

National Vaccine Injury Compensation Program (VICP)

?PREVENTION OF SIRVA?

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Background to SIRVA

- Bodor et al. (Vaccine Related Shoulder Dysfunction. Vaccine 2006; 25(4): 585-587)
 - Reported 2 cases of shoulder pain/dysfunction within 2 days of vaccination
 - Used ultrasound in both patients and 21 controls
 - Found that the bursa extended from 3-6 cm beyond the lateral border of the acromion and that it laid from 0.8 – 1.6 cm (0.31-0.62 inches) below the skin

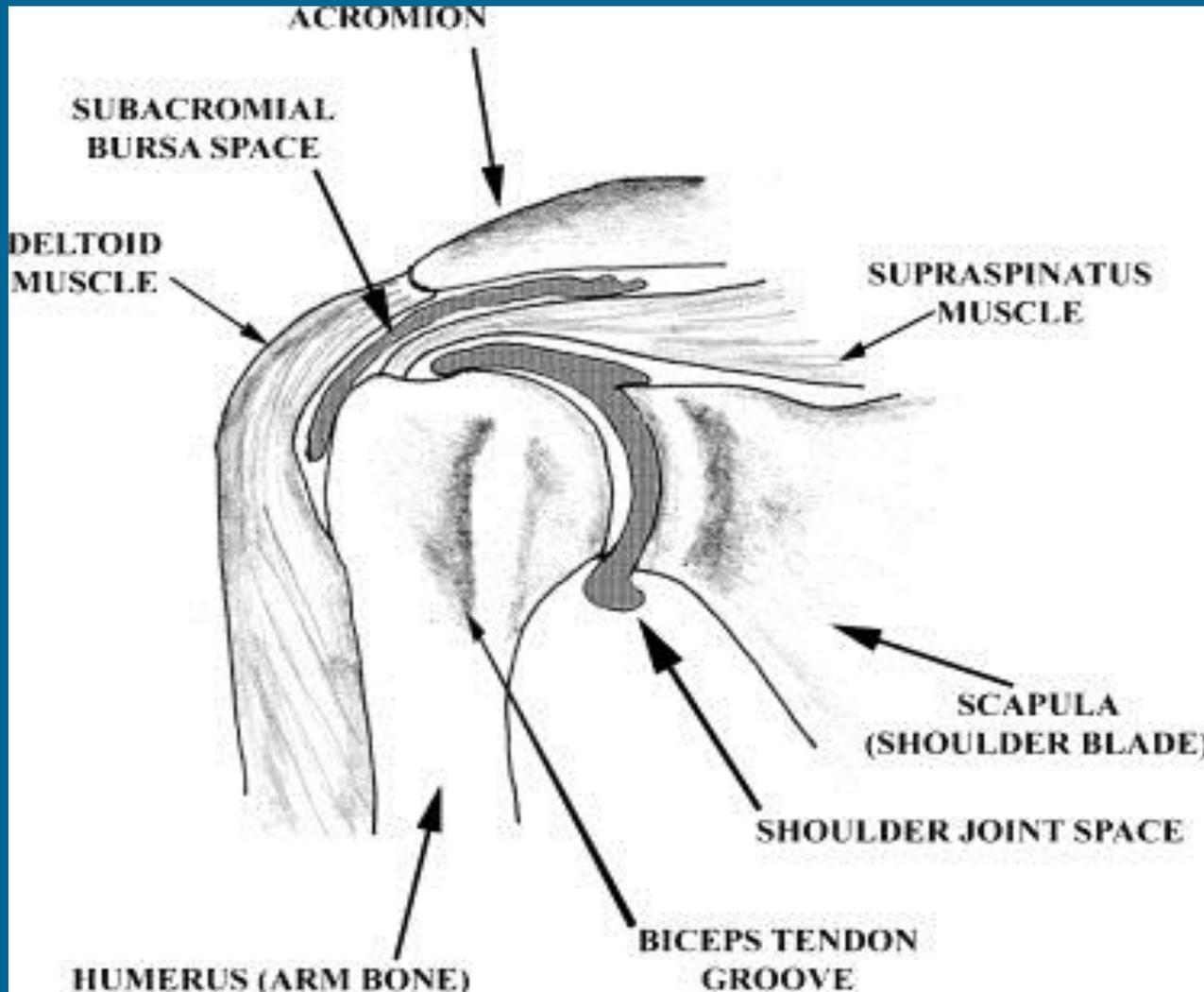


Background to SIRVA

- Bodor et al. (Vaccine Related Shoulder Dysfunction. Vaccine 2006; 25(4): 585-587) (contd)
 - Standard adult needle used for immunization is 1 inch
 - Authors proposed a theory
 - Vaccine was injected into the deltoid bursa causing a robust local inflammatory and immune response leading to bursitis, tendonitis and inflammation of the shoulder capsule
 - Author's solution- injections should not be performed in the upper 1/3 of the deltoid muscle



Shoulder anatomy



SIRVA Background

- Lippert et. al (Optimal intramuscular needle penetration depth. Pediatrics 2008; 122(30): e556-563)
 - Looked at recommended (CDC Pink Book 2007) CDC needle length for immunizations in patients 3-18 years of age and compared them to the average distance from the subcutaneous skin and the underlying muscle of both the thigh and the deltoid obtained from reviewing 250 MRI's
 - 11-61% risk of over penetrating the deltoid muscle



SIRVA Background

- Dumoned et al. (The Production of Arthritis in Rabbits by an immunologic reaction to fibrin; Brit Journal Exp Pathol 1962; 43: 373)
 - Injected antigen (fibrin) into the joint space
 - Found antigen-antibody complexes and acute inflammation



SENTINEL SIRVA PAPER

SIRVA – Shoulder Injury Related to Vaccine Administration

- Hallmark paper by Drs. Sarah Atanasoff, Tom Ryan and Rosemary Johan-Liang: Shoulder Injury Related to Vaccine Administration (SIRVA) (Vaccine 28 (2010) 8049-8052)
 - identified 13 vaccine injury cases between 2006-2010 in which shoulder pain led to significant shoulder pain and dysfunction.



