<9.5%
	>=40%	>=450	6-<7.5%
Category 3	10-<20%	250-<350	7.5-<9.5%
	20-<40%	350-<450	6-<7.5%
	>=40%	>=450	<6%
Category 4	10-<20%	250-<350	6-7.5%
	20-<40%	350-<450	<6%
Category 5	10-<20%	250-<350	<6%

https://www.who.int/publications/m/item/framework-for-allocation-of-limited-malaria-vaccine-supply

Country analysis & application to Gavi

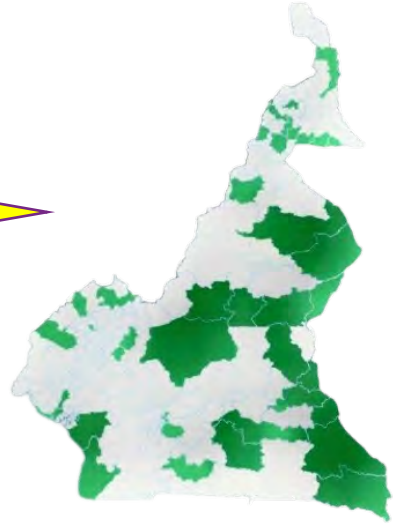
Stratification by category of need



Cat.	Target population Life births (2023)
1	697,514
2	69,441
3	156,889
4	7,071
5	1,078
other	99,599
Total	1,032,492

Illustrative example of Cameroon analysis in 2022. Actual implementation may differ.

Prioritization of areas for Phase 1 roll-out



Target population: ~250,000 children per year in 42/200 health districts in 10 regions

- Further prioritization to fit below the cap of 1M doses per year
- A sub-set of category 1 areas prioritized based on country's own criteria

Malaria vaccine supply availability

With appropriate planning, combined availability of RTS,S and R21 is expected to result in sufficient vaccine supply to benefit all children living in areas where malaria is a public health risk.

RTS,S/AS01		R21/Matrix-M
GlaxoSmithKline (GSK)	**Manufacturer**	Serum Institute of India (SII)
~US$10.00 per dose (EUR 9.30)	**Market Pricing (2024)**	US$ 3.90 per dose
• Limited overall supply of 18mds for 2023-25 → Intention: allocate to fewer countries to enable each country to scale up with the RTS,S doses available • Technology transfer of RTS,S to Bharat Biotech is underway, with prospects of increased supply and reduced prices	**Overall volumes available**	• Sufficient supply to meet realistic and planned demand

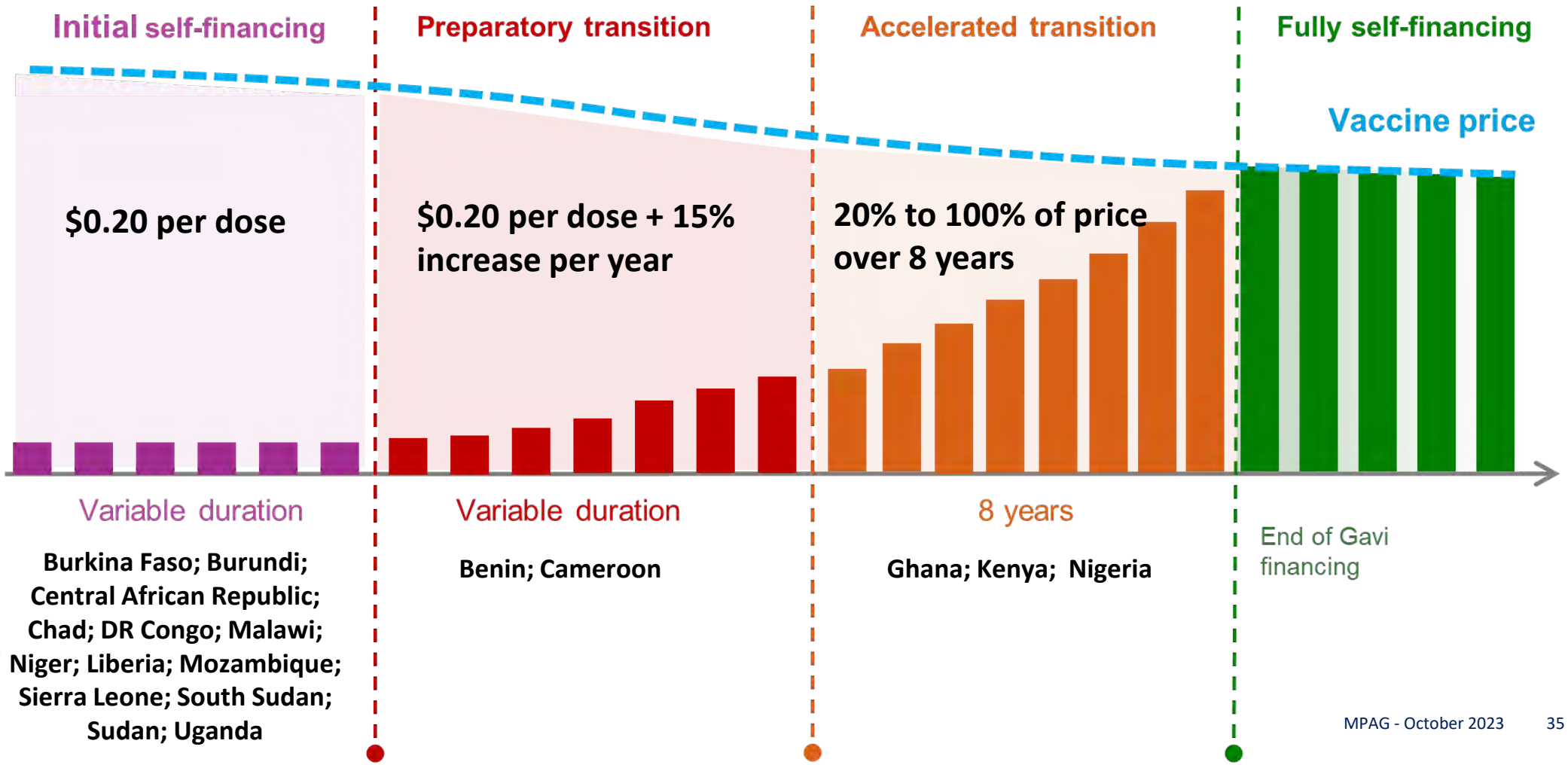
World Health Organization

Source:
UNICEF Malaria vaccine questions and answers. October 2023. https://www.unicef.org/supply/documents/malaria-vaccine-questions-and-answers
UNICEF Malaria vaccine price data. https://www.unicef.org/supply/documents/malaria-vaccine-price-data

Gavi co-financing: exceptional time-limited approach for malaria vaccines to facilitate affordability and uptake*

*To be reviewed no later than 2027

As a country GNI per capita increases, the level of its co-financing rises



Co-financing status of countries with approved malaria vaccine application

Burkina Faso; Burundi; Central African Republic; Chad; DR Congo; Malawi; Niger; Liberia; Mozambique; Sierra Leone; South Sudan; Sudan; Uganda

Benin; Cameroon

Ghana; Kenya; Nigeria

Next steps

- **Broader rollout of the RTS,S malaria vaccine is underway:** First vaccine shipments expected to arrive in countries in December 2023 for introductions starting in Q1 2024.
- **WHO pre-qualification review for R21/Matrix-M ongoing:** prerequisite for vaccine procurement by UNICEF for Gavi-eligible countries.
    - Earliest expected availability of R21 (shipped) for introduction in approved Phase 1 areas: May –June 2024
- **Gavi to inform countries about:**
    - Product matching exercise: considering countries' product preferences, supply availability and overarching market shaping considerations
    - Process and timelines for requesting support for scale-up beyond Phase 1 areas
- **Gavi accepts new applications 3-4 times / year** : next opportunity in January 2024

World Health Organization

Malaria Vaccine Coordination Team (MVCT)

Organizations currently represented:

- Co-chaired by WHO and Gavi Secretariat, created in early 2022
- MVCT provides a platform for coordination and information sharing
- Initial focus on support to design of the Gavi malaria vaccine programme
- Overtime, expected to support the ongoing implementation of the Gavi programme & coordination among partners

Thank you.

Credit: WHO/F.Combrink

Malaria Policy Advisory Group Meeting
30 October–1 November 2023, Geneva, Switzerland
Background document for Session 4

World Health Organization

Guiding principles for prioritizing malaria interventions in resource-constrained country contexts to achieve maximum impact

In line with the goals of the *Global technical strategy for malaria 2016–2030 (1)* and with Sustainable Development Goal 3, to ensure healthy lives and promote well-being for all at all ages, the World Health Organization (WHO) Global Malaria Programme continues to promote the principle of leaving no one behind and to ensure access to effective malaria interventions to all those in need.

Due to the heterogeneous distribution of malaria transmission and its determinants, subnational tailoring (SNT) provides an analytical framework to facilitate targeting each population with appropriate intervention packages for maximum impact. The WHO Global Malaria Programme recommends the use of subnational data on disease epidemiology and other relevant local contextual factors to facilitate the process of SNT. Once the strategies and intervention mixes have been defined in accordance with SNT, programmes can proceed to the prioritization of interventions for effective programming, based on available resources.

In response to ever increasing financial constraints, the WHO Global Malaria Programme and Regional Offices in consultation with Member States and technical partners have developed this guidance for national malaria control programmes, setting out the guiding principles for prioritizing interventions in resource-constrained settings to achieve maximum impact.[1] Prioritization is the process of selecting the most appropriate mixes of interventions for implementation and de-prioritizing others, considering financial constraints and programmatic feasibility. This process requires difficult choices to be made to minimize the negative impact of withholding some interventions included in the national strategic plan.

Prioritization must be guided by the basic principles of primary health care and universal health coverage: patient-centredness (community-focused), self-determination, accessibility, equity, quality, empowerment, intersectoral collaboration, value and sustainability, accountability and transparency.

Prioritization decisions must be informed by a good understanding of the baseline (historical) transmission intensity and disease burden in a given area, as the current situation reflects the impact of interventions. The magnitude of change from the baseline that is likely due to the interventions will help to determine the level of risk of resurgence and, by extension, the potential impact of the decision to remove the interventions. The baseline period is considered the time before preventive interventions were scaled up.

