



The National Vaccine Injury Compensation Program (VICP)

Clarification on Proposed Changes to the Vaccine Injury Table

Advisory Commission on Childhood Vaccines
September 4, 2014

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Overview



- VICP is currently updating the Vaccine Injury Table (VIT)
- In March 2012, the proposed revisions were discussed and approved by ACCV
- In June 2014, additional proposed revisions were discussed and approved by the ACCV
- VICP has modified some of the previous approved language in the Qualifications and Aids to Interpretation (QAIs)



Objectives



- To review the proposed revisions that were approved by the ACCV in March 2012
- To review the proposed revisions that were approved by the ACCV in June 2014
- To present the additional proposed revisions to the QAIs



REVIEW OF PROPOSED
VACCINE INJURY TABLE
CHANGES
APPROVED BY THE ACCV
MARCH 2012



Current Language

B. Vaccine-Strain Measles
Viral Infection in an
immunodeficient recipient

Approved March 2012

Vaccine-Strain Measles
Viral **Disease** in an
immunodeficient recipient

--Vaccine-strain virus
identified (time period: not
applicable)

--If strain determination
is not done or if laboratory
testing is inconclusive (time
period: ≤ 12 months)



VIT changes – varicella vaccine



Current Language

No condition specified

Approved March 2012

Disseminated varicella
vaccine-strain viral disease

-vaccine-strain virus
identified (time period: not
applicable)

-if strain determination is
not done or if laboratory
testing is inconclusive (time
period: 7-42 days)



VIT changes – varicella vaccine



Current Language

No condition specified

Approved March 2012

Varicella vaccine-strain viral reactivation (time period: not applicable)



General



Current Language

“Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed”

Approved March 2012

“Any acute complication or sequela (including death) of an illness, disability, injury, or condition listed ...”

(this wording is in every line of this table and thus has been moved to bottom of the Table under section (b) as provision that applies to all vaccines listed)



General



The covered conditions Shoulder Injury Related to Vaccine Administration and vasovagal syncope were added to the following vaccines:

- Vaccines containing tetanus toxoid
- Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s)
- Vaccines containing measles, mumps, or rubella components
- Vaccines containing polio inactivated virus
- Hepatitis B vaccines



General cont'd



The covered conditions Shoulder Injury Related to Vaccine Administration and vasovagal syncope were also added to the following vaccines:

- Haemophilus influenza type b polysaccharide conjugate vaccines
- Pneumococcal conjugate vaccines
- Hepatitis A vaccines
- 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



General



The covered conditions anaphylaxis, Shoulder Injury Related to Vaccine Administration and vasovagal syncope were added to the following vaccines:

- Human papillomavirus (HPV) vaccines
- Meningococcal vaccines
- Trivalent influenza vaccines
- Varicella vaccines



QAI New Language –Shoulder Injury Related to Vaccine Administration (SIRVA)



Shoulder Injury Related to Vaccine Administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of an injected vaccine. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known).



QAI New Language –Shoulder Injury Related to Vaccine Administration (SIRVA)



A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine administration;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).



QAI Changes – Brachial Neuritis

Current Language

Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

Approved March 2012

A vaccine recipient shall be considered to have suffered a brachial neuritis as a Table injury if such recipient manifests, within the applicable period, all of the following:

- (i) Pain in the affected arm and shoulder is a presenting symptom;
- (ii) Weakness;
 - (A) Clinical diagnosis in the absence of nerve conduction and electromyographic studies requires weakness in muscles supplied by more than one peripheral nerve.



QAI Changes – Brachial Neuritis, cont'd



Current Language

Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

Approved March 2012

(B) Nerve conduction studies (NCS) and electromyographic (EMG) studies localizing the injury to the brachial plexus are required before the diagnosis can be made if muscle weakness is limited to a single peripheral nerve.

(iii) Motor, sensory, and reflex findings on physical examination and the results of NCS and EMG studies, if performed, must be consistent in confirming that dysfunction is attributable to the brachial plexus; and

(iv) No other condition or abnormality is present that would explain the vaccine recipient's symptoms.



QAI New Language – Disseminated varicella vaccine-strain virus disease



Disseminated varicella vaccine-strain virus disease is defined as a varicella illness that involves the skin beyond the dermatome in which the vaccination was given and/or disease caused by vaccine-strain varicella in another organ. For organs other than the skin, disease, not just mildly abnormal laboratory values, must be demonstrated in the involved organ. If there is involvement of an organ beyond the skin, and no virus was identified in that organ, the involvement of all organs must occur as part of the same, discrete illness. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur 7– 42 days after vaccination.



QAI New Language – varicella –strain reactivation disease



Varicella vaccine-strain viral reactivation disease is defined as the presence of the rash of herpes zoster with or without concurrent disease in an organ other than the skin. Zoster, or shingles, is a painful, unilateral, pruritic rash appearing in one or more sensory dermatomes. For organs other than the skin, disease, not just mildly abnormal laboratory values, must be demonstrated in the involved organ. There must be laboratory confirmation that the vaccine-strain of the varicella virus is present in the skin or in any other involved organ, for example by oligonucleotide or polymerase chain reaction. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table.



