

Position Statement

Rotator Cuff Tendinopathy and Glenohumeral Arthritis are Unlikely to be Caused by Vaccine Administration

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Overview

There are an increasing number of claims that vaccine administration caused rotator cuff tendinopathy, adhesive capsulitis, and arthritis¹. The proposed theory is that vaccinations are occasionally inadvertently injected into the subdeltoid bursa contiguous with the subacromial bursa of glenohumeral joint. And that injection in this area damages shoulder tissue via an immune inflammatory response².

There is no high-quality evidence that demonstrates that vaccination can cause or contribute to common shoulder problems such as rotator cuff tendinopathy and arthritis. There are only descriptions of patients that perceive a relationship between vaccination and their shoulder problem^{3,4,5}.

When new symptoms arise, a contemporary event may be blamed⁶. The human mind is prone to this post hoc, ergo propter hoc fallacy (after this, therefore because of this). Temporal relationship does not imply causation, particularly among common events such as shoulder pain and immunizations.

Rotator cuff pathology is common as we age^{7,8}. Most of these changes eventually cause shoulder pain. Age-related conditions such as presbyopia (the need for reading glasses), carpal tunnel syndrome, arthritis, and rotator cuff tendinopathy arise slowly, and are typically first noticed at a specific time or after a specific event^{2,3}. The symptoms from rotator cuff tendinopathy can go unnoticed for years until attention is drawn to the shoulder, as happens after vaccination administered to the shoulder.

Immunizations are also very common⁹. Many individuals receive annual influenza vaccination to protect themselves and the vulnerable people they may come into contact with. Vaccination also limits the potential for epidemic spread of the flu. Vaccination usually causes muscle pain for a few days or weeks.

Common shoulder problems might arise, or come to attention, coincident with annual vaccination. These associations between immunization and shoulder pathology are extremely likely to occur coincidentally, even if they are perceived as causal.

There is a notable chance of overlap between newly symptomatic, age-appropriate shoulder pathology and vaccination without actual injury to the shoulder from vaccine. It can be estimated that nearly six million people that are vaccinated each year already have detectable rotator cuff tendinopathy, a substantial

percentage of whom have not yet noticed symptoms. People whose rotator cuff tendinopathy starts to be symptomatic within a few months of vaccination are at risk of misperceiving that the symptoms and the vaccination are related.

History

Within the past decade, the number of claims of shoulder injury from vaccination has increased substantially to over 600 cases per year¹. Several factors contributed to this rising number of claims.

Congress responded to vaccine manufacturers' in 1986 over concerns about potential tort liability by legislating a no-fault substitute called the National Vaccine Injury Compensation Program (VICP). The VICP is funded by a 75-cent excise tax on each covered vaccine and is administered by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS), the Department of Justice (DOJ), and the Court of Federal Claims (CFC). As of March 2019, the accumulated balance in the VICP Trust Fund was over \$3.8 billion.

All vaccines recommended by the federal Centers for Disease Control and Prevention (CDC) for routine use in children and pregnant women are covered by the VICP; for those vaccines, persons of any age may file claims for compensation. In 2005, the CDC recommended annual influenza vaccination in children, thereby making all influenza vaccine administrations eligible for compensation by the VICP, including those in adults.

In 2010, physician and nurse reviewers for the VICP from the Health Services and Resources Administration published a paper describing 13 people claiming injury from vaccination to the shoulder³. They coined the term Shoulder Injury Related to Vaccine Administration or SIRVA. The mean age of the 11 women and two men claimants was 50 years (range 26 to 83). MRIs in nine patients showed findings consistent with rotator cuff tendinopathy with bursitis. The descriptions interpreted as potential injury from vaccine might be age-appropriate changes to the rotator cuff. The MRI findings in these patients were not conclusively linked to damage from the vaccine.

In 2011, a National Academy of Medicine (NAM) committee on the adverse effects of vaccines concluded—based on a few case reports—that “the evidence convincingly supports a causal relationship between the injection of a vaccine and deltoid bursitis.”² The AAOS is critical of this conclusion. First, these were patient descriptions (case reports) rather than controlled experimental evidence. Second, “deltoid bursitis” is not a term used by musculoskeletal experts.