Prioritization of malaria interventions should be aligned with the broader national health prioritization processes and the development of health benefit packages, consistent with the principles of country ownership, cost-effectiveness, equity, financial risk protection and political acceptability *(2)*. The

[1] The review and inputs received from the managers of the national malaria control programmes of Cameroon, the Democratic Republic of the Congo, Nigeria, Rwanda and Zambia, the African Leaders Malaria Alliance, Bill & Melinda Gates Foundation, the Global Fund to Fight AIDS, Tuberculosis and Malaria, RBM Partnership to End Malaria and the United States President's Malaria Initiative to improve the contents of this document are gratefully acknowledged. This paper will be presented to and discussed by the WHO Malaria Policy Advisory Group at its 24th meeting on 30 October–1 November 2023 before wider dissemination.

criteria for prioritization include programmatic realities, which should be made explicit in decision-making.

This document provides guiding principles for prioritizing high-impact interventions, in particular early diagnosis and treatment, insecticide-treated nets (ITNs), indoor residual spraying (IRS), malaria vaccines and chemoprevention options in situations where resources are limited, in areas along the continuum of malaria transmission from high to very low.

Prioritization of interventions

In the face of limited resources, the following principles should guide the prioritization of malaria interventions:

- The primary objective is to prevent and minimize malaria-related deaths. This is assured by providing access to early diagnosis and effective treatment of all malaria cases, irrespective of the malaria transmission intensity. Providing prompt access to malaria diagnosis and treatment by maintaining existing services across all levels of the health care delivery system, including at community level, should be prioritized and guaranteed for all as a basic human right. Scaling back access to early diagnosis and treatment is not an option under any level of financial constraint. Surveillance of antimalarial drug resistance and histidine-rich protein 2 (HRP2) deletions is essential for selecting effective medicines and diagnostics for malaria case management.
- Expansion of case management of acute febrile illnesses at the community level to reach the unreached in remote areas should be carefully considered as part of the prioritization process, as the expansion of community services is dependent on the number and distribution of primary health care facilities, the level of community involvement in the mobilization of resources and the degree of institutionalization of community health workers as an integral part of the primary health care system. Similarly, new investments to improve malaria case management in the private sector should be part of a national strategy for private engagement in health service delivery *(3)*.
- Malaria affects pregnant women, as well as their fetuses and newborns. Therefore, preventive interventions for pregnant women, such as intermittent preventive treatment of malaria in pregnancy and routine distribution of ITNs, should be prioritized in all moderate to high transmission areas.
- WHO recommends either IRS or ITNs as vector control interventions for large-scale deployment *(4)*. The choice of which of these two interventions to deploy should be informed by contextual data, such as insecticide susceptibility, vector bionomics and intervention use, as well as relative cost-effectiveness. WHO does not recommend co-deployment of both IRS and ITNs
- For countries or parts of countries where deployment of ITNs is considered the appropriate choice, the *Guidance on the prioritization of insecticide-treated nets in situations where resources are limited (5)* provides a framework for the allocation of limited resources. To summarize, countries should conduct a desk-based exercise to calculate the resources required to do the following:

    1. Ensure access for the most vulnerable groups (e.g. pregnant women and children under 5 years of age), and commit funding for routine ITN distribution to vulnerable groups in all malaria risk areas.

    Then, the document guides programmes through the following steps for campaign deployment planning:

    2. Define the scope of ITN deployment:

        • Identify and exclude areas with very low current and historical malaria risk.
        • List and rank the areas targeted for ITN campaigns according to malaria risk.

3. Maximize coverage in areas identified for ITN deployment: Calculate the funding needed to ensure full coverage of pyrethroid-only nets.

If funding remains:

4. Maximize effectiveness: Calculate the funding required to substitute pyrethroid-only ITNs (or, where applicable, pyrethroid-pyriproxyfen nets) with pyrethroid-piperonyl butoxide (PBO) or pyrethroid-chlorfenapyr ITNs in areas of pyrethroid resistance by: i) replacing pyrethroid-PBO or pyrethroid-chlorfenapyr nets in areas that have previously received them, and ii) substituting pyrethroid-only ITNs with pyrethroid-PBO or pyrethroid-chlorfenapyr ITNs in additional geographical areas in decreasing order of malaria risk until the available funding has been used up.
5. Identify funding gaps that impede further effective coverage, and make that information available to potential funders.
6. Ensure adequate funding for epidemiological and entomological surveillance.

- IRS is relatively more expensive than ITNs per case averted. Under resource-constrained conditions, scaling up IRS should not be considered. The focus needs to lie, to the extent possible, on maintaining optimal population coverage with one effective vector control intervention. As such, countries need to carefully consider the resource implications of sustaining IRS instead of deploying ITNs. If countries are unable to maintain their IRS campaigns at the right times with effective coverage, it is advisable to switch to PBO or dual active ingredient nets and invest in social and behaviour change communication to ensure the effective use of ITNs.
- When changes are made in vector control strategies that lead to decreased/suboptimal intervention coverage, or when a vector control intervention such as IRS is withdrawn, establishment of strong surveillance and response capacity should be prioritized to mitigate a potential malaria increase.
- Investments in improving data quality, surveillance, and the quality and effectiveness of interventions across vector control, diagnosis and treatment should not be reduced as part of prioritization, as these are essential to achieve impact in existing intervention areas. This includes resources to secure the coverage and competence of health workers to provide quality care, and social behaviour change communication to increase public awareness on seeking care and increase the acceptance and use of interventions.
- WHO recommends the RTS,S/AS01 and R21-Matrix M malaria vaccines for the prevention of *Plasmodium falciparum* malaria in children living in malaria-endemic areas, prioritizing areas of moderate to high transmission. Under the current limited vaccine supply, a specific process has been developed by WHO, the United Nations Children's Fund and Gavi, the Vaccine Alliance, for prioritizing RTS,S vaccine allocation *(6)*.
- Chemoprevention should be targeted in areas where effective case management and appropriate vector control interventions are being deployed. New chemoprevention strategies should not be prioritized over and above case management and vector control in any given population. Geographical or age expansion of seasonal malaria chemoprevention (SMC), community deployment of intermittent preventive treatment of malaria in pregnancy, perennial malaria chemoprevention, post-discharge malaria chemoprevention and intermittent preventive treatment of malaria in school-aged children should not be implemented at scale if resources to ensure access to case management and coverage of effective vector control are limited.
- There is no evidence to inform when to scale back SMC and countries should do their utmost to maintain the intervention. However, if resources are not available, scale-down should be based on the principle of "least harm", de-prioritizing areas where incidence was lowest at the pre-SMC

baseline. Deployment of dual active ingredient ITNs, expansion of case management, and better surveillance, preparedness and response should be prioritized in these areas.

- Due to heterogeneous transmission in urban areas, countries should implement micro-stratification and identify focal areas of risk to target appropriate preventive interventions. In areas where transmission is intrinsically low (e.g. < 1% *P. falciparum* prevalence rate) due to urbanization, mass distribution of ITNs may not be appropriate and a more targeted deployment of interventions (ITNs, IRS or larviciding) is recommended *(7)*.

Prioritization is an iterative process, and it will need to be continuously revised as costs and funding opportunities change over time, as malaria epidemiology changes due to various factors, including man-made and natural disasters, when surveillance does not show the expected impact, when assessment of programme performance shows changing requirements to ensure the effectiveness of interventions, when new tools and knowledge become available, or as new threats emerge.

During all phases of planning and implementation, programmes should aim for optimization – the process by which programmes ensure that the strategies and effective interventions deployed achieve the maximum impact with the most efficient use of available resources.

Mobilizing additional resources is a continuous effort that should be pursued during and after the prioritization planning, based on the evidence-informed national strategic plan. In addition to planning operations based on existing/known resources, national programmes are encouraged to conduct further analyses to identify priority interventions that could be funded should additional resources become available. Such scenario planning will provide the basis to support resource mobilization efforts, including for domestic resources.

References

1. Global technical strategy for malaria 2016–2030, 2021 update. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/342995, accessed 16 October 2023).
2. Principles of health benefit packages. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/340723, accessed 16 October 2023).
3. Towards better engagement of the private sector in health service delivery: a review of approaches to private sector engagement in Africa. Geneva: World Health Organization; 2022 (https://iris.who.int/handle/10665/352905, accessed 16 October 2023).
4. WHO guidelines for malaria, 14 March 2023. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/366432, accessed 16 October 2023).
5. Guidance on the prioritization of insecticide-treated nets in situations where resources are limited. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/366406, accessed 16 October 2023).
6. Framework for the allocation of limited malaria vaccine supply. Geneva: World Health Organization; 2022 (https://www.who.int/publications/m/item/framework-for-allocation-of-limited-malaria-vaccine-supply, accessed 16 October 2023).
7. Global framework for the response to malaria in urban areas. Geneva: World Health Organization; 2022 (https://iris.who.int/handle/10665/363899, accessed 16 October 2023).

Annex: Additional reading

ITN ownership and usage to achieve personal and community protection

Lines J, Chitnis N, Paintain L. How insecticide-treated nets (ITNs) work: the biological mechanisms by which ITNs give personal- and community-level protection against malaria, version v1. Zenodo. 2022. doi:10.5281/zenodo.6393253.

Interventions recommended for large-scale deployment: insecticide-treated nets. In: WHO guidelines for malaria, 14 March 2023. Geneva: World Health Organization; 2023:42–3 (https://iris.who.int/handle/10665/366432, accessed 15 October 2023).

ITN requirements at population level

Insecticide-treated nets: practical info. In: WHO guidelines for malaria, 14 March 2023. Geneva: World Health Organization; 2023:60–1 (https://iris.who.int/handle/10665/366432, accessed 15 October 2023).

ITN campaigns and continuous distribution

Koenker H, Yukich J, Erskine M, Opoku R, Sternberg E, Kilian A. How many mosquito nets are needed to maintain universal coverage: an update. Malar J. 2023;22(1):200. doi:10.1186/s12936-023-04609-z.

Insecticide-treated nets: practical info. In: WHO guidelines for malaria, 14 March 2023. Geneva: World Health Organization; 2023:60–1 (https://iris.who.int/handle/10665/366432, accessed 15 October 2023).

Access to ITNs or IRS at optimal coverage levels

Co-deploying ITNs and IRS: practical info. In: WHO guidelines for malaria, 14 March 2023. Geneva: World Health Organization; 2023:70–1 (https://iris.who.int/handle/10665/366432, accessed 15 October 2023).

No scale-back of vector control in areas with ongoing malaria transmission

No scale-back in areas with ongoing local malaria transmission: practical info. In: WHO guidelines for malaria, 14 March 2023. Geneva: World Health Organization; 2023:73 (https://iris.who.int/handle/10665/366432, accessed 15 October 2023).

