

**Advisory Committee on Immunization Practices,
Centers for Disease Control and Prevention (ACIP, CDC)
COVID-19 Immunization Workgroup
Terms of Reference
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PURPOSE

This document defines the activities, membership, and administrative requirements associated with the establishment of a **COVID-19 Immunization Workgroup** under the Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention (ACIP, CDC). ACIP utilizes subgroups of the Committee, known as Workgroups (WGs), to review relevant published and unpublished data, and clinical and scientific knowledge, and develop options for presentation to the full ACIP parent committee during its public meetings to facilitate discussion, deliberation and development of recommendations. ACIP WGs are intended to augment the effectiveness of ACIP. The direction, focus, and pace of both ACIP and the individual WGs are guided by CDC and HHS policies and priorities, and by the need for expert input to inform development of CDC immunization policy. ACIP WGs serve a key **scientific role** in support of immunization recommendations. The COVID-19 Immunization WG has been specifically established to review data, as well as clinical and scientific knowledge on COVID-19 immunizations, to help develop COVID-19 immunization policy options for ACIP consideration to formulate recommendations to the Director of the CDC.

For the purposes of this document, Immunization refers to vaccines and other antibody protective products, to prevent disease, e.g., immunoglobulins.

BACKGROUND

COVID-19 is a disease caused by the SARS-CoV-2 virus. For some patients, COVID-19 can be severe, causing significant morbidity and mortality. Currently there are three vaccine manufacturers (Moderna, Novavax, and Pfizer) with a combined four COVID-19 vaccines authorized or approved for use in the United States. As the SARS-CoV-2 virus evolves, new formulations of the COVID-19 vaccine have been developed to better approximate currently circulating strains.

The COVID-19 WG was established in 2020 and met frequently to discuss immunization recommendations as the COVID-19 pandemic evolved. ACIP has three scheduled meetings per year, and as needed, to provide recommendations on existing and/or newly developed vaccines.

According to the 21st Century Cures Act (PL 114-255), ACIP shall also, as appropriate, consider new vaccines or new indications at its next regularly scheduled meeting after licensure; if the Committee defers making a recommendation, it will provide an update on the status of its review. Additionally, ACIP shall make recommendations in a timely manner for vaccines that are designated as breakthrough interventions or could be used in a public health emergency.

The purpose of this WG is to review available data, as well as clinical and scientific knowledge, to support the development of recommendations for ACIP consideration that are used to advise the Director of the CDC.

In accordance with the ACIP Charter, the COVID-19 WG will prepare information for the ACIP members to enable them to:

- Advise on population groups and/or circumstances in which a vaccine or related agent is recommended.
- Provide recommendations on contraindications and precautions for use of the vaccine and related agents and provide information on recognized adverse events.
- Provide recommendations that address the general use of vaccines and immune globulin preparations as a class of biologic agents, use of specific antibody products for prevention of infectious diseases, and special situations or populations that may warrant modification of the routine recommendations.
- Support committee deliberations on use of immunization to control disease including consideration of disease epidemiology and burden of disease, immunization safety, immunization efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and implementation issues.
- Revise or withdraw their recommendation(s) regarding a particular immunization as new information on disease epidemiology, immunization effectiveness or safety, economic considerations, or other data that becomes available.

The WG will also assist and support ACIP, in accordance with Section 1928 of the Social Security Act, to be able to establish and periodically review and, as appropriate, revise the list of immunization for administration to children and adolescents eligible to receive immunizations through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric immunization.

TOPICS UNDER DISCUSSION BY THE WORKGROUP

The following topics relevant to COVID-19 immunization for effective control of COVID-19 disease in the civilian population of the United States will be under discussion in the WG in multi-year efforts.

- 1) Risk-benefit and cost-benefit analyses of existing and newly FDA-authorized mRNA and other COVID-19 immunizations, and immunization schedules as it relates to COVID-19 immunization to inform use recommendations, personalized per age-group, major risk factors and health status.
- 2) To identify critical gaps in the existing scientific and clinical knowledge and methodologies related to the safety and efficacy of the COVID-19 immunizations, to inform the development of policy recommendations and further analyses and research by the CDC, other related federal agencies, and the scientific community.

