ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES: WORK GROUPS

Standard Operating Procedures: August 2018

Advisory Committee on Immunization Practices Secretariat

Centers for Disease Control and Prevention

Contents

I. Overview of Advisory Committee on Immunization Practices Work Groups

The role of the Advisory Committee on Immunization Practices (ACIP) is to assist the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) in development of public policy related to immunization of the civilian population in the United States. ACIP utilizes subgroups of the Committee, known as work groups (WGs), to review relevant published and unpublished data and develop recommendation options for presentation to the ACIP. 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 priorities, and by the perceived need for expert advice to inform development of immunization policy.

ACIP WGs are responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by the ACIP in an open public forum. WGs review specific topics in detail and elucidate issues in a manner that facilitates informed and efficient decision making by ACIP voting members.

Five WGs—the Adult Immunization, General Recommendations, Child/Adolescent Immunization, Evidence Based Recommendations, and Influenza WGs—are permanent. The remaining WGs are task oriented; such task-oriented WGs are developed in response to specific needs and are disbanded when the task at hand has been completed. A list of WGs that are currently active can be obtained from the ACIP Secretariat or the ACIP website.

Q.: When is the appropriate time to establish an ACIP WG?

A.: *ACIP WGs should be established when:*

- *Updates to existing recommendations are anticipated based on availability of new data (regarding safety, effectiveness, and/or programmatic issues, e.g., vaccine administration or storage).*
- *Licensure of a new vaccine or new indications for existing vaccines are anticipated.*
    - *In general, WGs should begin reviewing data 12-18 months prior to a potential decision on licensure; the length of time required for the WG to review data in anticipation of vaccine licensure will depend upon the complexity of the topic, and the amount of available data that exists.*
    - *Immunoglobulin therapies, monoclonal antibodies, and/or antimicrobial agents may be considered by ACIP only in relation to control of a disease for which there is a vaccine available or under consideration.*
- *Existing ACIP recommendations should be reviewed on a regular basis, at least every 7 years, and either revised, renewed, or retired with a vote by ACIP. The ACIP Secretariat will establish a WG if review of the recommendations identifies a need to revise the recommendations.*

Each WG operates under specific Terms of Reference (TORs) determined by the WG Chair *(see below)* and WG Lead *(see below)* at the time the WG is formed. The WG Chair and WG Lead, in consultation with other CDC staff, should re-evaluate the TORs annually. TORs should be formalized annually to provide documentation of the WG priorities for each

year. TORs will be included on the ACIP website along with a listing of current WG members and will be updated annually.

TORs should be sent to potential WG members as the WG is being formed. Additionally, TORs should be included in the WG Chair presentation to ACIP annually to ensure transparency. Examples of WG TORs can be obtained from the ACIP secretariat. TORs should be brief (<1 page) and include the following sections:

- Purpose of the WG
- Policy Topics Under Consideration by the WG
- WG Activities

Q.: How frequently should WG TORs be evaluated and/or updated?

A.: *TORs should be re-evaluated when major tasks are completed; when the WG Chair or WG Lead changes; if new issues relevant to the WG arise; when events result in shifts in public heath priorities; and annually between the June and October ACIP meetings.*

II. Work Group Membership

Each WG must include at least two voting members of ACIP, one of whom functions as WG Chair. A CDC subject matter expert (SME) serves as WG Lead, and generally is selected by the concerned CDC program. Other WG members may include ACIP *ex-officio* members, ACIP liaison representatives, and invited consultants. Most WGs should include a representative from CDC's Immunization Safety Office and Immunization Services Division. CDC staff may serve in a supportive or administrative function. During ACIP meeting presentations, CDC staff should be listed on the WG membership slide separately from WG members.

WGs are encouraged to invite a consumer representative to join as an expert consultant. An ideal consumer representative has experience or expertise relevant to the vaccine, disease or condition involved. It is desirable, though not required, that the individual have some degree of familiarity with vaccines. The WG should have a reasonable expectation that the candidate will be able to engage in a dispassionate, unbiased review of data and to comply strictly with the confidentiality requirements placed on all WG members. The ACIP Secretariat can help identify potential consumer representatives.

In order to facilitate participatory discussion among all WG members, consideration should be given to the overall number of WG members, including the invited liaison representatives and consultants serving on the WG, and the expertise each invited consultant brings to the WG. The recommended size of a WG is <15 members, not

including CDC staff supporting the WG. WG members may change when the WG TORs change and should be reassessed annually.

