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Shoulder Injury Related to Vaccine Administration

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With pharmacy technicians, pharmacists, and pharmacy interns now administering vaccines and the rush to get the coronavirus disease 2019 vaccination, safe and evidence-based vaccine administration is important for our community. A higher vaccination volume can result in a rushed immunization process and even nontraditional vaccination processes such as drive-through vaccination services. While vaccinating as much of the population as possible, we must do so safely. One uncommon but debilitating safety concern with vaccination administration is shoulder injury related to vaccine administration (SIRVA). SIRVA occurs when a vaccination is administered incorrectly into the shoulder capsule instead of correctly into the deltoid muscle. Symptoms of SIRVA start within hours to days and include pain, weakness, and impaired mobility of the affected shoulder, which may persist for up to months after the immunization. SIRVA can be debilitating and painful for patients, and it is avoidable by utilizing the correct vaccine administration technique.

Tips to avoid SIRVA:

- Expose the shoulder completely. When an article of clothing cannot be removed, roll the sleeve of the piece of clothing up to the shoulder rather than pull the neck of the shirt down over the shoulder.
- Always ensure that you and the patient are at the same level. Preferably you and the patient should both be sitting. Administering a vaccine while standing to a sitting patient increases the likelihood of injecting it into the shoulder capsule. This is particularly important to remember if the patient is in an automobile.
- If you have any doubt that you may have injected the vaccine too high into the shoulder, do not inject the vaccine, remove the needle, replace it with a new needle, and administer again into the proper location.
- For intramuscular injections, always inject at a 90-degree angle into the patient's deltoid.
- Always utilize a landmarking technique before injecting. Never assume you are injecting into the correct location by sight alone. To landmark the correct injection location, identify the bony protrusion on the top of the patient's shoulder called the acromion process, then measure two to three finger widths down from the acromion process. Next, identify where the start of the patient's armpit is. You should inject into the area above the beginning of the patient's armpit and below the two to three finger widths below the acromion process. To ensure that you do not administer the vaccine too far to either side, create a "V" with your fingers from the bottom of the appropriate injection area and inject within the limits of the "V."

Utilizing proper administration techniques for every patient will help ensure that no patients suffer from SIRVA. If you suspect that SIRVA has occurred for a patient, refer him or her to a medical provider for proper diagnosis and treatment. SIRVA is often not well managed by over-the-counter pain relievers, and corticosteroid injections are often needed to control pain. Any instances of SIRVA should be reported to your workplace event reporting system. The Centers for Disease Control and Prevention (CDC) also recommends that any vaccine errors such as SIRVA should be reported to the Vaccine Adverse Events Reporting System (VAERS). The VAERS website can be accessed at *www.vaers.hhs.gov/index.*

References:

- CDC. General Best Practice Guidelines for Immunization. *https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.*
- Bancsi A, Houle SKD, Grindrod KA. Shoulder injury related to vaccine administration and other injection site events. *Can Fam Physician.* 2019;65(1):40-42. Available at: *https://www.cfp.ca/content/cfp/65/1/40.full.pdf* (see Figure 1).
- Immunization Action Coalition. *https://www.immunize.org/technically-speaking/20181023.asp.*

National Pharmacy Compliance News

February 2021

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

DEA Publishes New Version of Pharmacist's Manual

The latest version of the *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* has been released by Drug Enforcement Administration's (DEA's) Diversion Control Division. The guide is provided to assist pharmacists in understanding the Federal Controlled Substances Act and its regulations as they pertain to the pharmacy profession. This edition has been updated to include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018, and replaces all versions of the guidance previously issued by the agency. The new *Pharmacist's Manual* can be accessed by visiting the DEA website.

Time to End VinCRIStine Syringe Administration

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and Food and Drug Administration (FDA). To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at www.ismp.org.

At the request of FDA, Pfizer has revised the prescribing information and product packaging for vin**CRIS**tine sulfate injection. Importantly, they have removed wording from the vin**CRIS**tine package insert that described direct intravenous (IV) injection of vin**CRIS**tine via a syringe. FDA recommended this revision at the request of ISMP, the National Comprehensive Cancer Network, and The Joint Commission.

The WARNINGS section of the package insert now states, "To reduce the potential for fatal medication errors due to incorrect route of administration, vin**CRIS**tine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated 'FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.'" More than 140 deaths are known to have occurred in the United States and globally due to accidental intrathecal injection of the drug via syringe, often when it was mixed up with, or wrongly assumed it was supposed to be given with, another drug meant for intrathecal administration, such as methotrexate. No such cases have been reported with dilution of vin**CRIS**tine in a minibag, due to physical differences in the packaging and the need for an administration set.

Unfortunately, some practice sites are still using syringes to administer IV vin**CRIS**tine. Based on data collected in response to the *ISMP Medication Safety Self Assessment for High Alert Medications* between September 2017 and March 2018 from 442 US hospitals, nearly 20% of respondents still used syringes at least part of the time, including 13% who always used syringes to administer IV vin**CRIS**tine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vin**CRIS**tine and other vinca alkaloids in a minibag of compatible solution, and not in a syringe, was among the very first *ISMP Targeted Medication Safety Best Practices for Hospitals,* which were launched in 2014[1]. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vin**CRIS**tine labeling.[2]

ISMP has frequently referred to wrong route administration of vin**CRIS**tine and vinca alkaloids as the "most serious of all medication errors." Patients experience tremendous pain and are often aware of their impending death, which typically occurs within days or weeks. There is no effective reversal once the mistake is made. Even with the labeling change, there is nothing to stop health care practitioners from administering vin**CRIS**tine via syringe (except if they can only get the drug dispensed in a minibag). We hope that every hospital and health system will investigate exactly how vin**CRIS**tine is being administered at any site that uses the drug. It is time to end the practice of syringe administration by making it a requirement for all vin**CRIS**tine doses to be diluted in a minibag.

