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Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner claims to the National Vaccine Injury Compensation Program, 2010–2016

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Abstract

Background: Since 2010, petitioner claims of shoulder injury related to vaccine administration (SIRVA) to the National Vaccine Injury Compensation Program (VICP) have been increasing.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Objective: To conduct a scientific review of clinical characteristics of SIRVA petitions to the VICP.

Methods: We queried the VICP's Injury Compensation System database for medical reports of alleged SIRVA and SIRVA-like injuries. Medical reports are summaries of petitioner claims and supporting documentation along with a VICP clinician reviewer diagnosis and assessment of criteria for concession. We conducted a descriptive analysis of SIRVA petitioner claims recommended by the VICP for concession as SIRVA injuries.

Results: We identified 476 petitioner claims recommended for concession. Claims per year increased from two in 2011, the first full year in the analytic period, to 227 in 2016. Median age was 51 years, 82.8% were women, and median body mass index was 25.1 (range 17.0–48.9). Four hundred cases (84.0%) involved influenza vaccine. Pharmacy or store (n = 168; 35.3%) was the most common place of vaccination followed by doctor's office (n = 147; 30.9%). Fewer than half of cases reported a suspected administration error; 172 (36.1%) reported 'injection too high' on the arm. Shoulder pain, rotator cuff problems, and bursitis were common initial diagnoses. Most (80.0%) cases received physical or occupational therapy, 60.1% had at least one steroid injection, and 32.6% had surgery. Most (71.9%) healthcare providers who gave opinions on causality considered the injury was caused by vaccination. A minority (24.3%) of cases indicated that symptoms had resolved by the last visit available in medical records.

Conclusions: Most conceded claims for SIRVA were in women and involved influenza vaccines. Injection too high on the arm could be a factor due to the risk of injecting into underlying non-muscular tissues. Healthcare providers should be aware of proper injection technique and anatomical landmarks when administering vaccines.

Keywords

Shoulder injury related to vaccine administration (SIRVA); National Vaccine Injury Compensation Program (VICP); Petitioner claims; Concession; Vaccination; Shoulder injury

1. Introduction

The National Vaccine Injury Compensation Program (VICP), authorized by the National Childhood Vaccine Injury Act of 1986, as amended, and administered by the Health Resources and Services Administration (HRSA), has been in operation since 1988. It is a no-fault alternative to the traditional tort system to adjudicate petitioner (i.e., individuals filing claims) claims of alleged vaccine-related injury [1]. The program covers all vaccines routinely recommended for children and/or pregnant women that have an excise tax placed on them and are added to the Vaccine Injury Table by the Secretary of the Department of Health and Human Services. Petitions may be filed with the VICP regardless of the age of the recipient; for example, because influenza vaccine is routinely recommended for children and is subject to an excise tax, it is a vaccine covered under the VICP and both children and adults who receive the influenza vaccine are eligible to file claims alleging a related injury or death.

The Vaccine Adverse Event Reporting System (VAERS), also authorized by the National Childhood Vaccine Injury Act of 1986, is a national spontaneous reporting system for

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adverse events following vaccines. VAERS, which is co-administered by the CDC and FDA, is used to conduct post-licensure vaccine safety monitoring and is separate and unrelated to the VICP [2]. A report to VAERS does not constitute or trigger a VICP petition, nor does a petition to VICP necessarily lead to a report to VAERS.

In 2010, physicians from the VICP published a case series studying 13 petitioners with severe arm and shoulder pain and reduced range of motion following vaccination; signs and symptoms lasted greater than six months and radiographic and surgical findings were consistent with injury to musculoskeletal structures of the shoulder [3]. The authors introduced the term shoulder injury related to vaccine administration (SIRVA) to describe these cases. SIRVA is thought to occur when vaccine is injected above or through the deltoid into underlying non-muscular tissues, such as the bursae, ligaments, and tendons [3]. Specific impairments include bursitis [4–8], bone erosion [8], and damage to the rotator cuff and bicipital tendons [4,6]. The authors, including a rheumatologist, hypothesized that an inflammatory response to vaccine contents in tissues other than the muscle may be causative [4,5,8]. Based on case series descriptions of SIRVA and SIRVA-like outcomes, a 2012 Institute of Medicine report concluded that deltoid bursitis can be causally associated with vaccination [9].

Through the federal rule-making process, VICP proposed (in 2015) and officially added (in 2017) SIRVA to the Vaccine Injury Table (Table) [10,11]. To gain entitlement to compensation under the VICP, petitioners must establish a vaccine-related injury or death has occurred, either by proving that a vaccine actually caused or significantly aggravated an injury (‘‘causation-in-fact”) or by demonstrating the occurrence of what is referred to as a ‘‘Table injury.” That is, petitioners may show that the vaccine recipient suffered an injury of the type enumerated in the Table corresponding to the vaccination in question and that the onset of such injury took place within the time period also specified in the Table. If so, the injury is presumed to have been caused by the vaccination, and the petitioner is entitled to compensation (assuming that other requirements are satisfied), unless it is found that the injury was caused by some factor other than the vaccination. Prior to SIRVA’s addition to the Vaccine Injury Table on March 21, 2017, VICP reviewed, adjudicated, and, where appropriate, conceded petitioner claims of SIRVA-like injuries based on causation-in-fact. During the time period from the 2010 case series publication [3] to the addition of SIRVA to the Vaccine Injury Table, alleged SIRVA petitions to VICP had been increasing substantially, especially for influenza vaccine [12].