Representatives of vaccine manufacturers may not serve as members of a WG but may, at the discretion of the WG Chair and WG Lead, be invited to make presentations to the group and answer questions. Experts from the private sector who do not represent vaccine manufacturers may be asked to make presentations to the WGs or to participate in discussions at the discretion of the WG Chair and concurrence of WG Lead. Following these presentations, non-WG members are asked to leave so that deliberations are limited to members of the WG.

Participants in WGs are typically limited to U.S. residents, due to the increased cost of international teleconferences, but exceptions occur when expertise is needed from individuals living outside the United States.

Q.: How are WG members selected?

A.: *The process for WG member selection is as follows.*

- *The ACIP Secretariat will, in consultation with the WG Lead, recruit one ACIP voting member to serve as WG Chair, and at least one additional ACIP voting member. The ACIP secretariat will send an inquiry to all current voting ACIP members to assess interest. The ACIP voting members and WG Chair will be determined based on interest, need for expertise on the WG, and balancing ACIP members' available time.*
- *As an ACIP voting member's term expires, the person may continue to serve on the WG in a consultant role at the discretion of the WG Chair and WG Lead.*
- *At the time new ACIP members begin their terms, the Secretariat will request a list of the WGs they are interested in joining and balance these requests with the need to fill voting member positions on WGs. When feasible, the WG Chair will be replaced by an ACIP voting member who has already been on the WG for a period of time. The WG Chair will be chosen by the WG Lead in consultation with the outgoing WG Chair, but should be approved by the Secretariat in order to ensure balance of workload among ACIP voting members.*
- *The WG Lead will be designated by the CDC Center, Institute, or Office with responsibility for the concerned program/vaccine to be considered.*
- *The WG Chair and the WG Lead, in consultation with the ACIP Secretariat, will recruit additional members and consultants for the WG. The WG Chair and the WG Lead should work closely together to determine priorities, process, direction, and timeline for WG activities, again in consultation with the ACIP Secretariat.*

- *In consultation with the WG Lead and WG Chair, the ACIP Secretariat will extend invitations to those ex officio and liaison organizations requested by the WG Chair/WG Lead for representation on the WG. The organization or ex officio agency will designate the individual to represent the organization and agency and can request an alternate. When determining the organizations and ex officio liaisons to include, the existing size of and the relevance of the organization or ex officio background to the WG TORs. There should be an FDA liaison for each WG where a new vaccine or indication is under consideration by the WG.*
- *The WG Lead should extend requests for subject matter experts to serve as consultants to participate on a WG to ensure there is adequate expertise on the WG to provide evidence-based information to support ACIP deliberations. Consultants should serve as a resource to offer expertise on clinical, programmatic and basic scientific aspects of the vaccine-preventable disease and vaccine, and other factors. If these individuals do not have a conflict of interest (see below), consultants may participate in all discussions and deliberations. If a subject matter expert has a conflict of interest, he/she may participate in scientific discussions but may not participate in policy deliberations.*
- *A temporary consultant can be included in a WG to deal with an important but limited policy topic (i.e., involving interpretation of information and policy discussion over a period of months).*

III. Roles and Responsibilities

WG Chair

- Signs annual membership agreement form (see Appendix 1).
- Attends and participates in WG meetings on a regular basis.
- Completes timely review of materials as requested.
- Works with the WG Lead to identify potential WG members.
- Reviews WG membership to ensure necessary expertise is represented.
- Works with the WG Lead to set an agenda for WG meetings and for timelines of presentations at the full ACIP meetings.
- Provides overview presentation of WG topics at ACIP meetings, and other presentations if needed.
- Co-authors Morbidity and Mortality Weekly Report (MMWR) Policy Notes and Recommendations and Reports (comprehensive ACIP recommendation document).

ACIP Member(s)

- Signs annual membership agreement.
- Attends and participates in WG meetings on a regular basis.
- Completes timely review of materials as requested.
- Co-authors MMWR Policy Notes and Recommendations and Reports if authorship criteria are met.

