Vector Control Advisory Group

Standard operating procedures for Vector Control Advisory Group (VCAG) applicants

1. Background

Independent evaluation of the public health value of innovative new tools, technologies and approaches (collectively referred to as 'interventions') for vector control is needed to enable the World Health Organization (WHO) to provide evidence-based advice to Member States on their deployment. Such guidance is essential to ensure that the scarce resources available for disease control are used with maximum impact. In order to assist WHO in developing policy recommendations on new tools, the Vector Control Advisory Group (VCAG) assesses the public health value of new interventions and provides guidance on developing the evidence base required to inform such assessments.

Entities seeking VCAG's assessment of the public health value of a new intervention, as a prerequisite for the development of a WHO policy recommendation, are invited to submit a Request for Determination of Pathway form[1] to pqvectorcontrol@who.int. The submission will be reviewed by the WHO Pre-submission Coordination Committee to determine the applicable WHO evaluation pathway. Interventions identified as not yet being covered by an appropriate WHO policy recommendation will be subject to evaluation under the New Intervention Pathway, where evidence of public health value must be established before WHO will develop policy recommendations for such an intervention. Applicants will be guided through the evaluation process, as outlined in this document, with the support of the WHO VCAG Secretariat.

1 see https://www.who.int/pq-vector-control/resources/pathway/en/

World Health Organization

2. Functions of VCAG

VCAG has the following specific functions:

1. 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. Assess the public health value of new vector interventions submitted to WHO.

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

For more information on the role of VCAG, see the Terms of Reference at https://www.who.int/groups/vector-control-advisory-group.

3. Evaluation process

Once it has been determined that an intervention is not covered by a WHO policy recommendation and is therefore required to follow the New Intervention Pathway, the WHO VCAG Secretariat will initiate contact with the applicant/responsible lead and provide the forms, related documents, and important dates and deadlines for the following VCAG meeting. Typically, the completed VCAG submission will include the application form, a slide deck for the presentation, and supporting information as necessary (which may consist of draft/final epidemiological trial protocols, statistical analysis plans, standard operating procedures, associated trial results, and potentially any peer-reviewed publications stemming from the work). Together, these documents form the basis for the VCAG review. It is common for applicants to update their submission with new information over the course of time (thus having multiple interactions with VCAG) as the evidence base for assessing the intervention's public health value is being generated.

For a typical submission, the review process involves the assessment of the information and data submitted by the applicants in advance of each meeting in which they participate. This applicant material is reviewed in detail by a subgroup of VCAG members – the working group for that particular intervention. At the meeting, applicants are required to make a presentation to the whole of VCAG, summarizing the intervention, target disease(s) and the status of the trial(s), with appropriate supporting materials. Applicants also have the opportunity to ask VCAG for advice on particular aspects of their work. Following this interaction session, VCAG members engage in closed discussion to consolidate their feedback for the applicants. The working group assigned to the intervention leads the discussion, given their detailed assessment of the submission. Initial feedback is subsequently provided to the applicants, while formal recommendations and advice are provided to the applicants in the official meeting report.

It should be noted that, at all times, communication between applicants and VCAG members relating to VCAG activities is to take place only via the WHO VCAG Secretariat. While applicants will inevitably communicate with VCAG during meetings, and in some cases between meetings (i.e., as part of off-cycle reviews),

official communication relating to the assessment of any intervention is provided only through the WHO VCAG meeting report. The report is published biannually, approximately two months after each formal VCAG meeting.

4. Group composition

4.1. Members

There will be a maximum of 15 VCAG members at any given time, including two co-chairs. Nominees for VCAG membership are put forward by the WHO VCAG Secretariat, drawn from a roster of names that is maintained based on regular public calls for application. Approval of any VCAG member nomination comes from the Assistant Director-General of the Universal Health Coverage / Communicable and Non-communicable Diseases division within WHO.

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 avoid replacing a large proportion of the group in a single year, exceptional one- or two-year extensions may further be granted at the sole discretion of the WHO VCAG Secretariat.

Previous VCAG members may be invited to re-join VCAG, but this may only occur after a three-year gap from the lapse of their membership. During this interim period, the expertise of a previous member may be requested to complement that of existing members on an ad hoc basis. This should occur for no more than two meetings. Such ad hoc participation will prolong the required three-year gap in their membership accordingly.

