

SB355: Health Occupations - Pharmacists - Administration of Vaccinations

Heather Faust

**Oppose**

Honorable Chair and Members of the Education, Health, and Environmental Affairs Committee:

I strongly oppose SB 355: Health Occupations-Pharmacists-Administration of Vaccines, and I respectfully request that you vote NO on this bill.

Vaccination rates in Maryland are already quite high, so Marylanders are clearly not under-vaccinated. And doctors can already send their prescriptions to pharmacies if a family would prefer to receive a vaccine there instead of at the doctor's office. Therefore, I am not sure what issue this bill is intended to address, but I find it problematic and unnecessary.

SB 355 interferes with the doctor/patient relationship. It's well documented that the best health outcomes result from a collaborative relationship between families and doctors. Vaccines are not one-size-fits-all and should never be treated as such. The CDC's recommended schedule may require individual adaptation based on the needs and health situation of each individual. Whatever the supposed issue is, drive-by vaccinations without a physician prescription are not the answer and will not lead to improved health of our children but rather the opposite.

This bill creates a situation where pharmacists are placed in an inappropriate position of what amounts to practicing outside the scope of their license. They are not trained to assess patients for risks or contraindications, they may not have access to enough of a patient's medical history to make an appropriate determination about whether a particular vaccine should be given, and they are not in a position to monitor patients post-vaccination for any potential injuries or complications. They have plenty to do already and don't need more distractions. There's far too much pharmacy error already. Let's not add to it!

Pharmacies are also not equipped in practical terms for proper monitoring and patient care with regard to vaccines. For example, a patient is supposed to sit or lie down to receive the HPV vaccine and then must be monitored for at least 15 minutes afterward. Is there actually an appropriate location for this to safely take place in a pharmacy? Who will do the monitoring? Does the pharmacist actually have the time to follow the proper protocols?

What about when pharmacy student interns are involved in vaccinating patients, including children? We already know that SIRVA (Shoulder Injuries Related to Vaccine Administration) have increased significantly since pharmacists started vaccinating. (SIRVA is an injury directly caused by the improper administration of a vaccine, as opposed to an injury from the vaccine itself – ingredients such as allergens, heavy metals, preservatives, etc.) How does this bill address the fact that if pharmacies are to give more vaccines, these interns who are not yet licensed pharmacists will likely be administering a good number of them? Are the interns equipped to assess a child and review their medical history the way their family physician can? And why in the world would we want to ask them to do that in the first place? That's not their job! Do the interns even understand what vaccine injury looks like? Do they know what SIRVA is and how to avoid it? Does a licensed pharmacist actually have the time to supervise the increased number of

vaccinations that would likely be given by pharmacy students? And is that an appropriate use of their time and energies?

According to SB 355, the pharmacist administering a vaccine must “document at least one effort to inform the individual’s primary care provider or other usual source of care that the vaccination has been administered.” What if that one effort was not successful? Who will make sure that the information is appropriately noted in the patient’s medical record? What if there were complications? Who will follow up and care for the patient? There’s way too much room for error here and that greatly concerns me.

SB 355 also appears to be a blatant money-maker for pharmacies. We’re all familiar with the overwhelming and in-your-face marketing of vaccines at every pharmacy and every street corner anywhere near a pharmacy, with all kinds of appealing incentives being offered. The US and New Zealand are the only countries that allow direct-to-consumer marketing of pharmaceuticals, and it is totally out of control. The fact is that vaccines are a huge revenue source for pharmaceutical companies. Not only that, all those who administer vaccines are making big money from it as well, and that includes pharmacies.

Let people make an informed decision to get a vaccine because they’ve reviewed the information including the package insert and ingredients, discussed the benefits and risks with their regular health care practitioner, and decided that it’s an appropriate thing to do for themselves and their families. Not because someone at a chain pharmacy – who’s never met them and doesn’t know or care what their individual health needs might be – has bribed them with a \$10 gift card or a free turkey if they come in a get a “free” shot, to the financial benefit of the pharmacy! This incentivizing of vaccinations for monetary reasons is extremely objectionable. Money should never be the motivating factor in health care.

Thank you for your time and attention. I urge you to please vote NO on SB 355 and encourage your colleagues to do likewise.

See attached article about SIRVA.

Sincerely,

Heather Faust  
Catonsville, MD

# Getting it in the right spot: Shoulder injury related to vaccine administration (SIRVA) and other injection site events

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## **Introduction**

Shoulder injury related to vaccine administration, or “SIRVA,” is an uncommon but emerging phenomenon caused by an improper technique or landmarking for intramuscular deltoid injections.

