Vector Control Advisory Group (VCAG) on new tools, technologies and approaches – Terms of reference

1. Background

In 2017, the WHO process for the evaluation of vector control interventions was revised to better meet the needs of countries endemic for, or at risk of, vector-borne diseases. Under the revised process, the evaluation pathway to be followed is determined by whether or not an intervention is part of a class with an existing WHO policy recommendation.

Vector control tools, technologies and approaches (jointly referred to as ‘interventions’) that are already covered by a WHO policy recommendation follow the Prequalification Pathway. This pathway involves assessment of an intervention’s safety, entomological efficacy and quality, and is the responsibility of the WHO Prequalification Team (PQT-VCP).

Interventions not covered by a WHO policy recommendation follow the New Intervention Pathway in addition to the Prequalification Pathway. The New Intervention Pathway is supported by the Vector Control Advisory Group (VCAG), an independent advisory group that assesses the public health value of new interventions. VCAG is coordinated by a secretariat comprised of staff from the Global Malaria Programme (GMP), the Department of Control of Neglected Tropical Diseases (NTD) and PQT-VCP. The group reports to the Assistant Director General of the Universal Health Coverage/Communicable and Non-communicable Diseases division of WHO.

Developing policy and guidelines based on VCAG’s assessments and recommendations is the responsibility of the respective technical department (GMP or NTD) for the interventions in question (whether they target malaria or neglected tropical diseases). While a policy recommendation for an intervention is under development, PQT-VCP will evaluate one or more products that fall into this intervention class. If the outcome of both processes is positive, the technical department(s) will convene a guidelines development group to support the development of a
new policy recommendation, to be published as part of a guidelines document, and PQT-VCP will list the product.

VCAG’s Terms of Reference (ToRs) have been regularly reviewed and updated to reflect ongoing changes in WHO’s policy-making process and growing experience with the evaluation of vector control products and interventions. The latest revision date is indicated below the ToR title. The ToRs will be further amended when required to ensure continued consistency of VCAG operations with the ongoing alignment of the WHO policy making processes.

2. VCAG mandate

To provide an assessment of the public health value of new vector control interventions submitted to WHO. As part of this work, VCAG provides advice to WHO technical departments and, via the VCAG secretariat, to product developers.

Functions

The VCAG has the following specific functions:

1. To provide guidance to product developers, innovators and researchers (jointly referred to as ‘applicants’), through WHO, on the generation of epidemiological data and study designs to enable assessment of the public health value of new vector control interventions.

2. To assess the public health value of new vector interventions submitted to WHO.

3. To provide advice to WHO on the public health value of new interventions.

3. Membership

VCAG will consist of up to 15 members, including two co-chairs. VCAG members will serve in their personal capacities to represent the broad range of expertise relevant to vector control, including vector biology, ecology, genetics and population biology, insecticides and insecticide resistance, epidemiology of vector-borne diseases, regulatory aspects, study design, statistics, and product development.

VCAG members will be appointed to serve for an initial period of three years, and will be eligible for re-appointment only once for another three year period. To support the move to a staggered process of replacing VCAG members, WHO may, exceptionally, grant an additional extension of one or two years to some VCAG members to avoid replacement of a large proportion of the group within one year. A VCAG member, who has completed her/his maximum allowed contiguous term on the group, can be re-appointed to the group after a three-year gap in their membership.

In the selection of VCAG members, due consideration will be 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.

Periodically, depending on the skill set required within VCAG, the secretariat will issue a call for new members. In addition, the secretariat will accept nominations at any time from experts. The names of the nominees will be placed on a roster and the secretariat
will draw from the roster of nominees. VCAG members will be nominated by the Director of the Global Malaria Programme (GMP), the Director of the Department of Control of Neglected Tropical Diseases (NTD) and the Director, Regulation and Prequalification, for approval and appointment by the Assistant Director-General of the Universal Health Coverage / Communicable and Non-communicable Diseases division.

The Co-chairs will be appointed by the secretariat from among existing VCAG members. Each co-chair will then serve for a period of three years, after which they will continue to serve as VCAG members, until the end of their established term.

Prior to being confirmed as VCAG members, and prior to renewal of their term, nominees, and current VCAG members, will complete a WHO Declaration of Interest (DOI) form. The DOI form will be submitted to the VCAG secretariat in a timely manner, allowing for an adequate assessment of members’ disclosures. In addition, prior to confirmation by WHO of their appointment as VCAG members, nominees shall be required to sign a WHO confidentiality agreement. All VCAG members will be required to provide an updated DOI form before each meeting. Attendance at a VCAG meeting will not be permitted without a submitted and cleared DOI form.