4.2. Temporary advisors

Additional experts may be invited on an ad hoc basis to participate in VCAG meetings, as deemed appropriate by the WHO VCAG Secretariat. These experts may be selected by referring to the established roster of experts maintained by the Secretariat or by reaching out to specific individuals with the required expertise. The role of these ad hoc experts is to augment the expertise of VCAG in order to carry out an assessment of submission(s) and provide technical advice on the public health value of the intervention.

Participating in VCAG meetings as an ad hoc expert does not lead to VCAG membership. Individuals wishing to be considered for formal membership will still need to apply through the regular public membership calls.

Both members and temporary advisors operating on an ad hoc basis will be required to complete a WHO Declaration of Interest (DOI) form and are subject to the same rules of confidentiality.

4.3. Working groups

Working groups are smaller subgroups of VCAG members that have been assigned to perform the in-depth reviews of a particular intervention. Composition of a working group will normally include experts with a range of diverse expertise, including

entomology, epidemiology, biostatistics and modelling, product development and regulation. Efforts will be made to maintain the working group's initial composition while the given intervention remains under review by VCAG. However, WHO may alter the working group's composition over time to enable a stage-appropriate review of the submission or to address logistical issues (e.g., virtual hosting of the meeting).

A working group will normally consist of four or more experts, three of which should be full members of VCAG at any given meeting. The overall ratio of full members to temporary advisors, however, is not restricted. The WHO VCAG Secretariat will nominate a VCAG member as the lead for each working group.

The working group for a given intervention will be assigned prior to the VCAG meeting (or carried over from previous meetings, where appropriate). Upon receipt of the full submission from the applicants, working group members are tasked with conducting a technical review of the material and developing feedback that will be discussed internally (with the support of the Secretariat) prior to the meeting. During the VCAG meeting, immediately following the applicants' presentation and Q&A session, working group members will share their initial thoughts on their review of the submission in closed discussion with the rest of VCAG. Feedback will be consolidated and tentative recommendations developed, which will be delivered to the applicants following the closed session. The working group will be responsible for developing the written text summarizing the discussions and recommendations for inclusion in the VCAG meeting report.

5. VCAG meetings

5.1. Planning and timeline

The standard timeline for the meeting preparations and development of the meeting report are outlined in Annex 1.

Three months prior to a VCAG meeting, the WHO VCAG Secretariat will reach out to applicants who have previously engaged with the Prequalification Team for Vector Control Products (PQT-VCP) and the WHO VCAG Secretariat to find out whether they are interested in participating in the upcoming meeting. Responses should briefly describe the progress made by the applicant group and what they plan to present at the meeting. The WHO VCAG Secretariat will then establish whether the applicants' face-to-face interaction with VCAG at the upcoming meeting is warranted. Applicants should confirm their participation 10 weeks in advance of the meeting to vcag@who.int.

5.2. VCAG meetings

WHO will generally convene two VCAG meetings per year (either in-person or virtually); this frequency may be adjusted as necessary.

VCAG meetings may consist of open and closed sessions. Open sessions provide an opportunity for VCAG to interact with applicants and other interested stakeholders. These sessions are open to all interested parties, and often involve presentations or updates on policy recommendations or guidelines in the field of vector control.

Closed sessions are for applicants only to present planned, ongoing or completed trials. These sessions are attended only by VCAG members, relevant VCAG applicants and their collaborators (if invited by the applicant), and the WHO VCAG Secretariat (and affiliated staff). Applicant interactions with VCAG consist of:

a) applicant presentation to VCAG and Q&A;

b) closed discussion (VCAG only); and

c) VCAG feedback to applicants.

The duration of each applicant session will be determined based on the status of their trial. For example, applicants providing an update on a trial may be allocated less time than applicants presenting a new study protocol or the outcomes of a trial.

Closed sessions may also be held to discuss and address specific topics on which WHO has requested VCAG guidance, such as the development or revision of preferred product characteristics or guidance documents. These sessions will involve VCAG members and the WHO VCAG Secretariat only.

5.3. Documentation for meetings

The WHO VCAG Secretariat will provide the necessary forms and templates to applicants prior to each meeting (ensuring applicants are using the latest versions). The documents that applicants need to submit in advance of meetings will depend on the status of the intervention in the evaluation process, as outlined below.

a) New applicants should submit:

- completed application form and supporting materials, as indicated in the form;
- completed VCAG PowerPoint template.

b) Applicants providing updates or results should submit:

- completed application form, outlining any activities conducted since the previous submission, and outcomes achieved. It is important to highlight the extent to which any VCAG recommendations made in the previous meeting report have been addressed;
- completed VCAG PowerPoint template.