In 2017, HRSA and the Centers for Disease Control and Prevention (CDC) initiated a joint scientific review to evaluate clinical characteristics of SIRVA petitions to the VICP since the time this condition was described by Atanasoff and colleagues [3].

2. Methods

Our review of SIRVA petitions used information from the Injury Compensation System, a VICP administrative database that is maintained by HRSA as a part of routine program administration. The process for identifying, reviewing, categorizing, and analyzing SIRVA petitions is detailed below.

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2.1. VICP administration procedure and review of petitioner claims

Petitions for compensation for alleged vaccine-related injuries are received and administratively processed by the VICP. To initiate the claims process, an individual files a petition with the U.S. Court of Federal Claims, typically through a lawyer. Then, the U.S. Department of Health and Human Services medical staff reviews the petition, determines if it meets the medical criteria for compensation and makes a preliminary recommendation. The U.S. Department of Justice develops a report that includes the medical recommendation and legal analysis and submits it to the Court. The report is presented to a court-appointed special master, who decides whether the petitioner should be compensated, often after holding a hearing in which both parties can present evidence. If compensation is awarded, the special master determines the amount and type of compensation. The Court orders the U.S. Department of Health and Human Services to award compensation. Even if the petition is dismissed, if certain requirements are met, the Court may order the Department to pay attorneys' fees and costs. The special master's decision may be appealed and petitioners who reject the decision of the court (or withdraw their petitions within certain timelines) may file a claim in civil court against the vaccine company and/or the health care provider who administered the vaccine.

2.2. Activities specific to the joint HRSA-CDC review of SIRVA petitions

In an effort to identify all potential cases of SIRVA in the Injury Compensation System, we conducted a broad search and queried the database for the following alleged injuries: ‘‘SIRVA,” ‘‘arm pain,” ‘‘shoulder pain,” ‘‘bursitis,” ‘‘rotator cuff tendonitis,” and ‘‘adhesive capsulitis.” In this initial query, we included medical reports for any of the above conditions even if the original VICP clinician reviewer determined that the alleged injury was not consistent with SIRVA or a SIRVA-like injury. We limited the search to petitions received from July 1, 2010 through December 31, 2016. We manually reviewed medical reports and abstracted demographic and clinical information into a customized Microsoft Access database. We used SAS software (version 9.4) for review and descriptive analysis. We excluded petitions if the initial VICP clinician reviewer documented a diagnosis other than SIRVA in the medical report (examples included brachial neuritis, lipoma, cellulitis, and others). For the final analysis, we included as ‘‘cases” the petitions for which the Medical Analysis Branch recommended concession for a SIRVA injury to the U.S. Department of Justice. This activity was determined to be a public health function that does not require institutional review board approval.

3. Results

Petitions to the VICP for SIRVA and SIRVA-like injuries have increased every year since the initial case series of petitioner claims for SIRVA to VICP was published (Fig. 1), rising from 2.5% of total petitioner claims in 2011 to 41.9% in 2016 (Fig. 2). Our initial query (using the broadest criteria specified in the Methods) yielded 913 medical reports during the analytic period, 105 of which VICP clinician reviewers determined to be conditions other than SIRVA. Of the remaining 808, the Medical Analysis Branch recommended 476 petitions for concession for SIRVA as causation-in-fact; we included these cases in the final review (Fig. 3). Demographics and characteristics of cases are summarized in Table 1.

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Median age of the cases was 51 years (range 16–92), 82.8% were women, and median body mass index (BMI) was 25.1 (range 17.0–48.9; normal BMI is 18.5–24.9).

3.1. Vaccination

A total of 489 administered vaccines were documented in the 476 petitions. Two cases received two vaccines in the injured arm, and one received three in the injured arm; the remaining six additional vaccines were administered in the non-injured arm. Four hundred cases (84.0%) involved injectable inactivated influenza vaccine. Place of vaccination was reported in 449 cases; 168 (37.4%) indicated receipt of vaccination at a free-standing or store-based pharmacy, followed by 147 (32.7%) at a doctor's office (Table 2). Fewer than half (216; 45.4%) of vaccine records included information on credentials of vaccinators; ''nurse," (RN/LPN) (103; 47.7%) was the most frequent vaccinator when credentials were known. Just under half (227; 47.7%) of medical reports indicated an alleged error in vaccine administration. The most common error, as reported by petitioners, was injection too high on the arm (172; 75.8%) (Table 3).

3.2. History and physical examination

Median time from vaccination to seeking healthcare was 15 days (range: 0–190) (Table 4). Most (447; 93.9%) cases complained of shoulder pain at their initial post-vaccination evaluation and 31.1% also reported limited range of motion at this first visit. Neurologic symptoms such as weakness, numbness, and paresthesia were infrequently mentioned. Most (327; 68.7%) cases reported that pain began on the day of vaccination; an additional 13.1% reported that it began the following day. On physical exam, tenderness to palpation (271; 56.9%) and limited range of motion (266; 55.9%) were common. Healthcare providers listed shoulder pain as the diagnosis in approximately one-third of cases at the initial post-vaccination visit.

