Terms of Reference for the Immunization and vaccines related implementation research advisory committee (IVIR-AC)

21 Oct 2021

The Immunization and Vaccines Implementation Research Advisory Committee (IVIR-AC) is a principal advisory group to WHO providing independent appraisal of and advice on implementation research related to vaccines and immunization, to inform public health decisions. It was initially established as the Quantitative Immunization and Vaccines Related Research (QUIVER) advisory committee in 2007 to put modelling evidence into both methodologic context and best practices for the Strategic Advisory Group of Experts on Immunization (SAGE) and the Immunization, Vaccines, and Biologicals (IVB) Department. It's remit expanded to include other areas of vaccine implementation research such as methods reviews of vaccine value assessments, effectiveness and impact studies. These Terms of Reference (TOR) update the TORS established in October 2011 (Annex 1). The update to the TORs were motivated by the need to realign the different committees advising the IVB Department and to specify in more detail the remit of the IVIR-AC committee's work on implementation research.

IVIR-AC will act as an advisory group (AG) to WHO, reviewing modelling evidence including for issues raised in discussions by SAGE. To inform important strategic policy questions from SAGE, multiple-model comparison approaches are encouraged rather than relying on modeled evidence from one group only. The reason for this is a) to increase understanding and transparency of modeling methods, b) to characterize the robustness of different model predictions to changes in inputs, structures, assumptions and parameters, to assess their impact for policy recommendations, and/or (c) synthesize conclusions from several models in order to inform policy recommendations.

IVIR-AC will act as an advisory body to WHO in this field.

I. Functions

IVIR-AC has no executive, regulatory or decision-making function. IVIR-AC is a multi-disciplinary and independent advisory body. Its sole role is to provide advice and recommendations to WHO.

In its capacity as an advisory body to WHO, the IVIR-AC shall have the following functions:

1. *IVIR-AC combines relevant expertise to provide an in-depth understanding of model best practices, nuances and caveats which is critical for decisions related to strategies, policies, and programs that rely on modelled evidence.*
2. *IVIR-AC is tasked with reviewing (i) quantitative methods in vaccine-related research as well as (ii) implementation research related to estimating the performance, impact and value of vaccines and to advise the Department of Immunization, Vaccines and Biologicals on their relevance and applicability*

3. *With regards to (i) quantitative methods in vaccine research, IVIR-AC reviews research questions put forward by WHO Secretariat and advises WHO on the appropriate model structure and features.*
4. *With regards to (ii) implementation research, IVIR-AC evaluates methods and approaches that aim to inform WHO of the performance, impact and proposed value of vaccines in coordination with other relevant committees in WHO.*

II. Composition

1. IVIR-AC shall have up to 15 members[1], who shall serve in their personal capacities to represent the broad range of disciplines relevant to:
   - Mathematical modelling/quantitative methods in vaccine research
   - Economic analysis of vaccine development, planning and/or implementation
   - Methodologic approaches to vaccine performance and impact
   - Value estimation of vaccines (pricing, procurement, needs estimation and/or regulation of medicines)
   - Health systems and programme delivery

2. In the selection of the IVIR-AC members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance.

3. Members of the IVIR-AC, including the Chairperson, shall be selected and appointed by WHO and is by default delegated from ADG to the Director of Department of Immunization, Vaccines, and Biologicals following an open call for experts. The Chairperson's functions include the following:

   - to chair the meeting of the IVIR-AC;
   - to liaise with the WHO Secretariat between meetings.

   In appointing a Chairperson, consideration shall be given to gender and geographical representation.

4. Members of the IVIR-AC shall be appointed to serve for a period of 2 years and shall be eligible for reappointment for another three years. A Chairperson is eligible for reappointment as a member of the IVIR-AC. Their appointment and/or designation as Chairperson may be terminated at any time by WHO if WHO's interest so requires or, as otherwise specified in these terms of reference or letters of appointment. Where a member's appointment is terminated, WHO may decide to appoint a replacement member.

