National Vaccine Injury Compensation Program (VICP)

PREVENTION OF SIRVA?
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Advisory Commission on Childhood Vaccines
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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

  - 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

  • 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
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
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

<table>
<thead>
<tr>
<th>Total Cases FY 2011-2014</th>
<th>Total Compensation FY 2011-2014</th>
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<tbody>
<tr>
<td>136</td>
<td>$22,054,673.70</td>
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</table>
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.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Injury</th>
<th>Time Interval</th>
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<tbody>
<tr>
<td>All vaccines administered by injection</td>
<td>Shoulder Injury Related to Vaccine Administration (SIRVA)</td>
<td>≤ 48 hours</td>
</tr>
</tbody>
</table>
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

  - 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

• 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

<table>
<thead>
<tr>
<th><strong>PROS</strong></th>
<th><strong>CONS</strong></th>
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<tbody>
<tr>
<td>• Ensures a universal standard amongst all vaccine administrators</td>
<td>• Enforcement would be difficult as each state has its own regulations</td>
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<tr>
<td>• Increase likelihood that proper vaccination will be performed</td>
<td>• Cost/benefit ratio</td>
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<tr>
<td>• Likely to decrease amount of SIRVA injuries</td>
<td>• Cost to vaccine administrator</td>
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<td></td>
<td>• Cost to provide/oversee certification</td>
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<td></td>
<td>• Would the expense outweigh the benefit of decreased SIRVA cases?</td>
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<tr>
<td></td>
<td>• Who would oversee certification?</td>
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<td>• Major nursing, medical assistant organizations?</td>
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**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