3.3. Diagnostic evaluation

In the course of evaluation and treatment, 384 (80.7%) cases had magnetic resonance imaging (MRI) of the shoulder performed (Table 5). The most common MRI findings, per the radiology reports, were tendonitis, tendinosis, or ''tendinopathy" (189; 49.2%), complete or partial rotator cuff tears (170; 44.3%), and bursitis (132; 34.3%); 21 (5.5%) MRIs were read as normal. MRI findings were not mutually exclusive, with many MRIs reporting multiple findings. Median time from vaccination to MRI was 82 days. Routine shoulder x-rays, performed in 55.7% of cases, did not provide substantive information to aid in the diagnosis of SIRVA or related conditions.

3.4. Clinical course

Physical or occupational therapy was commonly prescribed; 381 (80.0%) cases had at least one treatment visit. Two hundred eighty-six (60.1%) had at least one steroid injection into the affected shoulder joint in the course of care (Table 6). One-third of cases (155; 32.6%) had surgery. The severity and duration of symptoms varied; 24.3% of cases indicated that symptoms had resolved by the last visit available in the medical records. Residual symptoms

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experienced by the remainder of cases included persistent pain, limited range of motion, impingement, weakness, and muscle atrophy.

3.5. Healthcare provider opinions on causality

A total of 334 medical reports included documentation from 416 healthcare providers who gave opinions on whether or not they believed the shoulder injury was related to vaccination. The majority (299; 71.9%) indicated they believed the injury was caused by vaccination, 70 (16.8%) healthcare providers indicated they did not believe vaccination caused the injury, and the remaining 47 (11.3%) attributed the injury to non-vaccine related causes including cervical spine injury, pre-existing shoulder injuries, nerve injuries, and arthritis. These results stratified by specialty are summarized in Table 7.

4. Discussion

Petitioner claims to the VICP for alleged SIRVA and SIRVA-like injuries have risen dramatically since the initial case series of petitioner claims for SIRVA to VICP was published in 2010 [3]. In the time period between that publication and the addition of SIRVA to the Vaccine Injury Table, the VICP recommended concession as causation-in-fact for 58.9% of the 808 claims for SIRVA or related shoulder injuries.

We found many similarities between our case series and other case reports described in the literature, including a predominance of women and adult patients [3,6]. The median age of our cases was 51 years, with only one, a teenager, below age 18 years. Children and adolescents receive many vaccines, and children over the age of three years are recommended to be vaccinated in the deltoid region for intramuscular injections. In a study of bone strikes during vaccination of children, Lippert and Wall determined that use of the recommended needle lengths by age can lead to over-penetration of the deltoid muscle in 10.6–61.3% of cases [13]. Despite this potential risk, children are rarely the subject of petitioner claims for SIRVA in the VICP. In general, soft tissue shoulder injuries, such as ligament disruptures and bursitis, are uncommon in pediatric populations [14].

Initial research on potential vaccination-related shoulder injuries suggested that people with lower BMI might be at greater risk of over penetration of the deltoid muscle and therefore at increased risk for injury [4,15]. However, later case series analyses indicated that BMIs generally ranged from normal to obese [3,16]. We did not find evidence of low BMI preponderance in our cases; the median BMI was in a range that CDC defines as ‘‘overweight” [17] and the distribution of BMI of our cases is similar to the BMI distribution of the United States general population.

Most (84.0%) of our cases involved inactivated influenza vaccine (Table 2). This is the most common vaccine administered in the United States, with approximately 150 million doses distributed annually [18] and the majority of doses administered in adults. As such, it is not surprising that inactivated influenza vaccine was the most frequently implicated vaccine. In addition, the most common place of vaccination was in pharmacies or stores (Table 2), which is consistent with SIRVA reports received by the Vaccine Adverse Event Reporting

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System (VAERS) of atypical shoulder pain and dysfunction following inactivated influenza vaccine [19].

SIRVA can be broadly defined as pain that begins within 48 h of vaccination and reduced range of motion [11]. This definition is sensitive enough to include almost all musculoskeletal injuries that can result from injection, but such a broad definition makes it difficult to describe SIRVA as a discrete clinical entity. Consistent with this lack of specificity, we observed that initial diagnoses at the first clinical exam varied (Table 4), with shoulder pain being the most common finding and most common initial diagnosis, followed by rotator cuff problems and bursitis. Common findings on MRI included tendonitis/osis/inopathy, rotator cuff tears and bursitis (Table 5). Similar findings have been previously described in case reports of shoulder injury following vaccination [16,20]. Although less common, bone edema and necrosis was also evident among our cases, which has also been reported in the literature [8,21]. A general clinical or radiographic finding among our cases was evidence of injury to internal structures, primarily, but not limited to, the tendons of the rotator cuff and bursae. MRI findings in our cases should be interpreted with caution and not be equated with prima facie evidence of a causally associated injury. Such findings are not uncommon among people in the age group of our cases, independent of vaccination (i.e., shoulder pathology is common in middle age and old age) [22]. In addition, corticosteroid injection into and around the joint may also be responsible for some MRI findings [23].

Less than a quarter (24.3%) of cases reported that their symptoms had resolved or largely resolved by the last clinic appointment available in the medical records. However, all petitioners in the analysis were seeking financial compensation for an alleged SIRVA injury and had a disincentive to acknowledge resolution of symptoms (a possible perceived barrier to receiving compensation), so this finding may not be unexpected. Medical interventions were common; the majority of cases were referred for physical or occupational therapy or received corticosteroid injections into the affected joint and around one-third had surgery. Due to potential bias in self-reporting of recovery status, it is not possible to evaluate either the impact or relative impact of specific treatments for SIRVA.

