Overview of Proposed Changes to the Vaccine Injury Table
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HRSA Healthcare Systems

Overview

- Process of Changing the Vaccine Injury Table (VIT)
- Institute of Medicine (IOM) Report
- Proposed Changes to VIT
- Questions

Vaccine Injury Table

- Lists specific injuries and the time frames in which they must occur
- Legal mechanism for defining complex medical conditions
- Allows legal “presumption of causation”
- Provides compensation unless alternative cause unrelated to vaccine is found
- Individuals without a table injury may still file a claim

Vaccine Injury Table

To qualify as a Table injury, petitioner must demonstrate that:

- They received a vaccine set forth in the Table
- They sustained, or had significantly aggravated, any illness, disability, injury or condition set forth in the Table in association with the vaccine received, or died from the administration of the vaccine
- The first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Table and no alternative cause is found
- The condition also must meet the definition included by HHS in regulations found in the Qualifications and Aids to Interpretation or QAI, which are referenced later

Vaccine Injury Table Revisions

- **The Secretary of HHS may modify the Table by promulgating regulations after consulting with the Advisory Commission on Childhood Vaccines (ACCV).**
- **Modifications may include:**
  - Addition or deletion of vaccines to the Table
  - Addition to or deletion from the list of injuries, disabilities, illnesses, conditions, and deaths on the Table, affording a presumption of causation
  - Changing time periods for the first symptom or manifestation of the onset or the significant aggravation of any Table injury or death
  - Addition to, deletion from, or change to the definition of injuries or conditions listed in the QAI

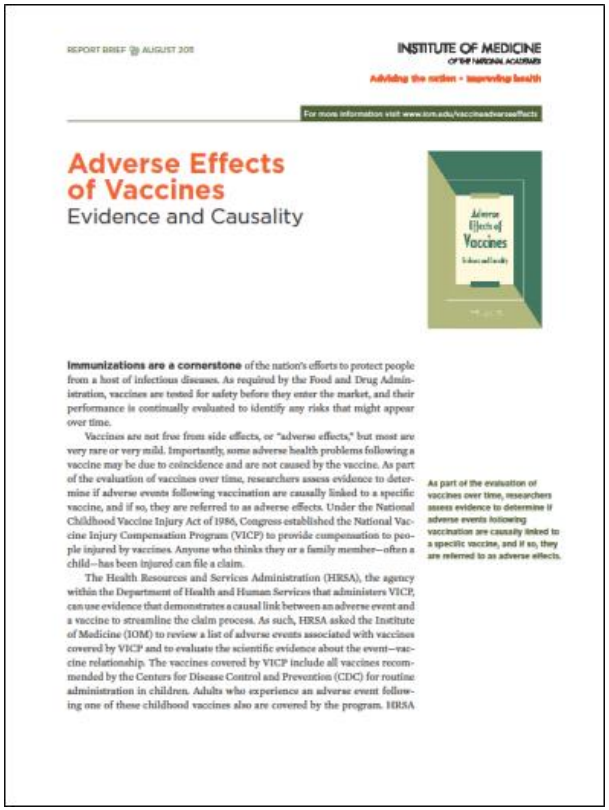
Vaccine Injury Table Revisions

- The Table revisions apply to petitions filed after the effective date of the regulation.
- The statute of limitations set forth in the Vaccine Act still applies, with one exception.
- A person who may be eligible to file a petition based on the revised Table may file a petition if the injury or death occurred not more than 8 years prior to the table revision.
- Such petitions must be filed within 2 years of the effective date of the regulation.

IOM Vaccine - AE Review

- Congress created the original Table in 1986 as a mechanism allowing a legal presumption of causation for certain vaccines and conditions.
- Congress called for Institute of Medicine (IOM) reviews of the scientific and medical literature on vaccine adverse events in 1991 and 1994, and for the Secretary of HHS to modify the Table once these findings were made available.
- Previous IOM reports on vaccines and adverse events in 1991 and 1994 led to rulemaking changes in 1995 and 1997.
- Since the 1997 revisions to the Table, 9 vaccines had been added to the Table without any IOM reviews of the adverse events associated with the use of these vaccines.

