I. Background and rationale

A WHO guideline is any document developed by the World Health Organization containing recommendations for clinical practice or public health policy. A recommendation tells the intended end-user of the guideline what to do in specific situations to achieve the best health outcomes possible, individually or collectively. It may offer a choice among different interventions or measures having an anticipated positive impact on health and implications for the use of resources. Recommendations help the user of the guideline to make informed decisions on whether to undertake specific interventions, clinical tests or public health measures, and on where and when to do so. Recommendations also help the user to select and prioritize across a range of potential interventions using products and/or strategies.

WHO develops guidelines in response to requests from Member States, WHO country offices, external experts or other stakeholders for guidance on a clinical or public health problem or policy area. This generally happens when they are uncertain about what to do or how to choose among a range of potential policies or interventions. Uncertainty can be triggered by a new public health problem or emergency; the uncovering of new evidence; an absence of good-quality evidence (or of any evidence at all); or a change in resource availability or access to services.

The Thirteenth Global Programme of Work (2019) (GPW 13) calls on the WHO Secretariat to reinforce its science- and evidence-based normative work, anticipate and assess the impact of research and discovery on public health and focus on supporting countries in the implementation of WHO’s norms, standards and agreements. Guidelines are the fundamental means through which the Organization fulfils its technical leadership in health, as identified in the GPW. WHO has adopted internationally recognized methods and standards for guideline development to ensure that its guidelines are of the highest quality. WHO guidelines must be developed in observance of the following principles:

- Guidelines address an area of uncertainty and an unmet need for guidance.
- Guidelines reflect the core WHO value of the “right to health”.
- The process of developing recommendations is explicit and transparent: the user can see how and why a recommendation was developed, by whom, and on what basis.
- The process of developing guidelines is multidisciplinary and includes all relevant expertise and perspectives, including input from stakeholders.
- The processes and methods used in each step of guideline development aim to minimize the risk of bias in the recommendations.
- Recommendations are based on a systematic and comprehensive assessment of the balance of a policy’s or intervention’s potential benefits and harms and explicit consideration of other relevant factors.
- The evidence used to develop WHO guidelines is publicly available.
- Recommendations can be implemented in, and adapted to, local settings and contexts.
- Guidelines should be tailored to a specific audience. (The audiences that WHO guidelines target include public health policy-makers, health programme managers, health-care providers, patients, caregivers, the general public and other stakeholders.)
The WHO Global Malaria Programme has decided to establish one standing Guideline Development Group (GDG) to support the development of WHO recommendations for malaria and ensure consistency in how evidence is used to inform policy across all malaria interventions and strategies. Previously, the development of policy recommendations and guidance was undertaken by either standing Technical Expert Groups or ad hoc Evidence Review Groups. The GDG is made up of external experts whose central task is to develop evidence-based recommendations. The GDG also performs the important task of advising on the scope and key questions of the recommendations in PICO (Patient/Problem/Population, Intervention, Comparison/Control, Outcome) format. The GDG may delegate the detailed evidence review and drafting of recommendations to a dedicated ad hoc Evidence Review Group (ERG) if the technical area of the recommendation is judged to be highly specific. In this case, the GDG reviews the evidence and finalize the recommendations. All recommendations are reviewed by the Malaria Policy Advisory Committee (MPAC) and the Guidelines Review Committee (GRC) before being published.

II. Aims and functions

The GDG advises the Director, GMP in the development of evidence-based recommendations through ensuring consistency and continuity in the development of policy recommendations across the department. The mandate for the GDG is to advise on the development and harmonization of all recommendations related to all aspects of malaria control and elimination.

The GDG advises the Director, GMP, specifically by:

- providing input into the scope of the policy recommendations;
- assisting the internal steering groups which include members from WHO departments and regional offices whose work deals directly with the topic of the recommendation, in developing the key questions in PICO format;
- choosing and ranking priority outcomes that guide the evidence reviews and focus the recommendations;
- critically reviewing and providing input into the summaries of evidence and Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence profiles or other assessments of the quality of the evidence used to inform the recommendations;
- drafting recommendations or reviewing draft recommendations in the cases when an ERG has been delegated the task of examining the GRADE evidence profiles and drafting recommendations; and
- reviewing and approving the final draft policy recommendations before submission to the MPAC and GRC.

The development of recommendations by the GDG may be undertaken using one of three configurations: 1) the GDG supports the development as constituted; 2) a core number of GDG members is supplemented by a limited number of subject matter experts; or 3) an Evidence Review Group is convened and supplemented by two members of the GDG and the evidence review and draft recommendations are reviewed by the full GDG. The appropriate configuration should be proposed by the steering group supporting the policy recommendation and is decided by the GMP Director in consultation with the GDG chair as needed.

III. Membership and structure
The GDG is multidisciplinary and composed of members from all WHO regions. Its membership is balanced in terms of gender and geography. The aim is to have a diverse group that includes the following areas of expertise; GDG members may satisfy more than one of the areas listed below:

- relevant technical experts - Individuals selected for their technical expertise in malaria are critically important to GDGs but do not dominate the group;
- end-users, such as programme managers, who will adopt, adapt, and implement the recommendation. The aim is to ensure that the final guideline document is useful to its end-users, readily understood by them, and that interventions are likely to be implementable;
- representatives of groups most affected by the recommendations, such as service users and representatives of disadvantaged groups;
- experts in regulatory processes with relevant experience in bringing products to market;
- experts in assessing evidence and developing recommendations informed by evidence; and
- other technical experts as required (e.g. a health economist or an expert on equity, human rights and gender).

