

**Immunization Safety Review Committee
Institute of Medicine
Charge to the Committee**

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Benefits of Vaccines

- **Smallpox eradicated**
 - In 1900 - >20,000 cases and 1,000 deaths
- **Polio eliminated**
- **Control or near elimination of**
 - Measles
 - Mumps
 - Rubella
 - Tetanus
 - Diphtheria
 - Pertussis
 - Haemophilus influenzae type b (Hib)

Reasons for Increasing Vaccine Safety Concerns

- No vaccine is perfectly safe
- Temporal association with serious illnesses
 - Coincidental or causal
- High vaccine coverage
 - Benefits of vaccines not as obvious

Vaccine Safety Hypotheses

- Number of hypotheses linking vaccines to adverse events increasing
- Broader range of medical conditions
- Often limited scientific data
- Definitive, but divergent opinions lead to a polarized climate

The Challenge Re: Vaccine Safety Hypotheses

- **Evaluation – rapid, credible, expert**
- **Causality determination - likelihood based on totality of evidence and scientific information**
- **Prioritization – follow-up based on several factors**
- **Response - appropriate for each hypothesis**

End Products from the Committee

- **Plausibility assessment about causal role of vaccines, with likelihood rating**
- **Categorization of appropriate level of public health concern**
- **Set of comments about potential future activities**

Product 1: Plausibility Assessment

- If evidence is adequate, make definitive judgment about causality
- If evidence is limited,
 - Evaluate biologic plausibility
 - Evaluate strength of evidence for competing causes
 - Perform synthesis of evidence and scientific information
 - Formulate a likelihood rating or give a probability judgment

Product 2: Appropriate Level of Public Health Concern

- **Plausibility Assessment/likelihood rating**
- **Significance Assessment**
 - Number of persons potentially affected
 - Seriousness of health concern or condition
 - Other
- **Categorization of the appropriate level of public health concern (very low – very high)**

Product 3: Comments on Potential Future Activities

- Research**
- Surveillance**
- Communications**
- Policy review**

Guidance Regarding the Appropriate Public Health Response

- Plausibility assessment with likelihood rating
- Categorization of appropriate level of public health concern
- Set of comments on potential future activities

The Committee is NOT Being Asked to:

- Make public health policy
- Set agency agendas for research, surveillance, communication, or policy
- Make overly general or overly specific comments

Uniqueness of this Committee

- Standing committee – meet 3-4 times per year
- Issue timely, brief and focused reports
 - Within 60 to 90 days of meeting
- Perform more explicit assessment of causality
- Provide appropriate level of public health concern
- Comment on a broader scope of potential public health responses
- IOM more proactive in the dissemination of information to lay and professional audiences

Vaccine Safety Challenges 1997-2000

