Updating the Vaccine Injury Table following the 2011 IOM Report on Adverse Effects of Vaccines

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Advisory Commission on Childhood Vaccines, March 8, 2012

Objective: To seek advice and concurrence on the proposed changes to the NVICP's Vaccine Injury Table (VIT)

1) History and Overview
   - Reason for IOM Review on Vaccine Adverse Events (AE)
   - IOM Vaccine-AE Review History
   - IOM Committee Review Methods, Causality Framework, and Causality Conclusions
   - Preparation sequence: Proposals to update VIT and it's Qualifications & Aids to Interpretation (QAI)
   - Acknowledgements of the working group members of the HRSA/CDC Public Health Task Force

2) Legal and Policy implications in updating the VIT

3) Translation of IOM's causality conclusions to VIT Updates
   - Varicella Vaccine AE Additions (Dr. Catherine Shaer)
   - MMR Vaccine AE Additions (Dr. Mary Rubin)
   - Injection-Related AE Additions to multiple vaccines (Dr. Tom Ryan)
   - Anaphylaxis Additions to multiple vaccines (Dr. Sarah Atanasoff)
   - Additional proposals to change/add to the Aids to Interpretation (Dr. Stacy Stryer)
   - Additional items from Working Group deliberations (Dr. Tom Shimabukuro)

4) Next Steps and Project Timeline (Estimated)

IOM Vaccine - AE Review

- **Purpose**: Review the current medical and scientific evidence on vaccines and AEs in order to update the National Vaccine Injury Compensation Program's Vaccine Injury Table (VIT) and the Qualifications & Aids to Interpretation (QAI), thus providing provide the scientific basis for future review/adjudication of VICP claims.
- Congress created the original VIT in 1986 as a compromise mechanism allowing a legal presumption of causation for certain vaccines and conditions.
- Due to uncertainties over what injuries are vaccine-related, Congress called for IOM reviews of the scientific and medical literature on vaccine adverse events, and for the Secretary of HHS to modify the VIT 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 last revision to the VIT in 1997, there have been 9 vaccines added to the program without any expert reviews or independent examination of the adverse events associated with the use of these vaccines.

History behind 2011 IOM Report

- Contract initiation September 2008; IOM Committee (15 members) convened.
- Charge to Committee April 2009: Independent review of the current epidemiological, clinical, and biologic literature (started with 4 vaccines).
  - Framework for categorizing the evidence of causality
  - Describe the strength of evidence regarding biological mechanisms underlying theories when evidence is not enough for causal conclusions
  - Develop a report on the evidence regarding AEs associated with vaccines
- Supplemental funding (all within HHS) through VICP/HRSA, NVPO/HHS and ISO/CDC in September 2009 allowed the addition of 4 more vaccines for review.
- Committee reviewed a total of 8 vaccines, constituting 12 of 16 vaccine antigen combinations found in 92% of VICP claims: Hep A, Hep B, human papillomavirus, influenza, meningococcal, MMR, tetanus-containing, and varicella.

Current Vaccines Listed in VIT

Last IOM-based revisions to the VIT-QAI was 1997 and covered the following vaccines

- Diphtheria, tetanus, pertussis (DTP, DTaP, DT, TT, or Td)
- Measles, mumps, rubella (MMR or any components)
- Polio (OPV or IPV)

Nine vaccines added to the VIT since last IOM review

- Hepatitis B vaccine
- *Haemophilus influenza* type b (Hib) vaccine
- Varicella virus vaccine
- Rotavirus vaccine
- Pneumococcal conjugate vaccine
- Hepatitis A vaccine
- Trivalent influenza vaccine
- Meningococcal vaccine
- Human papillomavirus vaccine

- Final report publically released 8/25/11
- Dr. Ellen Clayton (Committee Chair) briefed ACCV (9/1/11) and the National Vaccine Advisory Committee (9/13/11).

REPORT BRIEF AUGUST 2011

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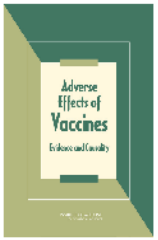
For more information visit www.iom.edu/vaccineadverseeffects

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

There were no recommendations, only findings

Adverse Events Reviewed

- Working list of adverse events was generated by HRSA's Division of Vaccine Injury Compensation (DVIC) medical staff based on the alleged injury petitions to VICP and current science with input from Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) staff through the Health and Human Services Interagency working group.

- Public input sought through ACCV and the IOM project website. Working list was first posted on December 2009.