5. IVIR-AC members must respect the impartiality and independence required of WHO. In performing their work, members may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of any real, potential or apparent conflicts of interest. To this end, proposed members/members shall be required

[1] Members serve as full participants and partake in the decision-making process of the meeting in which they are involved.

to complete a declaration of interests form and their appointment, or continuation of their appointment, shall be subject to the evaluation of completed forms by the WHO Secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.

6. Following a determination that a proposed member's participation in the IVIR-AC would not give rise to a real, potential or apparent conflict of interest, the proposed member will be sent a letter inviting them to be a member of the IVIR-AC. Their appointment to the AG is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, IVIR-AC members have an ongoing obligation to inform the WHO of any interests real or perceived that may give raise to a real, potential or apparent conflict of interest.

7. As contemplated in paragraph II.4 above, WHO may, from time to time, request IVIR-AC members to complete a new declaration of interest form. This may be before an IVIR-AC meeting or any other IVIR-AC -related activity or engagement, as decided by WHO. Where WHO has made such a request, the IVIR-AC member's participation in the IVIR-AC activity or engagement is subject to a determination that their participation would not give rise to a real, potential or apparent conflict of interest.

8. Where an IVIR-AC member is invited by WHO to travel to an in-person IVIR-AC meeting, WHO shall, subject to any conflict of interest determination as set out in paragraph II.6 above, issue a letter of appointment as a temporary adviser and accompanying memorandum of agreement (together 'Temporary Adviser Letter). WHO shall not authorize travel by an IVIR-AC member, until it receives a countersigned Temporary Adviser Letter.

9. IVIR-AC members do not receive any remuneration from the Organization for any work related to the AG. However, when attending in-person meetings at the invitation of WHO, their travel cost and per diem shall be covered by WHO in accordance with the applicable WHO rules and policies.

10. Under emergency situations: ad-hoc reviews in between IVIR-AC meetings with selected IVIR-AC experts are possible to facilitate the speed and quality of work at short notice.

III. Operation

1. The IVIR-AC shall normally meet twice each year. However, WHO may convene additional meetings. IVIR-AC meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO) or virtually, via video or teleconference.

   IVIR-AC meetings may be held in open and/or closed session, as decided by the Chairperson in consultation with WHO. Their preparation will be ensured by SOPs as per the advice of the director of the department of Immunization, Vaccines, and Biologicals (Annex 2)

(a) Open sessions: Open sessions shall be convened for the sole purpose of the exchange of non-confidential information and views, and may be attended by Observers (as defined in paragraph III.3 below).

(b) Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the members of the IVIR-AC and essential WHO Secretariat staff.

2. The quorum for IVIR-AC meetings shall be two thirds of the members.

3. WHO may, at its sole discretion, invite external individuals from time to time to attend the open sessions of an advisory group, or parts thereof, as "observers". Observers may be invited either in their personal capacity, or as representatives from a governmental institution / intergovernmental organization, or from a non-state actor. WHO will request observers invited in their personal capacity to complete a confidentiality undertaking and a declaration of interests form prior to attending a session of the advisory group. Invitations to observers attending as representatives from non-state actors will be subject to internal due diligence and conflict of interest considerations in accordance with FENSA. Observers invited as representatives may also be requested to complete a confidentiality undertaking. Observers shall normally attend meetings of the IVIR-AC at their own expense and be responsible for making all arrangements in that regard.

   At the invitation of the Chairperson, observers may be asked to present their personal views and/or the policies of their organization. Observers will not participate in the process of adopting decisions and recommendations of the IVIR-AC.

4. The IVIR-AC may decide to establish smaller working groups (sub-groups of the IVIR-AC) to work on specific issues. Their deliberations shall take place via teleconference or video-conference. For these sub-groups, no quorum requirement will apply; the outcome of their deliberations will be submitted to the IVIR-AC for review at one of its meetings.

