

Immunization in Practices Advisory Committee (IPAC)

Overview

Established since 2010, the Immunization Practices Advisory Committee (IPAC) is an independent committee of experts which provides external advice to WHO's Department on Immunization, Vaccines and Biologicals (IVB) on the review and formulation of policies, recommendations, standards and guidance to strengthen the delivery of vaccines at service delivery levels in line with realizing the goals of the Decade of Vaccine (2011-2020) and its Global Vaccine Action Plan (GVAP).

At the mid-point of the Action Plan, the Strategic Advisory Group of Experts (SAGE) on Immunization expressed grave concerns in 2016 on the slow progress towards increasing equitable access to lifesaving vaccines and that countries are not on track to reach 2020 targets. In response, the critical functions of the IPAC were revisited in light of need to address immunization practices at the country level through strong immunization systems, as part of broader health systems, and the continuous innovation and quality improvement of all aspects of immunization services.

These terms of reference will enter into effect in mid-2017 and IPAC membership composition will be revisited accordingly.

Mandate

The overall mandate of the IPAC is to provide independent and expert advice to the Director of WHO's Immunization, Vaccines and Biologicals Department (IVB) on how to strengthen immunization service delivery and programme management to :

- Leverage innovative approaches and technologies that can maximize reach and equitable access to vaccines up to the last mile, and to
- Optimize operational efficiency and management of vaccination programmes at country level.

The IPAC has no executive, regulatory or decision-making functions for WHO. Recommendations made and advice given by IPAC are recorded as stated and need to be approved by the Director of WHO IVB before they are formally endorsed as official WHO positions.

Critical functions

The scope of work of IPAC is organized around two principal workstreams and core areas of work.

1. – Innovations for equitable immunization coverage

The **first** critical function is to review and make recommendations on the programmatic suitability of innovative vaccine products and delivery and cold chain technologies for country level use, which are close to licensure or

licensed, but not widely adopted but have the potential to improve access to vaccines and operational efficiency of delivering vaccinations.

In particular, IPAC would provide advice and guidance on:

- Defining the programmatic needs for innovation in immunization delivery;
- Identifying and prioritizing innovative products, technologies, and practices which are close to licensure or licensed, to strengthen national immunization programmes; and
- Assessing the programmatic suitability of such products, technologies, and practices for broader country roll-out.

2. – Immunization Service Delivery and Programme Management

The **second** critical function is to provide advice, recommendations and guidance on immunization practices to strengthen routine immunization programmes. This workstream of the IPAC would focus on best practices and new approaches to strengthening immunization programme implementation at country level within the broader health systems context including novel approaches and strategies to:

- Design service delivery strategies to reach the unreached ;
- Integrate immunization services with other health interventions;
- Optimize immunization supply chain systems; and
- Improve operational efficiencies and management of national immunization programmes (including human resources and immunization data management).

Linkages with other WHO Advisory Bodies, Expert Committees/Groups

The work of IPAC will be conducted in synergy with the existing network of WHO advisory committees as follows:¹

Relation to the Strategic Advisory Group of Experts (SAGE) on immunization: IPAC regularly takes note of outcomes of SAGE meetings and decisions, assists in operationalizing SAGE recommendations for country practice and reports to SAGE on IPAC deliberations and activities. IPAC recommendations which could potentially lead to policy changes are regularly brought to the attention of SAGE. SAGE may involve IPAC in discussions on operational and implementation issues and request IPAC to provide evidence-based reviews of such issues, drawing upon IPAC's unique country and field experience.

Relation to the Product Development for Vaccines Advisory Committee (PDVAC): PDVAC provides strategic advice and recommendations to WHO related to vaccine candidates at the Phase 2 stage of clinical evaluation or earlier. The committee's remit is for disease areas where there is substantial disease burden in low and middle income countries, no vaccines or products currently exist, and there is some ongoing product development activity which may benefit from WHO guidance. PDVAC may exceptionally consider evaluation of novel delivery technologies, particularly if there are specific product development aspects that it is best placed to address such as development of clinical and regulatory pathways, value propositions and Preferred Product Characteristics (PPCs). IPAC may provide operational and programmatic suitability expertise to PDVAC for the development of guidance related to new vaccines and technologies. Where appropriate, IPAC and PDVAC may set up joint working groups.