Despite this lack of evidence, shoulder injury was added to the Vaccine Injury Table in March 2017. Problems listed by the Secretary of Health and Human Services on the Vaccine Injury Table are presumed compensable, while other claimed injuries must be proven in court. Given the likelihood that shoulder pathology and vaccination will be coincident without being related, it is misleading for new shoulder pains to be automatically compensable.

Following these developments, the number of claims for shoulder injury rose from 10 in 2011 to 671 in 2018¹. Essentially all of these are adult claims (in a program designed to promote childhood vaccination), with the vast majority attributed to influenza vaccine administration.

More than half of all VICP claims are now for shoulder pain after vaccine administration, with typical compensation amounts between \$75,000 and \$200,000.

There is a history of harm from similarly well-meaning but misguided assertions of causality^{10,11,12}. One common theme is that the associations are supported by rationale, plausibility, patient description, and fervent advocacy often accompanied by self-interest. However, they are not supported by scientific evidence—meaning that there are no experiments with controls or other methods to limit bias.

In the case of perceived shoulder injury after vaccination, there are only descriptions of patients that believe their shoulder problem is due to vaccination. In contrast, post-marketing surveillance study of thousands of patients receiving the Hepatitis A vaccine found that musculoskeletal problems were equally common before and after vaccination¹³. There is also no evidence that intra-articular injection of vaccines causes harm; one study of intentional intra-articular injection still induced immunity but did not lead to any harm¹⁴.

As well as the VICP, there is a separate voluntary reporting mechanism for surveillance: The Center for Disease Control's Vaccine Adverse Event Reporting System. Two recent papers summarize reports to both programs.

In the paper describing reports to the VICP, the mean age of people with uncontested claims for "SIRVA" was 51, 83% were women, and 84% involved influenza vaccine⁵. Among the 384 claimants with an MRI, a specific diagnosis was not given for each patient. Instead, 1145 observations were described in the 384 patients, 771 (67%) of which could be related to rotator cuff tendinopathy and 132 (12%) to glenohumeral arthritis. There were only 21 instances of "capsular" thickening (1.8%) and it is not clear if some of these were associated with rotator cuff tendinopathy or glenohumeral arthritis. There were no reports of vaccine-specific pathophysiology and only 10 instances of "synovitis."

Among 1220 reports to VARES, the median age was 52 (range 16 to 94; only 2 under 17 years of age), 86% were women, and there was no vaccine specific pathophysiology noted. Most of the reports mentioned medical evaluations describing common shoulder diagnoses⁴.

With these considerations in mind, the members of the American Academy of Orthopaedic Surgeons (AAOS) take the position that, in the absence of high quality scientific evidence, vaccination administered to the shoulder is unlikely to cause or contribute to common shoulder pathologies such as rotator cuff tendinopathy and glenohumeral arthritis and should be removed from the Vaccine Injury Table.

Call for Evidence

The growing number of claims for shoulder injury to the VICP is an example of how policy (in this case making a firm determination about causality when the science is incomplete and tying that to pre-approved

compensation) can influence illness. There can be a form of the nocebo effect (an idea can create or add to illness) at work^{15,16} as well as the influence of secondary gain¹⁷. The fact that autism claims to the VICP were disallowed and deemed not compensable is inconsistent with the current decision-making regarding automatically compensable conditions listed on the VICP Injury Table. Autism was excluded because the science showed a very low probability of association¹⁹. That is also the case for the shoulder.

It is possible there may be a rare, vaccine-specific, severe pathology related to injection into the subacromial bursa and glenohumeral joint. Many of the reported cases to date could have alternative explanations and more evidence is needed to define a unique, vaccine-specific pathology. Given the potential for widespread misdiagnosis and mistreatment of individual patients and increased vaccine hesitancy resulting in diminished collective immunity, we must insist on strong scientific evidence before supporting the idea that vaccine administration causes common shoulder problems such as idiopathic adhesive capsulitis, rotator cuff tendinopathy, or glenohumeral arthritis. To date, none of the reported cases have demonstrated causality between findings on MRI and at surgery and vaccination. We lack high-quality evidence of a specific and harmful inflammatory response from vaccination. Absent such evidence, vaccine administration should be presumed merely coincident with these common shoulder pathologies, including glenohumeral arthritis and rotator cuff tendinopathy.

Surgeons can validate a patient's experience of pain after vaccination without validating the concept that vaccine causes common chronic shoulder pathology. This distinction is important because of the nocebo effect (ideas can cause harm) and the current lack of high-quality evidence of vaccine-specific pathology.