SIRVA Paper

- In the 13 claims: all were adult, 85% were women, average BMI 27.2
- All had shoulder pain, 93% occurred < 24 hours after vaccination, in 54%, the pain occurred immediately after vaccination
- 46% of patients had concerns about vaccine administration, notably that the vaccine was given too high
- Most common findings- pain, decreased range of motion
- Tingling, numbness weakness- uncommon



SIRVA Paper

- 39% underwent EMG's – none had findings suggestive of a neurologic disorder
- Most common MRI findings- fluid collections in deep deltoid, or overlying the rotator cuff tendons, bursitis, fluid “greater than typically seen within the bursa, tendonitis rotator cuff tears
- Symptom duration – from 6 months to many years,
- >50% required at least 1 corticosteroid injection
- 31% required surgical intervention, and half of the 31% required a 2nd surgical intervention



SIRVA Paper Findings

- Atanasoff, Ryan et al. determined that:
 - all the patients in their study “developed shoulder symptoms limited to the vaccinated shoulder. They had all the symptoms and physical findings consistent with a local immune-mediated inflammatory musculoskeletal shoulder injury”
 - In fact, in one of their cases, a surgeon replicated the path of vaccine administration by inserting a needle during surgery. The needle coursed through inflamed and scarred bursa, thickened tissue around a damaged tendon and the tip of the needle actually came in contact with bone, (also effected, very friable)



SIRVA Paper Conclusions

- Atanasoff, Ryan concluded:
 - “rapid onset of pain with limited range of motion following vaccination is consistent with a robust and prolonged immune response within already sensitized shoulder structures, following injection of antigenic substances into the subacromial bursa or the area around the rotator cuff tendon”
 - Literature supports possibility that vaccine can be unintentionally injected into the structures underlying the deltoid muscle due to inappropriate needle length and/or injection technique