Relation to the Immunization and Vaccines Related Implementation Research Advisory Committee (IVIR-AC): IVIR-AC reviews research methods and quality of information for impact evaluation assessments, reviews operational research methods to minimize barriers and improve coverage, and defines improved methods for monitoring of immunization programmes. IPAC may provide country-level expertise to IVIR-AC as needed and request IVIR-AC to

¹ The hierarchy of WHO immunization-related advisory committees and their interactions and demarcations is further described here: http://www.who.int/immunization/policy/WHO_vaccine_development_policy.pdf?ua=1

assist with defining and conducting the necessary research. IPAC and IVIR-AC continuously coordinate work on overlapping themes related to operational research and monitoring of immunization programmes.

Relation to the Programmatic Suitability of Vaccine Candidates for WHO Prequalification Standing Committee (PSPQ-SC): PSPQ-SC is an independent body reporting to the Director WHO EMP. Two IPAC members are part of the PSPQ-SC. IPAC must be involved in any further development or change of criteria of PSPQ process. IPAC has, however, no distinct role of endorsing PSPQ-SC recommendations.

Relation to other WHO advisory boards: IPAC proactively communicates and shares information with other WHO immunization and non-immunization advisory boards and expert committees, such as the Expert Committee on Biological Standardization (ECBS) and the Global Advisory Committee on Vaccine Safety (GAVCS). In some cases, where IPAC recommendations have specific safety or standards implications, these are formally brought to the attention of the relevant committee for review.

Membership and Observers

The IPAC comprises 11 members, who serve in their personal capacity. To be considered as an IPAC member, individuals must be recognized experts in the field of immunization and can be either nominated or self-apply.

The membership of IPAC seeks to reflect a representation of the following:

- Areas of expertise: Immunization service delivery, programme design, operations and management of immunization programmes, immunization products, tools and technologies, vaccine and logistics management, information systems, monitoring and evaluation, regulatory issues and health systems strengthening.
- Professional affiliation: Immunization programme managers, public health specialists, medical professionals, academics, representatives of civil society and of governmental or non-governmental organizations.
- Geographic and gender balance: All efforts are made to ensure equitable geographic and gender balance.

IPAC members are appointed by the Director WHO IVB in light of recommendations made by a selection panel, following a broad public call for nominations. The selection panel is designated by the Director WHO IVB and consists of two senior IVB staff (including one staff from the IPAC Secretariat), the IPAC chair and three observers and follows an established protocol.

Prior to being appointed to the IPAC or to the renewal of a term, nominees and members are required to complete a WHO declaration of interest form and a confidentiality undertaking.

IPAC members are appointed to serve for an initial term of three years, which can be renewed once. Appointments are renewed by the Director WHO IVB, in consultation with the IPAC chair and Secretariat.

Observers representing the following organizations are regularly invited to all IPAC meetings: WHO Regional Offices, UNICEF Programme Division and Supply Division and the Gavi Secretariat. Other observers representing global immunization partners such as the Bill and Melinda Gates Foundation, the US Centers for Disease Control and Prevention, the European Centre for Disease Prevention and Control, PATH, John Snow Inc., Agence de Médecine Préventive, Médecins Sans Frontières, the International Federation of Pharmaceutical Manufacturers & Associations, the Developing Countries Vaccine Manufacturers Network and others, are invited to attend IPAC meetings in view of the agenda items discussed. Observers represent their institutions and do not serve in their personal capacity. It is expected that observer institutions are represented by one and the same person for a continuous period of time. Observers are invited to all open IPAC sessions, but have no voting rights.

All background documents, papers, presentations and reports presented to IPAC shall be treated as confidential and may not be publicly disclosed or used by members or observers without prior approval by WHO. Detailed reports are released and published regularly after each IPAC meeting.

As a WHO advisory committee, neither IPAC as a whole, nor individual members can speak or act on behalf of WHO, or attend meetings on behalf of WHO without prior consent from WHO. Correspondence with outside parties on IPAC issues must be copied to the WHO Secretariat in all cases. IPAC members may be approached outside of meetings for their views, comments and statements on particular matters of public health concern and asked to state their views, as a member of IPAC, or speak to the views of the committee. Members shall refrain from commenting and refer such enquiries to the WHO Secretariat.

Membership in IPAC may be terminated at the discretion of the Director WHO IVB for any one of the following reasons: a) Failure to attend two consecutive IPAC meetings; b) Change in affiliation or status, resulting in a conflict of interest; or c) Lack of professionalism, such as a breach of confidentiality, or misrepresentation of IPAC or of WHO IVB.

Role of Chair

The chair of IPAC is appointed for a non-renewable three-year term by the Director WHO IVB. Eligibility for the post of chair is dependent on having previously served on IPAC for a period of not less than one year. The person appointed as chair should have a broad knowledge of the full scope of the areas of work that concern IPAC, and have proven meeting management and chairing skills.

