

Terms of Reference Poliovirus Containment Advisory Group (CAG)

The global strategy for minimizing facility-associated risk of release of poliovirus post-eradication is described in the WHO Global Action Plan for Poliovirus Containment¹. This is achieved through: risk elimination by destruction of poliovirus materials in all facilities except those designated as serving critical functions e.g., polio vaccine production and control, crucial research, diagnostics, etc. requiring the retention of needed polioviruses post-eradication e.g., laboratories and vaccine production facilities; and the biorisk management of facilities retaining polioviruses by compliance with facility-, immunization coverage- and environmental control- safeguards described in the WHO Global Action Plan for Poliovirus Containment. The 'Biorisk management standard for facilities retaining polioviruses post-eradication' of the WHO Global Action Plan for Poliovirus Containment provides the framework for facility compliance verification and containment certification following the Containment Certification Scheme (CCS)². The containment requirements described in the WHO Global Action Plan for Poliovirus Containment is line with other relevant standards and documents³.

In resolution WHA71.16⁴, the World Health Assembly urged all Member States to complete or initiate survey and inventory activities for the relevant polioviruses, reduce to an absolute minimum the number of facilities designated as serving critical functions requiring the retention of needed polioviruses post-eradication, accelerate the progress with national containment certification processes following the CCS, etc.

The Poliovirus Containment Advisory Group (CAG) acts as an advisory body to the Director-General of WHO and make recommendations on technical issues related to the implementation of the WHO Global Action Plan for Poliovirus Containment and relevant issues associated with poliovirus containment.

I. Functions:

In its capacity as an advisory body to WHO, the CAG is expected to provide:

1. Recommendations to WHO on technical issues arising from implementation of the WHO Global Action Plan for Poliovirus Containment, and guidance and recommendations associated with its revision, when appropriate;
2. Guidance or recommendations on the containment requirements for the handling of poliovirus-related materials used for purposes of diagnostics, research, polio vaccine production and control, etc [which includes but not limited to the production of virus-like particle (VLP), poliovirus pseudovirus technology, novel oral poliomyelitis vaccine (nOPV), S19- and S19/N18S- poliovirus strains, PVSRIPO, etc⁵.];

¹ WHO Global Action Plan for Poliovirus Containment. Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>

² Containment Certification Scheme (CCS). Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>

³ Such as but not limited to: Containment Certification Scheme (CCS), Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM Guidance), 2nd edition (2021), WHO Laboratory Biosafety Manual and Associated Monographs, 4th edition (2020), Guidelines for the safe production and quality control of poliomyelitis vaccines, Annex 4, WHO TRS No 1016 and Annex 3, WHO TRS No 1028 (Amendment to Annex 4 of WHO TRS No 1016), ISO 35001: Biorisk management for laboratories and other related organisations (2019), etc.

⁴ Seventy-First World Health Assembly Resolution WHA71.16 Poliomyelitis – containment of polioviruses (2018). Available at: https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf

⁵ S19-poliovirus strains: S19 with the structural (capsid) protein encoding P1-region (of Wild poliovirus or Sabin polioviruses; serotypes 1, 2 or 3); S19/N18S-poliovirus strains: S19 with the structural (capsid) protein encoding P1-region (of Wild poliovirus or Sabin polioviruses; serotypes 1, 2 or 3) with mutation (substitution) of asparagine (N) by serine (S) at amino acid 18 of the non-structural protein 2A for better growth in Vero cells and PVSRIPO: Neuro-attenuated recombinant poliovirus; live attenuated Sabin serotype 1 poliovirus with heterologous internal ribosomal entry site (IRES) of human rhinovirus type 2.

3. Guidance on the identification, risk categorization, destruction and the appropriate containment requirements for the retention and handling of potentially infectious materials, polioviruses and associated tools, etc.;
4. Guidance on the identification of acceptable alternative measures of compliance with the requirements of the WHO Global Action Plan for Poliovirus Containment in the interim period, before certification of WPV eradication.
5. Oversight function for issues related to poliovirus containment and containment documents e.g., WHO Global Action Plan for Poliovirus Containment, CCS, PIM guidance, etc., including the endorsement of these documents, when needed⁶.