CDC WG Lead

- Works with WG Chair to identify potential WG members.
- Works with the WG Chair to set an agenda for WG meetings and for timelines of presentations at ACIP meetings.
- Coordinates WG meetings, documents roll call, takes minutes or designates another person on the WG (e.g., other CDC staff member) to do so (see Work Group Teleconferences and Meetings, below).
- Coordinates developing agenda proposals, background and briefing documents, and presentations on behalf of the WG for ACIP meetings.
- Leads development of MMWR Policy Notes and Recommendations and Reports documents.
- Attends and participates in monthly WG Lead meetings, routinely uploads documents to the ACIP SharePoint site, completes a timely review of materials, and responds to requests from the ACIP Secretariat.
- Works with the Adult Immunization and Child/Adolescent Immunization WG Lead to review immunization schedule footnotes annually.

Liaison Representatives and *Ex-Officio* Members

- Signs annual membership agreement and conflict of interest forms.
- Attends and participates in WG meetings on a regular basis.
- Completes timely review of materials as requested.
- Communicates the perspective of the organization or agency they represent at WG meetings.
- Additional information for FDA representatives to ACIP WGs can be found in Appendix 2.

Consultants

- Signs annual membership agreement and conflict of interest forms.
- Attends and participates in WG meetings on a regular basis.
- Completes timely review of materials as requested.
- Serves as a subject matter expert during WG meetings and calls.

CDC Staff

- Provide administrative support and technical expertise to ACIP WGs.
    - CDC staff on WGs bring subject matter expertise and current professional focus in areas relevant to the goals of the WG. CDC staff are aware of agency priorities, and of current and anticipated policy issues that may arise in association with the focus of each WG and are responsible for working with the WG Lead to ensure that the focus, direction, and timing of WG efforts remain compatible with the needs of CDC and HHS.
- As needed, perform, coordinate, or identify scientific studies and outbreak investigations to address questions that arise regarding vaccine policy decisions; conduct analysis of data addressing efficacy, effectiveness, safety, feasibility, and economic aspects of immunization policy; and participate in evaluation of quality of the evidence, e.g. GRADE review.
- Additional information for ISO and ISD representatives to ACIP WGs can be found in Appendix 2.

IV. Work Group Teleconferences and Meetings

WGs accomplish most of their work through teleconferences. When the group is active, a set day and time for routine monthly teleconferences (e.g., 2 PM EST on the last Friday of the month) is usually established. This allows standing teleconferences to be arranged and WG members to anticipate and reserve time for these teleconferences. The frequency of WG teleconferences may change depending on the urgency of the issue(s) being considered by the group. Most WGs meet once per month, but some WGs meet twice monthly, particularly in the time period leading up to an ACIP meeting when the WG may need to meet more frequently.

Most WG teleconferences are held using a call-in number or Skype business teleconference software, and are not operator assisted. The same number may be used for all teleconferences for a particular WG. Teleconferences should not be recorded.

The development of a brief (1-2 page) summary of each WG meeting will facilitate the function of the WG; the taking of minutes is best accomplished by a WG member other than the WG Chair or the WG Lead, in order to allow the WG Chair and WG Lead to lead and manage the meeting effectively. WG meeting minutes are confidential and may be shared by the WG Chair/WG Lead with WG members.

Minutes and slides from each WG teleconference should be uploaded to the ACIP SharePoint sites by the WG Lead on a regular basis (e.g., monthly or quarterly).

When needed, an in-person WG meeting may be arranged either immediately before or after a full ACIP meeting. The Secretariat cannot support these meetings financially, but may be able to reserve a room in the Global Conference Center if a need is identified early. In-person meetings should be used with discretion: ACIP voting members should primarily focus on the public meeting discussions. Please consult with the Secretariat prior to scheduling an in-person WG meeting during an ACIP meeting.

Q.: Are there special considerations for WG meetings in relation to FACA requirements?

A.: *Yes. To be able to operate in closed meetings, ACIP WGs must observe certain guidelines that allow them to function exempt from FACA requirements. ACIP WGs function in a fact-finding role, do not include a quorum of voting ACIP members, and do not vote on policy; they are therefore exempt from FACA requirements.*

As FACA-exempt groups, ACIP WGs are not allowed to render consensus advice or recommendations directly to the Federal government. ACIP WG Chairs, other WG representatives, or the WGs per se are not empowered to speak on behalf of ACIP. Rather, they are utilized by ACIP to gather and organize information upon which ACIP can deliberate and act. Thus, while ACIP WGs can and should examine specific topics in detail and define the issues, including development of options for recommendations, the actual processes of group deliberation terminating in development of immunization recommendations must occur in the open public forum of ACIP meetings in compliance with FACA requirements.

Q.: How are "straw polls" used during WG meetings?