With 476 petitioner claims, this is the largest case series of suspected SIRVA and SIRVA-like injuries to date. The VICP clinician reviewer assessment documented in medical reports allowed us to exclude cases that petitioned for compensation, but whose injuries were unlikely to have been SIRVA, with reviewer diagnoses including brachial neuritis, cervical radiculopathy, complex regional pain syndrome, arthritis, and others. The medical reports (summaries) that served as our data source were based on comprehensive medical records submitted to the VICP as part of the claims adjudication process. During the medical report abstraction process, our physician-nurse adjudication committee was in frequent consultation to adjudicate issues when questions and disagreements arose, which minimized inter-reviewer variation.

Our review has limitations. All petitioners submitting claims to the VICP are seeking monetary compensation for perceived injuries from vaccination, which may impact their use of the healthcare system (i.e., frequency and type of care), reported severity of symptoms, and statements on recovery status. Because the VICP only covers certain vaccines, some

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vaccines, such as pneumococcal polysaccharide and recombinant zoster vaccines, are not included in the VICP; thus, SIRVA injuries related to such vaccines would not be captured in our case series. In addition, SIRVA is different from other compensable injuries in the VICP. Most of the other Vaccine Injury Table injuries are rare conditions, whereas shoulder injuries are common, accounting for approximately 1% of all primary care visits in the United States [24]. As the VICP system is designed to give claimants the benefit of doubt, it is possible, if not probable, that cases of shoulder injuries that were not related to vaccination (i.e., pre-existing or coincidentally occurring) were included in petitioner claims and conceded by the VICP. Furthermore, since we have neither denominator data nor an unvaccinated comparison group, we cannot determine the risk of SIRVA or individual risk factors. Finally, our abstraction documents were medical reports from the VICP, which are legal documents and not designed for use in epidemiologic analysis.

5. Conclusions

Petitioner claims for SIRVA to the VICP increased substantially from 2010 to 2016, following the initial SIRVA case series publication from the VICP and the open vetting process for adding SIRVA to the Vaccine Injury Table. With hundreds of millions of doses of adult vaccines distributed in the United States in the 2000 s, including 100–150 million doses of influenza vaccines distributed annually in recent influenza seasons, conceded petitioner claims for SIRVA in the VICP still appear to be relatively uncommon. However, true SIRVA is likely preventable. Injection too high on the arm could be a factor due to the risk of injecting into underlying non-muscular tissues (bursa, tendons, ligaments, and bones). Healthcare providers and clinical practice coordinators should ensure that all staff members who administer vaccines receive proper training on vaccination technique. When injecting into the deltoid, care should be taken to ensure that the injection is placed in the thick, centrally located portion of the deltoid muscle, away from the upper third of the deltoid where the risk of over penetration into underlying structures of the shoulder is greatest.

6. Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention, the Health Resources and Services Administration, or the U.S. Department of Health and Human Services.

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Abbreviations:

SIRVA	shoulder injury related to vaccine administration
VICP	National Vaccine Injury Compensation Program
HRSA	Health Resources and Services Administration

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CDC	Centers for Disease Control and Prevention
BMI	body mass index
MRI	magnetic resonance imaging

References

[1]. Cook KM, Evans G. The national vaccine injury compensation program. Pediatrics 2011;127(Suppl 1):S74–7. [PubMed: 21502255]

[2]. Shimabukuro TT, Nguyen M, Martin D, DeStefano F. Safety monitoring in the vaccine adverse event reporting system (VAERS). Vaccine 2015;33 (36):4398–405. [PubMed: 26209838]

[3]. Atanasoff S, Ryan T, Lightfoot R, Johann-Liang R. Shoulder injury related to vaccine administration (SIRVA). Vaccine 2010;28:8049–52. [PubMed: 20955829]

[4]. Bodor M, Montalvo E. Vaccination-related shoulder dysfunction. Vaccine 2007;25:585–7. [PubMed: 17064824]

[5]. Uchida S, Sakai A, Nakamura T. Subacromial bursitis following human papilloma virus vaccine misinjection. Vaccine 2012;31:27–30. [PubMed: 23122992]

[6]. Martin Arias LH, Sanz Fadrique R, Sainz Gil M, Salgueiro-Vazquez ME. Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations. Vaccine 2017;35:4870–6. [PubMed: 28774564]

[7]. Cook IF. Subdeltoid/subacromial bursitis associated with influenza vaccination. Hum Vaccin Immunother 2014;10:605–6. [PubMed: 24284281]

[8]. Salmon JH, Geoffroy M, Eschard JP, Ohl X. Bone erosion and subacromial bursitis caused by diphtheria-tetanus-poliomyelitis vaccine. Vaccine 2015;33:6152–5. [PubMed: 26458794]

[9]. Institute of Medicine (U.S.). Committee to Review Adverse Effects of Vaccines. In: Stratton KR, editor. Adverse effects of vaccines: evidence and causality Washington, D.C.: National Academies Press; 2012.

[10]. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table. Health and Human Services. Federal Register; 2015. p. 45132–54.

[11]. Vaccine Injury Table. Health and Human Services Rockville, MD; 2017.

[12]. National Vaccine Injury Compensation Program 2018.