References

1. <https://www.nbcwashington.com/investigations/Half-of-All-New-Federal-Vaccine-Injury-Cases-Allege-Shots-Given-Incorrectly-481441201.html>
2. <http://www.nationalacademies.org/hmd/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx>
3. Atanasoff S, Ryan T, Lightfoot R, Johann-Liang R. Shoulder injury related to vaccine administration (SIRVA). *Vaccine*. 2010 Nov 29;28(51):8049-52. 10.1016/j.vaccine.2010.10.005. Epub 2010 Oct 16. PubMed PMID: 20955829.
4. Hibbs B, Ng C, Museru O, Moro P, Marquez P, Woo EJ, Cano M, Shimabukuro. Reports of atypical shoulder pain and dysfunction following inactivated influenza vaccine, Vaccine Adverse Event Reporting System (VAERS), 2010-2017. 2019. *Vaccine*. <https://doi.org/10.1016/j.vaccine.2019.11.023>
5. E. M. Hesse, S. Atanasoff, B. F. Hibbs et al., Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner claims to the National Vaccine Injury Compensation Program, 2010–2016, *Vaccine*, <https://doi.org/10.1016/j.vaccine.2019.11.032>
6. van Hoorn BT, Wilkens SC, Ring D. Gradual Onset Diseases: Misperception of Disease Onset. *J Hand Surg Am*. intra Dec;42(12):971-977.e1. doi:10.1016/j.jhsa.2017.07.021. Epub 2017 Sep 9. PubMed PMID: 28899587.
7. Liu TC, Leung N, Edwards L, Ring D, Bernacki E, Tonn MD. Patients Older Than 40 Years with Unilateral Occupational Claims for New Shoulder and Knee Symptoms Have Bilateral MRI Changes.

- Clin Orthop Relat Res. 2017 Oct;475(10):2360-2365.doi: 10.1007/s11999-017-5401-y. Epub 2017 Jun 9. PubMed PMID: 28600690; PubMed Central PMCID: PMC5599397.
8. Teunis T, Lubberts B, Reilly BT, Ring D. A systematic review and pooled analysis of the prevalence of rotator cuff disease with increasing age. *J Shoulder Elbow Surg.* 2014 Dec;23(12):1913-1921. doi: 10.1016/j.jse.2014.08.001. Review. PubMed PMID: 25441568.
 9. <https://www.cdc.gov/flu/fluview/coverage-1617estimates.html>
 10. Grottkau B. Whiplash and Other Useful Illnesses. *N Engl J Med* 2003; 348:1413-1414.
 11. Lucire, Y. Constructing RSI: Belief and Desire. New South Wales, 2002, ISBN 0 86840 778 X
 12. Shorter, E. From paralysis to fatigue: A history of psychosomatic illness in the modern era. New York, NY, 1992. US: Free Press.
 13. Black S, Shinefield H, Hansen J, Lewis E, Su L, Coplan P. A post-licensure evaluation of the safety of inactivated hepatitis A vaccine (VAQTA, Merck) in children and adults. *Vaccine.* 2004 Jan 26;22(5-6):766-72. PubMed PMID: 14741171.
 14. Trollmo C, Carlsten H, Tarkowski A. Intra-articular immunization induces strong systemic immune response in humans. *Clin Exp Immunol.* 1990 Nov;82(2):384-9. PubMed PMID: 2242620; PubMed Central PMCID: PMC1535122.
 15. Colloca L, Barsky AJ. Placebo and Nocebo Effects. *N Engl J Med.* 2020 Feb 6;382(6):554- 561. doi: 10.1056/NEJMra1907805. Review. PubMed PMID: 32023375.
 16. Barsky AJ. The Iatrogenic Potential of the Physician's Words. *JAMA.* 2017 Dec26;318(24):2425-2426. doi: 10.1001/jama.2017.16216. Erratum in: *JAMA.* 2018 Feb 27;319(8):833. PubMed PMID: 29090307.
 17. Davidhizar R. The pursuit of illness for secondary gain. *Health Care Superv.* 1994 Sep;13(1):10-5. PubMed PMID: 10172109.
 18. Maugh TH II, Zajac A (2010-03-13). "'Vaccines court' rejects mercury-autism link in 3 test cases". *Los Angeles Times.* Retrieved 2019-01-16.

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