<sup>1-9</sup> Patients with SIRVA present with shoulder pain and a limited range of motion. Symptoms occur when the patient had no prior shoulder injury or pain, and symptoms do not typically resolve on their own.<sup>1-6,9</sup> SIRVA is more painful and debilitating than the typical soreness that many patients feel after an intramuscular deltoid injection.<sup>1-6,9</sup> A review of the literature suggests a lack of data about SIRVA, and many cases are likely underreported, leading to an unknown incidence.<sup>1</sup> While this injury is rare in Canada, the National Vaccine Injury Compensation Program in the United States added SIRVA to its list of recognized vaccine injuries earlier in 2017.<sup>10</sup> Now that most pharmacists in Canada can be authorized to administer vaccines,<sup>11</sup> it is important they know how to landmark appropriately to prevent SIRVA, to recognize it in a patient and to know when to refer patients if they suspect this injury.

Pharmacists are highly accessible health professionals when it comes to immunization in Canada. For example, 30% of Canadian adults who received an influenza vaccine last year did so in a pharmacy.<sup>12</sup> We developed an infographic to guide all health professionals in the proper administration of intramuscular deltoid injections and to help in the prevention and identification of SIRVA (Figure 1). To develop the infographic, we performed a literature search using terms related to SIRVA (“Shoulder injury related to vaccine administration,” “shoulder dysfunction after injection,” “incorrect vaccine

administration," "bursitis," "frozen shoulder" and "rotator cuff tear"), causes of SIRVA ("improper landmarking," "improper injection technique" and "incorrect deltoid injection"), diagnosis of SIRVA ("ultrasound," "imaging" and "differential diagnosis") and other injection site events ("radial nerve injury," "axillary nerve injury," "neuropathy in shoulder," "lipoatrophy," "nodules" and "cellulitis") in the PubMed, Embase and Google Scholar databases. We also searched for relevant grey literature such as government reports using the Google search engine. What follows is an explanation of what pharmacists need to know to prevent and identify SIRVA.

### **What is SIRVA?**

SIRVA is a rare sequela of the body's immune response to direct injection of a vaccine into the shoulder capsule instead of the deltoid muscle.<sup>1-6</sup> It causes inflammation in the musculoskeletal structures of the shoulder such as the bursae, tendons and ligaments, resulting in shoulder pain and a limited range of motion that can persist for months without treatment.<sup>1-6,9</sup> Patients will often present to a physician months after the injection because of their inability to manage

**Figure 1** An infographic to help health professionals prevent shoulder injury related to vaccine administration

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increasing amounts of pain and being unable to perform daily tasks.<sup>1-3</sup> These patients are often diagnosed with various complications such as bursitis, rotator cuff tears or frozen shoulder syndrome.<sup>1-6,9,13</sup> SIRVA is an emerging topic, as the first case report was published in 2006 by Bodor and Montalvo.<sup>4</sup> Recent publications have reported more cases of SIRVA, in which vaccines were injected too high into the shoulder or at an incorrect angle, emphasizing the growing need for awareness.<sup>1-6,9,13,14</sup> Of note, SIRVA is not caused by the ingredients in the vaccine itself but by the incorrect placement of the vaccine into the shoulder joint.<sup>1-6</sup> Therefore, a review of proper landmarking and injection technique is essential to preventing SIRVA.<sup>1-9</sup>

### **How to recognize SIRVA**

It is common to experience a dull muscle ache after a vaccine injection that disappears within a few days.<sup>1,2,4,6</sup> Treatment can include an ice pack or over-the-counter analgesics such as acetaminophen or ibuprofen.<sup>2-4</sup> The key to recognizing SIRVA is that the pain will often begin within 48 hours of vaccine administration and will not improve with over-the-counter analgesics.

<sup>1,2,4</sup> In fact, months may pass by, and patients will still complain of increasing pain, weakness and impaired mobility/function.<sup>1,2,4</sup> Community pharmacists can play a key role in recognizing these patients, as they may request pharmacist assistance in selecting an over-the-counter analgesic. Furthermore, when patients present to the pharmacist complaining of shoulder pain or that they cannot lift their arm to brush their teeth, pharmacists should ask if they had a vaccine in that arm recently and refer them to a physician for diagnosis if SIRVA is suspected.<sup>2</sup> Physician assessment and management will typically include diagnostic imaging such as an ultrasound, corticosteroid injections and physiotherapy.<sup>2,6,9</sup>