COMMITTEE TO REVIEW ADVERSE EFFECTS OF VACCINES
DECEMBER 2009 WORKING LIST OF ADVERSE EVENTS TO BE CONSIDERED BY THE COMMITTEE

DTaP/Tetanus Containing Vaccines	Hepatitis A Vaccine	Meningococcal Vaccine	MMR Vaccine
• Anaphylaxis or Anaphylactic Shock	• Anaphylaxis or Anaphylactic Shock	• Anaphylaxis or Anaphylactic Shock	• Anaphylaxis or Anaphylactic Shock
• Arthropathy (Arthritis, Arthralgia)			• Arthropathy (Arthritis, Arthralgia)
• Autism*			• Autism*
• Autism Spectrum Disorders (ASD)/Pervasive Developmental Disorders (PDD)*			• Autism Spectrum Disorders (ASD)/Pervasive Developmental Disorders (PDD)*
• Ataxia			• Ataxia
• Bell's Palsy	• Bell's Palsy		
			• Brachial Neuritis
			• Chronic Fatigue Syndrome
		• Chronic Headaches	
• Chronic, Remitting Demyelinating Diseases: ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis	• Chronic, Remitting Demyelinating Diseases: ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis	• Chronic, Remitting Demyelinating Diseases: ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis	• Chronic, Remitting Demyelinating Diseases: ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis
• Chronic Urticaria			
• Complex Regional Pain Syndrome			• Complex Regional Pain Syndrome
• Convulsions: ▪ Febrile, Afebrile ▪ Infantile Spasms ▪ Myoclonic Epilepsy			• Convulsions: ▪ Febrile, Afebrile ▪ Infantile Spasms ▪ Myoclonic Epilepsy
• Encephalopathy/Encephalitis		• Encephalopathy/Encephalitis	• Encephalopathy/Encephalitis
• Fibromyalgia			• Fibromyalgia
			• Hearing Loss
	• Hepatitis (autoimmune)		• Hepatitis
• Immune Thrombocytopenic Purpura			
• Insulin-dependent Diabetes Mellitus			• Insulin-dependent Diabetes Mellitus
• Monophasic Demyelinating Diseases: ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis	• Monophasic Demyelinating Diseases: ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis	• Monophasic Demyelinating Diseases: ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis	• Monophasic Demyelinating Diseases: ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis
• Myocarditis			
• Opsoclonus Myoclonus Syndrome			• Opsoclonus Myoclonus Syndrome
• Optic Neuritis			
• Serum Sickness			
• Sudden Infant Death Syndrome (SIDS)			

Also see General Considerations on page 4.

* "Secondary" autism or autistic features arising from chronic encephalopathy, mitochondrial disorders and/or other underlying disorders will be considered by the Committee. For "Primary" autism, VICP has asked the IOM to consider the review of the medical literature post *Immunization Safety Review: Vaccines and Autism (2004)* report. In particular, VICP is interested in the Committee's review on more recent theories of "neuroinflammation" and "hyperarousal/overexcitation of the immune system via multiple simultaneous antigenic stimulation."

COMMITTEE TO REVIEW ADVERSE EFFECTS OF VACCINES
DECEMBER 2009 WORKING LIST OF ADVERSE EVENTS TO BE CONSIDERED BY THE COMMITTEE