- 3) To review and summarize data, clinical and scientific knowledge related to adverse events associated with COVID-19 immunizations to inform immunization recommendations in terms of precautions and contraindications to receipt of immunization.

DESCRIPTION of WORKGROUP ACTIVITIES

The following activities provide a framework for the COVID-19 immunization WG multi-year efforts which may involve data requests from other Federal and private partners:

1. Review and summarize existing data and published and unpublished research and clinical knowledge related to the safety, effectiveness, and immunogenicity of COVID-19 immunizations authorized or approved in the United States.
2. Summarize literature reviews of the epidemiology of COVID-19 disease and SARS-CoV-2 virus.
3. Assess the benefit-risk balance for administration of COVID-19 immunization products at the same time as other immunizations.
4. Identify areas where additional data and research are needed to inform COVID-19 immunization recommendations.
5. Develop COVID-19 immunization recommendations.
6. Review and summarize the existing clinical and scientific information available; and gaps in the existing knowledge, including from other federal agencies like the FDA, where appropriate relating to bio distribution, pharmacokinetics and persistence of the spike protein, mRNA, and lipid nanoparticles to inform immunization recommendations.
7. Review and summarize the existing clinical and scientific information (including from federal agencies like the FDA, where appropriate); gaps in the existing knowledge regarding potential impurities (e.g., DNA contamination and endotoxins) in existing immunization products and their health impacts to inform immunization recommendations.
8. Review and summarize the existing scientific knowledge, and gaps, regarding the cumulative short- and long-term impact of repeated boosting immunization including non-specific effects (e.g., IgG4 class switching, immune imprinting, viral evolution under leaky immunizations) to help inform immunization recommendations.
9. Examine the impact of COVID-19 immunization on COVID-19 and all cause deaths, hospitalizations, and disability to inform immunization recommendations.
10. Analyze existing data and scientific knowledge regarding cardiovascular, thrombotic, neurological, immunological and other serious adverse events potentially caused by COVID-19 immunization.
11. Review and summarize available data, information, and gaps regarding long-term Covid effects from scientific literature and clinical experience associated with COVID-19 immunization products and COVID-19 infection to inform policy recommendations.
12. Map existing COVID-19 immunization policies in countries around the world and how they compared to the US.

13. Analyze existing data and scientific knowledge related to the safety of COVID-19 immunization during pregnancy.

MEMBERSHIP

Workgroup Leadership: The COVID-19 Immunizations WG is chaired by one of the ACIP, CDC members appointed to serve as Special Government Employees. The Workgroup Lead (WGL) is a federal employee, identified by the Immediate Office of the Director in consultation with the appropriate CDC program. The WG Chair, in consultation with the WGL, ACIP, CDC DFO, determines the WG's membership and work priorities and deliverables to the full committee.

Workgroup Membership: The COVID-19 Immunizations WG is composed of experts who are appointed based on their professional, scientific, technical, or other expertise. They are experts who are regarded as an authority or a practitioner of unique competence and skill by other persons in their profession, or occupation. Upon request, HHS federal agencies named in the ACIP charter may also appoint members to serve on WGs. The COVID-19 Immunizations WG will be composed of members from a variety of disciplines. The WG will engage with the following disciplines on WG activities to:

- Public health science and practice;
- Public health policy development, analysis, and implementation, including development and execution of immunization programs for children and adults;
- Clinical and medical practice, and patient-care experience;
- Epidemiology;
- Molecular biology;
- Immunology;
- Virology;
- Drug and vaccine safety; and
- Consumer perspectives and/or social and community aspects of immunization programs

Due to the complexity and variability of information to be gathered, additional external subject matter experts may also be invited to provide data and presentations to the WG and answer questions during COVID-19 Immunization WG meetings on an ad hoc basis. Such additional external subject matter experts will not be members of the WG and will not participate in any deliberations or WG discussions.

MEETINGS, ADMINISTRATION, and TIMELINES

1. Administrative Oversight: The WGL will work with the WG Chair to arrange meetings, document meeting proceedings, and report to the ACIP on the COVID-19 Immunization WG's activities and findings.