References

1. *www.ismp.org/guidelines/best-practices-hospitals*
2. *www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids*

What Pharmacists Need to Know About Biosimilar and Interchangeable Biological Products

This column was prepared by FDA, an agency within the US Department of Health and Human Services, that protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the US, including therapeutic proteins (eg, filgrastim), monoclonal

antibodies (eg, adalimumab), and vaccines (eg, influenza and tetanus).

Section 351(k) of the Public Health Service Act (PHS Act) provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product, which can help provide more affordable treatment options for patients. For example, on March 23, 2020, FDA-approved insulin products were transitioned to regulation as biological products under the PHS Act, which means that transitioned insulin products are open to competition from future biosimilars, including interchangeable biosimilars.

Key Terms for Biosimilar and Interchangeable Products

- **Biosimilar Product:** A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved reference product.
- **Interchangeable Product:** An interchangeable product is a biosimilar that meets additional approval requirements and may be substituted for the reference product without the intervention of the prescribing health care provider.
- **Reference Product:** A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar or interchangeable product is compared.

Are Biosimilars the Same as Generic Drugs?

Biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients. Biosimilars and generics are approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics, and there are important differences between them.

For example, the manufacturer of a generic drug must demonstrate, among other things, that the generic contains the same active ingredient as the brand name drug and that the generic is bioequivalent to the brand name drug. By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness.

Unlike generics, biosimilars are generally prescribed by brand name by a health care provider, while interchangeables, like generics, may be substituted without the involvement of the prescribing health care provider, depending on state laws.

What is the Purple Book?

The Purple Book database contains information on FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research, including licensed biosimilar and interchangeable products, and their reference products. It also contains information about all FDA-licensed allergenic, cellular, and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research .

The Purple Book has simple and advanced search capabilities and some information that you can find includes the proprietary (brand) name and nonproprietary (proper) name of biological products, applicant (company), dosage form, product presentation (eg, autoinjector, vial), route of administration, and strength. The Purple Book also will display FDA-approved interchangeable products and note with which brand product each interchangeable product may be substituted.

Are Therapeutic Equivalence Codes Assigned to Biological Products?

FDA does not assign therapeutic equivalence codes to biological products listed in the Purple Book like it does for small molecule drugs listed in the "Orange Book." The Purple Book provides information about whether a biological product has been determined by FDA to be biosimilar to or interchangeable with a reference product.

Can Interchangeable Products Be Substituted at the Pharmacy?

Many states have laws that address pharmacy-level substitution, including permitting substitution of interchangeable products, and the specific laws vary from state to state.

There are currently no FDA-approved interchangeable products. Once there are, interchangeables, by definition, can be expected to produce the same clinical result as the reference product in any given patient.

Biosimilar and interchangeable products meet FDA's rigorous standards for approval, and patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

Where Can I Find Additional Resources?

- *fda.gov/biosimilars*
- *purplebooksearch.fda.gov*
- *fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act*
- *fda.gov/media/135340/download*

Final Insanitary Conditions at Compounding Facilities Guidance Released by FDA

Continuing efforts to protect patients from exposure to poor quality compounded drugs, FDA has published final guidance for compounding facilities regarding insanitary conditions. The final guidance, *Insanitary Conditions at Compounding Facilities Guidance for Industry,* provides recent examples of insanitary conditions that FDA has observed at compounding facilities and details corrective actions that facilities should take when they identify these conditions. The guidance is intended to help compounders identify and prevent such issues at their facilities.

While some compounders work hard to meet quality standards, FDA says its investigators continue to observe poor conditions that impact drug quality and that have the potential to harm patients. These include the presence of dirt, mold, insects, trash, peeling paint, unclean exhaust vents, and dirty high-efficiency particulate air filters.

In response to the draft guidance, FDA states that it has also added recommendations for compounders to use risk management tools to develop appropriate controls to prevent insanitary conditions at facilities. The guidance also addresses the regulatory actions that FDA may take in response to these conditions.

The Role of the Public Member on the Board of Pharmacy

By Joe Ligori, Public Member, Utah Board of Pharmacy

Did you know that the Utah Board of Pharmacy members are not all pharmacists or in the medical profession? Yes, there is a member who is a representative of the Utah consumers at large. This Utah citizen is on the Board to represent the viewpoint and concerns of Utah consumers, and to ensure that decisions being made are in the best interest and life safety of the citizens of Utah. Decisions that are made by the Board are monitored by the public representative to ensure that the ones affecting the citizens are clear and understandable to all.

This role is described in the Pharmacy Practice Act in Section 58-17b-201.

(1) There is created the Utah State Board of Pharmacy consisting of five pharmacists, one pharmacy technician, and one member of the general public.

(a) The public member of the board shall be a Utah resident who:

(i) is 21 years of age or older;

(ii) has never been licensed to engage in the practice of pharmacy;

(iii) has never been the spouse of a person licensed to engage in the practice of pharmacy;

(iv) has never held any material financial interest in pharmacy practice; and

(v) has never engaged in any activity directly related to the practice of pharmacy.

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