5. IVIR-AC members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the IVIR-AC.

6. Reports of each meeting shall be submitted by the IVIR-AC to WHO. All recommendations from the IVIR-AC are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the IVIR-AC.

7. The IVIR-AC shall normally make recommendations by consensus. If, in exceptional circumstances, a consensus on a particular issue cannot be reached, minority opinions will be reflected in the meeting report.

8. Active participation is expected from all IVIR-AC members, including in working groups, teleconferences, and interaction over email. IVIR-AC members may, in advance of IVIR-AC meetings, be requested to review meeting documentation and to provide their views for consideration by the IVIR-AC.

9. WHO shall determine the modes of communication by the IVIR-AC, including between WHO and the IVIR-AC members, and the IVIR-AC members among themselves.

10. IVIR-AC members shall not speak on behalf of, or represent, the IVIR-AC or WHO to any third party.

IV. Secretariat

WHO shall provide the secretariat for the IVIR-AC, including necessary scientific, technical, administrative and other support. In this regard, the WHO Secretariat shall provide the members in advance of each meeting with the agenda, working documents and discussion papers. Distribution of the aforesaid documents to Observers will be determined by the WHO Secretariat. The meeting agenda shall include details such as: whether a meeting, or part thereof, is closed or open; and whether Observers are permitted to attend.

V. Information and documentation

1. Information and documentation to which members may gain access in performing IVIR-AC related activities shall be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. In addition, by counter signing the letter of appointment and the accompanying terms and conditions referred to in section II(5) above, IVIR-AC members undertake to abide by the confidentiality obligations contained therein and also confirm that any and all rights in the work performed by them in connection with, or as a result of their IVIR-AC -related activities shall be exclusively vested in WHO.

2. IVIR-AC members and Observers shall not quote from, circulate or use IVIR-AC documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.

3. WHO retains full control over the publication of the reports of the IVIR-AC, including deciding whether or not to publish them.

Annex 1 – October 2011 Terms of Reference for IVIR-AC

Immunization and vaccines related implementation research advisory committee (IVIR-AC)

Terms of reference

Background

The Quantitative Immunization and Vaccines Related Research (QUIVER) Advisory Committee was established in 2007 with the main responsibility of reviewing quantitative methods in vaccine related research and to advise the Department of Immunization, Vaccines and Biologicals (IVB) on their relevance and applicability.

Given the importance of implementation research in immunization, the Department felt it necessary to enhance the functions of this advisory group to also include implementation research in addition to the existing functions of reviewing and advising on quantitative methods in vaccine research. Therefore, in the last meeting of QUIVER in October 2011, the proposal was endorsed and the Initiative for Vaccine Research (IVR) proceeded with the revision of the terms of reference and membership composition.

Specific functions

IVIR-AC has no executive, regulatory or decision-making function. Its sole role is to provide advice and recommendations to Director, IVB specifically on the following areas:

1. Matters related to implementation research and their relevance to immunization policies and practices.
2. Agenda setting and prioritization of implementation research in immunization which may include identifying potential research projects/issues and, where necessary, also reviewing the proposed methodologies for conducting such research.
3. Review progress of implementation research and advise/guide researcher/research groups as appropriate.
4. Review best practices relating to methods for conducting and reporting on quantitative immunization and vaccines-related research.
5. Facilitate and participate, where appropriate, in IVIR-AC subcommittees or expert working groups as required to address specific subjects in greater depth before review by IVIR-AC, and guide the work of such groups towards the stated objectives.

Relation to other advisory bodies, expert groups, technical committees

Relation to SAGE: IVIR-AC meeting conclusions will be reported by the IVIR-AC Chair to SAGE. At the same time IVIR-AC will review outcomes of SAGE meetings and decisions in order to complement and support the work of SAGE.

Relation to IPAC: The work of the Immunization Practices Advisory Committee is important for IVIR-AC. Therefore, as far as possible, the secretariat will ensure that there is complementarity and regular interaction between the two advisory committees.

Annex 2 – SOPs for IVIR-AC meeting preparations