IOM Report



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For more information visit www.iom.edu/vaccineadverseeffects

Adverse Effects of Vaccines
Evidence and Causality

Immunizations are a cornerstone of the nation's efforts to protect people from a host of infectious diseases. As required by the Food and Drug Administration, vaccines are tested for safety before they enter the market, and their performance is continually evaluated to identify any risks that might appear over time.

Vaccines are not free from side effects, or "adverse effects," but most are very rare or very mild. Importantly, some adverse health problems following a vaccine may be due to coincidence and are not caused by the vaccine. As part of the evaluation of vaccines over time, researchers assess evidence to determine if adverse events following vaccination are causally linked to a specific vaccine, and if so, they are referred to as adverse effects. Under the National Childhood Vaccine Injury Act of 1986, Congress established the National Vaccine Injury Compensation Program (VICP) to provide compensation to people injured by vaccines. Anyone who thinks they or a family member—often a child—has been injured can file a claim.

The Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services that administers VICP, can use evidence that demonstrates a causal link between an adverse event and a vaccine to streamline the claim process. As such, HRSA asked the Institute of Medicine (IOM) to review a list of adverse events associated with vaccines covered by VICP and to evaluate the scientific evidence about the event—vaccine relationship. The vaccines covered by VICP include all vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration in children. Adults who experience an adverse event following one of these childhood vaccines also are covered by the program. HRSA

As part of the evaluation of vaccines over time, researchers assess evidence to determine if adverse events following vaccination are causally linked to a specific vaccine, and if so, they are referred to as adverse effects.

http://www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx

IOM Committee Review Methods

- **Two types of evidence were used**
  - Epidemiologic evidence from studies of populations
  - Mechanistic evidence derived primarily from biological and clinical studies in animals and humans
- **For weight of evidence, IOM used a summary classification scheme that incorporated both the quality and quantity of the individual studies**

IOM Committee Review Methods

- **For each vaccine-adverse event relationship, IOM made 3 assessments**
  1. Weight-of-Epidemiologic Evidence (4 levels = high, moderate, limited, and insufficient).
  2. Weight-of-Mechanistic Evidence (4 levels = strong, intermediate, weak, and lacking).
  3. Causality Assessment: overall assessment made from position of *neutrality* and moved from neutral position only when the combination of epidemiologic and mechanistic evidence suggested a more definitive assessment regarding causation.

- **Four categories of causation evidence**
  1. Convincingly supports a causal relationship
  2. Favors acceptance of a causal relationship
  3. Inadequate to accept or reject a causal relationship
  4. Favors rejection of a causal relationship

Summary of Causality Conclusions

- **Convincingly supports a causal relationship (14 AE/vaccine relationships)**
  - Varicella (VZV) Vaccine
    - Disseminated VZV without other organ involvement
    - Disseminated VZV with subsequent infection resulting in pneumonia, meningitis, or hepatitis
    - Vaccine strain viral reactivation without other organ involvement,
    - Vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis
  - MMR vaccine
    - Measles inclusion body encephalitis
    - Febrile seizures
  - MMR, varicella, influenza, hepatitis B, tetanus-containing, and meningococcal vaccines
    - Anaphylaxis
  - Injection-related (potential for any vaccine intended for intramuscular administration in upper arm)
    - Syncope
    - Deltoid bursitis (what HRSA has termed Shoulder Injury Related to Vaccine Administration or SIRVA)

Summary of Causality Conclusions

- **Favors acceptance of a causal relationship (4 AE/vaccine relationships)**
  - HPV and anaphylaxis
  - MMR and transient arthralgia in female adults
  - MMR and transient arthralgia in children
  - Certain trivalent inactivated influenza vaccines used in Canada and oculorespiratory syndrome

Summary of Causality Conclusions

- **Inadequate to accept or reject a causal relationship (135 AE/vaccine relationships – 85% of all relationships)**
  - IOM states that "… inadequate to accept or reject …" means just that – inadequate
  - Found in the vast majority of IOM conclusions on causality
  - Included vaccines and demyelinating diseases; one of the most common categories of alleged injuries currently being filed with the VICP

