

## Position Statement

# Rotator Cuff Tendinopathy, Adhesive Capsulitis, and Arthritis Can Not 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.*

There is a misperception that vaccine administration can cause injury to the shoulder joint<sup>1</sup>. The proposed theory is that: vaccinations are occasionally inadvertently injected into the subdeltoid bursa contiguous with the subacromial bursa or glenohumeral joint and damage to the shoulder tissue can occur via immune response. There is no scientific evidence that demonstrates that vaccination administration can injure the shoulder. There are only descriptions of patients with common shoulder problems, such as idiopathic adhesive capsulitis and rotator cuff tendinopathy, temporally related to vaccination.

Temporal relationship does not imply causation, particularly among common events such as shoulder pain and immunizations. Most individuals develop shoulder pain from rotator cuff pathology as we age. It is natural to assume that a disease started when symptoms appeared, but that perception is inaccurate for diseases that develop gradually<sup>2,3</sup>. For instance, age-related conditions such as presbyopia (the need for reading glasses), carpal tunnel syndrome, arthritis, and rotator cuff tendinopathy come on very slowly, but are typically first noticed at a specific time or after a specific event<sup>2,3</sup>.

Immunizations are also very common as many individuals are administered annual influenza vaccinations. The likelihood of first noticing a shoulder problem around the time of an immunization is highly likely. Most of these associations between immunization and shoulder pathology will be coincidental, even if they are perceived as causal.

To appreciate the magnitude of this opportunity for misperception, consider that 45% of adults aged 50-64 have flu vaccination each year, and that the prevalence of detectable rotator cuff abnormalities in this age group is about 20%<sup>4,5</sup>. There are 63.4 million Americans in this age range, 28.5 million of whom will be vaccinated each year, and 5.7 million of whom will already have detectable rotator cuff tendinopathy. If one assumes that a quarter of those individuals will notice new shoulder symptoms within three months of their annual vaccination, and that 70% of people with gradual onset of disease misperceive their symptoms as new, roughly one million people might inaccurately and inappropriately believe they were injured by vaccination each year<sup>2</sup>.

Beyond the association-causation fallacy, a number of factors have aligned to create a human-made epidemic of perceived shoulder injury from vaccine. In 1986, Congress responded to vaccine manufacturers' 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.

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.” These case reports were in obscure scientific medical journals with limited peer review, and “deltoid bursitis” is not a term used by musculoskeletal experts with respect to injury. Although the evidence was weak in a few case reports, shoulder injury was still added to the Vaccine Injury Table in March 2017. Injuries listed by the Secretary of Health and Human Services in the Vaccine Injury Table are presumed compensable, while other injuries must be proven in court.

Following these developments, the number of claims for shoulder injury rose from 10 in 2011 to 671 in 2018. 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 SIRVA, with typical compensation amounts between \$75,000 and \$200,000<sup>6</sup>. Specialized regional law firms, which widely advertise their experience with the VICP, account for the majority of SIRVA compensation cases<sup>8,9</sup>.

***The members of the American Academy of Orthopaedic Surgeons (AAOS) take the position that vaccination administered to the shoulder cannot cause or contribute to common shoulder pathologies such as rotator cuff tendinopathy, glenohumeral arthritis, and adhesive capsulitis.***

There is a history of harm from similarly well-meaning but misguided assertions of causality<sup>10-12</sup>. 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. The case for SIRVA is no exception. The strongest existing clinical evidence regarding SIRVA is actually exculpatory: a post-marketing surveillance study of thousands of patients receiving the Hepatitis A vaccine found that shoulder problems were equally common before and after vaccination<sup>13</sup>. There is also no evidence that intra-articular injection of vaccination causes harm; one animal study found that an intra-articular injection still induced immunity but did not lead to any harm<sup>14</sup>. Finally, as an anatomic counter-rationale, the subdeltoid bursa is a very narrow space at the undersurface of the deltoid muscle, just above the proximal humeral bone, and it seems unlikely that a vaccination needle could be forced deep enough to contact bone. If contact with bone occurred, moreover, it likely would be noticeable enough that the person injecting would think twice and redirect the needle.

Given the potential for widespread misdiagnosis of individual patients and unjustified expense to society, we must insist on strong scientific evidence before supporting the idea that vaccine administration causes

idiopathic adhesive capsulitis or rotator cuff tendinopathy. Absent such evidence, vaccine administration should be presumed merely coincident with these common shoulder pathologies.

## References

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