[13]. Lippert WC, Wall EJ. Optimal intramuscular needle-penetration depth. Pediatrics 2008;122:e556–63. [PubMed: 18694903]

[14]. Kraus R, Pavlidis T, Heiss C, Kilian O, Schnettler R. Arthroscopic treatment of post-traumatic shoulder instability in children and adolescents. Knee Surg Sports Traumatol Arthrosc 2010;18:1738–41. [PubMed: 20217390]

[15]. Cook IF, Williamson M, Pond D. Definition of needle length required for intramuscular deltoid injection in elderly adults: an ultrasonographic study. Vaccine 2006;24:937–40. [PubMed: 16191454]

[16]. Okur G, Chaney KA, Lomasney LM. Magnetic resonance imaging of abnormal shoulder pain following influenza vaccination. Skeletal Radiol 2014;43:1325–31. [PubMed: 24722656]

[17]. Division of Nutrition, Physical Activity, and Obesity About Adult BMI. Atlanta, GA; 2017.

[18]. National Center for Immunizations and Respiratory Diseases. Historical Reference of Seasonal Influenza Vaccine Doses Distributed; 2018.

[19]. Shimabukuro TT. Reports of shoulder dysfunction following inactivated influenza vaccine in the Vaccine Adverse Event Reporting System (VAERS), 2010–2016 Atlanta, GA: Advisory Committee on Immunization Practices; 2017.

[20]. Barnes MG, Ledford C, Hogan K. A ‘‘needling” problem: shoulder injury related to vaccine administration. J Am Board Fam Med 2012;25:919–22. [PubMed: 23136333]

[21]. Kuether G, Dietrich B, Smith T, Peter C, Gruessner S. Atraumatic osteonecrosis of the humeral head after influenza A-(H1N1) v–2009 vaccination. Vaccine 2011;29:6830–3. [PubMed: 21803092]

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[22]. Kvalvaag E, Anvar M, Karlberg AC, Brox JI, Engebretsen KB, Soberg HL, et al. Shoulder MRI features with clinical correlations in subacromial pain syndrome: a cross-sectional and prognostic study. BMC Musculoskelet Disord 2017;18:469. [PubMed: 29157224]

[23]. Borick JM, Kurzweil PR. Magnetic resonance imaging appearance of the shoulder after subacromial injection with corticosteroids can mimic a rotator cuff tear. Arthroscopy 2008;24:846–9. [PubMed: 18589276]

[24]. Wofford JL, Mansfield RJ, Watkins RS. Patient characteristics and clinical management of patients with shoulder pain in U.S. primary care settings: secondary data analysis of the National Ambulatory Medical Care Survey. BMC Musculoskelet Disord 2005;6:4. [PubMed: 15691370]

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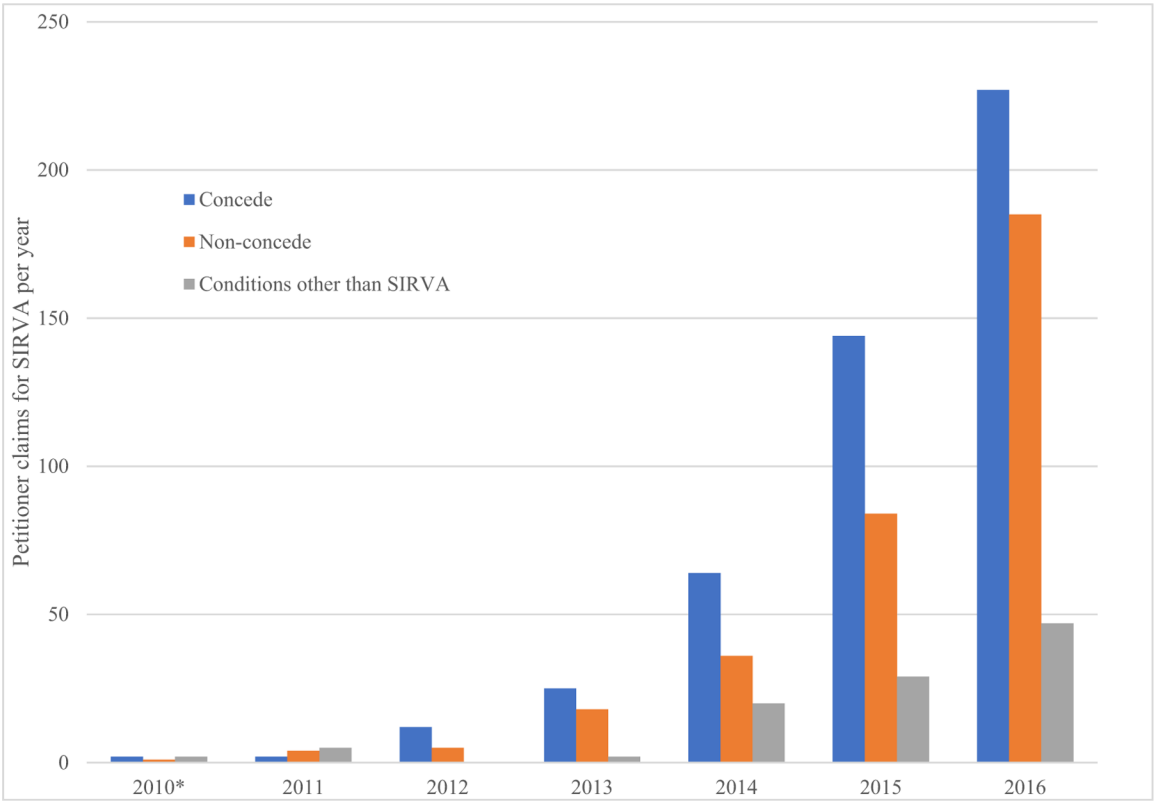

Fig. 1.

