Shoulder Injury Related to Vaccine Administration (SIRVA)

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SIRVA – Background

- 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 Institute of Medicine (IOM) reviewed the scientific and medical literature finding that the evidence convincingly supported a causal relationship between vaccine administration and deltoid bursitis.
Learning Objectives

By the end of this training, you will be able to:

• Define SIRVA

• Understand the key difference between SIRVA and Common Injection Site Reactions

• How to avoid SIRVA

• Understand the National Vaccine Injury Compensation Program (VICP)
Definition of SIRVA

• Severe, persistent shoulder pain and limited range of motion (ROM) after the administration of an intramuscular vaccine in the upper arm

• Prolonged restriction of function that can include:
  • Deltoid or shoulder bursitis
  • Tendonitis
  • Rotator cuff tear
  • Impingement syndrome
  • Adhesive capsulitis
  • Frozen shoulder

• SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.)
Definition of SIRVA (cont.)

The subacromial bursa may extend 3 cm to 6 cm below the acromion border.

Figure 1. Cross-section of the shoulder joint
Definition of SIRVA (more)

Onset and Duration of Symptoms

Atanasoff et al. described 13 cases:

Cases were reported to Vaccine Injury Compensation Program (VICP) from 2006–2010

- 93% (12 of 13) developed pain within 24 hours
- 54% (7 of 13) experienced pain immediately after vaccination
- 46% (6 of 13) reported they thought the vaccine was given “too high” in the arm

Symptoms lasted from 6 months to years

Interventions

- Over 1/2 of the patients required 1 or more corticosteroid injections
- 31% of patients required surgery, and 1/2 of those patients required a second surgery
What SIRVA is Not

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).
Difference Between SIRVA and Common Injection Site Reactions

With most vaccines, injection site reactions are common.

Soreness or a dull ache in the muscle for 1–3 days
Tdap and Shingrix tends to be more common and more pronounced

*Pain abates with cold compresses and OTC analgesics* (acetaminophen, ibuprofen)

*Key difference with SIRVA*

Pain does not abate with OTC analgesics, cold compresses or time.
Difference Between SIRVA and Common Injection Site Reactions (cont.)

SIRVA is not related to the vaccine itself, but rather the site of injection.

- When properly administered, IM injections produce a systemic immune response
- Transient pain is common at the injection site, or mild soreness for a day or two
- With SIRVA, the vaccine produces an immune response, but it provokes a local immune-mediated inflammatory response in the bursa

*SIRVA is the first recognized side effect based on HOW a vaccine is given*
Differences Between SIRVA and Common Injection Site Reactions (more)

These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle going into and around the underlying bursa of the shoulder, resulting in an inflammatory reaction.
How to Avoid SIRVA

To avoid SIRVA, make sure clinic staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper intramuscular administration technique.
How to Avoid SIRVA (cont.)

Injection Technique – Considerations

New guidance for injections supported by research and published case reviews

1. Ensure the patient is sitting

2. Get eye level with the patient (i.e., kneel or sit) to ensure a 90-degree angle is achieved for the IM injection

Never stand while the patient is sitting – a 90-degree angle cannot be achieved (exception is if patient is on an elevated exam table or similar)
How to Avoid SIRVA (more)

Injection Technique – Considerations

- Ensure the patient rests their hand in their lap or dangles the arm downward – this ensures that the deltoid can be properly be viewed. Avoid having the patient rest the arm on a desk or table, since this changes the visibility of the landmarks.

- Aim for the lower 2/3 of the deltoid (the upper 1/3 has been associated with the reported SIRVA cases and supported by evidence in Atanasoff et al.) in the thickest part of the deltoid.

- Spacing should be above the armpit, approximately 2–3 fingerbreadths (2 inches) below the acromion.

- Some experts are suggesting using a smaller needle length in females 70 kg or less, to avoid over penetrating the deltoid.

- Some experts recommend a few degrees of abduction laterally, so the bursa is mostly covered by the acromion.
National Vaccine Injury Compensation Program (VICP)

HISTORY:
• Media reports of adverse reactions following DTP vaccinations
• Series of lawsuits
• Withdrawal of manufacturers resulting in vaccine shortages

PURPOSE:
• NO FAULT program
• Compensate individuals injured by certain vaccines
• Ensure a stable vaccine supply

FUNDING:
• An excise tax of 75¢ on each disease prevented in a vaccine is used to fund the Vaccine Injury Compensation Trust Fund. For example, the tax on the measles, mumps and rubella vaccine is $2.25.

CAUSATION:
• Compensation for a claim does not necessarily mean that the vaccine caused the alleged injury. Over 80% of VICP compensation results from negotiated settlements in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury.
National Vaccine Injury Compensation Program (VICP) (cont.)

SIRVA was added to the VICP list of recognized vaccine injuries in 2017

- The injury is now considered “on table,” meaning that it was added to the Vaccine Injury Table (VIT)
- Consideration for addition of SIRVA to the VIT was in review since 2012
Conclusions

• Vaccines save lives – Every visit is an opportunity for prevention through vaccination
  • Most people who receive vaccines have no serious problems, but like any drug, it could have side effects
  • Side effects are typically rare and mild
  • In rare cases, vaccines can cause serious problems, such as severe allergic reactions
  • The VICP exists to provide compensation to injured individuals

• Protect yourself
  • Stay up to date with vaccine information (www.immunize.org, APhA Webpage, AzPA courses)
  • Always provide the VIS prior to vaccination
  • Report any adverse reactions to Vaccine Adverse Event Reporting System (VAERS)

• SIRVA can be avoided by following new guidance for administration of IM injections
Questions & Discussion