

ACIP Evidence-Based Recommendations Work Group Update

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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 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 Evidence Tables

□ 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

□ Next Steps:

- Develop draft Frequently Asked Questions (FAQ) documents to supplement current GRADE handbook that will clarify how to address common questions concerning implementation of GRADE by ACIP Work Groups

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
- ❑ A draft algorithm has been developed for Work Groups to utilize when determining whether preparation of GRADE evidence tables is advisable
- ❑ **Next steps:**
 - Pilot the draft algorithm and revise as needed

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>)
 - 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**
- ❑ **A draft EtR framework with each element of the framework tailored to ACIP needs has been developed and is currently being piloted**

Draft EtR Framework Criteria

□ Statement of Problem

- Public health priority
- Burden of disease

□ Benefits and Harms

- Balance of desirable and undesirable effects
- Certainty in evidence (evidence profiles)

□ Values and Preferences of target population

□ Acceptability to stakeholders

□ Resource Use

- Health Economic Analyses

□ Feasibility

- Implementation considerations

Type of Recommendation

- ❑ **Draft includes 4 types of recommendation**
 - “We recommend against the Intervention”
 - “We recommend that the intervention not be routinely recommended for all persons but be available for individual clinical decision-making”
 - “We recommend the intervention”
 - “We do not recommend the intervention at this time”
- ❑ **These types of recommendation will replace former “Category A” and “Category B” labeling of recommendations**

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

□ Next Steps:

- Further clarify how to implement the framework consistently and transparently
- Incorporate feedback and present draft materials to ACIP **February 2018**

Timeline

- ❑ **NOV, DEC 2017; JAN, FEB 2018:**
 - EBRWG meetings focused on refining specific elements of EtR framework and guidance information
- ❑ **FEB 2018 ACIP meeting:**
 - Present draft EtR framework
- ❑ **MAR, APR, MAY 2019:**
 - EBRWG meetings focused on refining guidance on development and use of GRADE evidence tables
- ❑ **JUN 2018 ACIP meeting:**
 - Present final proposals and vote on proposed modifications

Evidence-Based Recommendations Work Group Members

ACIP Members

Arthur Reingold (Chair)

Grace Lee

Paul Hunter

Liaison Representatives

AAP – Sean O’Leary

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