SMC distribution strategies

Seasonal malaria chemoprevention with sulfadoxine–pyrimethamine plus amodiaquine in children: a field guide, second edition. Geneva: World Health Organization; 2023 (https://iris.who.int/handle/10665/368123, accessed 15 October 2023).

Guiding principles for prioritizing malaria interventions in resource-constrained country contexts to achieve maximum impact

24th meeting of the WHO Malaria Policy Advisory Group

30 October – 1 November 2023

World Health Organization

Contents of the presentation

WHY

The purpose

HOW

The process of development

WHAT

The proposition

WHAT NOT

The boundaries

WHO

The target audience

WHERE

The relations with subnational tailoring, national strategic plan and national plan of action

WHEN

The use of the guidance

HOW OFTEN

The process of updating

World Health Organization

WHY – the need

Applications of NMCP to GC7 window 1 and 2 (submitted in Q1-Q2 2023), faced a significant funding gap compared to Global Fund country allocations.

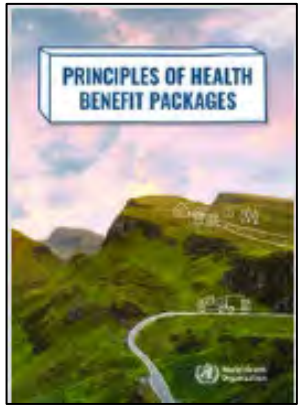
Several countries applying to window 1 requested frontloading of interventions in years 1 & 2, leaving gaps in essential services in year 3.

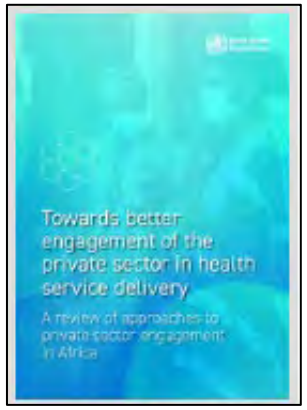
Adjustments in case management led to bigger gaps in vector control

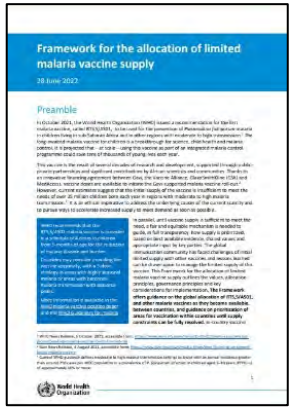
World Health Organization

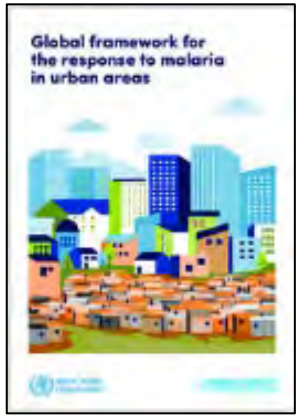
The estimated malaria funding gap for Windows 1 and 2 is approximately USD 1 billion to sustain essential services (case management in the public sector, ITNs in moderate to high transmission areas and SMC) without considering needs for optimal product selection and full programme support, which make the gap significantly higher

HOW – the resources









World Health Organization

HOW - development before MPAG

July – August (ver 1-11)

Originators

- WHO/GMP core group
- WHO/GMP senior management team
- WHO Regional Malaria Advisers

- *Over 15 contributors, iterative*

September (ver 12)

Technical Partners (Round 1)

- ALMA
- BMGF
- Global Fund
- RBM
- USAID - PMI

Over 25 contributors, one round

October (ver 14)

NMCP and ALL (Round 2)

- NMCP of Cameroon, Democratic Republic of Congo, Nigeria, Rwanda and Zambia
- BMGF
- Global Fund
- USAID-PMI
- WHO/GMP senior management team
- WHO Regional Malaria Advisers

- *Over 30 contributors, one round*

World Health Organization

WHAT – general contents

Framing to
GTS for malaria and SDG3
and sub-national tailoring

Clarity on definition

Core Principles: PHC and UHC, equity, values, baseline transmission, country ownership, cost-effectiveness, financial risk protection, political acceptability

Prioritizing high-impact interventions: early diagnosis and treatment, insecticide-treated nets (ITNs), indoor residual spraying (IRS), malaria vaccines and chemoprevention

Prioritization as iterative and dynamics process,
always ensure optimization and resource mobilisation based on evidence-based national strategic plan

Document lean & clean (4 pages)

Contents based on WHO guidelines and guidance

Additional reading

- *ITN community protection*
- *ITN requirements*
- *ITN distribution strategies*
- *ITN and IRS optimal coverage*
- *Scale-back vector control*
- *SMC distribution strategies*

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Prioritizing high impact interventions: malaria case management

- The primary objective is to prevent and minimize malaria-related deaths, providing access to early diagnosis and effective treatment of all malaria cases in all transmission areas
- Maintain diagnosis and treatment in existing services, including at community: **scaling-back is not an option**
- Surveillance and response to drug resistance and HRP2 deletions is essential
- Expansion of case management of acute febrile illnesses at community level and in the private sector should be carefully considered

World Health Organization

Prioritizing high impact interventions for pregnant women

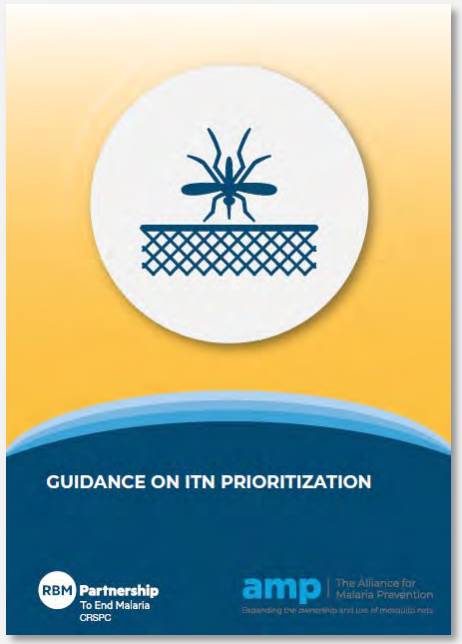
- Preventive interventions for pregnant women, such as intermittent preventive treatment of malaria in pregnancy and routine distribution of ITNs, should be prioritized in all moderate to high transmission areas

World Health Organization

Prioritizing high impact interventions: large scale deployment of insecticide-treated nets

Guidance on the prioritization of insecticide-treated nets in situations where resources are limited

Developed in 2023 with RBM and AMP to support national malaria programmes prioritize WHO-recommended interventions on deployment and choice of ITNs when programmes do not have sufficient budget to deploy the most effective ITNs to all populations at risk



https://www.who.int/publications/i/item/9789240069428

ITN prioritization in situation where resources are limited

Commit funding for routine ITN distribution to vulnerable groups in all areas with risk of malaria

Step 1: Ensure access for vulnerable groups

Calculate the funding needed to ensure full coverage of these at-risk areas with pyrethroid-only nets

Step 3: Maximize coverage

Identify funding gaps to increase coverage and make information available to potential financers

Step 5: Identify funding gaps

Step 2: Define ITN deployment scope

Identify and exclude areas with very low current and historical malaria risk (will it remain so in the absence of ITNs?)

List and rank the areas targeted for ITN campaigns according to malaria risk.

Step 4: Maximize effectiveness

4a. <u>Replace</u> ITNs with pyrethroid-PBO or pyrethroid-chlorfenapyr nets in areas that already have them

If resources remain, go to 4b. If not, Step 5

4b. <u>Substitute</u> pyrethroid-only ITNs with more effective ITNs in additional areas in decreasing order of malaria risk

Step 6: Ensure adequate funding for surveillance

Allocate sufficient funding to strengthen epidemiological and entomological surveillance

A robust surveillance system is needed to ensure timely detection of potential resurgence of malaria in areas no longer receiving ITNs

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World Health Organization

Prioritizing high impact interventions: large-scale deployment of indoor residual spraying

- WHO recommends either IRS or ITNs for large-scale deployment – no co-deployment
- Under resource constraints, no scaling-up of IRS
- Maintain optimal population coverage with one effective vector control intervention
- If unable to maintain IRS campaigns at the right times with effective coverage, switch to PBO or dual active ingredient nets and invest in SBCC to ensure the effective use of ITNs
- When IRS is withdrawn, establishment of strong surveillance and response capacity should be prioritized to mitigate a potential malaria increase

Prioritizing high impact interventions

Surveillance and program support

Maintain investments in surveillance and data quality, and program support to ensure effectiveness of vector control, diagnosis and treatment

Maintain resources to secure coverage and competence of health workers to provide quality care, and SBCC to improve treatment seeking, acceptance and use of interventions.

Chemoprevention

Maintain seasonal malaria chemoprevention as there is no evidence to inform scaling back.

If resources are not available, scale-down SMC in areas where incidence was lowest at baseline.

SMC expansion or new chemoprevention strategies should not be prioritized over case management and vector control if resources are limited.

Malaria Vaccines

RTS,S/AS01 and R21-Matrix M malaria vaccines for prevention of falciparum malaria in children living in malaria-endemic areas, prioritizing areas of moderate to high transmission.

Under the current limited vaccine supply, a specific process has been developed by WHO, UNICEF and Gavi for prioritizing RTS,S vaccine allocation.

World Health Organization

WHAT NOT – the boundaries

NOT a process to review and update WHO guidelines nor WHO guidance documents

NOT the avenue to endorse new intervention mixes not recommended by WHO

NOT providing strict criteria nor data thresholds for decision-making of NMCPs

NOT providing simplification of complex decisions in the form of flowchart

NOT replacing existing WHO documents

WHO is the target audience

- National Malaria Program Managers
- National Malaria Advisory Committee
- Technical development partners of NMCPs
- Funding Agencies supporting NMCPs

World Health Organization

WHERE AND WHEN TO USE

Operational Unit
(district or equivalent)

WHO recommended interventions with clear targeting **criteria***

(transmission setting, age group, seasonality, efficacy, access etc.)