Submitted petitioner claims for SIRVA and SIRVA-like conditions to the VICP by year and concession status (N = 913), July 2010-December 2016. *Data from 2010 includes petitioner claims from July through December. SIRVA – shoulder injury related to vaccine administration, VICP – National Vaccine Injury Compensation Program.

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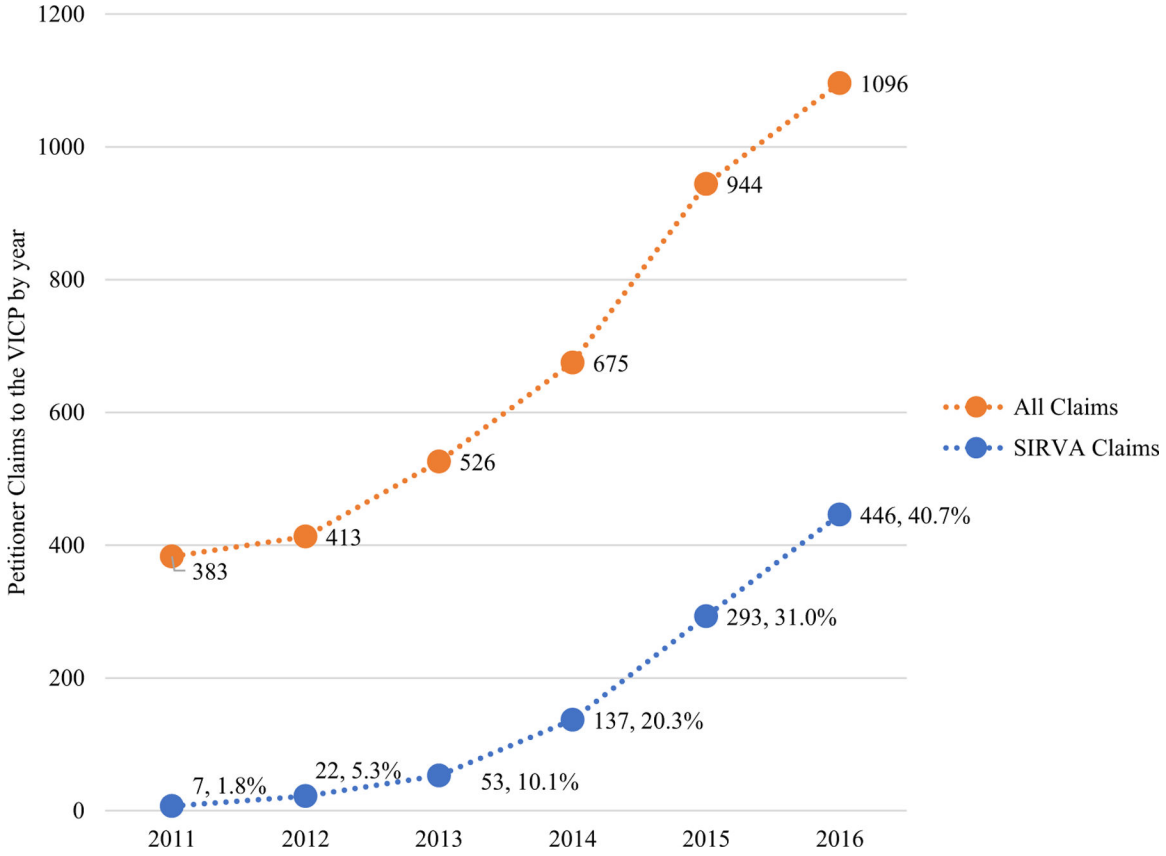

Fig. 2.

Total submitted petitioner claims and submitted claims for SIRVA to the VICP by year and concession status, January 2011-December 2016*. *Data are presented using different time points than released VICP data, which is presented by fiscal year, not calendar year. SIRVA – shoulder injury related to vaccine administration, VICP – National Vaccine Injury Compensation Program.

