

WHO Guidelines for the Diagnosis and Treatment of Malaria

- *updates*

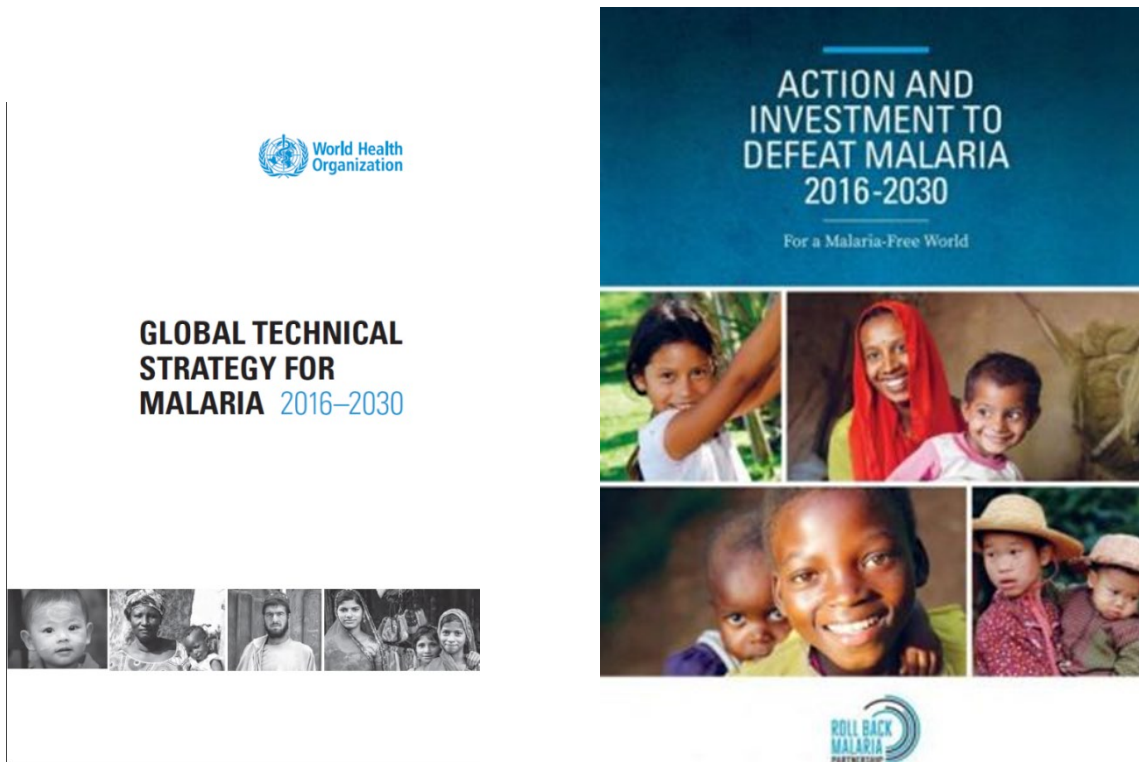
Dr. Peter OLUMESE,
Global Malaria Programme
WHO, Geneva, Switzerland.

Estimated malaria cases & deaths (2020)

- **The Global Malaria Picture**
 - 87 countries and territories
 - Half world at risk (3.2 billion).
- **highly concentrated in sub-Saharan Africa**
 - Globally, there were an estimated 241 million cases of malaria \approx 95% in Africa; 3% in South East Asia
 - Globally, 627 000 deaths - 96% in Africa
 - malaria was the 4th highest cause of death among children in Africa (10% of child death in sub-Saharan Africa), - claiming the life of 1 child every 2 minutes.