Hepatitis B Vaccine	Human Papilloma Virus Vaccine	Influenza Vaccine	Varicella Vaccine
	• Amyotrophic Lateral Sclerosis		
• Anaphylaxis or Anaphylactic Shock	• Anaphylaxis or Anaphylactic Shock	• Anaphylaxis or Anaphylactic Shock	• Anaphylaxis or Anaphylactic Shock
• Arthropathy (Arthritis, Arthralgia)	• Arthropathy (Arthritis, Arthralgia)	• Arthropathy (Arthritis, Arthralgia)	• Arthropathy (Arthritis, Arthralgia)
		• Asthma	
		• Bell's Palsy	
• Brachial Neuritis	• Brachial Neuritis	• Brachial Neuritis	
		• Cardiac: ▪ Myocardial Infarction ▪ Stroke ▪ Sudden Death	
			• Cerebellar Ataxia
• Chronic, Remitting Demyelinating Diseases: ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis ▪ Neuromyelitis Optica	• Chronic, Remitting Demyelinating Diseases: ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis ▪ Neuromyelitis Optica	• Chronic, Remitting Demyelinating Diseases: ▪ Chronic Inflammatory Disseminated Polyneuropathy ▪ Multiple Sclerosis ▪ Neuromyelitis Optica	
• Complex Regional Pain Syndrome		• Complex Regional Pain Syndrome	
• Convulsions: ▪ Febrile, Afebrile ▪ Infantile Spasms ▪ Myoclonic Epilepsy			• Convulsions: ▪ Febrile, Afebrile ▪ Infantile Spasms ▪ Myoclonic Epilepsy
			• Disseminating Oka VZV Infection (in the immunocompromised)
• Encephalopathy/Encephalitis		• Encephalopathy/Encephalitis	• Encephalopathy/Encephalitis
• Fibromyalgia		• Fibromyalgia	
			• Hepatitis
	• Hypercoagulable States		
• Insulin-dependent Diabetes Mellitus			
			• Meningitis
• Monophasic Demyelinating Diseases: ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis	• Monophasic Demyelinating Diseases: ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis	• Monophasic Demyelinating Diseases: ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis	• Monophasic Demyelinating Diseases: ▪ Acute Disseminating Encephalomyelitis ▪ Guillain-Barré Syndrome ▪ Transverse Myelitis
		• Oculorespiratory Syndrome	
			• Oka VZV Zoster
	• Pancreatitis		
			• Pneumonia
• Polyarteritis Nodosa		• Polyarteritis Nodosa	
		• Small Fiber Neuropathy	
	• Syncope		
• Systemic Lupus Erythematosus		• Systemic Lupus Erythematosus	
			• Thrombocytopenia
	• Thromboembolic Events		
• Vasculitis		• Vasculitis	

Also see General Considerations on page 4.

Adverse Events Reviewed

Footnote expansions - AE List

- * "Secondary" autism or autistic features arising from chronic encephalopathy, mitochondrial disorders and/or other underlying disorders will be considered by the Committee. For "Primary" autism, VICP has asked the IOM to consider the review of the medical literature post *Immunization Safety Review: Vaccines and Autism (2004) report. In particular, VICP is interested in the Committee's review on more recent theories of "neuroinflammation" and "hyperarousal/overexcitation of the immune system via multiple simultaneous antigenic stimulation."*

- General Considerations: In addition to the specific adverse events, the committee will review general considerations for the eight vaccines. General considerations include underlying (susceptible) populations, "immune dysfunction", **vaccine administration issues, anaphylaxis** and autoimmune diseases (time interval), and sequential vaccination issues.

Adverse Events Reviewed

- The IOM Committee added 10 of their own adverse events.
  - All-cause mortality and seizures: influenza vaccine
  - Optic neuritis: MMR , influenza, hepatitis B, and DTaP vaccines
  - Neuromyelitis optica: MMR vaccine
  - Erythema nodosum: hepatitis B vaccine
  - Stroke and small fiber neuropathy: varicella vaccine

- The final working list constituted a diverse array of adverse events numbering 76 different adverse events and 158 adverse event-vaccine combinations; included 3 adverse events in the general category of injection-related events.

IOM Committee Review Methods

- For each vaccine-AE 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

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 and the consistency of the group of studies in terms of direction of effect.

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Summary of Causality Conclusions

- Convincingly supports a causal relationship (14 AE/vaccine relationships)
  - Varicella vaccine
    - Disseminated Oka VZV without other organ involvement
    - Disseminated Oka 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)
    - 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 and vaccine relationships)

1. HPV and anaphylaxis
2. MMR and transient arthralgia in female adults
3. MMR and transient arthralgia in children
4. 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; the most common alleged injuries currently being claimed to VICP

Summary of Causality Conclusions

- Favors rejection of a causal relationship (5 AE and vaccine relationships)

1. MMR vaccine and type 1 diabetes
2. DTaP vaccine and type 1 diabetes
3. MMR vaccine and autism
4. Trivalent inactivated influenza vaccine (TIV) and asthma/reactive airway disease episodes
5. TIV and Bell's palsy.

Preparation Sequence: Working Groups

- Task Force consisting of members from the Immunization Safety Office (ISO)/CDC, Division of Vaccine Injury Compensation (DVIC)/HRSA, and Office of General Counsel (OGC)/HHS established in September 2011

- **Phase 1 – Science based only:** Nine VIT Update Work Groups (VITU-WGs; 1 for each vaccine and 1 for injection-related events) reviewed IOM Report + updated literature on all Vaccine-Adverse Effect (AE) combinations using a consistent approach (organizing Phase 1 worksheets).