A.: *When there are several different opinions about an issue expressed during a WG meeting or the WG Chair and WG Lead want to ensure all members' perspectives are considered, a "straw poll" can be conducted. A straw poll is not a vote on policy and the goal is not to come to consensus, but rather to document the different opinions of the WG members and help with continued deliberations. Results of straw polls should be kept within the WG, but can be summarized during a presentation at the public ACIP meeting. ACIP voting members, liaison representatives, and consultants with no conflicts of interest should be included in straw polls. Federal employees should not be included. These polls can be done over email or during teleconferences.*

V. Confidentiality

Unlike ACIP meetings, which are open to the public, WG meetings/teleconferences are not public meetings; data presented during these meetings/teleconferences are often

proprietary and should not be distributed to people other than approved WG members. To ensure confidentiality of data, the following guidelines should be implemented by all WGs.

1. Roll call by the WG Lead should be taken at the start of each WG teleconference to document names of members who are participating; the roll call of participants should be incorporated into brief meeting minutes, which may be compiled by the WG Lead or someone designated to do so by her/him.
2. At the beginning of each WG meeting/teleconference where any material that is not already publically available is being discussed, the WG Lead should state that the meetings are closed and information discussed is confidential and should not be distributed or used in presentations.
3. Only WG members and invited consultants should participate in WG meetings.
4. If the parent organization of a liaison representative wishes to obtain information about WG proceedings, the organization should contact the WG Lead to request a presentation. Liaison representatives serving on WGs should not share WG proceedings, discussion, or slides with the parent organization unless permission is granted by the person who presented this information to the WG.
5. Slides distributed at WG meetings or shown during teleconferences should be marked as confidential and should not be shared with people who are not WG members.
6. To minimize the possibility that slides may be extracted or used outside the WG meeting, PowerPoint presentations should be saved and distributed as .PDF (Portable Document Format) files.
7. WG members should not discuss WG deliberations with anyone representing or employed by a vaccine manufacturer.

VI. Pharmaceutical Companies and Work Groups

Presentations given by pharmaceutical companies to ACIP provide critical information on clinical trials and other studies assessing the safety and efficacy of vaccine products. Guidance for WGs includes:

- If a company and or lobbyist reaches out to a WG member to discuss WG proceedings, the WG member should inform the WG lead immediately.
- When feasible, WGs should provide opportunities for companies with plans to submit a biologics licensing application (BLA) to FDA for a vaccine product to update the WG if new data are available. Relevant updates from companies with products already licensed should be considered when new products are under consideration for use by the WG.

- All information, data, and slides presented during WG calls are confidential. However, all documents related to WGs are subject to FOIA requests. In the event that WG Lead receives a FOIA for materials from some or all WG meetings, the WG Lead will be requested to review and provide all such materials; in consultation with the CDC FOIA Office, the WG Lead may identify items that need to be redacted, e.g. proprietary information (http://intranet.cdc.gov/ocio/about/foia/).
- After pharmaceutical presentations to the WG and time for questions, the company should exit the call. The WG should discuss the implications of the data presented and the importance of presenting the data to ACIP only when company representatives have left.
- All presentation topics by pharmaceutical companies on the ACIP agenda must be presented to the WG prior to presentation at meetings of ACIP.
- The final presentation for ACIP will be more concise, and should be reviewed and approved by the ACIP WG Chair and WG Lead (with consultation from the FDA *ex officio* member serving on the WG, when needed) prior to the ACIP meeting.
- The WG lead (or other CDC staff member serving on the WG) should present a summary of the WG's interpretation of the data presented by the company during the same ACIP session, if appropriate.

Guidance for pharmaceutical companies includes:

- Representatives of vaccine manufacturers should not contact any ACIP WG member for the purpose of promoting a product scheduled for presentation at an ACIP meeting or to suggest recommendations for consideration by ACIP.
- Representatives of vaccine manufacturers should contact the WG Lead when they have data they would like to present to the ACIP WG. Vaccine manufacturers also may be solicited by WG Leads for presentation on specific topics of interest.
- Data that can be proposed for presentation may include data on products under consideration for licensure or post-licensure data on a product that may inform current discussions of the WG.
- The time allocation for the ACIP presentation should be approximately 15 minutes, with an additional 5 minutes for questions. Longer or shorter presentations may be needed; final time allocations will be determined by the WG Lead and the ACIP steering committee during agenda development.
- Presentations must be submitted to the WG Lead 3 weeks prior to the ACIP meeting for review and approval. This provides time for review and incorporation of feedback. If changes are requested, the final presentation should be reviewed by the WG Lead. The deadline for final submission for printing of slides is the Wednesday 1 week prior to the ACIP meeting.