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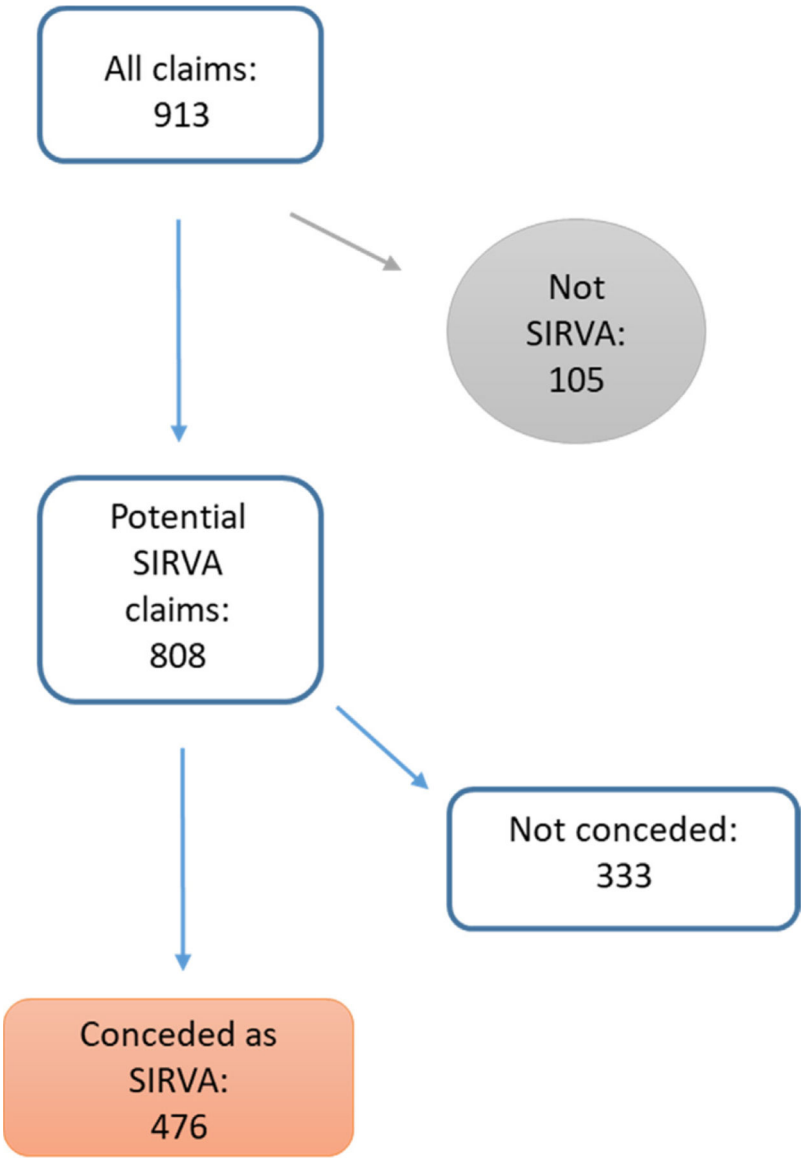

Fig. 3.

Identification of conceded SIRVA claims from all claims for shoulder injuries received by the VICP. SIRVA – shoulder injury related to vaccine administration, VICP – National Vaccine Injury Compensation Program.

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Table 1

Petitioner characteristics in conceded petitions (claims) for SIRVA to the VICP, July 2010-December 2016.

Characteristics	Conceded petitions, N = 476 n (%)
Sex	
Male	82 (17.2)
Female	394 (82.8)
Age in years	
0–17	1 (0.2)
18–49	218 (45.8)
50–64	170 (35.7)
65 and older	75 (15.8)
Missing	13 (2.7)
Median age (range)	51 (16–92)
BMI categories	
Underweight (<18.5)	5 (1.1)
Normal (18.5–24.9)	215 (45.2)
Overweight (25–29.9)	151 (31.7)
Obese (≥30)	82 (17.2)
Missing	23 (4.8)
Median BMI (range)	25.1 (17.0–48.9)

SIRVA – shoulder injury related to vaccine administration, VICP – National Vaccine Injury Compensation Program, BMI – body mass index.

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Table 2

Characteristics in conceded petitions (claims) for SIRVA to the VICP, July 2010-December 2016.

Vaccine type*	Conceded petitions, N = 476* n (%)
Inactivated influenza	400 (84.0)
Tetanus, diphtheria, pertussis	57 (12.0)
Pneumococcal conjugate	11 (2.3)
Tetanus, diphtheria	6 (1.3)
Pneumococcal polysaccharide	4 (0.8)
Hepatitis A	3 (0.6)
Hepatitis B	2 (0.4)
Meningococcal conjugate	2 (0.4)
Measles, mumps, rubella	1 (0.2)
Human papillomavirus	1 (0.2)
Other or unspecified	2 (0.4)
Vaccinator credentials	
Nurse (RN or LPN)	103 (21.6)
Pharmacist	71 (14.9)
Medical assistant	26 (5.5)
Physician assistant or nurse practitioner	8 (1.7)
Physician	6 (1.3)
Pharmacy technician	2 (0.4)
Unknown or missing	260 (54.6)
Place of vaccination	
Pharmacy or store	168 (35.3)
Doctor’s office	147 (30.9)
Workplace	72 (15.1)
Hospital	31 (6.5)
Emergency department or urgent care	16 (3.4)
Health department	12 (2.5)
Nursing home or senior living facility	1 (0.2)
Unknown or missing	29 (6.1)

SIRVA – shoulder injury related to vaccine administration, VICP – National Vaccine Injury Compensation Program, RN – registered nurse, LPN – licensed practical nurse.

* Not mutually exclusive; 489 vaccines were received by 476 patients (i.e., some patients received simultaneous vaccinations); percentages add up to > 100%.

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Table 3

Petitioner reported vaccination errors in conceded petitions (claims) for SIRVA to the VICP, July 2010-December 2016.*

Petitioner reported vaccination error†	Petitions with reported errors, N = 227 n (%)
Injection too high	172 (75.8)
Extremely painful injection	35 (15.4)
Hit something hard	12 (5.3)
Improper technique	9 (4.0)
Difficult administration	8 (3.5)
Seated while vaccinator standing	8 (3.5)
Injection too deep	6 (2.6)
Repeat injection	4 (1.8)
Wrong site	3 (1.3)
Wrong needle length	3 (1.3)
Hit nerve	1 (0.4)
Vaccinator not looking	1 (0.4)
Other vaccination error	16 (7.0)

SIRVA – shoulder injury related to vaccine administration, VICP – National Vaccine Injury Compensation Program.

*There were a total of 476 conceded petitions, of which 227 (47.7%) documented a petitioner-reported vaccination error.

†Not mutually exclusive.