All applicants are requested to use the VCAG PowerPoint template to present their work at the meeting. The template provides an outline of useful information for applicants to share with VCAG during their interactions; however, it can be adapted to meet the applicant's needs. In the PowerPoint presentation, it is not necessary to include detailed information about how the intervention works, as this information will have already been provided as part of the VCAG application form and supporting information. The PowerPoint presentation is an opportunity for applicants to provide a comprehensive overview of their work (including updates as necessary), address key points, such as how they have responded to VCAG recommendations, and raise any specific questions they might have.

Applicants are asked to provide their completed application form, supporting documentation and PowerPoint template six weeks in advance of the meeting. The WHO VCAG Secretariat will confirm receipt of the application form and supporting information within 48 hours by email.

It is the applicants' responsibility to submit high-quality, complete documentation. If applicants submit documentation that is incomplete or of poor quality, the WHO VCAG Secretariat will request that applicants revise the documentation and resubmit without delay in order to maintain the established timelines.

5.4. Attendance at the meeting

As applicants are seeking VCAG's assessment of the public health value of a new intervention as a prerequisite for WHO policy recommendation, it is important that – where possible – both the researchers performing the trials and the potential/actual manufacturers of the intervention attend the VCAG meetings. This is particularly important for manufacturers that have engaged independent researchers to conduct some or all of the required epidemiological studies. Manufacturers should be engaged from the start of the process, as it will be their responsibility to engage with WHO PQT-VCP as part of the prequalification of the intervention and its life-cycle management.

The composition of the team that will present to VCAG is at the discretion of the applicant. It should, however, be noted that WHO encourages broad participation with a particular focus, where feasible, for researchers from the disease-endemic countries (where the trials are being conducted) to present the work.

5.5. Meeting report

After each VCAG meeting, the working group supporting the assessment of a specific intervention will prepare a summary of the discussions and recommendations. This summary will be shared with the applicants. The review serves to avoid accidental publication of factual inaccuracies or proprietary information; it is not to edit or remove specific recommendations made by VCAG. Individual sections of the report will be compiled into an electronic draft and subsequently shared with the wider VCAG. The draft report is then finalized and published, approximately two months after the meeting.

The final meeting report will provide a summary of the intervention reviewed at the meeting and a record of VCAG's advice and recommendations to each applicant, as provided during scheduled biannual meetings and through off-cycle reviews.

6. Off-cycle reviews

In the event that applicants request an urgent review of materials and it is more than three months until the next scheduled face-to-face VCAG meeting, the WHO VCAG Secretariat may be able to facilitate an off-cycle review. The WHO VCAG Secretariat, in consultation with the VCAG co-chairs, will review the documentation and use predetermined criteria (see below) to decide whether materials warrant an off-cycle review.

Annex 2 outlines the process and timelines for off-cycle reviews. During an off-cycle review, the relevant VCAG working group reviews the VCAG application form and associated materials electronically. The working group provides its provisional advice to the applicants via the WHO VCAG Secretariat, and the official report from the off-cycle review is incorporated into the next meeting report.

6.1. Justifications for an off-cycle review

The WHO VCAG Secretariat will use the following criteria to decide whether an off-cycle review is warranted:

1. **Number of off-cycle reviews per year:** Applicants will be asked to limit the number of requests for off-cycle reviews to one per calendar year.

2. **Rationale for urgency of the review:** Applicants need to provide adequate justification, explaining the grounds for requesting an urgent review of materials.

3. **Timing:** The submission of documents for an off-cycle review must be received more than a full three months before the next scheduled meeting.

4. **Status of the materials:** Applicants new to VCAG will need to interact with VCAG at a face to-face meeting prior to having any documentation reviewed off-cycle.

5. **Respect for VCAG workload:** Individuals within working groups may not be requested to complete more than one off-cycle review within a given inter-meeting period, out of respect for their voluntary contributions of time and expertise to the advisory group.

6. **Quorum of working group:** A minimum of 50% of the previously established working group (from when the applicants last participated in a VCAG meeting) must be available to review the submitted documents.

7. **Multiple requests within an inter-meeting period:** If the Secretariat receives requests from multiple VCAG applicants for off-cycle reviews in the same period, priority will be given to those applicants who made the request first and to those for whom the minimum quorum of the working group is available.

8. **Priority of applicant material:** A new protocol in the early stages of

预览已结束，完整报告链接和二维码如下：
https://www.yunbaogao.cn/report/index/report?reportId=5_25925