Suggestions by Atanasoff/Ryan

- Agreed with Bodor that avoidance of top 1/3 of deltoid
- Seated position for both administrator and recipient
 - Taught in nursing schools
 - Standing position could result in syncope for the vaccine recipient
- A few degrees of arm abduction laterally so that the bulk of the bursa is protected by the acromion process
 - Suggested by Dr. Lightfoot (contributor to SIRVA article) based on anatomical position



Petitioners alleging upper extremity injuries FY 2011-2014

Total Cases FY 2011-2014	Total Compensation FY 2011-2014
136	\$22,054,673.70



Proposed Table criteria for SIRVA

Proposed Vaccine Injury Table addition for SIRVA

Proposed Qualification and Aids (Q&A):

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. 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.

Vaccine	Injury	Time Interval
All vaccines administered by injection	Shoulder Injury Related to Vaccine Administration (SIRVA)	≤ 48 hours



Proposed Table criteria for SIRVA

Proposed Vaccine Injury Table addition for SIRVA

Proposed Qualification and Aids (Q&A):

- 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).



Proposed Table criteria for SIRVA

Proposed Vaccine Injury Table addition for SIRVA

Proposed Qualification and Aids (Q&A):

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

1. No prior history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
2. Pain occurs within the specified time frame;
3. Pain and reduced range of motion are limited to the shoulder in which the vaccine was administered; and
4. No other condition or abnormality is present that would explain the patient's symptoms (e.g. EMG/NCV or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).



Traditional Vaccine Administrators

Doctors, Nurses, Nursing assistants, Medical assistants

- Above professions require graduation from an accredited school or training program
 - Knowledge and competency obtained by a combination of non-clinical (course work) and clinical (on-the-job) training
- Licensure/scope of practice dictated by medical board of the state
- No specific certification needed for vaccine administration
 - Typically this skill learned in school, on the job training
 - “see one, do one, teach one”



Need for non-typical vaccine administrators

- Low vaccination rates
 - In 1995, influenza vaccination rates in ages >65 years of age was 54-74%
 - Healthy People 2010 (published by HHS in 2000)
 - Goal of 90% immunization rate for influenza in >65 year old population
 - Disproportionately low vaccination rates in impoverished and rural populations



Need for non-typical vaccine administrators

- Immunization obstacles (Santoli. *Pediatr Ann* 1998; 27: 366-74, Gore. *Soc Sci Med* 1999: 48: 1011-27, Orenstein. *J Health Care Poor Underserved* 1990; 1: 315-330)
 - Patient related
 - Apathy, lack of knowledge, inability to pay, transportation
 - Provider related
 - Missed opportunities, misconceptions regarding contraindications to immunizations
 - Clinic related
 - Inadequate staff and service hours



Steps taken to broaden vaccination coverage

- 1993- Secretary of Health and Human Services Donna Shalala tasked the American Pharmacists Association (APhA) to develop a plan to train pharmacists to deliver immunizations (J Am Pharm Assoc. 2011; 51:704-712)
- 1996, APhA House of Delegates passes resolution calling pharmacist to assume one of the following 3 roles: advocate, facilitator and immunizer
- Initial role of pharmacists focused on influenza/pneumococcal vaccinations
- Greatest expansion of pharmacists role in providing immunizations occurred after the 2009 H1N1 influenza pandemic



Current role of pharmacists in vaccinations

- Over 200,000 pharmacists trained to provide vaccinations (January 2013; American Pharmacists Association)
- Pharmacists licensed to administer vaccines in all states and US territories
- Regulation occurs at the state level
 - 44 states can give any vaccine
 - Each state varies as to whether they require a specific protocol, a prescription from a physician or a combination of both in order to administer a vaccination
 - Each state varies in regards to the minimum age in which vaccines can be given



Current role of pharmacists in vaccinations

- 1998-1999- 5% of vaccines given by pharmacists
- 2010-2011- >18% of vaccinations given by pharmacists (National Adult and Influenza Immunization Summit 2013)
- National Flu Survey 2012
 - 32.5% adults vaccines given in doctors office
 - 19.7% adult vaccines given in a pharmacy or store