QAI New Language – vasovagal syncope



Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected vaccine. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant sequelae. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously with vasovagal syncope. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: organic heart disease, cardiac arrhythmias, transient ischemic attacks, hyperventilation, metabolic conditions, neurological conditions, and seizures. Episodes of recurrent syncope occurring after the applicable time period are not considered to be sequelae of an episode of syncope meeting the Table requirements.



QAI Changes –Anaphylaxis



Current Language

“...an acute, severe, and potentially lethal systemic reaction....”

“...Autopsy findings may include acute emphysema....edema of the hypopharynx...there may not be significant pathologic findings”

Approved March 2012

“...an acute, severe, and potentially lethal systemic reaction **that occurs as a single, discrete event with simultaneous involvement of two or more organ systems....**”

“**There are no specific pathological findings to confirm a diagnosis of anaphylaxis**”



QAI Changes – Vaccine-strain measles viral disease



Current Language

“This term is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.”

Approved March 2012

“This term is defined as a measles illness that involves the skin and/or another organ (such as the brain or lungs). Measles virus must be isolated from the affected organ or histopathologic findings characteristic for the disease must be present. Measles viral strain determination may be performed by methods such as polymerase chain reaction test and vaccine-specific monoclonal antibody. If strain determination reveals wild-type measles virus or another, non-vaccine-strain virus, the disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur within 12 months after vaccination.”



QAI Changes - Encephalopathy



Current language

“...the following clinical features in themselves do not demonstrate a an acute encephalopathy... in themselves do not demonstrate and acute encephalopathy...high-pitched and unusual screaming, persistent inconsolable crying...”

Approved March 2012

“...the following clinical features in themselves do not demonstrate a an acute encephalopathy... in themselves do not demonstrate and acute encephalopathy...high-pitched and unusual screaming, **poor feeding**, persistent inconsolable crying..., **or symptoms of dementia.**”



QAI Changes - Encephalopathy



Current language

“... An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by ...”

Approved March 2012

“... **Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known,** an encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by...”



QAI Changes - Encephalopathy



Current language

“... An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). ...”

Approved March 2012

“... An underlying condition or systemic disease (such as an autoimmune disorder, malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, metabolic disturbance, prenatal or perinatal central nervous system (CNS) injury), or

An acute event shown to be unrelated to the vaccine such as head trauma, stroke, transient ischemic attack, complicated migraine, drug use (illicit or prescribed) or an infectious disease.”



QAI Changes - Encephalopathy



Current language

“Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group”

Approved March 2012

Language deleted.



QAI New Language - Encephalitis



Encephalitis. A vaccine recipient shall be considered to have suffered an encephalitis if an injury meeting the description below of an acute encephalitis occurs within the applicable time period and results in a chronic encephalopathy.

(i) Acute encephalitis. Encephalitis is indicated by evidence of neurologic dysfunction, as described in subparagraph (A) below, plus evidence of an inflammatory process in the brain, as described in subparagraph (B) below.

A. Evidence of neurologic dysfunction consists of either:

- (1) one of the following neurologic findings referable to the CNS: focal cortical signs (such as aphasia, alexia, agraphia, cortical blindness); cranial nerve abnormalities; visual field defects; presence of primitive reflexes (such as Babinski's sign or sucking reflex); or cerebellar dysfunction (such as ataxia, dysmetria, or nystagmus); or
- (2) an acute encephalopathy as set forth in subparagraph (c)(2)(i) of this section.



QAI New Language – Encephalitis cont'd



B. Evidence of an inflammatory process in the brain (central nervous system or CNS inflammation) must include cerebrospinal fluid (CSF) pleocytosis (>5 white blood cells (WBC)/mm³ in children >2 months of age and adults; >15 WBC/mm³ in children <2 months of age); or at least two of the following:

- (1) Fever (temperature \geq 100.4 degrees Fahrenheit);
- (2) Electroencephalogram findings consistent with encephalitis, such as diffuse or multifocal nonspecific background slowing and periodic discharges; or
- (3) Neuroimaging findings consistent with encephalitis, which include, but are not limited to brain/spine magnetic resonance imaging (MRI) displaying diffuse or multifocal areas of hyperintense signal on T2-weighted, diffusion-weighted image, or fluid-attenuation inversion recovery sequences



QAI New Language – Encephalitis cont'd



Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, encephalitis shall not be considered to be a condition set forth in the Table if, after evaluating the entire medical record, the preponderance of evidence shows that it was caused by:

- (A) an underlying malignancy that led to a paraneoplastic encephalitis,
- (B) an infectious disease associated with encephalitis, including a bacterial, parasitic, fungal or viral illness (such as herpes viruses, adenovirus, enterovirus, West Nile Virus, or human immunodeficiency virus), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing;
- (C) acute disseminated encephalomyelitis (ADEM). Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on MRI are distinct with ADEM displaying evidence of acute demyelination (scattered, focal or multifocal areas of inflammation and demyelination within cerebral subcortical and deep cortical white matter; gray matter involvement may also be seen but is a minor component); or
- (D) other conditions or abnormalities that would explain the vaccine recipient's symptoms.