Accepting to be a VCAG member means that the individual experts are acting in their personal and individual capacity only, in relation to their work in the VCAG, 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 conflict of interest;
3. shall have an ongoing obligation throughout their tenure to inform WHO of any changes to their affiliations or the information that they would have disclosed on the DOI form.

Summaries of declared interests will be read out at the start of VCAG meetings, and disclosed in VCAG reports, which will be posted on the WHO website. The list of VCAG members and related biographical information will be made publicly available on the WHO-VCAG website.\(^4\)

VCAG members will not be remunerated for their participation in VCAG meetings. However, travel expenses and per diem incurred by attendance at VCAG will be reimbursed by WHO in accordance with applicable WHO rules and policies.

Membership in the VCAG may be terminated at any time by WHO, if WHO’s interest so requires, and/or for any of the following reasons:

1. failure to attend two consecutive meetings of VCAG;
2. a conflict of interest incompatible with serving on the VCAG; and
3. a lack of professionalism involving, for example, a breach of confidentiality.

WHO may decide to appoint a new member in replacement of any VCAG member whose membership would have been so terminated.
4. Roles and responsibilities

a. VCAG members

VCAG members have a responsibility to provide WHO with high quality, well-considered advice and recommendations on matters described in these Terms of Reference. VCAG members play a critical role in ensuring the reputation of VCAG as an internationally recognized advisory group on new interventions for vector control.

VCAG has no executive or regulatory function. Its role is solely to provide advice and recommendations to WHO. This includes providing advice and recommendations on the public health value of new interventions in vector control, as needed.

Information and documentation to which VCAG members may gain access in performing VCAG related activities will be considered as confidential and may not be publicly disclosed by VCAG members. VCAG members will not speak on behalf of, or otherwise represent VCAG, or WHO, to any third party. In the event that VCAG members are approached by non-WHO sources for their views, comments and statements on particular matters of public health concern and asked to state the views of VCAG, they will refrain from comment and refer such enquiries to the WHO VCAG secretariat.

The responsibilities of VCAG members include the following:

• To provide guidance to applicants, through WHO, on the generation of epidemiological data on a new vector control intervention required to allow VCAG’s assessment of public health value. The provision of this advice may require a review of entomological data as these data may inform the epidemiological study design and supporting studies. In cases where entomological evaluations are conducted alongside epidemiological trials to generate supporting/explanatory evidence, VCAG is expected to review and guide the study design.

• To review the epidemiological data for a new vector control intervention to determine whether this evidence demonstrates public health value, and to assess supporting entomological data, where generated and submitted as supporting information.

• To provide advice to WHO, and via WHO to its advisory groups, to inform the formulation of potential WHO policy recommendations for a new vector control intervention based on VCAG’s assessment of public health value.

• To advise and support WHO on the development of guidance for evaluation of epidemiological efficacy of new vector control interventions.

In addition to attendance of VCAG meetings, active participation will be expected of VCAG members throughout the year, including, but not limited to:

• review of applicant submissions leading up to meetings,
• off-cycle reviews of applicant submissions (when necessary),
• participation in video and teleconferences,
b. Co-chairs

The co-chairs’ responsibilities include the following:

- to chair the meetings of the VCAG;
- to liaise with the WHO secretariat during and between the meetings;
- to facilitate a productive and respectful discussion;
- to assist the WHO secretariat in finalizing the report of each VCAG meeting; and
- to participate in meetings of WHO advisory groups, as an observer, as and when invited by WHO.

c. Temporary advisors

Additional experts may be invited as temporary advisors to VCAG meetings, as deemed appropriate, to further contribute to specific agenda items. The temporary advisors will be required to complete a WHO Declaration of Interest (DOI) form and the rules of confidentiality will apply to them. Their participation will be captured in the Meeting Report.

d. Role of the secretariat

WHO, through the VCAG secretariat, will provide any necessary scientific, technical and other support to VCAG.

VCAG meetings will be convened and organized by the secretariat. The secretariat will provide VCAG members in advance of each meeting a meeting agenda, working documents and discussion papers, as well as any other relevant information. Distribution of the meeting pre-reads to observers and invited experts will be subject to the protection of confidential information, as determined by the secretariat.

The secretariat will provide VCAG applicants with clear guidance concerning the submission of data and with a MS PowerPoint template to guide their presentation to VCAG (See VCAG SOPs). The Secretariat will follow-up with the applicants on the progress of the new vector control interventions and will organize interactions with VCAG, as and when needed.