- Any slide outlining the measures used in the studies presented should include the study population, comparison groups, and outcome measures.
- A strengths and limitations slide should be included in the conclusion section of the talk.

VII. Work Group Resources

The most significant internal resources available to ACIP WGs are the expertise and energy of WG Leads and other CDC staff. In addition, the Secretariat is dedicated to support the work of ACIP WGs including logistics, oversight of issues of science and policy, day-to-day oversight of WGs, and interactions with ACIP membership.

The ACIP Executive Secretary, or "Designated Federal Official," (DFO) is a senior consultant to the Director at the National Center for Immunization and Respiratory Diseases (NCIRD). The DFO is responsible for the committee's overall management and compliance with FACA law.

Additional resources at CDC (e.g., the Office of General Counsel, Federal Advisory Committee Management Branch/Management Analysis and Services Office) are available and can be accessed through the ACIP Secretariat, as well as support for GRADE and cost-effectiveness evaluations.

A monthly meeting of WG Leads is organized by the Secretariat to get input from WG Leads on issues related to ACIP processes and to discuss any challenges or questions specific to a WG among the WG Leads. The Secretariat also provides support to the WG Leads for the ACIP SharePoint site and coordinates annual membership agreement and conflict of interest paperwork.

Funds for support of ACIP activities are limited. Requests for specific support for additional expenses that will enhance ACIP functioning (e.g., extra meeting rooms, equipment, travel of additional persons to ACIP meetings) will be considered by the ACIP Secretariat. CDC routinely supports travel costs for the duration of ACIP meetings for ACIP voting members only. CDC rarely may support travel for invited speakers making presentations during the ACIP meeting, or may agree to provide funding for an additional night for ACIP members. Such requests should be brought to the ACIP Secretariat for consideration on a case-by-case basis, with justification for the increased costs. In some instances, it may be necessary to deny reasonable requests for financial support.

VIII. Preparing for ACIP Meeting Presentations

Submitting Agenda Items for ACIP Meetings

Topics for inclusion in the agenda for an upcoming ACIP meeting are solicited by the ACIP Secretariat approximately 3 months before the ACIP meeting, and are due 2 weeks later. Requests for agenda proposals are sent to voting ACIP members, WG leads and ACIP Steering Committee members. A standard template form is used, and includes the following items:

- Justification for inclusion of topic
- Proposed presentations, including topic, presenter, question(s) to be addressed by the ACIP
- Any additional pertinent information

Following compilation of all agenda proposals, the ACIP Steering Committee meets to prepare a detailed agenda, which is then sent back to WG Leads and any others who have submitted proposals. The ACIP secretariat finalizes the draft agenda within 1-2 days of the Steering Committee meeting, and distributes and posts on the ACIP web site. The draft meeting agenda may be modified as needed up to the week of the ACIP meeting.

ACIP Briefing Documents

In advance of each ACIP meeting, a briefing book will be prepared for the CDC Director that includes information on the topics being presented at ACIP and items on which a vote will be taken. The ACIP Secretariat will request briefing documents from WG Leads after the draft agenda has been distributed. Briefing documents will be due 3 weeks prior to the ACIP meeting. A standard template form is used (not to exceed two pages), and includes the following items:

- Topic
- Statement of status of the vaccine or topic and key issues
- Background
- Reason topic is being presented to ACIP: information, discussion, vote, VFC vote (if applicable)
- Policy options
- Consensus of ACIP WG
- Implications of ACIP decision

ACIP Background Materials

In order to prepare voting ACIP members, ex-officio members, and liaison representatives for the issues to be discussed during each ACIP meeting, background materials are

prepared and distributed in advance of each meeting. Background materials can be submitted for all topics on an ACIP agenda, but are required for major issues and items on which a vote will be taken. Background materials will be requested from WG Leads approximately six weeks prior to each ACIP meeting, and will be due two weeks in advance of the meeting.

A cover letter should be prepared that highlights the information that is most important for the members to read. Examples of cover letters may be requested from the ACIP Secretariat, and will be circulated when background materials are requested. The background materials can include key WG summaries, draft MMWR Policy Notes or Recommendations and Reports, key articles or studies, or a summary of key issues. Background materials are not considered to be confidential and may be shared in a limited fashion (e.g., by liaisons within their organizations). If confidential information needs to be shared with the voting ACIP members, the WG lead should reach out to the ACIP Secretariat to facilitate that process.