QAI Changes – Chronic Arthritis



Current Language

“...the following shall not be considered as chronic arthritis: musculoskeletal disorders....Reiter’s syndrome, or blood disorders.”

Approved March 2012

(NEW) “Chronic arthritis is defined as persistent joint swelling with at least two additional manifestations of warmth, tenderness, pain with movement, or limited range of motion, lasting for at least 6 months”

“...the following shall not be considered as chronic arthritis: musculoskeletal disorders....Reiter’s syndrome, or blood disorders, or arthralgia (joint pain) or joint stiffness without swelling.”



Current Language

“This term is defined by a serum platelet count less than 50,000/mm³.”

Approved March 2012

“This term is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm³ with normal red and white blood cell indices “



Current Language

“Chronic Encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.”

Approved March 2012

“A chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable **Table** time period **as an acute encephalopathy or encephalitis**, persists for at least 6 months from the date of vaccination.

(ii) Individuals who return to their baseline neurologic state, **as confirmed by clinical findings, within 6 months of their acute encephalopathy or encephalitis** shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy or encephalitis.”



Glossary – Injected



“Injected” refers to the intramuscular or subcutaneous needle administration of a vaccine



Glossary – immunodeficient recipient



“Immunodeficient recipient” is defined as an individual with an inherited or acquired disorder resulting from an identifiable defect in the immunological system which impairs the body’s ability to fight infections. The identifiable defect, such as absent T lymphocytes in severe combined immunodeficiency or decreased CD4 cell counts in acquired immunodeficiency syndrome must be demonstrated in the medical records.



Glossary – significantly decreased level of consciousness



“Significantly decreased level of consciousness” is indicated by the presence of one or more of the of the following clinical signs...”



Glossary – Seizures



Current Language

“Seizure and convulsion. For purposes of paragraphs (b) (2) of this section, the terms, “seizure” and “convulsion” include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.”

Approved March 2014

The term “seizure” includes myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures, but not absence (petit mal), or **pseudo seizures**. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.



Glossary - sequela



“The term “sequela” means a condition or event which was actually caused by a condition listed on the Vaccine Injury Table”



REVIEW OF PROPOSED
VACCINE INJURY TABLE
CHANGES
APPROVED BY THE ACCV
June 2014



VIT Changes - Category Modifications



1. Modified category of “Trivalent influenza vaccines” to “Seasonal influenza vaccines”
2. Modified category IX from Haemophilus influenzae type b polysaccharide conjugate vaccines to Haemophilus influenzae type b vaccines



PROPOSED MODIFICATIONS TO CLARIFY LANGUAGE IN THE QAIs



QAI Changes - Encephalopathy



Approved March 2012

“...an encephalopathy shall not be considered to be a condition set forth in the Table if after evaluating the entire medical record, the preponderance of evidence shows that it was caused by:”

- (A) an underlying condition or systemic disease (such as autoimmune disorder, malignancy, structural lesion, psychiatric illness, dementia, genetic disorder...”

Proposed modified Language

“...an encephalopathy shall not be considered to be a condition set forth in the Table if it is shown that the encephalopathy was caused by:

- (A) An underlying condition or systemic disease shown to be **unrelated to the vaccine** (such as malignancy, structural lesions, psychiatric illness, dementia, genetic disorder...”



QAI Changes –Chronic Encephalopathy



Approved March 2012 *

“a chronic encephalopathy occurs when a change in mental or neurologic status...persists for at least six months from the date of vaccination.”

Modified Language

“A chronic encephalopathy occurs when a change in mental or neurologic status...persists for at least 6 months from **the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis**”



QAI Changes –Chronic Encephalopathy



Approved March 2012 *

“Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within 6 months of their acute encephalopathy or encephalitis shall not be presumed to have suffered residual neurologic damage from that event...”

Modified Language

“Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within less than 6 months **from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis** shall not be presumed to have suffered residual neurologic damage from that event...”



QAI Changes – Thrombocytopenic Purpura



Approved March 2012

“Thrombocytopenic purpura does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura that are mediated, for example, by viral or fungal infections, toxins or drugs....”

Modified Language

“Thrombocytopenic purpura does not include cases of immune thrombocytopenic purpura that are mediated for example, by viral or fungal infections...**However, if culture or serologic testing is performed, and the viral illness is attributed to the vaccine-strain measles virus, the presumption of causation will remain in effect”**



QAI Changes – Shoulder Injury Related to Vaccine Administration (SIRVA)



Approved March 2012

“SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of an injected vaccine.”

Modified Language

“SIRVA manifests as shoulder pain and limited range of motion after the administration of a vaccine **intended for intramuscular administration in the upper arm**”



ACCV recommendation



- Concur with the recommendations
- Do not concur with the recommendations