II. Composition

1. The CAG shall have up to a maximum of 11 members⁷, who shall serve in their personal capacities to represent the broad range of disciplines relevant to poliovirus containment. In the selection of the CAG members, consideration shall be given to attaining an adequate distribution of technical expertise, geographical representation and gender balance. Potential CAG members include expert in the fields of virology specifically poliovirus, biorisk management, biosecurity, laboratory science, vaccine production and control, containment engineering, etc.
2. Members of the CAG, including the Chairperson, shall be selected and appointed by WHO following an open call for experts. The Chairperson's functions include the following:
 - to chair the meetings of the CAG;
 - to liaise with the WHO CAG Secretariat between meetings.

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

3. Members of the CAG shall be appointed to serve for a period of three years and shall be eligible for reappointment once only. A Chairperson is eligible for reappointment as a member of the CAG, but is only permitted to serve as Chairperson for one term, unless circumstances require otherwise. 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.
4. CAG 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, CAG members shall be required to complete a declaration of interests form and their appointment, or continuation of their appointment, shall be subject to the evaluation of these completed forms by the WHO Secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.
5. Following a determination that a proposed member's participation in the CAG 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 CAG or a letter of reappointment in case of an extension of membership together with the terms of reference of the CAG, Code of Conduct for WHO Experts and confidentiality undertaking. Their appointment or reappointment to the CAG is subject to WHO receiving the countersigned invitation letter and letter of agreement. Notwithstanding the requirement to complete the WHO declaration of interest form, CAG members have an ongoing obligation to inform the WHO of any interests real or perceived that may give rise to a real,

⁶ In 2018, the Strategic Advisory Group of Experts (SAGE) on immunization transferred the function of oversight of containment and containment-related documents to the Containment Advisory Group.

⁷ CAG members serve as full participants and partake in the deliberations and the adoption of the recommendations made during CAG meetings, teleconferences or other relevant CAG activities.

potential or apparent conflict of interest. This includes any changes in situation or circumstance requiring the need for new disclosure.

6. As contemplated in paragraph II.4 above, WHO may, from time to time, request CAG members to complete a new declaration of interest form. This may be before a CAG meeting or any other CAG-related activity or engagement, as decided by WHO. Where WHO has made such a request, the CAG member's participation in the CAG activity or engagement is subject to a determination that their participation would not give rise to a real, potential or apparent conflict of interest.
7. Where a CAG member is invited by WHO to travel to an in-person CAG 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 CAG member, until it receives a countersigned Temporary Adviser letter.
8. CAG members do not receive any remuneration from the Organization for any work related to the CAG. 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.

III. Operation

1. The CAG shall normally meet in-person once to twice each year. However, WHO may convene additional meetings. CAG meetings may be held in-person at WHO headquarters in Geneva or another location, as determined by WHO or virtually, via video or teleconference. Teleconferences are held once every two months or on ad hoc basis depending on the submission of issues from stakeholders related to the implementation of the WHO Global Action Plan for Poliovirus Containment.

CAG meetings may be held in open and/or closed sessions, as decided by the Chairperson in consultation with WHO.

- (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 CAG and WHO CAG Secretariat staff.

2. The quorum for CAG 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 CAG meetings, 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 CAG 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 recommendations of the CAG. Such observers are the Chair of the Containment Working Group of the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC-CWG) who serves as the Liaison Officer of the GCC-CWG to CAG, etc.

4. The CAG may decide to establish smaller working groups (sub-groups of the CAG) to work on specific issues e.g., CAG – Expert Support Group (CAG – ESG) on Novel Poliovirus Strains, etc. 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 CAG for review and recommendation(s) at one of its meetings.
5. CAG members are expected to attend meetings. If a member misses two consecutive meetings, WHO may end his/her appointment as a member of the CAG.
6. Reports of each meeting or teleconference shall be submitted by the CAG to WHO (Director-General). All recommendations from the CAG 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 CAG.
7. The CAG 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 CAG members, including in working groups, teleconferences, and interaction over e-mail. CAG members may, in advance of CAG meetings, be requested to review meeting materials and to provide their views for consideration by the CAG.
9. WHO shall determine the modes of communication by the CAG, including between WHO and the CAG members, and the CAG members among themselves.
10. CAG members shall not speak on behalf of, or represent, the CAG or WHO to any third party.

IV. Secretariat

WHO shall provide the secretariat for the CAG, 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. The Containment Team, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND is the current Secretariat of CAG.

V. Information and documentation

1. Information and documentation to which members may gain access in performing CAG 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, CAG 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 CAG-related activities shall be exclusively vested in WHO.
2. CAG members and Observers shall not quote from, circulate or use CAG 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 CAG, including deciding whether or not to publish them.