ACIP Presentations

WG Leads should collect meeting presentation files for meeting handouts from all presenters in your session. Approximately 2-3 weeks before each ACIP meeting the ACIP Secretariat will request presentation files for printing. The ACIP Secretariat can assist with printing needs up to one week prior to the meeting. If there are files that should go to ACIP members only (ACIP, ex-officio, liaison representatives) or voting members only, please indicate that in the file name. For any presentations that are not received electronically by one week in advance of the meeting, the WG Lead will be responsible for coordinating printing, photocopying, and delivery of hard copy per the instructions below.

- **Compile your presentations in sets** with handouts in chronological order; ready to be slipped straight into meeting binders (e.g., if you have five individual handouts, put them in sets with handouts #1, 2, 3, 4, 5 in order).
- **For ACIP membership:** 25 sets as handouts, 6 slides/page, 3 inch hole punch, collated and stapled; black/ white unless you need them to be in color (e.g., child/adolescent and adult immunization schedules).
- **For public:** 200 sets as handouts, six slides/ page, regular paper, collated and stapled.
- Delivered in labeled boxes to the Global Communications Center (Building 19) marked with ACIP meeting, name of session and session date.

All presentation files will be converted to PDFs and shared with ACIP members, ex-officio, and liaison representatives via ShareFile prior to the meeting. These files do not have to be the final presentations and can be the same files that are used for printing. Recipients will be instructed that the meeting slides should not be shared or used in presentations

without permission from the Work Group Lead. Final versions of all slides presented at the meeting will be posted on the ACIP website following the meeting.

Electronic presentation files will be loaded on a laptop computer in the meeting room for presentation at the ACIP meeting. Presentation files may be updated before the meeting starts, or at breaks, on meeting days, brought to us in person on a flash drive by the WG Lead only. We cannot accommodate several people updating their files, all for the same session.

WG Leads should send the presentation files for your session to Stephanie Thomas (hkp4@cdc.gov), as a group. Please use the following naming format to ensure that the person operating the meeting computer can pull them up easily and in the proper order. For example:

- 01 HPV introduction Kempe
- 02 HPV review Markowitz
- 03 HPV proposed recommendations Meites
- 04 HPV recommendation vote Meites
- 05 HPV VFC Santoli

- Often the manufacturers provide their files to you as PDF files; if possible, we prefer PPT.

IX. Evidence-Based Decision and Cost-effectiveness Analyses

CDC vaccine recommendations are developed using an explicit evidence-based method based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. Key factors considered in development of recommendations include the balance of benefits and harms, type or quality of evidence, values and preferences of the people affected, and health economic analyses. More information about GRADE can be found in the ACIP's GRADE handbook (https://www.cdc.gov/vaccines/acip/recs/grade/downloads/handbook.pdf).

Most issues that ACIP will vote upon require a GRADE evaluation of the evidence. However, a "when to GRADE" algorithm is currently under development and once it is finalized a link will be added here. A summary of the GRADE evidence should be included in the MMWR Policy Note, and the GRADE evidence tables are published on the ACIP website (https://www.cdc.gov/vaccines/acip/recs/grade/table-refs.html). If it is determined that a GRADE evaluation is not needed, the rationale for why GRADE is not being done should be clearly documented. The ACIP Secretariat is available to assist with questions about GRADE.

Additionally, In February 2018 the ACIP adopted use of an evidence to recommendations framework. Information about the framework will be added here and on the ACIP website when available.

The ACIP also provides guidance for the development of health economics studies (https://www.cdc.gov/vaccines/acip/committee/guidance/economic-studies.html). These procedures should be followed for economic analyses to be presented to the ACIP to ensure that economic data presented to the ACIP and its WGs are uniform in presentation, understandable, and of the highest quality.

X. Preparing MMWR Reports

Following approval by the CDC Director, ACIP's recommendations are published in MMWR as a Policy Note whereby they become official policy. The MMWR Policy Note and Recommendations and Reports documents summarize both the ACIP recommendations (language voted upon by ACIP; e.g., the vaccine should be used for outbreak response) and guidance for use (CDC's guidance for use which is not voted upon by ACIP; e.g., how to determine when an outbreak is occurring, dose spacing, etc.).