  - Recommended 21 Vaccine-AE combinations to move to Phase 2 (in addition to IOM's conclusively supports and favors acceptance categories, few were from IOM's inadequate to accept or reject categories).

  - Phase 1 complete (November 2011)

Preparation sequence: Phase 2

MMR - Transient arthralgia women	CS
MMR - Transient arthralgia children	CS
MMR - Measles inclusion encephalitis	CS
MMR - Chronic Arthritis/arthropathy	I
MMR - Febrile Seizures	CS
VARICELLA VIRUS - Disseminated Oka VZV Without Other Organ Inv	
VARICELLA VIRUS - Disseminated Oka VZV with Other Organ Inv	CS
VARICELLA VIRUS - Vaccine Strain Viral Reactivation w/o Other Organ Inv	
VARICELLA VIRUS - Vaccine Strain Viral Reactivation with Other Organ Inv	CS
VARICELLA VIRUS - Anaphylaxis	CS
FLU - Seizures Febrile	I
FLU - Guillain-Barré Syndrome	I
FLU - Anaphylaxis	CS
FLU - Live Attenuated/Asthma Exacerbation	I
HEP A - Anaphylaxis	I
HUMAN PAPILLOMA - Anaphylaxis	FA
DTAP - Encephalitis and Encephalopathy	I
MENINGOCOCCAL - Anaphylaxis	CS
INJECTION-RELATED - Complex Regional Pain Syndrome	I
INJECTION RELATED - Deltoid Bursitis	CS
INJECTION-RELATED - Syncope	CS

Phase 2 : Science + Policy based

- Phase 2 included further discussions within VITU-WGs and with the entire Task Force (with policy overlay).
- Out of the 21 V-AE pairs, 9 Phase 2 draft worksheets resulted (of 11 V-AE pairs) which recommended proposals for changes/updates to the VIT.
- A 10th Phase 2 worksheet was proposed to add QAI wording for “encephalitis”.

Phase 2 complete (January 2012)

IOM Causality Conclusion: Convincingly supports

Vaccine	Adverse Event	VIT Revision
Varicella	Disseminated varicella infection (widespread chickenpox rash shortly after vaccination)	Add (new)
Varicella	Disseminated varicella infection with subsequent infection resulting in pneumonia, meningitis, or hepatitis in individuals with demonstrated immunodeficiencies.	Add (new)
Varicella	Vaccine strain viral reactivation (appearance of chickenpox rash months to years after vaccination)	Add (new)
Varicella	Vaccine strain viral reactivation with subsequent infection resulting in meningitis or encephalitis (inflammations of the brain)	Add (new)
MMR	Measles inclusion body encephalitis	Add (under vaccine strain measles dz)
MMR	Febrile seizures (a type of seizure that occurs in association with fever and is generally regarded as benign)	No (no long-term sequelae)

IOM Causality Conclusion: Convincingly supports

Vaccine	Adverse Event	VIT Revision
MMR	Anaphylaxis (a very rare but sudden allergic reaction)	No (already there)
Varicella	Anaphylaxis	Add (new)
Influenza	Anaphylaxis	Add (new)
Hepatitis B	Anaphylaxis	No (already there)
Tetanus Toxoid	Anaphylaxis	No (already there)
Meningococcal	Anaphylaxis	Add (new)
Injection-Related Event	Deltoid bursitis (frozen shoulder, characterized by shoulder pain and loss of motion)	Add (to all injected)
Injection-Related Event	Syncope (fainting)	Add (to all injected)

IOM Causality Conclusion: Favors Acceptance

Vaccine	Adverse Event	IOM Causality Conclusion (VIT Revision)
HPV	Anaphylaxis	Favors Acceptance (Add-new)
MMR	Transient arthralgia (temporary joint pain) in women	Favors Acceptance [a] (No – no long term sequelae)
MMR	Transient arthralgia in children	Favors Acceptance (No – no long term sequelae)
Influenza	Oculorespiratory syndrome (a mild and temporary syndrome characterized by conjuctivitis, facial swelling, and upper respiratory symptoms)	Favors Acceptance [b] (No – particular vaccine not manufactured)

[a] The committee attributes causation to the rubella component of the vaccine

[b] The committee attributes causation to 2 particular vaccines used in three particular years in Canada