Global Technical Strategy

- To achieve the future, synergy amongst stakeholders



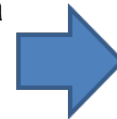
- ☐ Innovation
- ☐ Manufacturing
- ☐ Funding

Global Technical Strategy -opportunities

- Increasing focus on elimination & surveillance
- Acceleration of efforts and a shift on strategic priorities

3 Key pillars

1. **Ensure universal access** to malaria prevention, diagnosis and treatment
2. **Accelerate efforts towards elimination** and attainment of malaria-free status
3. **Transform malaria surveillance** into a core intervention



Attractive Market

- ☐ New medicines
- ☐ Manufacturing capacity
- ☐ New diagnostics
- ☐ Broader reach
- ☐ Funding

... with less risk

2 supporting elements

1. **Harnessing innovation and expanding research**
 1. Basic and implementation research
 2. Action for rapid update of tools
2. **Strengthening the enabling environment**
 1. Strong political commitment/multisectoral / cross-border
 2. Capacity development/health system strengthening

Global Technical Strategy

- Progress towards first Milestone point (2020)

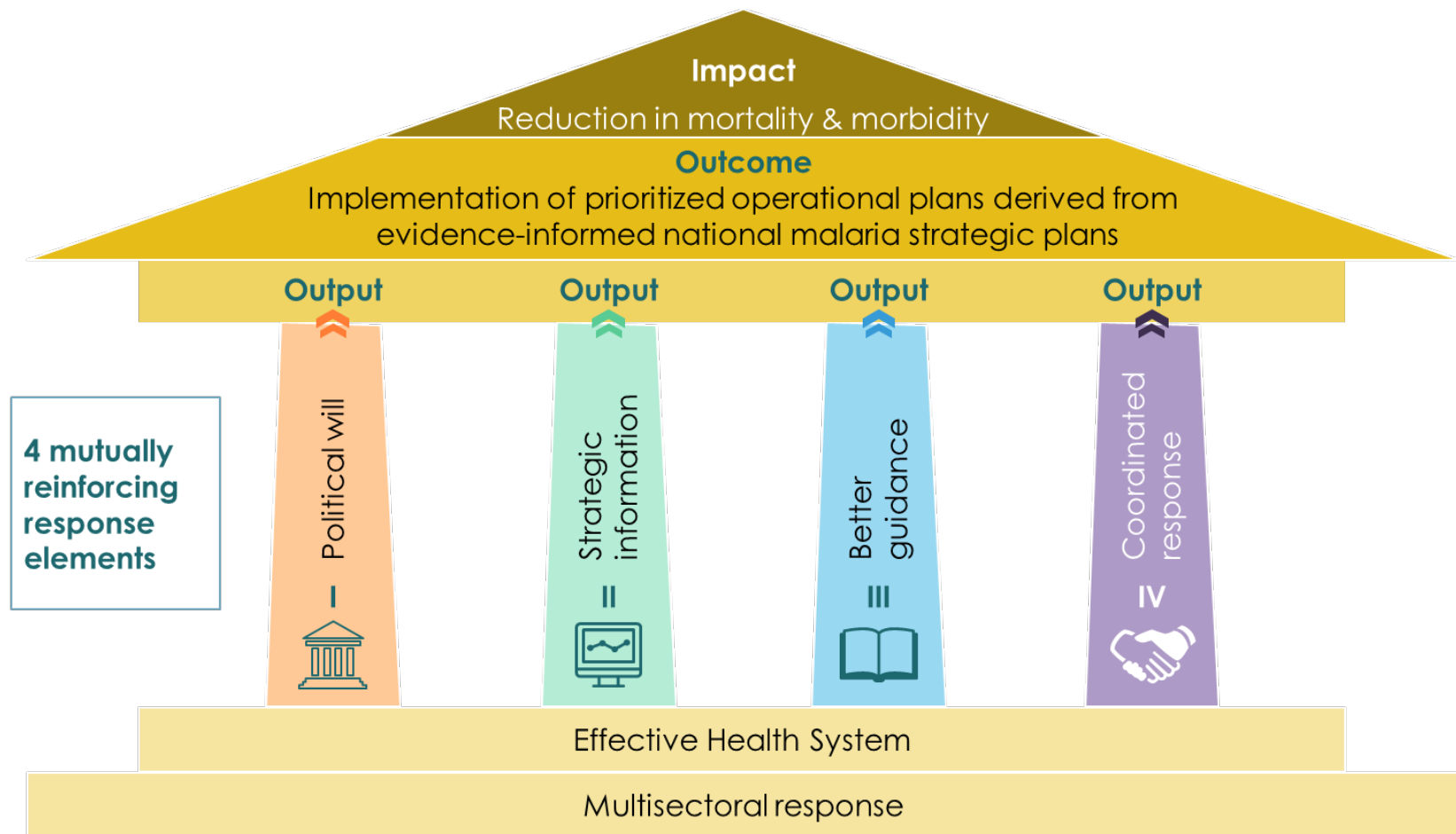
Goals	Milestones		Targets
	2020	2025	2030
1. Reduce malaria mortality rates globally compared with 2015	At least 40%	At least 75%	At least 90%
2. Reduce malaria case incidence globally compared with 2015	At least 40%	At least 75%	At least 90%
3. Eliminate malaria from countries in which malaria was transmitted in 2015	At least 10 countries	At least 20 countries	At least 35 countries
4. Prevent re-establishment of malaria in all countries that are malaria free	Re-establishment prevented	Re-establishment prevented	Re-establishment prevented