Development of the Policy Note is led by the WG Lead. The WG Chair and other ACIP (or WG) members who meet authorship criteria should be included as co-authors on each Policy Note. The Secretariat encourages WG Leads to approach ACIP members to be included as co-authors early in the process of developing the Policy Note to allow for participation and co-authorship. The WG Lead also is responsible for developing the MMWR Recommendations and Reports (comprehensive summary of ACIP recommendations).

The WG Lead should meet with OADS prior to drafting each Policy Note and the OADS Checklist should be followed (http://intranet.cdc.gov/od/oads/osq/guide_rec/docs/CDC-Policy-Notes-Development-and-Reporting-Checklist.docx). The WG Lead should also meet with MMWR prior to developing a Recommendations and Reports document.

A Policy Note should be drafted before an ACIP vote is requested and the draft Policy Note should be distributed to ACIP members in the background materials for the session in which the vote is requested. The ACIP Secretariat will preschedule each Policy Note with MMWR to ensure prompt publication once the recommendation is approved by the CDC Director. Similarly, a Recommendations and Reports document should be drafted and distributed to ACIP members before a vote is requested.

After clearance and prior to publication, sections of the MMWR that discuss a particular product should be shared with the company making that product to ensure there are no factual errors or literature that was not included. At the time where there are proofs, the embargoed document should be shared with any pharmaceutical company that has a vaccine named in the document (with the exception of the schedule and general guidance documents). This is for awareness purposes only and edits can be made only if factual errors are identified.

XI. Termination of Work Groups

Five ACIP WGs are designated "permanent" WGs, since recurring tasks occur annually (influenza, child/adolescent immunization, adult immunization, and evidence based recommendations) or approximately every 3-5 years (general recommendations). The remaining WGs are designated "task-oriented," and are established when needed (Section I), and disbanded once the stated terms of reference have been completed. It is often the case that the WG has completed its terms of reference, but an ACIP recommendation statement (Policy Note or Recommendations & Reports for publication in MMWR) is still in progress. If there is not a need to have ongoing, regular WG discussion, the WG Chair and WG Lead may disband the WG, and the draft recommendations can be circulated to WG members for review and comment until a final draft is ready to put into CDC clearance.

It may happen that and ACIP WG is established and completes its TORs, and is then disbanded but at a later date new information becomes available that necessitates regrouping the WG, e.g. new safety data, a new vaccine, etc. This has occurred, for example, with the Rotavirus Vaccine WG. Therefore, a WG does not need to stay in existence "in case" a future need arises, but can be disbanded and reestablished as required, with the original WG members and/or with new WG members. When the WG Chair and WG Lead agree that it is reasonable to disband the WG, the WG Lead sends out an email to WG members thanking them for their service and contributions, and informing them of any next steps, e.g. ACIP recommendation review and publication plans.

XII. Appendices

Appendix 1: Additional Information for FDA, ISO, and ISD Representatives to ACIP WGs

FDA Representatives to ACIP Work Groups

In most circumstances, the ACIP considers vaccines once they have been licensed by the FDA. While ACIP reviews the safety and efficacy data available to them during deliberations, they rely on FDA to conduct a review of all data submitted for licensure. Therefore, the FDA representative to the ACIP Work Group provides expertise in the licensure, indications, and package insert of vaccines under consideration. While information being reviewed by FDA is confidential during the pre-decisional phase, the FDA makes available on its website its reviews of the biologic license application within 30 days of the approval. While the FDA representative cannot discuss trade secrets, confidential commercial or financial information from the applicant, he/she can still provide guidance and perspective to inform ACIP Work Group discussions based on publicly available information, including all information made available to the public that is not available elsewhere.

- Open lines of communication between the Work Group Lead and FDA representative are important to ensure ACIP Work Group deliberations and proposed recommendations are appropriate and in line with licensure considerations and information made available to the public by FDA upon approval of the vaccine.
- When recommendations are proposed that are not aligned with the licensed indications, it is important to ensure any concerns from FDA are communicated to the CDC Work Group Lead.
- Given that the FDA representative is often in the middle of the review for the vaccine under consideration, FDA representatives are prohibited from providing certain information in the ongoing review until an approval decision has been made.
- When there are scientific or policy concerns (i.e., differences between FDA and the Work Group's interpretation of data and/or proposed recommendations) that are challenging to resolve within the Work Group, both the FDA representative and the CDC Work Group Lead should communicate these concerns to leadership for further collaborative discussion.