Requirements for Pharmacists to administer vaccinations

- Active pharmacy license and be in good standing
- CPR training
- vaccine certification (required by most states)
 - APhA –gold standard- Pharmacy based Immunization Delivery Certificate
 - 20 hour interactive class – self study and live portions
 - \$99.00 fee for this certificate
 - Offered at various locations across the country



Value of pharmacists as Vaccine administrators

- Steyer et al. (Vaccine 22; 2004: 1001-1006)
 - Found that there was a statistically significant increase in vaccination rate of influenza in the >65 year old population in those states that allowed pharmacists to administer vaccinations



Adequacy of Vaccine administration training

- Nursing Schools, Medical Assistant training programs
 - Taught intramuscular technique in the classroom, then supervised in a clinical setting, competency obtained after direct supervision by teachers
 - Major method is to be in same position as vaccine recipient; either both sitting or standing, feel for the acromion process, go 3 fingers width below this point and insert the needle at 90 degrees to the surface of the deltoid



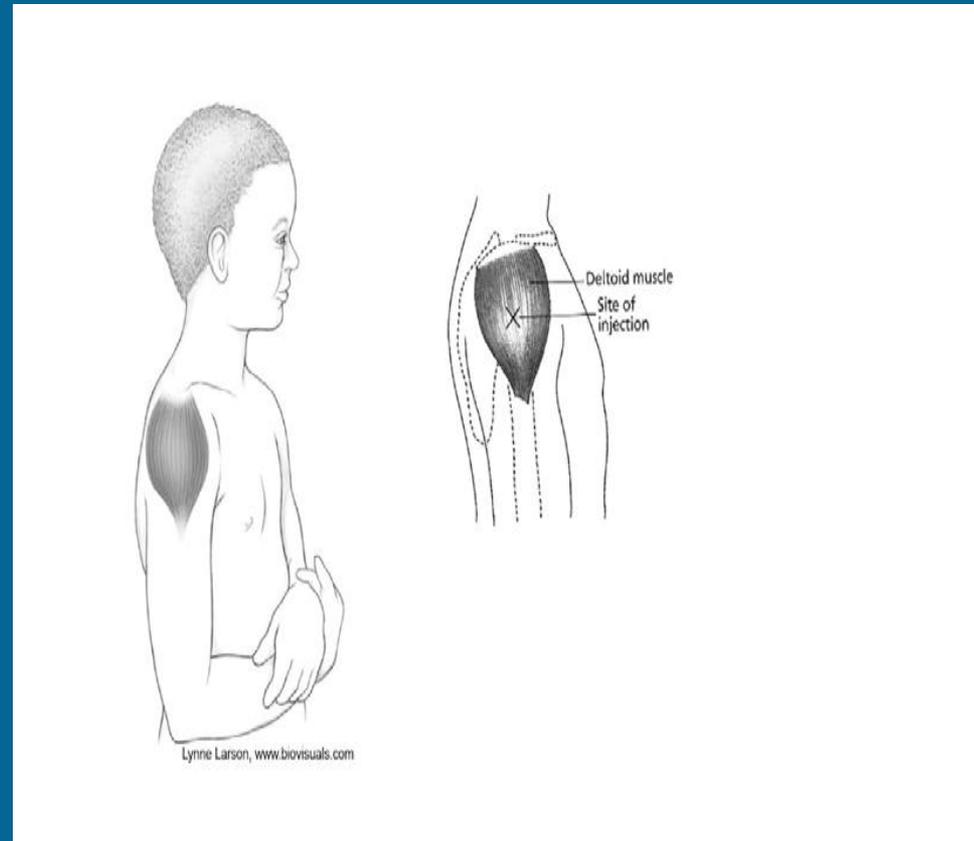
Published Recommendations

- CDC, the AAP and APhA have published detailed recommendations on vaccine administration
- The next 3 slides summarizes their policies specific to intramuscular vaccinations