The GDG consists of up to 15 members, including a chair and co-chair, appointed by the Director, GMP to serve a term of four years, renewable once. Term lengths may vary between members to ensure a rotation that does not disrupt the functioning of the Group.

GMP maintains a public call for applications from experts and manages a roster of experts from which the GDG and ad hoc ERGs are drawn from. In the selection of members, due consideration is given to attaining the broadest possible international representation in terms of diversity of knowledge, experience and approaches, equitable geographical representation and gender balance as per WHO rules and regulations.

GDG and ad hoc ERGs members act in their personal and individual capacity only, in relation to their work in the GDG, and:

1. must not seek or accept instructions from any Government or from any authority external to the Organization;
2. must be free of real, potential, apparent or perceived conflicts of interest;
3. must maintain confidentiality regarding unpublished data and on recommendations in development;
4. shall have an ongoing obligation throughout their tenure to inform WHO of any changes to their affiliations or the information that they have declared on the WHO Declaration of Interest (DOI) form.

Prior to being confirmed as GDG members, and prior to renewal of their term, nominees, and current GDG members, shall be required to complete a DOI form. The DOI form is submitted to the GMP Secretariat in a timely manner, allowing for an adequate assessment of any disclosures related to the topics on the agenda for specific meetings. The list of GDG and ad hoc ERGs members and related biographical information is made publicly available on the GMP website. In addition, prior to confirmation by WHO of their appointment as GDG members, nominees shall be required to sign a WHO confidentiality agreement. Attendance at a GDG meeting is not permitted without a submitted and cleared, and thereafter updated, DOI form. Summaries of declared interests are read out at the start of GDG meetings, and disclosed in GDG reports, which are posted on the WHO website.
GDG and ad hoc ERGs members are not remunerated for their participation in GDG meetings. However, travel expenses and per diem incurred by attendance at GDG are reimbursed by WHO in accordance with applicable WHO rules and policies.

Membership in the GDG or the appointment of an ad hoc ERG member may be terminated at any time by GMP, if WHO’s interest so requires, and/or for any of the following reasons:
1. failure to attend two consecutive meetings of GDG;
2. a conflict of interest incompatible with serving on the GDG; and
3. a lack of professionalism involving, for example, a breach of confidentiality.

In the event that GDG membership is terminated, WHO may review the roster of experts and appoint a replacement.

Additional ad hoc experts may be invited as temporary advisors to GDG meetings, as deemed appropriate, to contribute to specific topics. The temporary advisors are required to complete a DOI form and sign a confidentiality undertaking.

IV. Roles and responsibilities of GDG members

Members of GDG and ad hoc ERGs members have a responsibility to provide the Director, GMP with high quality, well considered, evidence-informed advice and recommendations on matters described in these terms of reference.

The GDG has no executive or regulatory function. Its role is to provide advice and recommendations to the Director, GMP. GDG members and ad hoc ERG members may be approached by non-WHO sources for their views, comments and statements on matters of the GDG and asked to state the views of GDG or of details related to GDG discussions. GDG members and ad hoc ERGs should refer all such enquiries to WHO-GMP.

The chair of the GDG is appointed by the Director, GMP. The chair should be an expert in facilitating groups that reach decisions based on consensus; be experienced at critically appraising and interpreting evidence and developing evidence-informed recommendations; and have no financial interests related to malaria guidelines broadly. Although the chair should have a general knowledge of the topic of the guideline, no one with strong views about the interventions under consideration should chair the GDG. The chair should have experience engaging in consensus-based processes involving people with different opinions. A co-chair is also appointed by the Director, GMP to stand in if the chair is absent and to share in the chair’s tasks and responsibilities. The expertise of the chair and co-chair should be complementary.

The chair’s responsibilities (and co-chair’s in the absence of the chair) include the following:
- To chair the meetings of the GDG;
- To help achieve consensus and help formulate a majority/minority position when consensus cannot be achieved on a given matter;
- To liaise with the Director and GMP Secretariat during and between the meetings;
- To facilitate a productive, respectful discussion;
- To assist the GMP Secretariat in finalizing the report of each GDG meeting; and
- To attend the Malaria Policy Advisory Committee meetings as needed to report back on the work of the GDG.

V. Meetings and operational procedures

GDG ordinarily meet as a group twice per year with a minimum quorum of half of the members, but the frequency and duration of meetings may be adjusted as necessary to support new or revised recommendation development. GDG meetings may also convened electronically (by teleconference) when required.

In addition to attendance of GDG meetings, active participation is expected of GDG members throughout the year, including, but not limited to, participation in video and teleconferences, interactions via e-mail, and review of documents, including through electronic means, as necessary and appropriate.

At the request of WHO, members of ERGs may attend GDG meetings to support discussions on the topic for which the ERG was established.

GDG members may be asked to participate in meetings of the MPAC as a presenter, as and when invited by GMP, to provide updates on the work of the Group.

The GDG advises the Director, GMP. Transparency is ensured as minutes are taken, circulated among GDG members, approved by the Director, and published on the GMP website following the meeting. Approved meeting agendas, documents, minutes and recommendations are published and continue to remain publicly available on the WHO-GMP website.

Meetings are normally conducted in the English language. All GDG documentation, including GDG reports and working documents, are normally provided in English.

Conclusions and recommendations of the GDG which are communicated to the Director, GMP, as a rule, are taken by consensus. In the exceptional situation that consensus cannot be reached the chair shall report the majority and minority views.

VI. Dissolution of GDG

The relevance of the GDG is assessed regularly by the Director, GMP based on a regular review of the terms of reference.