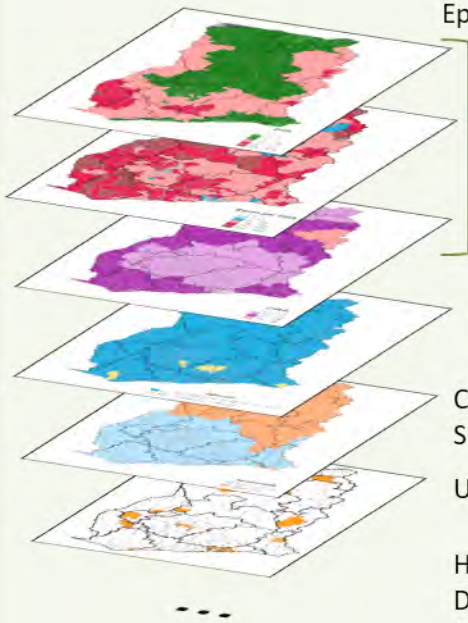
- LLIN, IRS, LSM,
- IPTp, IPTi, SMC,
- CM (Public HF, iCCM, private)

for each intervention, WHO has:
- Recommendation
- Good practice statement
- Country adaptation
- Additional considerations for targeting

Malaria Strategic Plan development

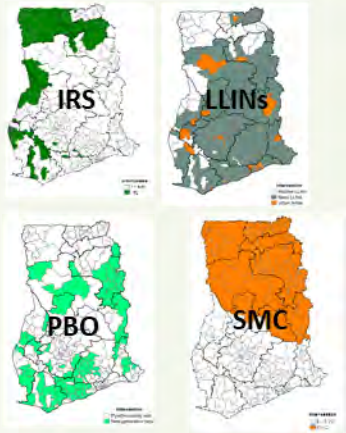
Stratification: Hierarchical ordering of one or multiple layers of information to make decisions

Indicators



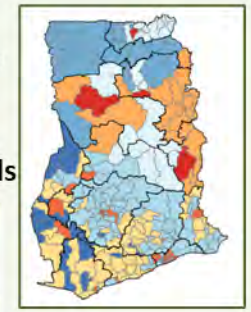
Epidemiology
Incidence
Prevalence
Mortality
Entomology
Climate & Seasonality
Urbanization
Health systems
Drug resistance
Conflict zones
Land use
etc

Intervention targeting: For each intervention, identify the operational unit that meets criteria + operational feasibility

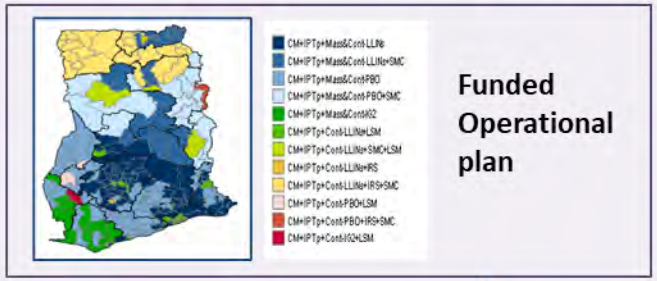


Mathematical models used to evaluate different scenarios and quantify impact of sub-nationally tailored intervention mixes

National Strategic Plan Intervention Mix Map & informed goals



Resource allocation and prioritization

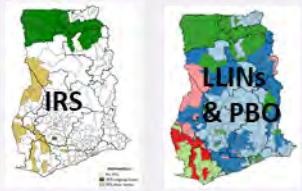


Funded Operational plan

Mathematical models may be used for resource prioritization through cost-effectiveness analysis of different scenarios

Prioritization: Prioritizing intervention to achieve maximum impact within a resource envelope

Implications:
- Less commodities
- Reduced coverage targets,
- Higher efficiency threshold
- Equity



Costing of national strategic plan

How much it costs

$$$

How much there is available

$

PROCESS FOR FINALISATION AND FURTHER UPDATES

New WHO guidance

New WHO guidance

MPAG review	November	December	June 2024	August 2024	Annual updates
	Finalisation of 2023 version	Publication and dissemination	Systematic collection of feedback from end users (NMCP and technical partners)	Revised 2023 version	Regular updates based on new WHO guidance

World Health Organization

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Malaria Policy Advisory Group Meeting
30 October–1 November 2023, Geneva, Switzerland
Background document for Session 4

World Health Organization

Update on subnational tailoring of malaria interventions and strategies

Strategic Information and Response Unit

Introduction

Subnational tailoring (SNT) is the use of local data and contextual information to determine the appropriate mix of interventions and strategies for a given area to achieve optimum impact on transmission and burden of disease at the strategic level or within a specific resource envelope. SNT can also be used to inform how new tools can be most effectively integrated within previously planned mixes of interventions, or for dynamic resource mobilization as additional funding opportunities become available.

SNT stems from the collective commitment to surveillance – a key pillar of the *Global technical strategy for malaria 2016–2030 (1)* – and the use of local data for decision-making by malaria programmes and partners to achieve malaria elimination. It is also aligned with one of the "High burden to high impact" (HBHI) response elements, which advocates for the use of strategic information to drive impact. This is anchored on the basic principles of good public health, i.e. that health policies should be informed by the best possible evidence derived from the best available data and information.

The SNT process

Mixes of interventions and strategies that are considered in the local response include not only those aimed at diagnosis, treatment and prevention, but also other major programmatic and health system actions required to reach the goal of malaria elimination, for example, actions required to strengthen the health workforce, improve access to and quality of care, strengthen the surveillance systems, achieve social and behaviour change, and expand the engagement of communities.

As such, the process requires system-wide and multi-stakeholder participation anchored on the broad principles of health sector priority-setting. Analytically, mixed methods approaches (qualitative and quantitative) are used. Descriptive, statistical, geospatial and mathematical modelling approaches all play a role.

The following essential steps are involved in the development and monitoring of prioritized malaria control and elimination programmes, as implemented under the SNT process:

- **Establish a national SNT team**, led by the national malaria control programme (NMCP), but including other government departments, and national, regional and global partners with consent from the NMCP. This team is responsible for the whole process, from data assembly and analysis to strategy development, resource mobilization and prioritization, and implementation.
- **Determine the criteria for tailoring interventions** (e.g. long-lasting insecticidal nets, indoor residual spraying, chemoprevention, diagnosis and treatment) and strategies (e.g. integrated community case management, seasonal malaria chemoprevention). The national team compiles all interventions and strategies under consideration and develops the criteria to be

used for tailoring each of them, building on the World Health Organization (WHO) normative guidance and adapting to the local context as needed.

- **Stratify malaria risk and its determinants**. Ecological, interventional, systemic, social and other determinants are stratified at operational units of relevance and in ways that respond to the specific question at hand, based on the agreed upon criteria from the previous step. As such, the process of stratification depends on the specific intervention or strategy under discussion and moves away from the use of epidemiological metrics alone. Statistical and geospatial methods are useful here.
- This information is then used to **develop various scenarios of intervention mixes** that have been tailored through the stratification process.
- **The impact of these scenarios is estimated using mathematical models**. At this point, the scenarios may be further refined.
- A consensus-based approach informed by the evidence is used to **select the final mix of interventions and strategies**. This strategic plan is then costed and used for resource mobilization.
- Once there is clarity on the available resources, the costed strategic plan is used as the basis to **further inform rational prioritization of investments to maximize impact** if the resources are insufficient. This is usually the most challenging part of the process. Further stratification of determinants and mathematical modelling are helpful at this point to guide and assess the impact of the various prioritization decisions.
- During the budgeting process, it is expected that sufficient capacity to **monitor the impact of the deployed intervention** packages will be set aside so that the response can be honed over time and resources re-prioritized as needed.

Principles

The principles adopted in the SNT process are aligned with the broader concepts of health priority-setting, with the aim of selecting the best possible options for addressing the most important health needs in the best way within available resources.

WHO defines priority-setting in the following way: “Priority-setting determines the strategic directions of the national health plan. Led by citizens who are the principals and decision-makers, priority-setting is a shared responsibility between the ministry of health (MoH) and the entire health stakeholder community” *(2)*.

In brief, the following principles underpin the malaria SNT process:

- **Ownership:** Countries set their own strategies for the response to malaria, and provide strong leadership responsible for strengthening their institutions and providing transparency in the investments. The development of strategic plans and investment priorities should be through wide participation and feedback by all stakeholders. Health priority-setting is inherently political. As such, it must reflect societal values and goals and involve compromise among stakeholders.
- **Evidence-informed and context-specific:** The choice of interventions and strategies should be underpinned by strong evidence of their effectiveness within a given context. WHO plays a key role in developing evidence-based normative guidance, which are developed to be flexible and responsive to the context. WHO is moving away from declaring some interventions as core and others as complementary. Instead, the aim is for the SNT process to guide the mixes of interventions that will result in the greatest impact.

- **Alignment:** External donor support must align behind these plans and objectives and prioritize the use of local delivery systems, including local partners, in support of the health system.
- **Harmonization**: Globally, donors coordinate, simplify procedures and share information to avoid duplication in the malaria response. Countries should provide efficient mechanisms for coordinating implementation activities.
- **Investment for results**: Countries and donors should agree to focus on real and measurable impact on development and invest in local systems that collect the required information.
- **Mutual accountability**: Measuring impact also requires all stakeholders (donors, countries, implementation partners) to be accountable for the results.
- **Capacity development**: Countries are fully responsible for improving national systems and capacities. To build the ability of countries to manage their own future, however, donors should support countries' capacities in the development of sound strategic and operational plans, delivery systems, and surveillance, monitoring and evaluation processes.

Updates on SNT support from the Global Malaria Programme Strategic Information and Response Unit

Since 2018, the Strategic Information and Response Unit has worked in close collaboration with WHO regional and country offices to respond to country requests for support in the implementation of the SNT process, specifically to inform single or multiple intervention strategic planning, resource mobilization, funding requests, budget negotiations, optimization of intervention implementation, and so on. In many countries, the application of SNT has sparked the integration of data use as part of countries' regular decision-making processes. However, it has also revealed the need for local capacity to conduct the analyses required for SNT in the short and long term. As a result, the Strategic Information and Response Unit organized two malaria epidemiological stratification workshops in July and September 2023, with participation of 22 NMCP staff and local universities. A third workshop is planned for November 2023, in collaboration with the WHO Regional Office for Africa. Members of the Strategic Information and Response Unit are also engaged in different initiatives to train individuals from NMCPs and partner organizations either directly or through specific platforms, such as the Applied Malaria Modeling Network (AMMnet).

