"This committee strongly supports the use of vaccines, and other countermeasures, predicated on evidence-based medicine, including rigorous evaluation and expansive, credible scientific data, for both safety and efficacy."

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# The Evidence-Based Process for Vaccine Policymaking.

The EtR process is designed to ensure a **transparent and public** deliberation. The following represents the standard evidence to recommendations process (EtR) for vaccine policymaking compared to the process used during the thimerosal flu vote during the June 2025 ACIP meeting.

STANDARD EtR POLICY PROCESS THIMEROSAL FLU POLICY PROCESS	
Work Group forms and the Terms of Reference are decided	NO
Work Group develops policy (PICO*) questions	NO
ACIP reviews all available data and concurrence with PICO* questions	NO
Work Group develops Evidence to Recommendations (EtR) for PICO* questions and proposed recommendation language	NO
ACIP preliminary review of EtR and proposed recommendation	NO
Work Group interpretation of the EtR and proposes language for recommendation	NO
ACIP reviews and discusses final EtR	NO
ACIP votes on proposed recommendation language	YES

<sup>\*</sup> Population, Intervention, Comparator, Outcomes

# Overview of Established Evidence to Recommendations (EtR) Process

# The Advisory Committee on Immunization Practices (ACIP)

#### The What

A group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States.

#### The Who

Up to 19 expert voting members, including a consumer representative, who are responsible for making vaccine recommendations.

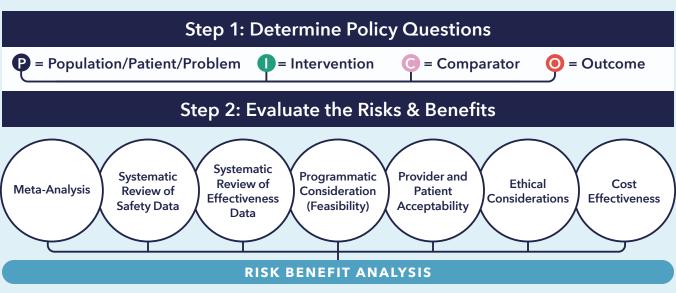
30 non-voting representatives from professional organizations who offer the perspectives of groups that will implement the recommendations.

#### The How

3 ACIP meetings a year open to the public and webcast under normal circumstances.

Work Groups led by an ACIP member supported by the CDC formed to develop and update recommendations following GRADE and Evidence to Recommendations (EtR) process.

# **Evidence to Recommendation Process (EtR)**



#### **Step 3: Provide a Recommendation**

Do not recommend the intervention

We recommend the intervention for individuals for shared clinical decision-making

We recommend the intervention

# **Hypothetical Policy (PICO\*) Questions for Thimerosal**

Population	All individuals 6 month of age or older
Intervention	Thimerosal free influenza vaccine
Comparator	Thimerosal containing influenza vaccine
Outcomes	Prevention of influenza (effectiveness)  Cumulative mercury risk level  Autism

<sup>\*</sup> Population, Intervention, Comparator, Outcomes

# **Example: WG Interpretation of EtR**

## **Balance of Risk and Benefits**

Undesirable risks **CLEARLY** outweigh desirable benefits in most settings

Undesirable risks **PROBABLY** outweigh desirable benefits in most settings

The balance between desirable benefits and undesirable risks is CLOSELY balanced or uncertain

Desirable benefits PROBABLY outweigh undesirable risks in most settings

Desirable benefits **CLEARLY** outweigh undesirable risks in most settings

Insufficient evidence to determine the balance of risk and benefits

## Type of Recommendation

- We recommend the intervention
- We recommend the intervention for individuals based on shared clinical decision-making
- We do not recommend the intervention