### **Other injection site events**

SIRVA results from an injection that is administered too high. There are other structures near the deltoid muscle that are at risk when a vaccine is improperly injected. In particular, injections that are below the deltoid can hit the radial nerve, and injections that are too far to the side of the deltoid can hit the axillary nerve.<sup>5,7,15,16</sup> When a nerve is hit, the patient will feel a strong shooting and burning pain immediately and may eventually develop paralysis or neuropathy that does not always resolve.<sup>5,7,15,16</sup> Therefore, in addition to preventing SIRVA, proper landmarking of the deltoid can also prevent nerve injuries from occurring.<sup>5,7,15,16</sup> In addition, health care professionals should choose a needle length based on the weight of the patient.<sup>15,17-19</sup> A needle that is too long may pass through the deltoid muscle and hit the bone instead.<sup>15,17-19</sup> While the patient will not feel if you hit the bone, the vaccine may not be fully absorbed into the muscle, leading to reduced immunity.<sup>15,17-19</sup> In addition, if the needle is too short, the vaccine can be administered subcutaneously instead of intramuscularly, which can sometimes result in decreased immunity as well as nodules, cellulitis or localized lipoatrophy.<sup>7,17,19,20</sup> A 2005 survey of Irish general practitioners and nurses discovered that the deltoid region was a popular site for injections, but most health care professionals were unaware of the structures that were at risk from injections in that area such as the axillary nerve or subdeltoid bursa.<sup>21</sup> Therefore, all health care professionals who provide injections, including pharmacists, should make landmarking and careful needle length selection a routine part of the injection workflow.

### **The pharmacist's role**

Pharmacists can play a significant role in preventing

SIRVA and other injection site events by reviewing proper landmarking technique. This includes using 2 to 3 finger widths (depending on the size of your fingers) from the acromion process to ensure you inject below the shoulder capsule and identifying the level of the armpit to ensure you inject into the deltoid.<sup>7,8,15,18-20</sup> After determining the upper and lower limits, you can use your thumb and forefinger to make a “V” to outline the deltoid and keep the “sweet spot” visible before picking up the needle.<sup>20</sup> The injection should always be given at a 90° angle using a darting motion.<sup>7,8,15,18-20</sup> In addition, choose a 5/8-inch needle for smaller patients weighing less than 60 kg (130 lb) and a 1-inch needle for patients who weigh 60 to 70 kg (130-152 lb).<sup>18</sup> Women weighing 70 to 90 kg (152-200 lb) or men weighing 70 to 118 kg (152-260 lb) should receive either a 1-inch or 1.5-inch needle.<sup>18</sup> A 1.5-inch needle should be used for women weighing more than 90 kg (200 lb) and men weighing more than 118 kg (260 lb).<sup>18</sup>

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If you accidentally insert the needle outside the properly landmarked area, you should pull the needle out, apply a new needle tip and try landmarking again. Do not inject. However, if you suspect that you administered the injection into the shoulder capsule, you should inform the patient about SIRVA and its symptoms, so the patient can access care in a timely manner.<sup>2</sup> If you suspect that a patient might be suffering from SIRVA, refer them to their physician for diagnosis, as an ultrasound is needed to determine the level and type of damage.<sup>1,2,5,9,13</sup> In addition, over-the-counter analgesics will not be effective for patients with SIRVA, as the preferred treatments include corticosteroid injections into the shoulder and physiotherapy.<sup>2,6,9</sup>

### **Practice tips**

Prevention of SIRVA and other injection site events is key. Here are some points to remember:

- Landmark every patient, never “eyeball it.”<sup>1-9</sup>
- Always sit or kneel to inject a seated patient.

Standing above a patient may increase the likelihood that you will inject too high.<sup>2,8,20</sup>

- To help decrease the amount of pain the patient experiences, have them sit with their hand placed on their hip with their elbow out and away from the body, as this will relax their deltoid muscle.<sup>2,8,20</sup>
- Expose the shoulder completely. When a shirt cannot be removed, roll the sleeve up rather than pull the shirt’s neck over the

shoulder.<sup>2</sup>

- If you hit bone, don't worry. The patient will not feel it, but you should pull the needle back slightly into their muscle before injecting.
- If you suspect you hit a nerve, pull the needle out completely, landmark properly and try again.
- If you suspect you inserted the needle too high, pull the needle out before injecting, landmark properly and try again.
- If you are unsure about a patient's weight, ask them so that you can use the proper needle length.<sup>16,18-20</sup>
- If you think you injected too high, or you suspect a patient has SIRVA, educate the patient about what SIRVA is and tell them to see a doctor if pain in their shoulder increases or if they lose range of motion after 2 days that does not improve.<sup>2</sup>
- Report SIRVA and other injection site events like any other injection reaction. Follow the protocol for your province.<sup>18</sup>

In conclusion, education and awareness are key to preventing SIRVA and other vaccine injuries related to improper landmarking of the deltoid muscle. The next time you inject a patient, pay attention to your technique. Even the most experienced health care professionals need to polish their skills once in a while. ■

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