CDC guideline for intramuscular administration

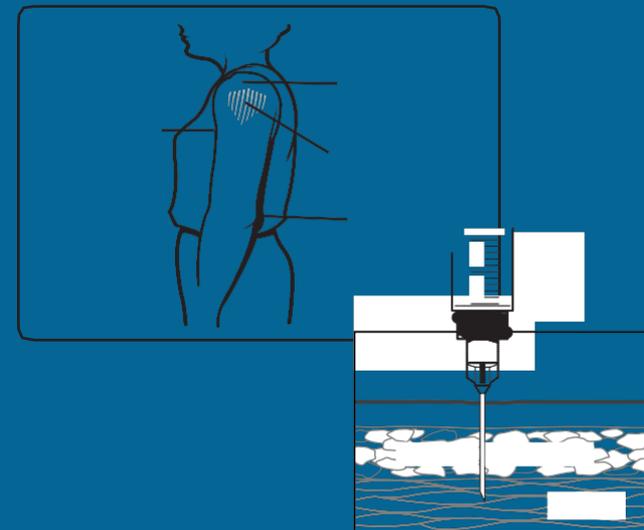
- Insertion of needle 90 degrees to surface of skin overlying the deltoid
- Needle length depends on age
 - 12 months – 2 years- 5/8 inch needle
 - 3 -18 years – 5/8 – 1 ¼ inch needle
 - Adults – 5/8 – 1 ½ inch needle



AAP intramuscular injection

131 page Immunization Training Guide

- Give in the central and thickest portion of the deltoid- above the level of the armpit and below the acromion
- 1- 1 ½ inch needle depending on size of patient
- Needle to be inserted 90 degrees to the skin



APhA recommendations (Journal of the Am Pharmacy Assoc. 2013;53(1): 102-103

- This article highlighted the... “inconsistencies regarding optimal vaccine administration”
- APhA recommend injecting into the thickest and most central portion of the deltoid



Considerations in SIRVA prevention

- Possibility of a universal certification process required by all vaccine administrators?
- Inclusion of SIRVA and specific guidelines in nursing school curriculums, medical assistant school curriculums, pharmacists certification courses, endorsement of the major medical organizations
- Possibility of giving vaccinations via other routes



Universal Certification Process

PROS

- Ensures a universal standard amongst all vaccine administrators
- Increase likelihood that proper vaccination will be performed
- Likely to decrease amount of SIRVA injuries

CONS

- Enforcement would be difficult as each state has its own regulations
- Cost/benefit ratio
 - Cost to vaccine administrator
 - Cost to provide/oversee certification
 - Would the expense outweigh the benefit of decreased SIRVA cases?
- Who would oversee certification?
 - Major nursing, medical assistant organizations?



Education and Inclusion of SIRVA specific guidelines

PROS

- Easier implementation on the national level
- Would supercede any regulation at the state level by offering only recommendations
- Costs would be reasonable

CONS

- Dependent on quality of outreach
- Dependent on implementation at teaching institutions
- Would take considerable time and energy to coordinate
- Would take cooperation and involvement of national organizations



Current State in SIRVA prevention

- CDC currently has a Vaccination Error Stakeholders Focus Group
 - Focuses on vaccination errors in general
 - Internal group at CDC with specific focus on vaccine administration errors
 - Individuals at CDC have specific interests in SIRVA
 - Partnerships with major health organizations



Goals & Ideas Moving forward in regards to SIRVA Prevention

- Update all administration guidelines to include SIRVA, additional instructions and pitfalls in deltoid intramuscular injections
 - Needle size
 - Avoidance of upper 1/3 of deltoid
 - Position of vaccine administrator and recipient
- Possible partnerships with national organizations to educate on SIRVA and promote correct vaccine administration to it's constituents



Goals & Ideas Moving forward in regards to SIRVA Prevention

- Work with nursing schools, medical assistant schools, APhA to implement SIRVA in curriculum and emphasis on correct vaccination methods

