

ACIP Evidence-Based Recommendations Work Group Update

Wendy Carr, PhD
ACIP Evidence-Based Recommendations
Work Group Lead

Advisory Committee on Immunization Practices
October 20, 2016

Evidence-Based Recommendations Work Group Members

ACIP Members

Arthur Reingold (Chair)

Grace Lee

Paul Hunter

Liaison Representatives

AAP – Sean O’Leary

AAFP – Margot Savoy (temp)

ACP – Amir Qaseem

NACI – Nadine Sicard and Shainoor Ismail

FDA – Roshan Ramanathan

Previous ACIP members

Jon Temte

Doug Campos-Outcalt

Lorry Rubin

Consultants

US GRADE Network - Rebecca Morgan

SAGE - Charles Wiysonge and Philippe DuClos

Robert Koch Institute STIKO - Thomas Harder
and Gerhard Falkenhorst

Ned Calonge

David Weber

CDC Contributors

EBRWG Lead - Wendy Carr (NCIRD)

ACIP Work Group leads - Tamara Pilishvili and
Kathleen Dooling

Immunization Services Division - Carolyn
Bridges and Megan Lindley

Evidence-Based Recommendations Work Group Purpose

- ❑ To provide a forum for discussion of best practices for the evidence-based recommendation process, including development and use of evidence tables and an evidence to recommendation framework to ensure consistency and enhance transparency in the development of ACIP recommendations, with the goal of developing a uniform approach to evaluation and use of the evidence base for ACIP recommendations

Aims of the Work Group

- ❑ **To potentially modify and/or propose additional guidance for the ACIP evidence-based recommendation process, including GRADE and subsequent use of an evidence to recommendation framework; specifically:**
 - To identify areas for improvement and harmonization regarding development and use of GRADE evidence tables among ACIP work groups
 - To propose criteria that should be considered when determining whether GRADE evidence tables should be prepared for vaccine recommendations
 - To develop a more transparent process outlining the formulation of recommendations that defines methods for the incorporation of additional factors that contribute to decision-making as well as GRADE evidence tables generated by systematic review

Aim #1: Harmonize Development and Use of GRADE Tables

- ❑ **CDC Work Group leads presented to the Work Group regarding areas of success as well as challenges encountered during the use of GRADE for past recommendations**
- ❑ **The following were identified as areas that could benefit from additional guidance:**
 - Immunogenicity data
 - Rating up a body of evidence after having previously rated down
 - Incorporation of observational data
 - Evaluating burden of disease

Aim #1: Harmonize Development and Use of GRADE Tables

□ Next Steps:

- Develop draft Frequently Asked Questions (FAQ) documents to use as addenda/supplements to current GRADE handbook that will clarify how to address common questions concerning implementation of GRADE by ACIP Work Groups
- Incorporate feedback and present draft materials to ACIP
June 2017

Aim#2: Propose Criteria Outlining When to GRADE Evidence for Recommendations

- ❑ **Reference materials would be useful to ensure consistent determination of when GRADE tables should be developed in support of a recommendation**

- ❑ **Next steps:**
 - **Develop draft checklist, flowchart, or text for Work Groups to utilize when determining if preparation of GRADE tables is necessary for a particular recommendation under consideration**
 - **Incorporate feedback and present draft materials to ACIP**

June 2017

Aim #3: Evidence to Recommendation (EtR) Framework Development (part 1)

- ❑ **Providing additional structure and clarity for the full spectrum of criteria evaluated during formulation of recommendations will increase transparency**
 - Define methods for the incorporation of additional factors that contribute to decision-making as well as GRADE evidence tables
- ❑ **Evidence to Decision (EtD) or Evidence to Recommendation (EtR) framework**
 - The GRADE Working Group developed (EtD) frameworks to support the process of moving from evidence to decisions through the DECIDE project (<http://www.decide-collaboration.eu>)
 - GRADE is only one consideration during recommendation development and as such is only one element of an EtR framework
 - Framework presented as a table including key background information, criteria for making a decision, and conclusions

Aim #3: Evidence to Recommendation (EtR) Framework Development (part 2)

- ❑ **WHO Strategic Advisory Group of Experts on Immunization (SAGE) Secretariat members presented the EtR methodology currently used by SAGE to the Work Group**
 - **Example:**
http://www.who.int/immunization/policy/position_papers/dengue/en/
- ❑ **Initial feedback from the EBRWG concerning potential development of an ACIP EtR framework, using the DECIDE EtD table and SAGE EtR table (modified from DECIDE) as templates was very positive**
- ❑ **Each element of the framework will need to be defined/tailored to ACIP needs**

Aim #3: Evidence to Recommendation (EtR) Framework Development (part 3)

□ Next Steps:

- Develop draft framework highlighting changes from the SAGE EtR framework
- Solicit feedback from EBRWG and CDC WG leads
- Incorporate feedback and present draft materials to ACIP
February 2017

Timeline

- ❑ **NOV, DEC 2016 & JAN 2017:**
 - EBRWG meetings focused on specific elements of EtR framework
- ❑ **FEB 2017 ACIP meeting:**
 - Present draft EtR framework
- ❑ **MAR, APR, MAY 2017:**
 - Revise framework and further define elements
 - Develop and review proposals to address harmonization of GRADE usage and when to GRADE evidence
- ❑ **JUNE 2017 ACIP meeting:**
 - Present proposals to address key questions
- ❑ **OCT 2017 ACIP meeting:**
 - Present final proposals and vote on proposed modifications