- Mortality reduction
 - 18% reduction achieved, **but 22% off track**
- Malaria cases
 - 3% reduction achieved, **but 37% off track**

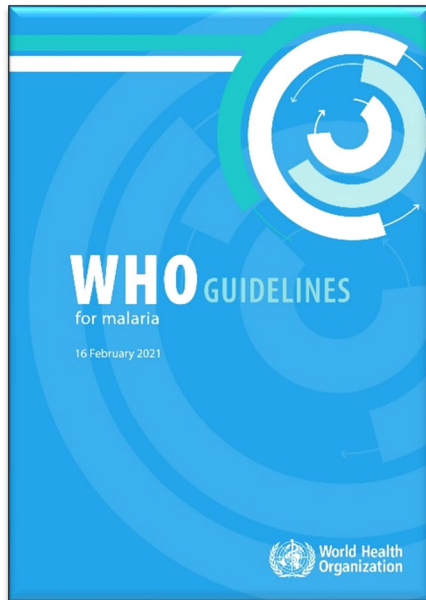
Global Technical Strategy for malaria 2016-2030

Off track to meet global targets

High Burden to High Impact: a targeted malaria response – was launched in 2018 to get back on track



WHO Guidelines for Malaria (2021)

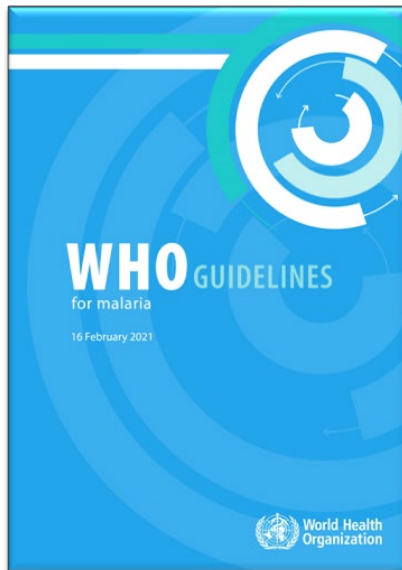


- These consolidated guidelines replace 2 guideline documents on the WHO website: **the Guidelines for the treatment of malaria, 3rd edition** and the Guidelines for malaria vector control.
- As new evidence becomes available, the recommendations will be reviewed and updated, where appropriate, **using WHO's transparent and rigorous guideline development process.**

Published in February 2021; and will be undated on a living basis
Available online: <https://www.who.int/publications/i/item/guidelines-for-malaria>

Malaria Chemotherapy and chemoprevention recommendations

Diagnosis and Treatment with Effective Medicines
(Malaria Case Management)



Several changes in guidelines have implications for manufacturers ...