Summary of Causality Conclusions

- **Favors rejection of a causal relationship (5 AE and vaccine relationships)**
  - MMR vaccine and type 1 diabetes
  - DTaP vaccine and type 1 diabetes
  - MMR vaccine and autism
  - Trivalent inactivated influenza vaccine (TIV) and asthma/reactive airway disease episodes
  - TIV and Bell's palsy

Modifying the Table

- 9 workgroups including medical staff from HRSA and the Centers for Disease and Prevention (CDC) reviewed the IOM conclusions
- Proposed changes were presented to the Advisory Commission on Childhood Vaccines (ACCV) in 2012, 2013 and 2014
- For each proposed change the ACCV voted to concur, not to concur, or to defer a recommendation
- The ACCV concurred with all the changes

ACCV Guiding Principles

- In 2006, the ACCV developed "Guiding Principles" for recommending revisions to the Table.
- Scientific and medical credibility should support changes, or rejection of proposed changes to the Table.
- Where there is credible scientific and medical evidence both to support and to reject a proposed change to the Table, the change should, whenever possible, be made to the benefit of petitioners

IOM Findings That Result in Additions or Changes to the Table

- **The scientific evidence convincingly supports a causal relationship**
  - Measles-mumps-rubella (MMR) vaccine and measles inclusion body encephalitis.
  - Varicella vaccine and vaccine disseminated varicella infection (widespread chickenpox rash shortly after vaccination)
  - Varicella vaccine and disseminated varicella infection with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies
  - Varicella vaccine and vaccine strain viral reactivation/with subsequent infection resulting in meningitis or encephalitis.
  - Varicella vaccine, influenza vaccine, meningococcal vaccine and anaphylaxis
  - Injection-related deltoid bursitis. For reasons detailed below, the Secretary proposed adding a more expansive injury of Shoulder Injury Related to Vaccine Administration (SIRVA) to the Table
  - Injection-related syncope

IOM Findings That Result in Additions or Changes to the Table

- **The scientific evidence favors acceptance:**
  - human papillomavirus vaccines and anaphylaxis
- **The scientific evidence is inadequate to accept or reject a causal relationship:**
  - Seasonal influenza vaccines and GBS

IOM Findings That Do Not Result in Changes to the Table Because the Injury Is Already on the Table

- **The scientific evidence convincingly supports a causal relationship**
  - MMR vaccine, Hepatitis B vaccine, Tetanus toxoid vaccine and anaphylaxis

- **The scientific evidence is inadequate to accept or reject a causal relationship:**
  - Tetanus toxoid-containing vaccines (including those containing the acellular pertussis component but not the whole cell pertussis component) and encephalopathy and encephalitis
  - MMR vaccine and chronic arthritis in women and children
  - MMR vaccine and encephalopathy or encephalitis

Findings That Do Not Result in Changes to the Table Because the Injury Is Transient in Nature

- **The scientific evidence convincingly supports a causal relationship**
  - MMR vaccine and febrile seizures
- **The scientific evidence favors acceptance of a causal relationship**
  - MMR vaccine and transient arthralgia in women and children

Proposed Changes to the VIT

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis	≤4 hours
	B. Brachial Neuritis ~~Any acute complication or sequela, including death, of the illness, disability, injury, or condition listed~~	2-28 days (not less than 2 days and not more than 28 days)
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis	≤4 hours
	B. Encephalopathy or encephalitis	≤72 hours
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour

Proposed Changes to the VIT

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
III. Vaccines containing measles, mumps, and rubella virus or any of its components (e.g., MMR, MM, MMRV)	A. Anaphylaxis	≤4 hours
	B. Encephalopathy or encephalitis	5-15 days (not less than 5 days and not more than 15 days)
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour
IV. Vaccines containing rubella virus (e.g., MMR, MMRV)	A. Chronic arthritis	7-42 days (not less than 7 days and not more than 42 days)
V. Vaccines containing measles virus (e.g., MMR, MM, MMRV)	A. Thrombocytopenic purpura	7-30 days (not less than 7 days and not more than 30 days)
	B. Vaccine-Strain Measles Viral Disease ~~infection~~ in an immunodeficient recipient --Vaccine-strain virus identified --If strain determination is not done or if laboratory testing is inconclusive	Not applicable ≤12 months