The chair, together with the WHO Secretariat, sets the IPAC meeting agenda, plans the modalities of discussion of each agenda item and coordinates recommendation sessions. The chair provides regular updates to SAGE on all issues dealt with by IPAC. The chair may also be required to attend other WHO meetings as appropriate.

Role of Members

IPAC members have the responsibility to provide the Director WHO IVB with high quality, evidence-based and independent advice and recommendations on the agenda topics discussed by the committee. In all cases, the work of IPAC and its working groups will strive to improve WHO IVB's ability to support countries in improving their immunization programmes and to increase equitable immunization coverage in line with the strategic objectives of the Global Vaccine Action Plan. This requires that IPAC as a whole and IPAC members individually work hand-in-hand and in full trust with the WHO Secretariat and relevant WHO counterparts.

IPAC members are expected to:

- participate in annual face-to-face meetings, review all background documents and materials and circulate presentations and other inputs prior to these meetings;
- participate in regular web-based meetings and actively contribute to IPAC online discussions in relevant fora and to IPAC publications;
- actively engage in IPAC working groups and task teams along with specific topic experts and WHO staff;
- represent IPAC in other WHO departmental, cross-departmental or other meetings at the request of meeting organizers, as advised by the IPAC chair and Secretariat.

Meetings and Operational Procedures

IPAC is expected to meet once per year face-to-face. The working language of IPAC is English. All members are required to attend and contribute to these meetings and to the development of meeting agendas. A two-year rolling calendar with dates for the next meetings and potential agenda items is made available for members and observers to plan in advance. IPAC utilizes an online discussion forum, open to IPAC members and observers, for further deliberations of IPAC matters.

In addition to the annual meetings, active participation is expected from all IPAC members throughout the year, including participation in regular web-based meetings, in IPAC working groups and task teams, in IPAC online discussions and in interactions by email.

IPAC decisions are taken by consensus and care is taken that decisions are based on the best quality and most up-to-date evidence. No IPAC decisions are taken in the online forum. For decisions to be taken outside the regular meetings, separate calls are organized by the Secretariat.

IPAC meetings are, in principle, open to all interested parties. In addition to members and observers, WHO may invite additional specific topic experts, including, but not limited to, representatives of technical agencies, non-governmental organizations, civil society, professional organizations, donor organizations, as well as developers and manufacturers of vaccines and immunization technologies. Chairs of IVIR-AC and PDVAC are regularly invited to attend IPAC meetings. Background documents and other materials are distributed via the IPAC website and online forum a minimum of two weeks prior to the meetings.

Before IPAC recommendations are accepted as a WHO position, they must be reviewed and formally endorsed by the Director WHO IVB. A summary of the IPAC meeting reports covering the main issues discussed and the resulting IPAC statements or recommendations will be published in the Weekly Epidemiological Records within 2 months of each meeting.

A repository of IPAC meeting reports and IPAC statements is regularly updated on the IPAC website at http://www.who.int/immunization/programmes_systems/policies_strategies/ipac/en/

Conflict of Interest and Confidentiality

IPAC members are required to regularly disclose potential conflicts of interest, which are reviewed by the IPAC Chair and the Secretariat. In case of a determined conflict of interest of an IPAC member, the following options may be applied by the WHO Secretariat in consultation with the IPAC chair: The member may be invited to continue to participate in the meeting or work, provided that the interest is publicly disclosed; The member may be asked not to take part in the portion of the meeting, discussion or work related to the interest or not participate in related decisions; or the member may be asked not to take part in the meeting or work altogether.

IPAC makes every effort to maintain confidentiality and holds closed sessions, if and when required.

Working Groups and Task Teams

IPAC working groups are established on specific priority themes by the IPAC Secretariat in consultation with the IPAC chair and act as additional resources, providing a specific set of expertise, not available in the full committee.

Working groups have distinct terms of reference including goals and objectives, processes, timelines and deliverables.

Working groups deliver their pre-defined output to the full committee during the annual face-to-face meetings and may provide additional information or request committee feedback on their proceedings during the regular online meetings. Once work towards the terms of reference of the working group is completed and successfully presented to the full committee, the group is terminated.

IPAC task teams are convened on an as-needed basis by the IPAC Secretariat in consultation with the IPAC chair. Task teams are established on a time-limited basis to deliver a defined output on a specific topic of interest. Task teams normally accomplish their tasks through the collection, description, analysis and presentation of available evidence. Once their output is successfully delivered to the full committee, the task team is dissolved.

Generally, a working group or task team will include at least two IPAC members and a WHO focal point who will take the lead in the preparations and discussions of the group or task team.

