

2. Methods

The Advisory Committee on Immunization Practices (ACIP) General Recommendations Work Group (GRWG) reviews the evidence for best practices regarding immunization and releases updated guidance every 3 to 5 years (see Appendix 2: Membership). Work group members are required to report conflicts of interests. Conflict of interest information for those individuals who must report is available upon request to the corresponding author. Relevant topics are those identified by ACIP as topics related to all vaccines, including timing and spacing of doses, vaccine administration, and vaccine storage and handling. New topics are added when ACIP decides previous ACIP good practice statements on general issues (such as combination vaccines, adolescent vaccination, or adult vaccination) should be revised and incorporated into the *General Best Practice Guidelines for Immunization*.

The best practice guidelines in this report update the previous ACIP *General Recommendations on Immunization (1)* and are based both on review and analysis of available scientific evidence and on expert opinion of the diverse group of health-care providers and public health officials who are members of GRWG. This group includes professionals from academic medicine (pediatrics, family practice, and pharmacy); international (Canada), federal, and state public health professionals; and a member from the nongovernmental Immunization Action Coalition (see Appendix 2: Membership). This revision involved consensus-building based on new evidence from the published literature and opinion from subgroups of subject matter experts consulted on specific topics.

The process by which the guidelines were drafted varied for each document; each document is therefore discussed individually below. ACIP voted to accept the proposed guidance in October 2014; for additional information, see www.cdc.gov/vaccines/acip/meetings/meetings-info.html.

Timing and Spacing of Immunobiologics

GRWG met monthly beginning in January 2011, and formed a subgroup to focus on review of guidelines around administration of simultaneous vaccination and febrile seizures. Meetings were held in April, May, and June 2011 to discuss the evidence. Other issues related to timing and spacing of vaccinations were discussed between February 2012 and September 2014 over 7 meetings (in February 2012, June 2012, August 2012, November 2012, January 2013, January 2014, May 2014, and September 2014). The evidence supporting this document is based on expert opinion and arrived at by consensus. Presentations of the evidence were made to ACIP in June 2011, October 2011, and February 2013. Major changes include 1) guidance for simultaneous vaccination in the context of a risk for febrile seizures and 2) clarification of the use of the grace period between doses of the measles, mumps, rubella, and varicella vaccine (MMRV).

Contraindications and Precautions

GRWG met monthly and focused on revisions to the Contraindications and Precautions section beginning in January 2012, over 6 meetings (January 2012, February 2012, June 2012, August 2012, November, 2012, December 2012, and January 2013; see www.cdc.gov/vaccines/acip/meetings/meetings-info.html). The evidence supporting this document is based on a review of the published literature. Publications about vaccination during surgery, hospitalization, and anesthesia were obtained from the databases PubMed and MDConsult, searched from 1973 to 2014 using the MeSH (medical subject headings) terms “anesthesia” and “immunization”. The search and selection of studies was limited to English-language and human studies. The search and selection process yielded 20 publications, including review articles, observational studies, and letters to the editor. Presentations of proposed best practices were made to ACIP in February 2013 and a vote from ACIP affirming the language below was made in October 2014. Major changes include 1) enhancement of the definition of a “precaution” to include any condition that might confuse diagnostic accuracy and 2) guidance to vaccinate during a hospitalization if a patient is not acutely moderately or severely ill.

Preventing and Managing Adverse Reactions

GRWG met monthly and focused on revisions to the Preventing and Managing Adverse Reactions section beginning in April 2013, following revision to the document by the Allergy Subgroup. Selected members from this subgroup participated in the April 2013 main work group call. GRWG then met again in May 2013. The evidence supporting this document is based on expert opinion and arrived at by consensus. Presentations of proposed guidance were made to ACIP in June 2013, and a vote from ACIP affirming the language below was made in October 2014. Major changes included 1) more descriptive characterization of anaphylactic allergy and 2) incorporation of protocols for managing adverse reactions. ACIP voted to accept the proposed statement in October 2014.

Vaccine Administration

An addition to the 2017 Vaccine Administration best practices was presented to ACIP on October 16, 2018, about health care provider exposure to vaccine components.

Storage and Handling of Immunobiologics

GRWG met in December 2013 to discuss Storage and Handling of Immunobiologics and met one additional time in January 2014. The evidence supporting this document is based on expert opinion and arrived at by consensus. A presentation of proposed language was made to ACIP in February 2014, and a vote from ACIP approving the language below was made in October 2014. Most of the 2011 language was removed because this content is now codified and continually updated in the CDC's Vaccine Storage and Handling Toolkit, available at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html. This content included Storage Units, Monitoring Storage Temperature, Vaccine Inventory, and Vaccine Transport.

Altered Immunocompetence

GRWG met twice in March and April 2014 to discuss best practices guidance for Altered Immunocompetence. This section incorporates general content from the Infectious Diseases Society of America (IDSA) policy statement *2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host (2)*, to which CDC provided input in November 2011. The evidence supporting this document is based on expert opinion and arrived at by consensus. ACIP voted to accept this proposed statement in June 2015.

Special Situations

GRWG met in April 2012 and then in 4 follow-up meetings in May, August, and November 2012, and January 2013. A focal point of discussion involved best practices guidance for intramuscular administration of persons with increased bleeding risk. Subject matter experts from the National Center for Birth Defects and Developmental Disabilities (NCBDDD) were invited to a work group meeting, and revisions to the guidance involving the timing of intramuscular administration were made in collaboration with these subject matter experts, primarily to ensure that ACIP's best practices guidance does not conflict with NCBDDD recommendations regarding the timing of clotting factor deficiency replacement. The evidence supporting this document is based on expert opinion and arrived at by consensus.

GRWG presented the Special Situations section to ACIP in February 2013. ACIP voted to accept the proposed statement in June 2015.

Vaccination Records

GRWG met in August and September 2013, and presented the vaccination records language to ACIP in October 2013. The evidence supporting this document is based on expert opinion and arrived at by consensus. ACIP voted to accept this proposed best practices guidance in June 2015.

Vaccination Programs

GRWG met in April 2014. The major revision to this section is the addition of language related to Affordable Care Act (3,4) coverage of adult vaccination. The evidence supporting this document is based on expert opinion and arrived at by consensus. GRWG presented this section to ACIP in June 2014. ACIP voted to accept this proposed statement in June 2015.

Vaccination Information Sources

GRWG met in September 2014 and presented this section to ACIP. The evidence supporting this document is based on expert opinion and arrived at by consensus. ACIP voted to accept this proposed statement in June 2015.

REFERENCES

1. Kroger AT, Sumaya CV, Pickering LK, Atkinson WL. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2011;1-60.
2. Rubin L, Levin M, Ljungman P, et al. 2013 IDSA clinical practice guideline for vaccination of the immunocompromised host. *Clin Infect Dis*. 2014;58(3):e44-100. DOI: 10.1093/cid/cit684
3. The Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010).
4. U.S. Department of Health and Human Services. Read the law: the Affordable Care Act, section by section. 2015; <https://www.hhs.gov/healthcare/about-the-law/read-the-law/index.html>. Accessed 9 March, 2017.