Table 1. List of countries for which the Strategic Information and Response Unit, in collaboration with the WHO regional and country offices and technical partners, has provided analytical support on SNT and related analyses between 2018 and 2023

2018–2020	2021–2023
HBHI Phase I countries: • Burkina Faso • Cameroon • Democratic Republic of the Congo • Ghana • Mali • Mozambique • Niger • Nigeria • Uganda • United Republic of Tanzania	**Continued support in all HBHI Phase I countries and HBHI Phase II countries:** • Benin • Burundi • Central African Republic • Côte d'Ivoire • Guinea • Liberia • Malawi • Sierra Leone • South Sudan • Togo • Zambia

E2020 countries:	Other countries:
• Comoros	• Congo • Ethiopia • Gambia • Guinea-Bissau • Indonesia • Madagascar • Sao Tome and Principe • Senegal • Somalia • Sudan

References

1. Global technical strategy for malaria 2016–2030, 2021 update. Geneva: World Health Organization; 2021 (https://iris.who.int/handle/10665/342995, accessed 7 October 2023).
2. Strategizing national health in the 21st century: a handbook. Geneva: World Health Organization; 2016 (https://iris.who.int/handle/10665/250221, accessed 7 October 2023).

Subnational tailoring of malaria interventions and strategies

UPDATE

MALARIA POLICY AND ADVISORY GROUP (MPAG) MEETING

30-31 OCTOBER 2023

GENEVA

Dr. Beatriz Galatas

Strategic Information and Response Unit

Global Malaria Programme

World Health Organization

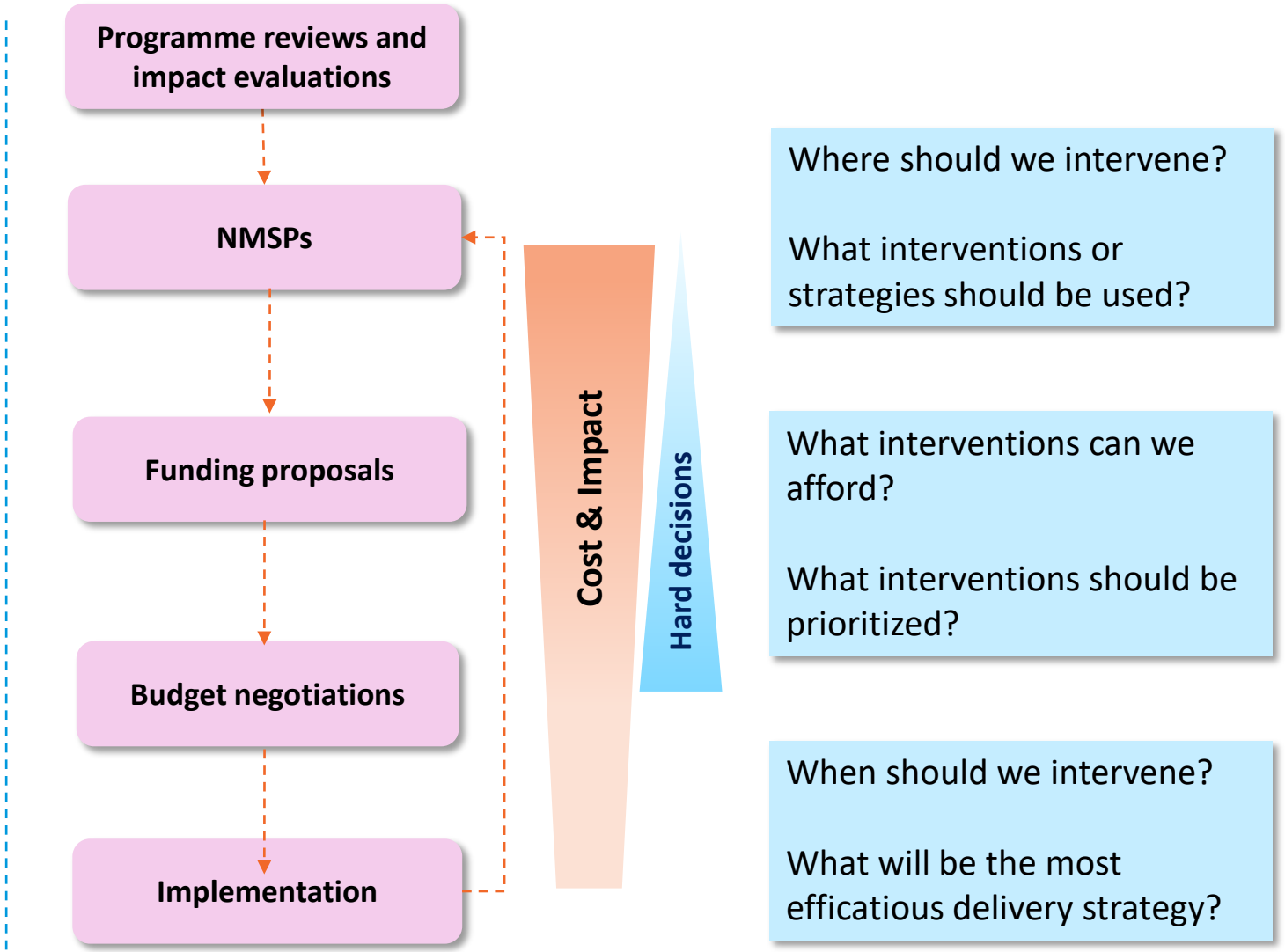
All maps shown in this presentation serve as examples and should not be used or interpreted outside of this explanatory context.

World Health Organization

What?

Subnational tailoring of malaria interventions (SNT)

The use of local data and contextual information to determine the appropriate mixes of interventions and strategies, for a given area, for optimum impact on transmission and burden of disease

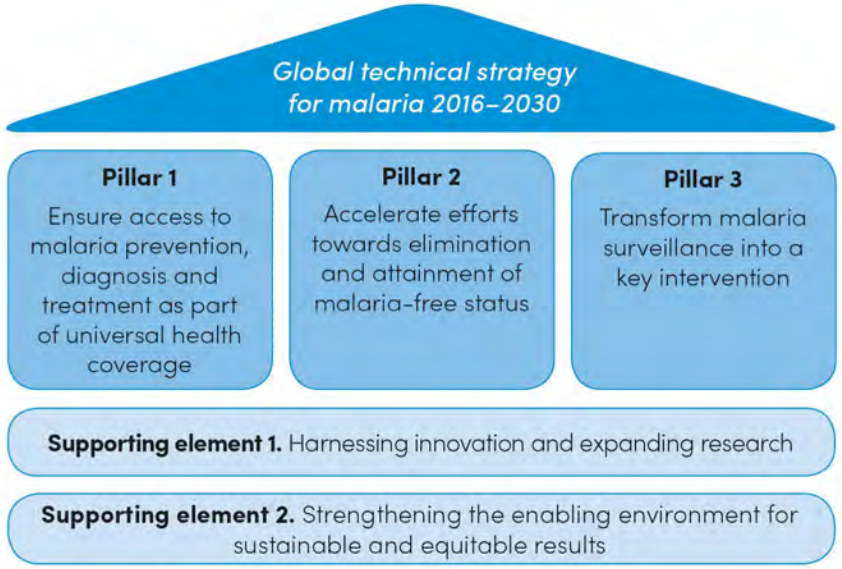


World Health Organization

Why?

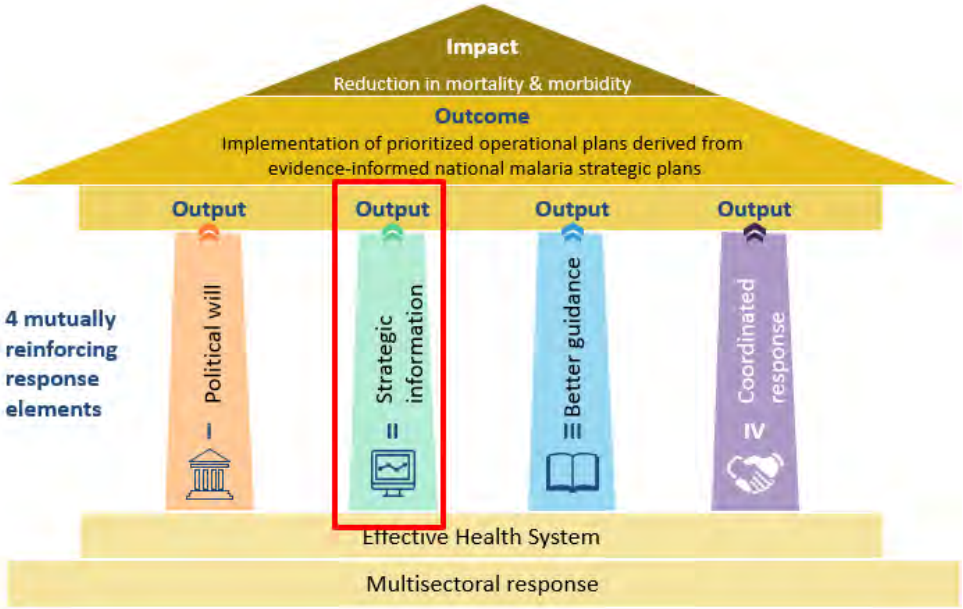
Anchored on the basic principles of good public health - that **health policies should be informed by the best possible evidence derived from the best available data and information.**

Global Technical Strategy



A key pillar of the GTS is the use of **surveillance and local data for decision making by malaria programs and partners** to achieve malaria elimination

