



IOM Report on Adverse Effects of Vaccines: What's Next?

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History:

The National Childhood Vaccine Injury Act of 1986 and the Institute of Medicine Studies

- Original Congressional enactment included a Vaccine Injury Table that provides a legal presumption of causation.
- Congress required scientific analysis of vaccine-associated adverse events (sections 312 and 313 of the National Childhood Vaccine Injury Act of 1986).
- Mandated Institute of Medicine (IOM) review, and expected that the IOM findings would be considered for possible incorporation into the Vaccine Injury Table by the Secretary, in consultation with Advisory Commission on Childhood Vaccines (ACCV).



“Section 312” IOM Report

- Vaccines covered:
 - Pertussis (DTP)
 - Rubella
- Report published in 1991
- Notice of proposed rulemaking (NPRM) published in August 1992
- Final rule published in February 1995



“Section 313” IOM Report

- Vaccines Covered:
 - Measles, Mumps
 - Diphtheria, Tetanus
 - Hepatitis B
 - Hib
 - Polio
- Report published in 1994
- NPRM published in November 1995
- Final rule published in February 1997



Adverse Effects of Vaccines

Evidence and Causality

IOM Report, 2011

- Updates to the Vaccine Injury Table long overdue (science >10 years old)
- Contract with IOM for a new report focused on 8 vaccines, 5 of which had not been previously reviewed
- Funded by HRSA, CDC and National Vaccine Program Office
 - Shared responsibility for vaccine injury compensation and vaccine safety



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- Scope of work required IOM to focus on biological mechanisms of injuries as well as the weight of the evidence on causation.
- Mechanisms information should be useful for all parties, including special masters.



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Evidence and Causality

IOM Report, 2011

- Process:
 - Internal HHS review of report
 - Internal initial recommendations regarding modifications to the Vaccine Injury Table
 - ACCV Guiding Principles
 - Internal initial recommendations regarding modifications to the Qualifications and Aids to Interpretation

GUIDING PRINCIPLES FOR RECOMMENDING CHANGES TO THE VACCINE INJURY TABLE

When recommending changes to the Vaccine Injury Table ("the Table"), members of the Advisory Commission on Childhood Vaccines (ACCV) shall utilize the following overarching guiding principles:

- The Table should be scientifically and medically credible; and
- Where there is credible scientific and medical evidence both to support and to reject a proposed change (addition or deletion) to the Table, the change should, whenever possible, be made to the benefit of petitioners.

Recognizing that it would be virtually impossible to agree upon a precise definition of scientific and medical credibility, the ACCV adopts the following additional guiding principles in furtherance of the above overarching principles:

- To the extent that the Institute of Medicine ("IOM") has studied the possible association between a vaccine and an adverse effect, the conclusions of the IOM should be considered by the ACCV and deemed credible but those conclusions should not limit the deliberations of the ACCV.
- To the extent there are data sources other than an IOM report, ACCV members should make an effort to assess the relative strength of those data sources. When making such assessments, ACCV members should acknowledge that differing sources of data should be afforded different weight and should do so by adopting the following hierarchy (listed from strongest to weakest sources of data):
 - Clinical laboratory data (such as PCR confirmation of vaccine strain virus following immunization against varicella)
 - Challenge/re-challenge/de-challenge data involving non-relapsing symptoms or diseases (particularly when documented in multiple individuals)
 - Controlled clinical trials (including, but not limited to, double-blind, placebo controlled clinical trials)
 - Controlled observational studies such as cohort and case control studies, including but not limited to studies based upon data from the Vaccine Safety Datalink (VSD) database
 - Uncontrolled observational studies such as ecological studies
 - Case series
 - Data from passive surveillance systems, including but not limited to the Vaccine Adverse Event Reporting System
 - Case reports
 - Editorial articles on scientific presentations
 - Non-peer reviewed publications

However, ACCV members should also consider additional factors that may affect the relative weight of a particular source of evidence, including, but not limited to:

- Particular methodological limitations associated with a study or source of evidence
- Potential bias associated with the conduct of a particular study or source of evidence, including analytic bias or bias resulting from potential conflicts of interest among the investigators
- Potential confounding factors that may have impacted the results of a particular study
- Biologic coherence, including whether there is a scientifically viable mechanism by which the vaccine could be associated with the particular adverse event under consideration (e.g., does it make sense to extrapolate the results of studies examining the health effects of wild type virus to a vaccine that is not a live attenuated viral vaccine?)
- Where appropriate, ACCV members should request assistance from members of the Health Resources and Services Administration, Division of Vaccine Injury Compensation or others associated with the Program in assessing the relative strength of the sources of evidence.
- In the absence of an IOM report or study considered to be definitive, ACCV members should assess not only the relative strength of the evidence but also the consistency of the evidence supporting the proposed change to the Table. Consistency across multiple sources of evidence generally should be considered an indication of credibility.
- When considering proposed changes to the Table, ACCV members should also remain cognizant of the important policy considerations underlying the Table. In an effort to give maximum effect to those policy considerations, where there is a split in credible scientific evidence supporting a proposed change to the Table:
 - In those instances where an Omnibus Proceeding under the VICP has addressed the particular injury under consideration, members of the ACCV should consider the causation finding(s) of the Special Master who presided over the Omnibus Proceeding but the finding(s) of the Special Master should not limit the deliberations of the ACCV; and
 - ACCV members should tend toward adding or retaining the proposed injury(ies).



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- Consultations:
 - Immunization Safety Task Force
 - ACCV
- Notice of Proposed Rulemaking
 - Statute requires:
 - At least 180 days of public comment
 - Public hearing
- Final rule

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- Effect of revisions
 - All changes are prospective.
 - If revisions would permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, even if an earlier petition had been filed, such person may file a claim no later than 2 years after the effective date of the revision (with an 8-year look back).



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