- ☐ Products
- ☐ Quantities
- ☐ new indications

Core Principles: Guides to the development of products

Early diagnosis and prompt effective treatment

—within 24-48 of the onset of malaria symptoms

Combination therapy

—improved efficacy; prevent or delay resistance

Rational use of antimalarials

—reduce the spread of drug resistance, limit wastage, and ensure effective case management of febrile illnesses

Appropriate weight-based dosing

—prolong the useful therapeutic life of medicines,



**For market success,
manufacturers must consider**

- ☐ Products that can be used at the community level with minimal or no training of the provider
- ☐ Pediatric formulations

Rational Use of Diagnostics

All cases of suspected malaria should have a parasitological test (microscopy or RDT) to confirm the diagnosis.

- The results of parasitological diagnosis should be available within less than two hours of the patient presenting.



Major opportunity for companies with appropriate specifications and quality RDT's

Uncomplicated falciparum malaria

Therapeutic objectives

- Cure the infection as rapidly as possible (elimination of the malaria parasites that caused the treated infection), thus preventing progression to severe disease
- reduce transmission (reduce infectious reservoir)
- Prevent the emergence and spread of antimalarial drug resistance



- ☐ Expansion of indication
- ☐ Wider use of primaquine
- ☐ We need a pediatric formulation for primaquine

Uncomplicated falciparum malaria

Treat with an ACT.

- The recommended ACTs are:
 - artemether plus lumefantrine
 - artesunate plus amodiaquine
 - artesunate plus mefloquine
 - dihydroartemisinin plus piperazine
 - artesunate plus sulfadoxine-pyrimethamine.



challenge ...
production of
dihydroartemisinin plus
piperazine

****** Pyronaridine plus artesunate (presently under review for inclusion in the Guidelines)***

We need additional capacity and suppliers!

Uncomplicated falciparum malaria

Reducing transmissibility of treated *P.falciparum* infections

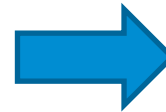
- In low transmission areas, give a single dose of 0.25mg/kg primaquine with ACT to patients with *P. falciparum* malaria to reduce transmission.

An additional indication of disease transmission is leading to ...

Expanded market AND opportunities for pediatric formulations

Uncomplicated non-falciparum malaria

- ☐ ACT use in the treatment of non-falciparum malaria.
- ☐ To prevent future relapse, treat people with vivax or ovale malaria with primaquine
- ☐ *The G6PD status of patients should be used to guide the administration of primaquine*



- ☐ Wider use and increased volumes of ACT for the treatment of non-falciparum malaria
- ☐ Incremental use of diagnostics
- ☐ Need for G6PD quantitative test – point of care tests

Severe malaria treatment

- Treat severe malaria with intravenous or intramuscular artesunate for at least 24 hours and until able to tolerate oral medication and complete with and ACT.

Pre-referral treatment

- a single rectal dose (10mg/kg) of artesunate before referral



Opportunities for Manufacturers ...

- ☐ For injection only 1 PQ'd manufacturer
Only drug for this indication
- ☐ In rural and hard to reach areas, need anti malarial before brought to a clinic
2 PQed suppliers of rectal artesunate

Reviews of guidelines on-going

- On-going policy reviews
 - Use of artesunate+pyronaridine in the treatment of malaria
 - Treating in the 1st trimester of pregnancy – Use of ACTs
- Reviews in the pipeline
 - Tafenoquine for anti-relapse treatment for vivax malaria
- Malaria diagnosis
 - Evaluations of *Pfhrp* 2/3 gene deletions and implications for case management and policy
 - G6PD quantitative or semi-quantitative point of care test

Progress with access

- The creation of new funding mechanisms – such as Global Fund to Fight AIDS, Tuberculosis and Malaria and the US President's Malaria Initiative – allowed for the wide-scale deployment of case management tools. Between 2000 and 2019, more than 3.0 billion RDTs and 3.4 billion ACTs were delivered to malaria-endemic countries (Public sector).

Thank you