High Burden to High Impact



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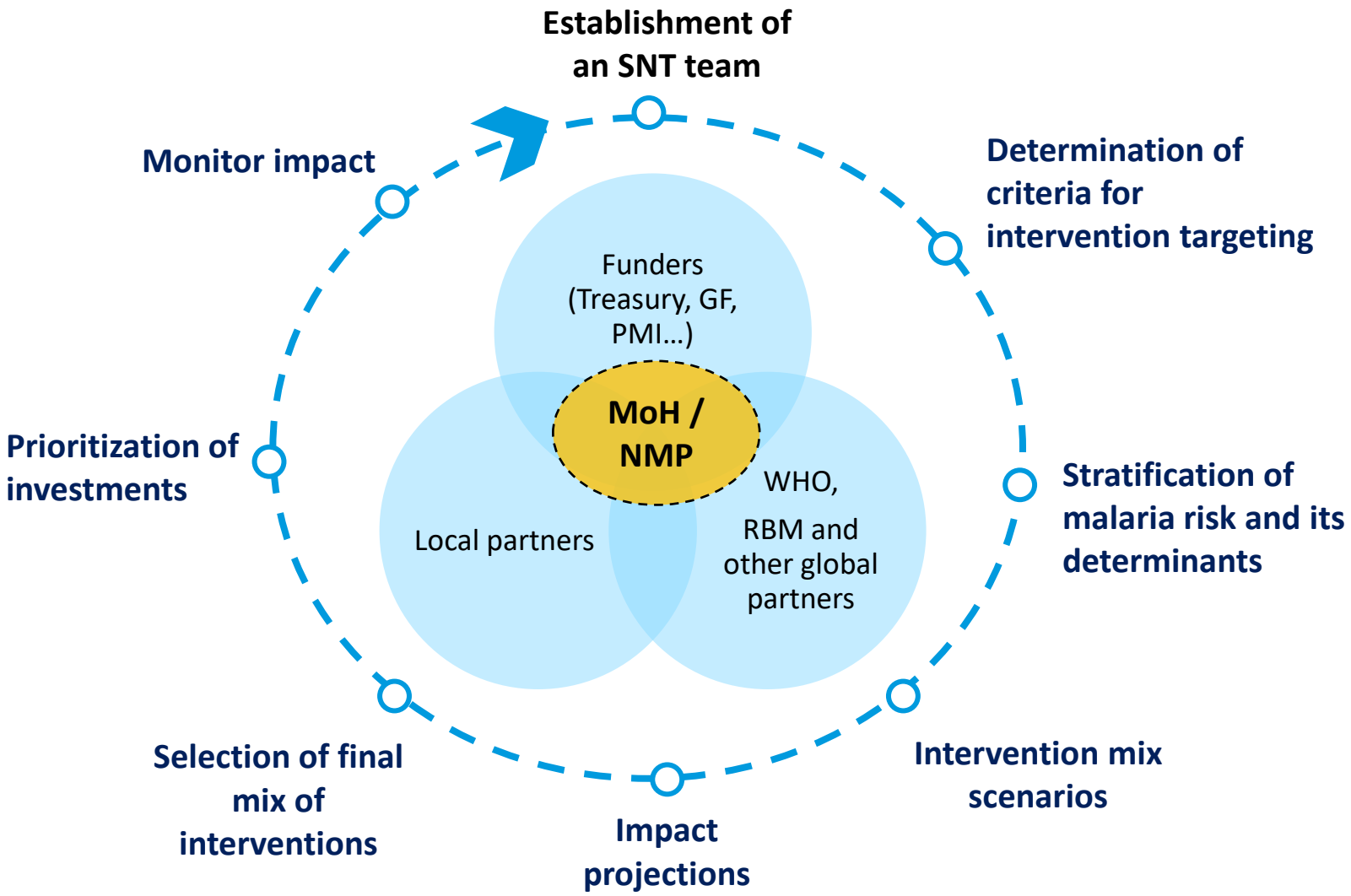
How?

The process requires a system-wide and multi-stakeholder participation anchored on the broad principles of health sector priority setting



World Health Organization

How?

Establishment of an SNT team

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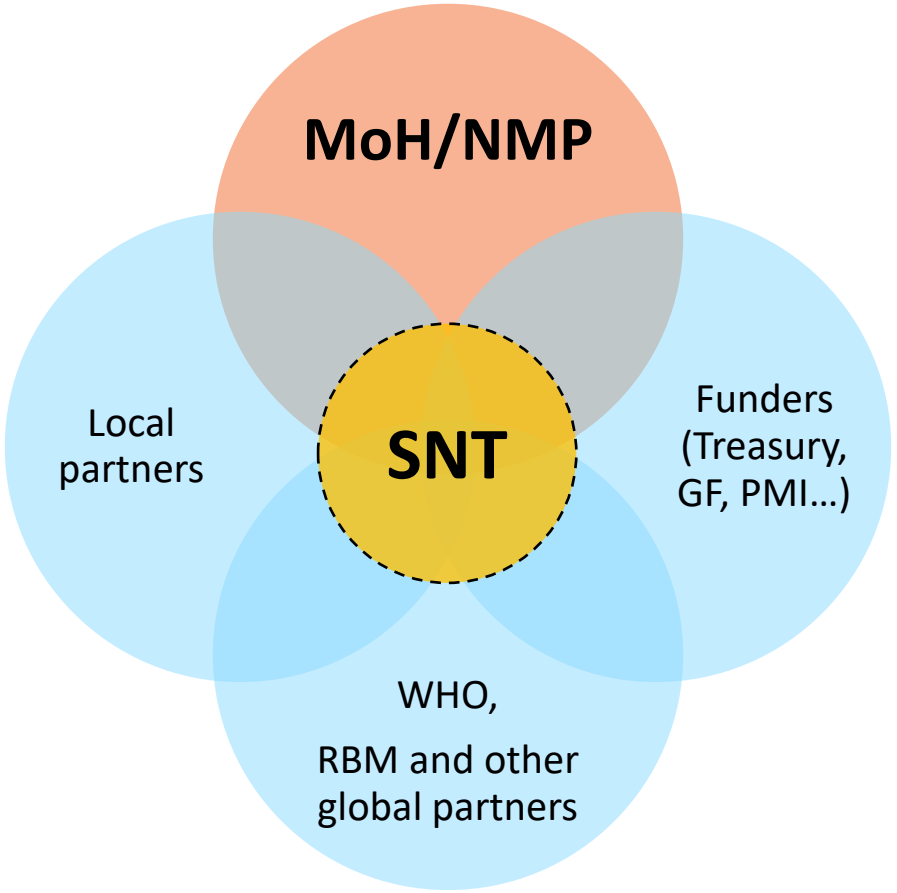

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Determination of criteria for intervention targeting

The national team compiles all **interventions and strategies under consideration and develops the criteria** to be used for tailoring each one of them building on the WHO normative guidance

WHO recommended interventions and targeting criteria adapted to country context

	Transmission (Incidence, Prevalence, Mortality, *etc*)	Age distribution of burden	Seasonality	Entomo-logical indicators	Environment and urbanicity	Vulnerable populations, conflict, emergencies	*etc*[1]
ITNs	+			+	+	+	
IRS	+		+	+			
LSM	+			+	+		
SMC	+	+	+				
MDA	+	+				+	
IPTp	+						
PMC	+	+	+				
Vacc.	+	+					
iCCM	+					+	
Surv.	+	+					
***etc*[2]**							

1- Health system capacity, access to care, EPI coverage, previous exposure to interventions, community acceptability …
2- Targeted improvements of case management, surveillance systems, intervention-specific delivery strategies …

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Stratification of malaria risk and its determinants

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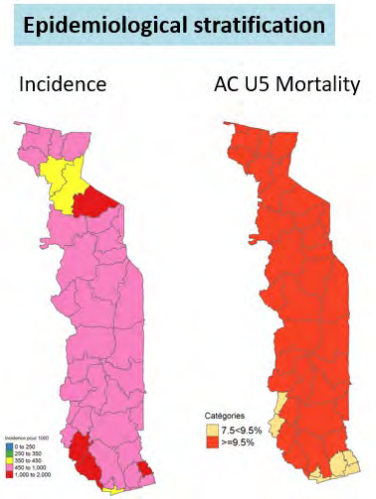

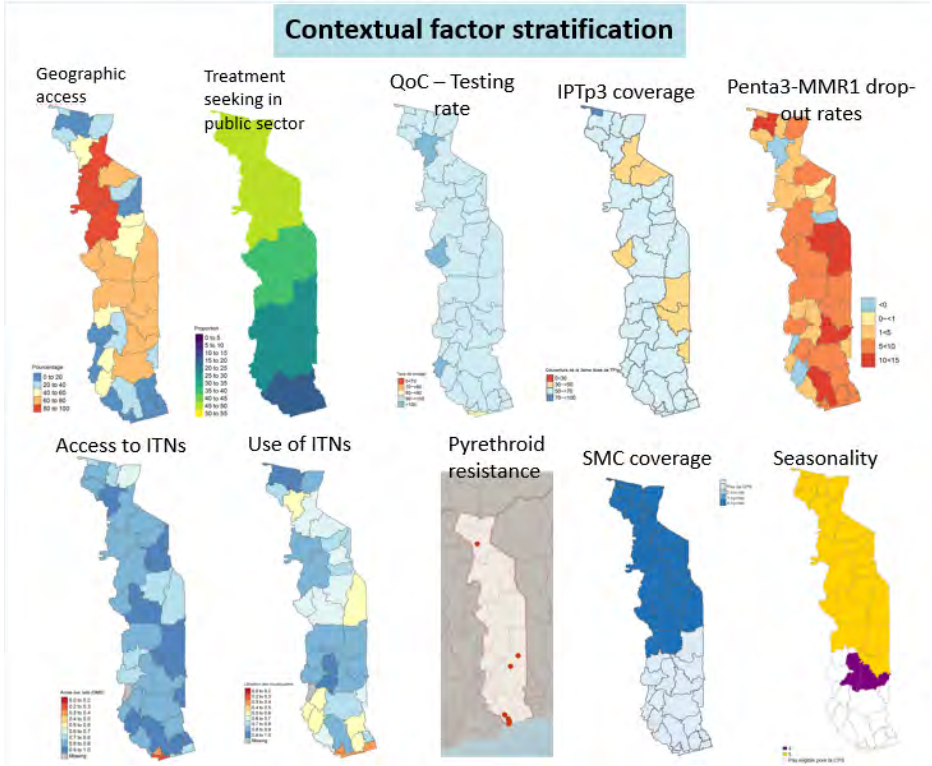

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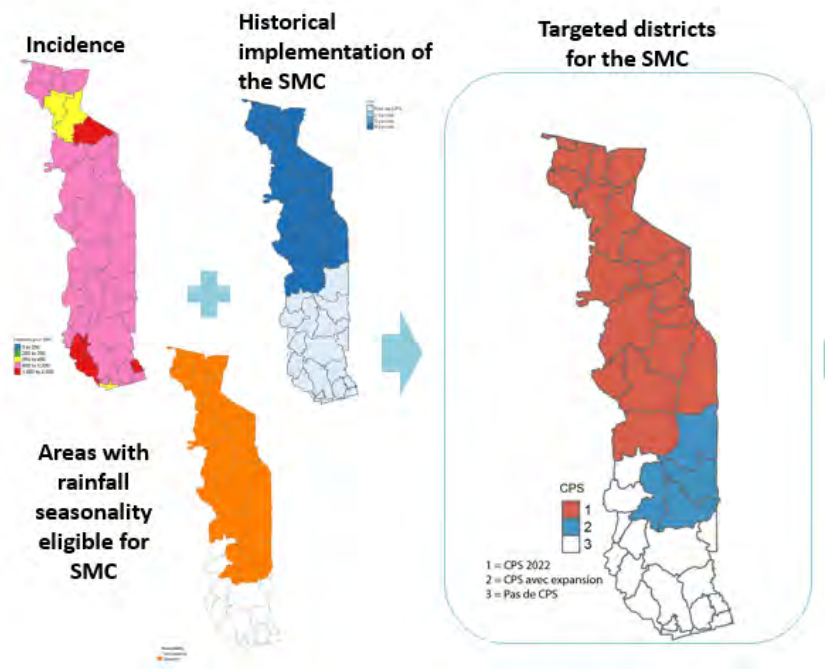
Intervention mix scenarios

