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# Medication Incidents in COVID-19 Vaccine Administration in Children: Contributing Factors and Prevention Strategies

Hundreds of medication incidents involving the administration of COVID-19 vaccines to children have been reported across Canada and the US.¹ Since adverse event and other reporting programs only capture a fraction of incidents, it is possible that thousands of children may have been affected.¹ Now that pharmacists in Manitoba are permitted to administer COVID-19 vaccines for children ages two years and older, it is imperative that pharmacy professionals are aware of potential COVID-19 vaccine-related medication incidents and strategies for prevention. Please use the incident prevention chart below to minimize the chance of pediatric patient harm in your pharmacy.

Incident Type	Description/Contributing Factors	Prevention Strategy
Wrong Dose/ Formulation	<ul> <li>Mix-up of adult and pediatric doses resulting in overor under-dosing.<sup>1</sup></li> <li>Vial or syringe mix-ups including the contributing factors:<sup>1</sup> <ul> <li>Age range on label may be missed.</li> <li>Wrong dose selected since only the injection volume is listed without the dose in mcg.</li> <li>Although adult and pediatric vials have different colored caps, removing the cap can create confusion about which formulation the vial contains.</li> <li>The prepared syringe maybe separated from its vial, and the pharmacist is unable to properly verify the dose.</li> </ul> </li> </ul>	<ul> <li>Store vaccines for different age ranges separately (2 to 5 years, 5 to 11 years, and 12 years and older). For instance, place the different doses in separate shelves or labelled plastic bins.<sup>1</sup></li> <li>Pay careful attention to the colour of the vial cap and the corresponding dose volume to ensure that the appropriate dose volume is being administered. Moderna and the CDC have produced useful graphics.</li> <li>Check the vial label three times to ensure the appropriate pediatric or adult dose is being administered.<sup>2</sup> These checks should be done when taking vials out of the fridge, during preparation, and prior to vaccine administration.</li> <li>Print pediatric syringe labels using electronic templates that are a specific color, such as green, and apply these labels right after pediatric vaccines are drawn up.<sup>3</sup></li> </ul>



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Incident Type	Description/Contributing Factors	Prevention Strategy
		<ul> <li>Always label individual syringes containing vaccines.<sup>1</sup> Preprinted labels that differentiate adult and pediatric doses should be readily available for those preparing the vaccines.<sup>1</sup></li> <li>Bring the labeled vaccine syringe for each patient into the vaccination area one at a time.<sup>1</sup> Verify the vaccine with the patient or parent by reading out the label.<sup>1</sup></li> <li>Ask for at least two patient identifiers, such as the full name and date of birth, before giving the vaccine.<sup>1</sup> Confirm the patient's age with the parent or caregiver.<sup>1</sup></li> </ul>
Wrong Interval	<ul> <li>Giving the first two doses of COVID-19 vaccine too close together.<sup>4</sup></li> <li>Administering the second dose later than the longest optimal period of 8 weeks.<sup>4</sup></li> <li>Scheduling errors may occur due to miscommunication between the pharmacy staff and patient.<sup>5</sup></li> </ul>	<ul> <li>Book the second appointment right after the first visit to ensure the patient is aware of when their second dose is due.<sup>5</sup></li> <li>Follow-up by phone, text, or email to ensure patients receive the second dose on time.<sup>5</sup></li> <li>Check the Public Health Information Management System (PHIMS) for the patient's immunization records to obtain a complete vaccination history and ensure the intervals between the COVID-19 vaccine doses are correct.</li> <li>Print out current COVID-19 immunization schedules for children and adults so that pharmacy staff can easily refer to these schedules for each vaccine.<sup>6</sup></li> <li>Counsel patients and parents on the importance of maintaining their own immunization records.<sup>6</sup></li> <li>Since recommendations for booster shots have changed over time, pharmacists should stay current by checking the Manitoba Health, Health Canada, and NACI websites.</li> </ul>