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Proposed Changes to the VIT

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
VIII. Hepatitis B vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
IX. Haemophilus influenzae type b (Hib) ~~conjugate~~ vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1 hour

Proposed Changes to the VIT

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
X. Varicella vaccines	A. Anaphylaxis	≤4 hours
	B. Disseminated varicella vaccine-strain viral disease	
	--Vaccine-strain virus identified	Not applicable
	--If strain determination is not done or if laboratory testing is inconclusive	7-42 days (not less than 7 days and not more than 42 days)
	C. Varicella vaccine-strain viral reactivation	Not applicable
	D. Shoulder Injury Related to Vaccine Administration	≤48 hours
	E. Vasovagal syncope	≤1 hour
XI. Rotavirus vaccines	A. Intussusception	1-21 days (not less than 1 day and not more than 21 days)
XII. Pneumococcal conjugate vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1 hour
XIII. Hepatitis A vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1 hour

Proposed Changes to the VIT

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
XIV. Seasonal ~~Trivalent~~ influenza vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
	D. Guillain-Barre Syndrome	3-42 days (not less than 3 days and not more than 42 days)
XV. Meningococcal vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
XVI. Human papillomavirus (HPV) vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage.	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1hour

Proposed Changes to the Qualifications and Aids to Interpretation (QAI)

- **Organizational changes to streamline and harmonize the QAI**
  - Revisions to make the QAI more concise
  - Addition of a newly added glossary that defines terms used in multiple places in the QAI (Chronic encephalopathy, significantly decreased level of consciousness, injected, and seizure)
- **Expansion**
  - Addition of definitions for new Table injuries, including SIRVA, disseminated varicella-strain virus disease, varicella vaccine-strain viral reactivation disease, GBS, and vasovagal syncope
- **Harmonization**
  - Definitions, such as acute encephalopathy and acute encephalitis, have been harmonized
  - Definitions for brachial neuritis and SIRVA have also been harmonized

Injuries added to VIT – Guillain-Barré Syndrome (GBS)

- GBS is a rare acute paralysis caused by dysfunction in the peripheral nervous system (the nervous system outside the brain and spinal cord) that may manifest with weakness, abnormal sensations, and/or abnormalities in the autonomic (involuntary) nervous system
- The IOM found the scientific evidence is inadequate to accept or reject a causal relationship between seasonal influenza vaccines and GBS
- However, scientific evidence demonstrates a small increased risk of GBS in the 6 weeks following administration of the monovalent 2009 H1N1 vaccines
- Although the scientific evidence does not show a causal association for current formulations of seasonal flu vaccines and GBS, the Secretary proposes including the injury of GBS for seasonal influenza vaccines on the Table in accordance with the ACCV Guiding Principles

Injuries added to the Table - SIRVA

- Shoulder Injury Related to Vaccine Administration is thought to result from the unintentional injection of a vaccine into tissues and structures lying underneath the deltoid muscle of the shoulder.
- The IOM reviewed the scientific and medical literature finding that the evidence convincingly supported a causal relationship between vaccine administration and deltoid bursitis.
- Atanasoff et al. published a case series reporting the experience of the Vaccine Injury Compensation Program with regard to shoulder injuries following vaccination. The IOM reviewed this article and commented that the cases were consistent with deltoid bursitis.

Timeline for modifying the VIT

- ACCV consulted on proposed changes to the Table.
- July 29, 2015 - The Notice for Proposed Rulemaking (NPRM) was published in the Federal Register for public comment.
- January 14, 2016 - A hearing to obtain comments from the public on the proposed changes to the Vaccine Injury Table was held
- January 25, 2016 – Public comment period concluded after 180 days.
- Public comments are currently being reviewed to develop a final rule to be published in the Federal Register.

Acknowledgements

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