Stratified layers required to inform intervention or strategy-specific criteria are used to develop various scenarios of intervention mixes

	Transmission (Incidence, Prevalence, Mortality, *etc*)	Age distribution of burden	Seasonality
SMC	+	+	+



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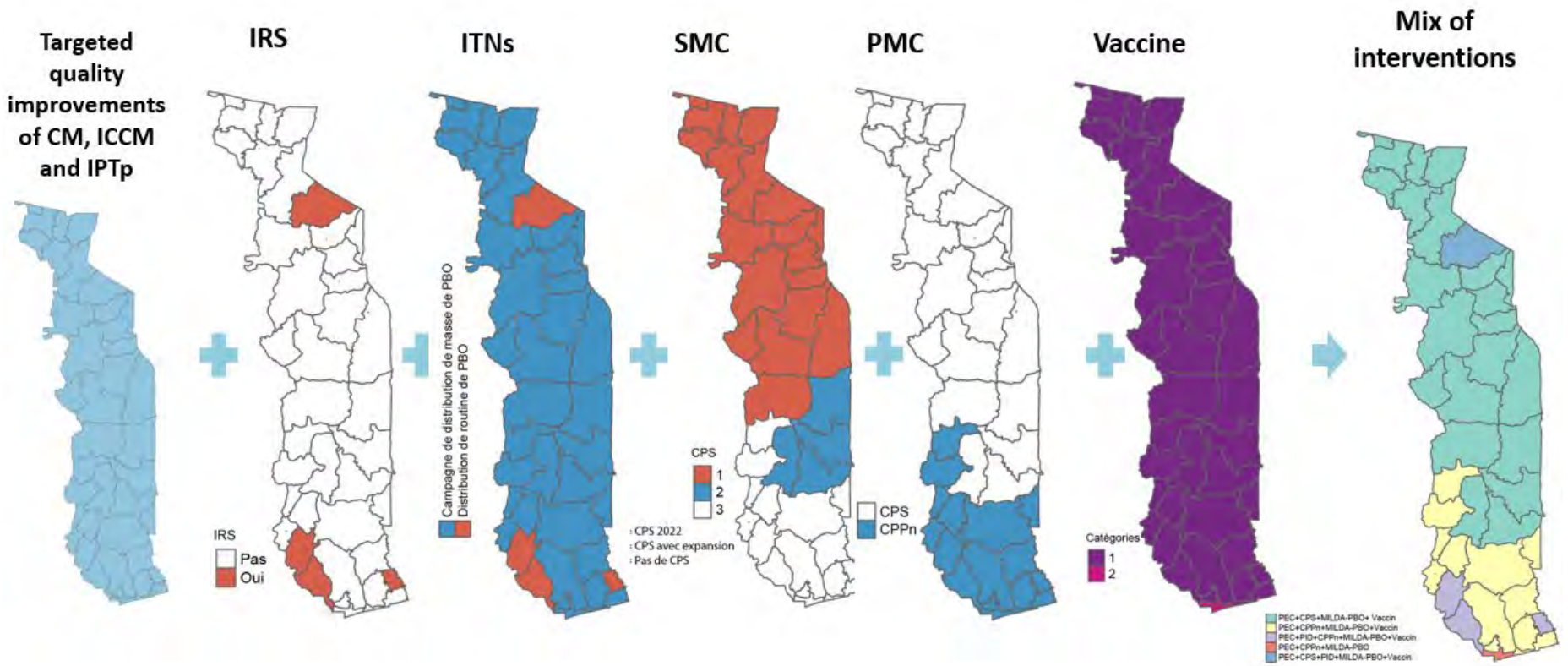

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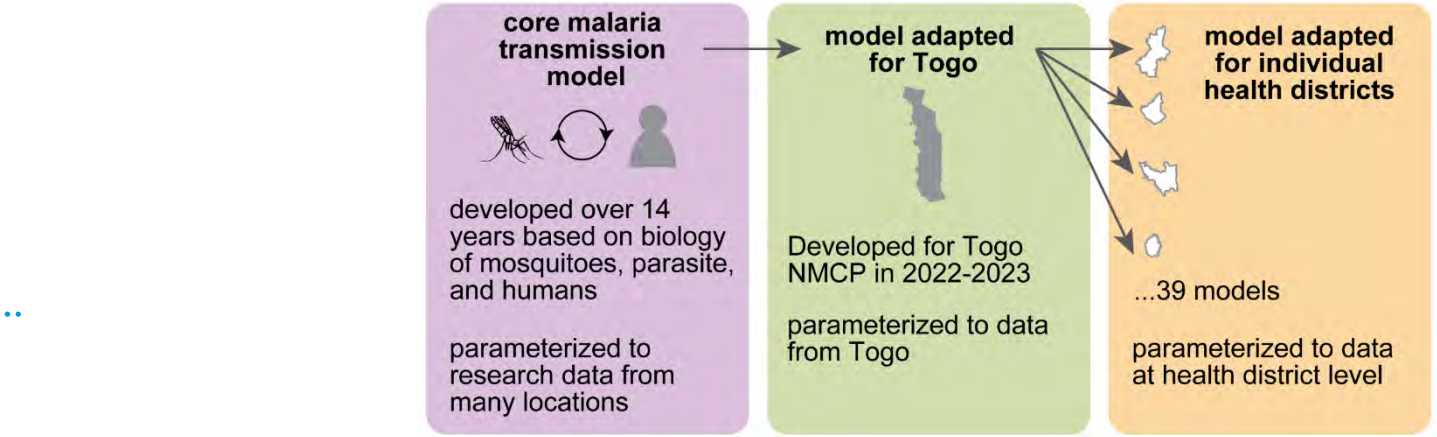
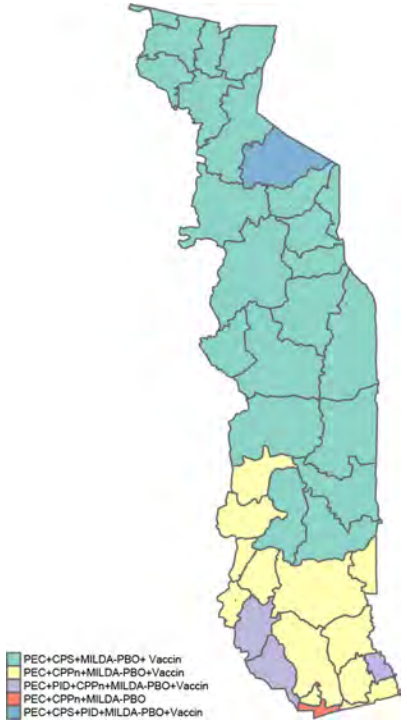
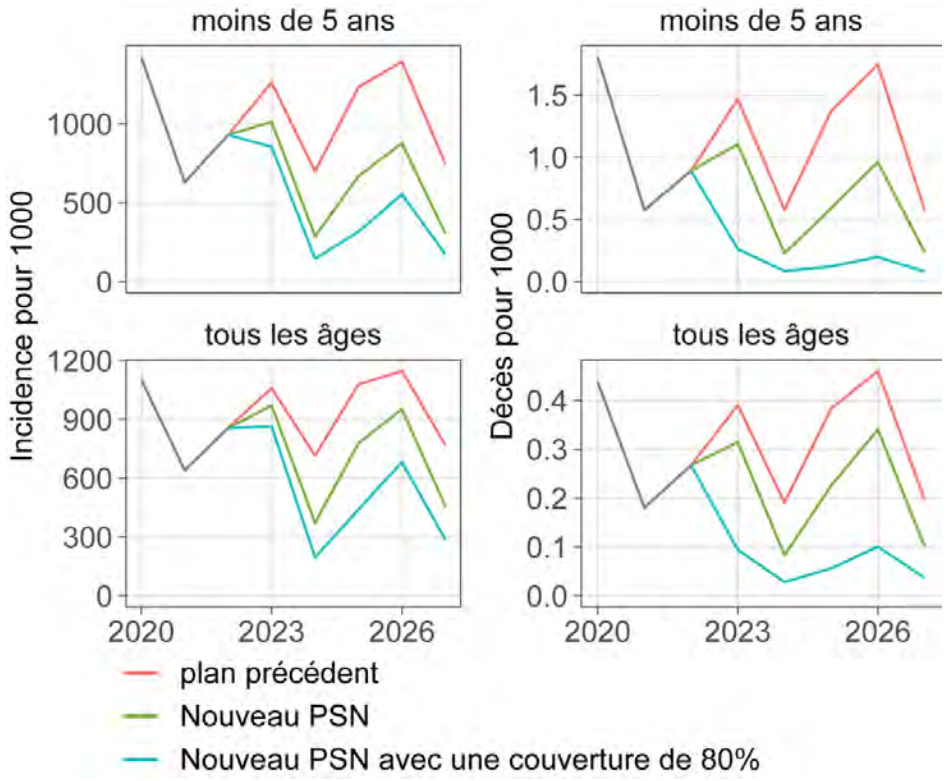
How?

Impact projections

The impact of these scenarios is estimated using mathematical models . At this point further refinements may be made to the scenarios. **A consensus based approached** informed by the evidence is used to select the final mix of intervention and strategies.