2. Meeting frequency and location: The COVID-19 Immunization WG will meet on an as needed basis as determined by the WG Chair and WGL. All COVID-19 Immunization WG meetings are convened virtually via teleconference.
3. Meeting structure: In addition to the WGL, at least two ACIP Special Government Employee members (one of whom serves as the COVID-19 Immunization WG Chair) must be present at each meeting for a quorum. An agenda, relevant publications, and background documents will be circulated as read ahead material prior to each meeting.
4. Conflicts of Interest: WG members will complete an ACIP WG Agreement and Conflict of Interest Certification process prior to participation on the WG. They will consent to abide by several guiding principles and disclose interests (e.g., employment, special interests, grants, or contracts) that a reasonable person could view as conflicts or potential conflicts of interest with their COVID-19 Immunization WG participation. Members will also disclose any potential conflicts of interest before each meeting. If a COVID-19 Immunizations WG member indicates a potential or actual conflict of interest, the ACIP, CDC DFO in consultation with the WGL will review and make a determination as to whether the individual must recuse themselves from participating in WG discussions that implicate such a conflict-of-interest concern.
5. Confidentiality: The discussions of the COVID-19 Immunizations WG may include information that is unpublished, protected, privileged, or confidential. WG deliberations, including policy options under consideration by the WG, are also considered confidential. Information of this nature must not be disseminated, distributed, or copied to persons not authorized to receive such information. When these types of information are distributed, the person/s presenting will identify the information as such, so all members are duly informed; and written materials shall be clearly marked as such. Unlike ACIP meetings, which are open to the public, COVID-19 Immunizations WG teleconferences are not subject to the open meeting requirements of the Federal Advisory Committee Act or the GSA Final Rule; data presented during these meetings/teleconferences are often proprietary and should not be distributed to people other than approved COVID-19 Immunizations WG members.
6. CDC Staff Involvement: CDC staff do not serve as members of the COVID-19 Immunizations WG but may provide administrative support and technical expertise to ACIP WGs, bringing subject matter expertise and current professional focus in areas relevant to the goals of the COVID-19 Immunizations WG. Consultation or informational presentations by CDC staff will be transparent and evident to minimize the risk of, or the appearance of, undue influence that would compromise the independence of the WG. The ACIP, CDC DFO and WGL of COVID-19 Immunizations WG, in consultation with the Chair of the COVID-19 Immunizations WG, will monitor the interaction between the WG and the agency staff to ensure that the WG activities and work products are appropriate and that there is not undue influence by the CDC or by any special interest group on the activities or work products of the WG.
7. Timelines: ACIP WGs are established when needed and terminated once the activities and work products stated in the terms of reference have been completed and the WG's charge has been fulfilled.
8. Subject content: Findings and opinions of the COVID-19 Immunizations WG members will be discussed at meetings. The COVID-19 Immunizations WG's findings will be presented to ACIP for consideration for action (discussion, deliberation and decision).
9. Workgroup Meeting Summaries: Meeting minutes will be created to capture the information gathered during each COVID-19 Immunizations WG meeting and teleconference.

10. Workgroup findings: The COVID-19 Immunizations WG will present findings (briefing documents, background materials, presentations) to ACIP for consideration and deliberation in a public meeting. Final versions of all slides presented at the ACIP meeting will be posted on the ACIP website following the meeting and included in the committee's official records.
11. Workgroup Record Keeping: All CDC FACA committees, subcommittees, and WGs are subject to the Federal Records Act. All records will be uploaded in the Federal Advisory Committee Management Portal. The summary report and other WG documents will become part of the ACIP's official records as required by GENERAL RECORDS SCHEDULE 6.2: Federal Advisory Committee Records

RECORDKEEPING and REPORTING

The WG Chair and WGL will present findings/outcomes/observations/recommendations to the ACIP parent committee for discussion, deliberations, further development of recommendations and vote in an open public forum. Approved ACIP recommendations adopted by the CDC Director will be published in the Morbidity and Mortality Weekly Report (MMWR). In addition, approved ACIP recommendations will be included in the ACIP meeting minutes and annual report.

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