Roles and Responsibilities

- Signs annual membership agreement.
- If the FDA representative has not signed an OGE 450 through FDA, they should complete the ACIP Work Group member conflict of interest form.
- Attends and participates in Work Group meetings on a regular basis (attends more than 75% of meetings).
- Completes timely review of materials as requested, including pre-clearance review of policy notes and Recommendations and Reports.
- Communicates either during the call or follows-up with the Work Group lead if there are concerns related to interpretation of data or potential conflicts between recommendations and language in the package insert, as permitted under its regulations
- As able to, provides updates to Work Group Lead about potential changes to a vaccine's indications.
- Known or approximate distribution dates for Healthcare Provider letters indicating changes to prescribing information relevant to work group deliberations should be communicated to the CDC Work Group Lead by the FDA representatives.
- Respond to communications from the Work Group Lead via email or phone. If they are unable to communicate a concern due to confidentiality restrictions, the FDA representative should inform their leadership of potential issues.

ISO Representatives to ACIP Work Groups

The ISO representatives to the ACIP Work Groups plays a key role ensuring that vaccine safety issues related to proposed new recommendations, changes to recommendations, new vaccine safety findings, and potential vaccine safety issues of concern are identified and considered during Work Group deliberations.

- Vaccine safety is a key component of the review of the evidence supporting proposed recommendations.
- There may be vaccine safety issues for special populations that may not be recognized by the ACIP Work Group, such as vaccination of pregnant women, or immunocompromised populations.
- There may be vaccine safety findings from routine surveillance, epidemiologic studies, or new issues of concern from provider groups, health officials or the general public for which the ACIP Work Group should be made aware.

- When recommendations are proposed for which there are potential vaccine safety concerns, it is important that these concerns are communicated to the CDC Work Group Lead.
- When there are vaccine safety or policy concerns (i.e., differences between ISO and the Work Group's interpretation of data and/or proposed recommendations) that are challenging to resolve within the Work Group, both the ISO representative and the CDC Work Group Lead should communicate these concerns to their leadership for further collaborative discussion.

Roles and Responsibilities

- Signs annual membership agreement.
- If the ISO representative has not signed an OGE 450 through CDC, they should complete the ACIP Work Group member conflict of interest form.
- Attends and participates in Work Group meetings on a regular basis (attends more than 75% of meetings).
- When needed, the ISO representative should pull available data, review literature, and conduct analyses to support ACIP Work Group deliberations.
- Completes timely review of materials as requested, focusing on vaccine safety and the safety studies supporting licensure. The ISO representative may be requested to co-author policy notes or recommendations and reports depending on the content.
- Communicates either during the call or follows-up with the Work Group Lead if there are concerns related to implementation issues.
- Presents related vaccine safety updates at ACIP meetings, as needed.

ISD Representatives to ACIP Work Groups

The ISD representative to the ACIP Work Groups plays a key role ensuring that implementation issues related to proposed new recommendations or changes to recommendations are identified and considered during Work Group deliberations.

- Implementations issues are considered as one piece of the evidence supporting proposed recommendations.
- While the scientific evidence should drive ACIP recommendations, implementation issues can help refine potential policy options supported by the evidence.
- Understanding implementation issues can also help how recommendations are framed.

- Clinical decision support is a key part of implementation of vaccine recommendations. Projecting how recommendations are translated into clinical decision support can also help refine potential policy options and clinical guidance.
- When recommendations are proposed for which there are implementation concerns, it is important that these concerns are communicated to the CDC Work Group Lead.
- When there are implementation or policy concerns (i.e., differences between ISD and the Work Group's interpretation of data and/or proposed recommendations) that are challenging to resolve within the Work Group, both the ISD representative and the CDC Work Group Lead should communicate these concerns to their leadership for further collaborative discussion.

<u>Roles and Responsibilities</u>

- Signs annual membership agreement.
- If the ISD representative has not signed an OGE 450 through CDC, they should complete the ACIP Work Group member conflict of interest form.
- Attends and participates in Work Group meetings on a regular basis (attends more than 75% of meetings).
- When needed, the ISD representative should pull available data, review literature, and conduct analyses around implementation issues to support ACIP Work Group deliberations.
- Completes timely review of materials as requested, focusing on implementation issues including language, how recommendations will be communicated, and how they will be incorporated into clinical decision support.
  Communicates either during the call or follows-up with the Work Group Lead if there are concerns related to implementation issues.