World Health Organization

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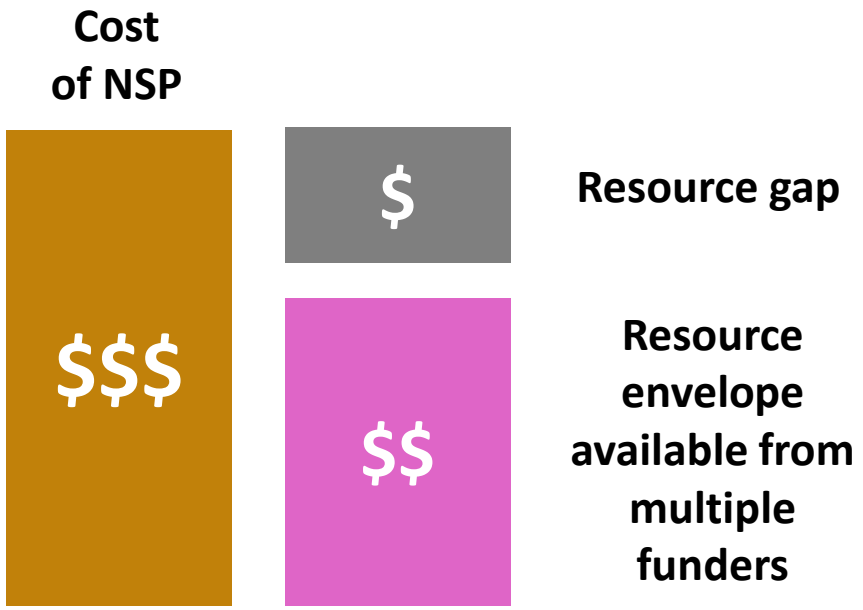
Impact projections

The impact of these scenarios is estimated using mathematical models . At this point further refinements may be made to the scenarios. **A consensus based approached** informed by the evidence is used to select the final mix of intervention and strategies.

Costing of agreed-upon plan

This plan is then costed and is used for resource mobilization.

Mathematical modeling is helpful as an advocacy tool for additional resource mobilization



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How?

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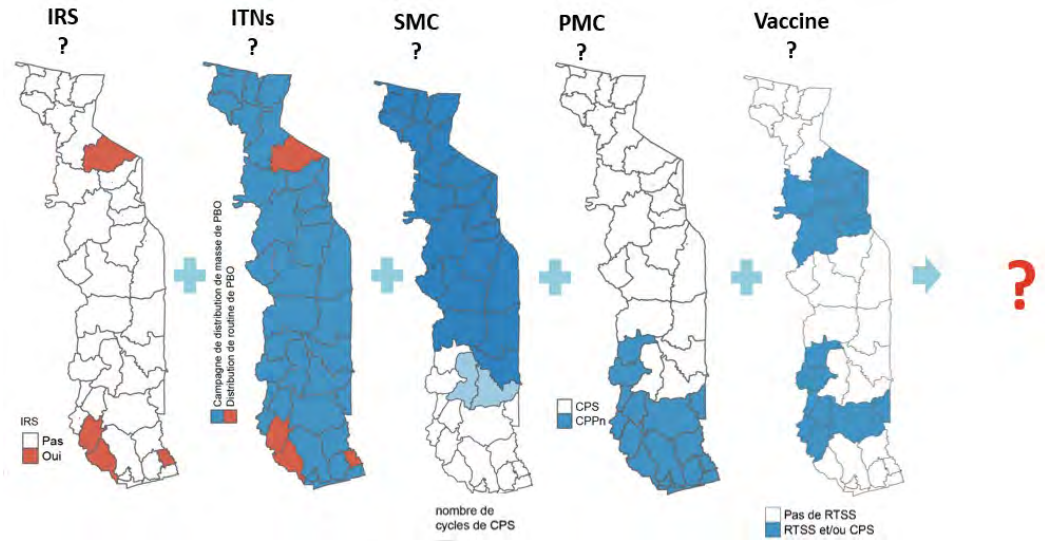
Mathematical modeling is helpful at this point to assess the impact of the various prioritization decisions.

Prioritization of investments

Once there is clarity **in the available resources, the costed strategic plan is used as the basis to further inform rational prioritization of investments to maximize impact** if the resources are insufficient.

This is usually the most challenging part of the process.

Mathematical modeling is helpful at this point to assess the impact of the various prioritization decisions.



	Transmission	Age distribution of burden	Seasonality	Entomo-logical indicators	Environment and urbanicity	Vulnerable populations	*etc*[1]
ITNs	++			++	+	+	++
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~~MDA~~						+	
IPTp	+						
PMC	+	+	+				
Vacc.	++	+					
iCCM	+					+	++
Surv.	+	+					

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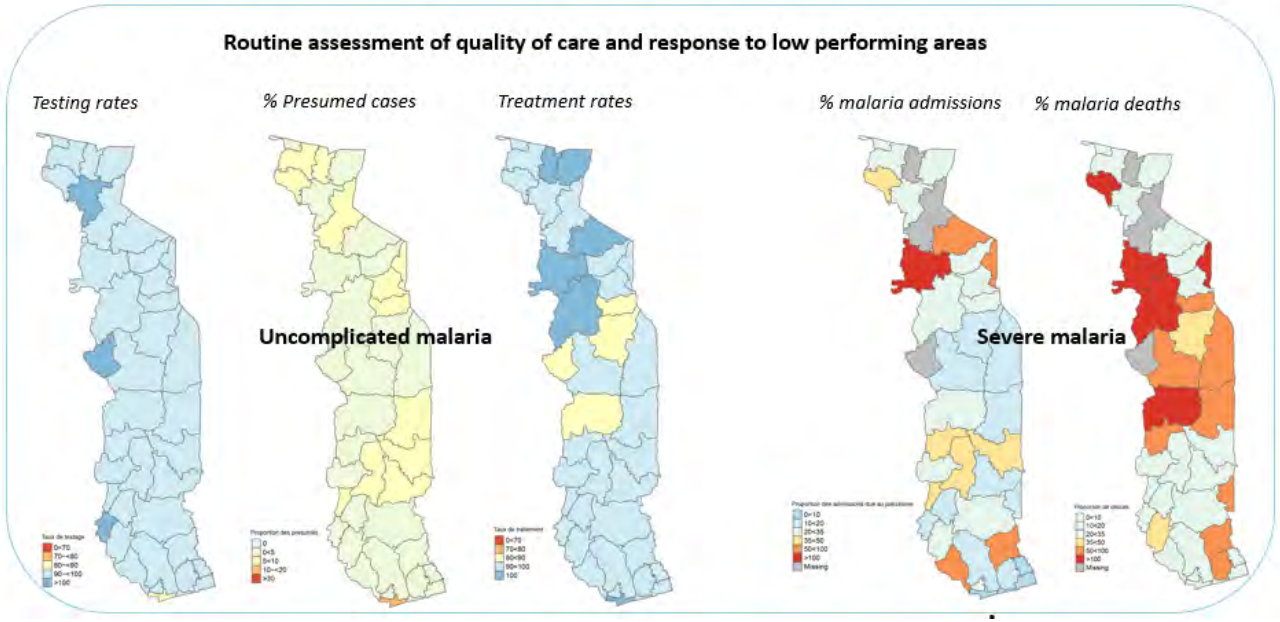
Monitor impact

During the budgeting process it is expected that sufficient **capacity to monitor the impact of the deployed intervention packages are set aside** so that the response is sharpened over time and resources are reprioritized as needed.



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Principles

*'Priority-setting determines **the strategic directions of the national health plan**. Led by citizens who are the principals and decision-makers, priority-setting is a shared responsibility between the ministry of health (MoH) and the entire health stakeholder community.'* (WHO definition)

Ownership

Countries set their own strategies for the response to malaria, provide strong leadership responsible for strengthening their institution and for providing transparency in the investments.

Evidence-informed

The choice of interventions and strategies should be underpinned by strong evidence of their effectiveness within a given context.

Alignment

External donor support aligns behind these plans and prioritizes the use of local delivery systems

Harmonization

Globally, donors coordinate, simplify procedures and share information to avoid duplication in the malaria response.

Invest for results

Countries and donors agree to focus on real and measurable impact on development and invest in local systems that collect the required information.

Mutual accountability

Measuring impact also requires that all stakeholders are accountable for results.

Capacity development

To build the ability of countries to manage their own future, donors should support countries capacities in the development of sound strategic and operational plans, delivery systems and surveillance, monitoring and evaluation processes.

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Summary of support GMP-SIR (2018-2023)

- Full SNT process
- Intervention-specific targeting support
- Retrospective analysis
- Malaria clinical incidence stratification support

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Country examples

- Successful process and country ownership – Togo, Guinea
- Sustainability and continuity – Ghana, Burkina Faso, Nigeria
- Multi-stakeholder engagements – Malaria vaccine allocation
- Potential of SNT in complex environments – Sudan, Yemen
- Capacity development plans – Malaria epidemiological stratification workshops

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Lessons learnt

- Malaria Strategic Information Technical Advisory Group (MSI-TAG) meeting debrief
- Next steps

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MSI-TAG Inaugural meeting
July 4th-6th 2023, Geneva

- To provide WHO with independent evaluation of the scientific, technical and strategic aspects of malaria surveillance, monitoring and evaluation.
- To recommend priorities to WHO and relevant technical units at all levels of the organization to strengthen national malaria surveillance, monitoring and evaluation systems and the use of data for decision making, including the installation of digital solutions and the assessment of surveillance systems.
- To advise WHO on approaches to enhance the use of data for national and subnational decision making to support efficient, effective and equitable implementation of malaria interventions to communities.
- To support WHO to review and improve the methods for estimation of the malaria burden, investments, interventions and impact for tracking global progress through the annual World Malaria Report.

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MSI-TAG: Summary of discussions on SNT

- SNT should be understood as the **use of local data to make decisions**. How data is used depends on the question at hand.
- **SNT should not be understood as modeling**. SNT is a process, modeling is a tool used in the process.
- **SNT should empower the end users**. At any point when the user is being disempowered or harmed, the analysis should be stopped
- The approach **for deciding where to remove interventions** (hardest decision of prioritization) should be understood as part of the **prioritization** exercise, and not mixed with eligibility or understood as a planning exercise alone.
- Currently, countries are not the main actors in the prioritization process. **More engagement with key prioritization players is required** to allow decisions to be informed by local data.
- It is encouraged that all countries **start evaluating their data** to understand its gaps and uncertainties and plan sustainable efforts to improve it. The use of the data depends on the confidence on it.
- **Methodological innovation** for the use of data is as important as the improvement of the data
- Various proposals from funders and partners on "**SNT evaluations**", with unclear purposes and approaches. The objective should focus on measuring the effectiveness of the process to understand how much did it inform decisions and what decisions – *Ongoing qualitative assessment conducted by Northwestern University*.

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Next steps

- Guiding principles for prioritizing malaria interventions in resources constrained country context to achieve maximal impact

- SNT manual

- Sustainable SNT support to countries through the WHO AFRO Communicable and non-conmmunicable disease cluster and the Precision Public Health Metrics unit (PPHM)

- Discussions with donors and the malaria community to support countries capacities in the development of sound strategic and operational plans, delivery systems and surveillance, monitoring and evaluation processes.

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Acknowledgements

National malaria control programs

Dr. Daniel Ngamije

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SIR unit

WHO regional and country offices

World Health Organization

Thank you

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