The WHO secretariat will be responsible for compiling, editing, publishing and disseminating VCAG meeting reports.
5. Meetings and operational procedures

a. Meetings

VCAG will normally convene for two meetings per year. Normally these are in-person meetings, at WHO HQ, but may be virtual meetings held online. WHO may convene additional meetings, including through teleconferences and videoconferences, on an ad hoc basis.

WHO may invite representatives from other UN entities and/or other relevant stakeholders as observers to VCAG meetings. Observers will not participate in the recommendation-making process but will be allowed to contribute to the discussions as invited by the co-chairs.

VCAG meetings will normally consist of open and closed sessions, as follows:

a) Open sessions: These provide an opportunity for VCAG to interact with applicants and other interested stakeholders, and are open to all interested parties.

b) Closed sessions: During these sessions applicants present their planned, ongoing or completed trials. VCAG provide guidance to applicants on the generation of epidemiological data and study designs. Where appropriate, VCAG provide their assessment of the public health value of new vector interventions submitted to WHO. Closed sessions are attended only by VCAG members, relevant VCAG applicants and their collaborators (if invited by the applicant), and relevant WHO staff. Closed sessions may also be held to address specific topics on which VCAG guidance has been requested by WHO.

The discussions of VCAG will be valid if two thirds of VCAG members are present at the meeting, either in person or through electronic means (teleconference or WebEx, etc.). VCAG recommendations to WHO will, as a rule, be taken by consensus. In the exceptional situation that consensus on a particular issue cannot be reached, the majority and minority view will be reflected in the report of the meeting.

Meetings will normally be conducted in the English language. Interpretation into a WHO official language other than English may be provided, subject to the availability of resources, and if so requested in writing at least six weeks before the opening of the meeting. All VCAG documentation, including VCAG reports and working documents, will normally be provided in English.

b. VCAG working groups

Working groups are established by VCAG to review applicant submissions in detail and provide guidance on information and data requirements; their review report is shared with the full VCAG for their consideration and approval before being shared with applicants. The working groups convene face-to-face, through teleconferences and electronically, though email, to review relevant submissions to VCAG.

VCAG working groups are designed to provide focused technical support to applicants, while continuing to draw on the broader group for advice and guidance. Each VCAG working group will normally comprise four or more VCAG members and temporary advisors, one of whom will be nominated by the secretariat to act as working group Lead. Composition of the VCAG working groups are selected by the secretariat in
consultation with VCAG chairs. All efforts will be made to maintain the working groups’ initial composition while a given intervention remains under review by VCAG. When the tenure of a member ends and they leave VCAG, the expertise lost from the working group will be replaced with those of a new member that will be appointed to the working group.

c. Meeting report and dissemination

For each meeting VCAG will draft and approve a report, with assistance from the WHO secretariat, as appropriate. The meeting report will provide a record of VCAG’s advice and recommendations to each applicant, as provided during off-cycle reviews and during face-to-face meetings. VCAG applicants will have an opportunity to review and provide feedback on the VCAG recommendations before they are made public. This review by the applicant serves to avoid accidental publication of factual inaccuracies and proprietary information, not to edit or remove specific recommendations made by VCAG. Final reports of each VCAG meeting will be submitted by the co-chairs of VCAG to WHO.

All recommendations from VCAG are advisory to WHO, which retains unfettered control over any subsequent decisions made or actions taken on any recommendations, proposals, policy issues or other matters considered by VCAG.

WHO also retains full control over the use and publication of the reports of VCAG, including whether or not to use and/or publish them and/or to provide such reports to other WHO advisory groups, including MPAC and/or STAG subject to the protection of all confidential information.

d. Off-cycle reviews

In the event that an applicant requests an urgent review and the next face-to-face VCAG meeting is due to take place more than three months from the request, there is the possibility of an “off-cycle review”, facilitated by the secretariat. During an off-cycle review the VCAG working group reviews the VCAG application form and associated materials electronically, through teleconferences or email and provides its provisional advice to the applicants. The official report from the off-cycle review will be incorporated into the next meeting report of VCAG once it has been reviewed by all members.

Endnotes

1. These revised terms of reference are effective as of 28 July 2020 and will be further amended in the near future to ensure consistency of VCAG operations with the ongoing alignment of WHO Policy recommendation approaches.


3. Public health value is described in document “The evaluation process for vector control products” (http://apps.who.int/iris/bitstream/handle/10665/255644/WHO-HTM-GMP-2017.13-eng.pdf) as proven efficacy to reduce or prevent infection and/or disease in humans.


5. It should be noted that assessment of entomological data, in the context of meeting data requirements for prequalification, and development of associated guidance on test procedures is the responsibility of the WHO PQT-VCP team.