2011 Institute of Medicine (IOM) Report generated - Proposals for Updates to the Vaccine Injury Table (VIT)

Anaphylaxis
Presented on behalf of the following VITU Vaccine Working Groups: Influenza, Meningococcal, Varicella, Human papilloma virus

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Vaccines to discuss the proposal for adding anaphylaxis as an injury to the Table:

1) Trivalent Influenza Vaccine
2) Meningococcal Vaccine
3) Varicella Vaccine
4) Human Papilloma Virus Vaccine
Summary Justification for Proposed Changes to the VIT

There are multiple, well documented, reports in the literature as well as reports of related laboratory and clinical evidence to support that anaphylaxis occurs after receipt of the trivalent influenza vaccines. Based on these reports the 2011 IOM committee found that the evidence convincingly supports a causal relationship between trivalent influenza vaccine and anaphylaxis. The IOM’s conclusion regarding the causal relationship between trivalent influenza vaccines and anaphylaxis was felt to be scientifically and medically credible.
Listing of Relevant Literature


Trivalent influenza – Anaphylaxis

Listing of Relevant Literature (cont.)


Summary Justification for Proposed Changes to the VIT

In 2011 the Institute of Medicine, following an extensive review of the scientific and medical literature, concluded that the evidence convincingly supported a causal relationship between meningococcal vaccines and anaphylaxis. The IOM’s conclusion regarding the causal relationship between meningococcal vaccines and anaphylaxis was felt to be scientifically and medically credible.
Listing of relevant literature

Summary Justification for Proposed Changes to the VIT

There are multiple, well documented, reports in the literature that anaphylaxis occurs after receipt of the varicella vaccines. Based on these reports the 2011 IOM committee found that the evidence convincingly supports a causal relationship between varicella vaccine and anaphylaxis. The IOM’s conclusion regarding the causal relationship between varicella vaccines and anaphylaxis was felt to be scientifically and medically credible.
Listing of relevant literature


Summary Justification for Proposed Changes to the VIT

There are multiple, well documented, cases in the literature of anaphylaxis occurring following receipt of the HPV vaccines. Based on these reports the 2011 IOM committee found that the evidence convincingly supports a causal relationship between HPV vaccine and anaphylaxis. The IOM’s conclusion regarding the causal relationship between HPV vaccines and anaphylaxis was felt to be scientifically and medically credible.
Listing of relevant literature


Current Table injuries and QAI:

There are currently no injuries on the Table for trivalent influenza, HPV, meningococcal or varicella vaccines.
## Anaphylaxis

### Proposed VIT for trivalent influenza, HPV, meningococcal and varicella vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Injury</th>
<th>Time Interval</th>
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<tbody>
<tr>
<td>Trivalent influenza vaccines</td>
<td>A. Anaphylaxis</td>
<td>≤ 4 hours</td>
</tr>
<tr>
<td></td>
<td>B. Any acute complication or sequela (including death) of above event</td>
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<td>Human papillomavirus (HPV) vaccines</td>
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Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.
Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.
Justification for proposed QAI

- “Anaphylactic Shock” to be removed because it is a condition included in the overall syndrome known as “Anaphylaxis”
- The word “allergic” to be removed from the current definition because it would exclude anaphylactoid reactions (nonallergic anaphylaxis). These reactions are a subtype of anaphylaxis and could possibly occur secondary to vaccination but are not considered “allergic”. “Anaphylaxis” includes anaphylactoid reactions.
- The wording regarding pathology findings is simplified in the proposed version since there are no specific autopsy findings for anaphylaxis.
## Anaphylaxis

Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.

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