Further details on purpose, structure and functioning of the working groups and task teams can be found in Appendix A.

Appendix A:

Purpose, Structure and Operational Procedures for IPAC Working Groups and ad-hoc Task Teams

Purpose of establishing a working group

Working groups are established by the WHO IPAC Secretariat in consultation with the IPAC chair. Working groups help to address specific questions identified by IPAC that require a specific set of expertise not available in the full committee. Working groups are intended to increase the effectiveness of IPAC deliberations by providing evidence-based information and options for recommendations - as well as the implications of each of the various options – to the full committee.

Working group TOR

Each working group operates under specific terms of reference, developed jointly by the working group chair and the WHO IPAC Secretariat and approved by the IPAC chair and the Director WHO IVB. Working group TOR define distinct goals and objectives, processes, timelines and deliverables.

Working group composition

A working group will normally consist of 5 to 9 members and include at least two IPAC members - one of whom will act as working group chair - and a WHO focal point, who will assist with the operations of the working group. Additional subject matter experts, selected to meet the required expertise and serving in their personal capacity, may be included in the working group. When appropriate, industry representation will be sought through the secretariats of the Developing Countries Vaccine Manufacturers Network (DCVMN) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA.) Occasionally the working group chair, in consultation with the WHO Secretariat, may request participation of additional experts, who are not members of the working group, on an ad-hoc basis.

Working group functions and reporting

Working groups provide a service to IPAC by gathering and organizing information and evidence upon which IPAC can deliberate. Working groups do not render advice or recommendations directly to the Director WHO IVB and working group chairs and members or participating experts are not empowered to speak on behalf of IPAC. The actual process of deliberation resulting in development of group consensus and IPAC recommendations occurs only in the public open forum of IPAC meetings.

Brief summary minutes of each working group meeting, approved by the working group chair, are submitted to the WHO IPAC Secretariat within 2 weeks of each working group meeting and made available to IPAC committee members. In addition, working groups deliver a presentation and submit a brief narrative report to the full committee during the annual IPAC face-to-face meetings, covering working group deliberations, outputs and deliverables. Working groups may provide additional information and/or request committee feedback on their proceedings during the regular IPAC online discussions.

Once per year, based on all presentations and reports, the full committee will review the set-up of each working group, its processes and deliverables and will issue a recommendation on its termination or continuation to the IPAC Secretariat.

Working group operational procedures

The working group chair, in consultation with the WHO focal point, will establish an annual work plan for the group. Working groups are expected to accomplish most of their dealings through web-based dialogue or teleconferences,

which should be scheduled well in advance with set dates and times. In addition, working groups will exchange emails and/or use the dedicated online discussion fora. Face-to-face meetings of working groups may facilitate progress. Such meetings should normally be scheduled in association with the annual IPAC meetings and be anticipated at least 2 months in advance.

WHO supports travel costs for the duration of IPAC meetings for IPAC members, WHO Regional Advisers and experts invited to present at the meetings. WHO may support travel for additional persons for the purpose of a working group meeting, as appropriate. Such requests should be submitted to the IPAC Secretariat for consideration on a case-by-case basis, with justification for any additional costs incurred.

Working Group Conflict of Interest

Working groups fully abide by the IPAC conflict of interest procedures. Prior to being appointed to a IPAC working group or to the renewal of a term, nominees, members and invited experts are required to complete a WHO declaration of interest form and a confidentiality undertaking.

In case of a determined conflict of interest of a working group member or invited expert, the following options may be applied by the WHO IPAC Secretariat in consultation with the working group chair: The member or invited expert may be invited to continue to participate in the meeting or work, provided that the interest is publicly disclosed; The member or invited expert may be asked not to take part in the portion of the meeting, discussion or work related to the interest or not participate in related decisions; or the member or invited expert may be asked not to take part in the meeting or work altogether.

Task Teams

IPAC task teams are convened on an as-needed basis by the IPAC Secretariat in consultation with the IPAC chair. Task teams are set-up with the aim of collecting, analysing and summarizing available evidence on specific IPAC topics of interest, particularly when such a task is determined to be extensive or particularly complex (e.g. systematic reviews). Task teams deliver their requested output to the full committee as basis for IPAC's deliberations on the specific topic and/or the development of recommendations.

Task teams may include external institutions and agencies delivering contract research. Task teams will include one to two IPAC members and a WHO focal point who will oversee and guide the set-up, preparations, dealings and outputs of the task team. Task teams are strictly time-limited and will be dissolved by the IPAC Secretariat, once the agreed deliverables have been submitted to the full committee.