IOM Causality Conclusion: Favors Rejection

Vaccine	Adverse Event	IOM Causality Conclusion (VIT Revision)
MMR	Autism	Favors Rejection (No – not currently listed)
Influenza	Inactivated influenza vaccine and Bell's palsy (weakness or paralysis of the facial nerve)	Favors Rejection (No – not currently listed)
Influenza	Inactivated influenza vaccine and asthma exacerbation or reactive airway disease episodes in children and adults	Favors Rejection (No – not currently listed)
MMR	Type 1 diabetes	Favors Rejection (No – not currently listed)
DT, TT, or aP containing	Type 1 diabetes	Favors Rejection(No – not currently listed)

IOM Causality Conclusion: Inadequate to accept or reject

Vaccine	Adverse Event	VIT Revision
Influenza	Asthma exacerbation	No – no long term sequelae
Influenza	Febrile seizures	No – no long term sequelae
Influenza	Guillian-Barre Syndrome (GBS)	Deferred [a]
Hepatitis A	Anaphylaxis	No – evidence not available
DT, TT, or aP containing	Encephalopathy/encephalitis	Yes – already listed on Table but QAI will be updated
Injection-Related	Complex Regional Pain Syndrome	No – not enough evidence yet

[a] *Waiting for peer-reviewed H1N1 active surveillance publications as trivalent flu vaccines containing the H1N1 strain are being submitted to the VICP.*

Acknowledgements: VITU Task Force Membership

CDC lead: Tom Shimabukuro
HRSA lead: Rosemary Johann-Liang
Administrative Support: Scott Beach

Vaccine/Topic	Primary ISO reviewer	Secondary ISO reviewer	OGC reviewer	Primary HRSA reviewer WG-LEADS	Project Officer Review
Varicella	Mike McNeil, Zanie Leroy	Jonathan Duffy, Shahed Iqbal	Elizabeth Saindon	Catherine Shaer	Rosemary Johann-Liang
Trivalent influenza	Tom Shimabukuro	Karen Broder, Penina Haber, Jorge Arana	Elizabeth Saindon	Sarah Atanasoff	Rosemary Johann-Liang
Hepatitis B	Mike McNeil	Pedro Moro	Emily Levine	Marco Melo	Rosemary Johann-Liang
Human papillomavirus	Theresa Harrington, Julianne Gee	Claudia Vellozzi	Anna Jacobs	Barbara Shoback	Rosemary Johann-Liang
Hepatitis A	Maria Cano	Mike McNeil	Anna Jacobs/ Andrea Davey	Marco Melo	Rosemary Johann-Liang
Meningococcal	Jonathan Duffy	Maria Cano	Elizabeth Saindon	Tom Ryan	Rosemary Johann-Liang
MMR	Jane Gidudu	Maria Cano, Zanie Leroy	Anna Jacobs	Mary Rubin	Rosemary Johann-Liang
DTaP/other tetanus-containing	Pedro Moro	Jorge Arana	Emily Levine	Stacy Stryer	Rosemary Johann-Liang
Injection-related	Beth Hibbs	Elaine Miller, Tom Shimabukuro	Emily Levine	Tom Ryan	Rosemary Johann-Liang

Project Timeline in Brief (subject to clearance time)

When	Tasks Involved
9/7/11	Organizing meeting of VIT Update-Task Force
End of 9/2011	Kick-off Meeting for the VITU-TF: Each of the 8 vaccine sections + Injection-related section of the IOM report will be reviewed by 9 Working Groups composed of reviewers from DVIC/HRSA, ISO/CDC and OGC
10/2011 to 2/2012	Primary internal review of the IOM Report by the 9 WGs to generate initial draft proposed changes to the VIT (and Aids to Interpretation)
2/2012	Immunization Safety Task Force Consultation
3/2012	ACCV Consultation
9-12/2012	Notice to Public Rule Making (NPRM) publication with public hearing 12/12 ???
3/13 to 9/2013	End of 6-month public comment period followed by addressing comments and clearance of Final Rule (9/13: second opportunity if needed to seek ACCV consultation)
12/2013	Publication of Final Rule (Federal Register)/Briefing

ACCV Recommendation

Choices

1. ACCV concurs with the proposed change(s) to the VIT (and Aids to Interpretation) and would like to move forward (with or without comments)

2. ACCV does not concur with the proposed change(s) to the VIT (and Aids to Interpretation) and would not like to move forward

3. ACCV would like to defer a recommendation on the proposed change(s) to the VIT (and Aids to Interpretation) pending further review at this meeting, or the next ACCV meeting June 14-15, 2012.