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Table 4

Initial post-vaccination medical evaluation in conceded petitions (claims) for SIRVA to the VICP, July 2010-December 2016.

Signs, symptoms, findings and initial diagnosis*	**Conceded petitions, N = 476 n (%)**
Presenting signs and symptoms	
Shoulder pain	447 (93.9)
Range of motion limitation	148 (31.1)
Numbness	37 (7.8)
Tingling or paresthesia	35 (7.4)
Swelling or erythema	26 (5.5)
Weakness	23 (4.8)
Other	16 (3.4)
Physical exam findings	
Tenderness	271 (56.9)
Range of motion limitation	266 (55.9)
Impingement	47 (9.9)
Weakness	40 (8.4)
Local swelling or erythema	31 (6.5)
Sensory loss	4 (0.8)
Other	42 (8.8)
Initial diagnosis	
Shoulder pain	152 (31.9)
Rotator cuff problems	66 (13.9)
Bursitis	56 (11.8)
Local reaction	39 (8.2)
Adhesive capsulitis	26 (5.5)
Adverse effects of vaccination	12 (2.5)
Neuritis	11 (2.3)
Impingement	9 (1.9)
Other	46 (9.7)
Not specified	88 (18.5)
Median time from vaccination to seeking healthcare (range)	15 days (0–970)

SIRVA – shoulder injury related to vaccine administration, VICP – National Vaccine Injury Compensation Program.

Footnote: Not all symptoms, findings, or diagnoses are typical for SIRVA.

* Not mutually exclusive.

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Table 5

Magnetic resonance imaging (MRI) findings in conceded petitions (claims) for SIRVA to the VICP, July 2010-December 2016.

MRI findings in 384 conceded petitions*,†	n (%)
Tendonitis/osis/opathy	189 (49.2)
Any rotator cuff finding	165 (43.0)
Partial rotator cuff tear	*134 (34.9)*
Complete rotator cuff tear	*36 (9.4)*
Multiple rotator cuff problems	*30 (7.8)*
Bursitis	132 (34.4)
Acromioclavicular arthritis	62 (16.2)
Labral tear	62 (16.2)
Fluid in the bursa	60 (15.6)
Joint edema	40 (10.4)
Muscle edema	37 (9.6)
Bone edema	28 (7.3)
Bicep tendon findings	25 (6.5)
Normal	21 (5.5)
Capsular thickening	21 (5.5)
Glenohumeral arthritis	20 (5.2)
Bone cyst	12 (3.1)
Synovitis	10 (2.6)
Other	61 (15.9)

SIRVA – shoulder injury related to vaccine administration, VICP – National Vaccine Injury Compensation Program.

Footnote: Many of these findings are common in patients with and without shoulder pain and may not be related to vaccination.

*Not mutually exclusive; many cases had multiple findings on MRI.

†There were a total of 476 conceded petitions, of which 384 (80.7%) had an MRI.

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Table 6

Treatments reported in conceded petitions (claims) for SIRVA to the VICP, July 2010-December 2016 (N = 476).

Treatment *	**Conceded petitions, N = 476 n (%)**
Physical or occupational therapy	381 (80.0)
Steroid injections	286 (60.1)
NSAIDs or other analgesics	240 (50.4)
Surgery †	155 (32.6)
Oral steroids	130 (27.3)
Exercise routine	111 (23.3)
Opiates	65 (13.7)
Chiropractic treatment	30 (6.3)
Muscle relaxant	29 (6.1)
Acupuncture	18 (3.8)
Surgical procedure *	Surgical cases, N = 155 n (%)
Subacromial decompression	67 (43.2)
Joint debridement	48 (31.0)
Rotator cuff repair	46 (29.7)
Diagnostic arthroscopy	46 (29.7)
Manipulation under anesthesia	21 (13.5)
Lysis of adhesions	15 (9.7)
Bursectomy	14 (9.0)
Distal clavicle excision	14 (9.0)
Synovectomy	11 (7.1)
Labral or SLAP repair	8 (5.2)
Other	52 (33.5)

SIRVA – shoulder injury related to vaccine administration, VICP – National Vaccine Injury Compensation Program, NSAIDs – nonsteroidal anti-inflammatory drugs, SLAP – superior labrum from anterior to posterior.

*Not mutually exclusive.

†Subset of cases with surgical treatment.

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Table 7

Healthcare provider opinions by specialty regarding causality among conceded petitions (claims) for SIRVA to the VICP, July 2010-December 2016 (416 statements in 334 medical reports).

Healthcare provider specialty	Believed vaccine caused injury	Believed vaccine did not cause injury	Believed alternate cause of injury	Total statements by provider specialty
Orthopedics	181 (73.0)	42 (16.9)	25 (10.1)	248
Primary care	137 (85.6)	17 (10.6)	6 (3.8)	160
Neurology	13 (56.5)	4 (17.4)	6 (26.1)	23
Physical or occupational therapy	19 (82.6)	–	4 (17.4)	23
Occupational medicine	12 (66.7)	3 (16.7)	3 (16.7)	18
Emergency medicine	11 (84.6)	–	2 (15.4)	13
Rheumatology	8 (61.5)	2 (15.3)	3 (23.1)	13
Physical medicine and rehabilitation	8 (80.0)	1 (10.0)	1 (10.0)	10
Other healthcare provider	10 (62.5)	2 (12.5)	4 (25.0)	16

SIRVA – shoulder injury related to vaccine administration, VICP – National Vaccine Injury Compensation Program.

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