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Incident Type	Description/Contributing Factors	Prevention Strategy
Wrong Site	<ul> <li>Administering the COVID-19 vaccine in the wrong site leading to inefficacy or injury.</li> <li>For intramuscular injections, the deltoid muscle is often the preferred site.<sup>2</sup></li> <li>If the deltoid muscle mass is deemed to be inadequate, use the anterolateral thigh muscle instead.<sup>2</sup> Pharmacists must have the information and knowledge to be competent in the administration of the anterolateral thigh injection.</li> <li>Improper landmarking technique may result in shoulder injury related to vaccine administration (SIRVA).<sup>5</sup> More information on SIRVA can be found in the College of Pharmacists of Manitoba (CPhM) Fall 2021 Newsletter.</li> </ul>	<ul> <li>Print out quick-reference resource sheets of the preferred injection site for each age group.</li> <li>For deltoid injections, avoid injecting too high on the upper arm to prevent shoulder injury.<sup>2</sup></li> <li>Advise patient to wear suitable clothing and ensure the patient's upper arm is bare.<sup>5</sup></li> <li>Set up in a manner that protects the patient's privacy.<sup>5</sup></li> </ul>
Improper preparation	<ul> <li>Administering an entire multidose vial to one patient.<sup>5</sup></li> <li>Measuring an incorrect volume, inadequate or no dilution of vaccines that need dilution.<sup>5</sup></li> <li>Administration of diluent alone.<sup>5</sup></li> <li>Misconnection between the needle and syringe.<sup>5</sup></li> </ul>	<ul> <li>Develop a quick-reference sheet for the dose preparation process of each vaccine for different age groups to support vaccine preparation.<sup>5</sup></li> <li>Confirm three times that the correct volume has been withdrawn.</li> <li>Always double check if the vaccine formulation requires dilution.</li> <li>Ensure diluents are clearly labelled to prevent mix-ups between the diluents and vaccines.<sup>6</sup></li> </ul>
Improper storage	<ul> <li>Poor organization of vaccines in the refrigerator or freezer led to the selection of wrong products.<sup>5</sup></li> <li>Cold-chain interruption leads to vaccine spoilage.</li> <li>Inadequate equipment to monitor the temperature of refrigerators.<sup>5</sup></li> </ul>	<ul> <li>Store the vaccines in refrigerators and freezers that are organized and clearly labelled.<sup>1</sup></li> <li>Avoid overcrowding the unit with many medications to facilitate air circulation.<sup>7</sup></li> <li>Vaccines have distinct storage requirements. Place quick reference sheets near the refrigerator listing requirements.</li> </ul>



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Incident Type	Description/Contributing Factors	Prevention Strategy
	<ul> <li>Lack of procedures to manage temperature deviations.<sup>5</sup></li> <li>It is the responsibility of the pharmacist to abide by CPhM's <u>Drug Distribution and Storage Practice Direction</u>.</li> </ul>	<ul> <li>Frequently record the temperature of the refrigerator and freezer on an appropriate log.<sup>7</sup></li> <li>Follow the refrigerator's manufacturer storage instructions and Manitoba Health's Cold Chain Protocol – Vaccines and Biologics.<sup>5</sup></li> <li>Develop a clear plan to manage temperature variations.<sup>5</sup></li> <li>Do not store food and drinks in the vaccine refrigerator as constant opening of the refrigerator will affect the internal temperature.<sup>7</sup></li> </ul>
Improper documentation	<ul> <li>Leads to the administration of an expired product past its beyond-use date and time.<sup>5</sup></li> <li>Scheduling errors due to staff unaware of recommended COVID-19 vaccine dose intervals or vaccinations not reported on PHIMS.</li> </ul>	<ul> <li>Write the name of the vaccine, dose and volume for injection, lot number, and beyond-use date and time on the syringe label.<sup>5</sup></li> <li>Label any opened or partially used vials with the puncture and beyond-use dates and times.<sup>5</sup></li> <li>After giving the vaccine, document the administration in the patient's profile and on PHIMS.<sup>1</sup></li> <li>Provide patients with documentation of their immunization, including the vaccine name, lot number, and date.<sup>5</sup> Mobile apps such as MyMedRec and CanImmunize can be used to store this information.<sup>5</sup></li> <li>Avoid error-prone abbreviations when documenting vaccine administration.<sup>6</sup> More information can be found on: <a href="https://www.ismp.org/recommendations/error-prone-abbreviations-list">https://www.ismp.org/recommendations/error-prone-abbreviations-list</a></li> </ul>

#### What to do if an Adverse Event or Medication Incident Happens

If a patient experiences Adverse Events following Immunization (AEFI) that are temporally associated with a vaccine without any other clear cause at the time, pharmacists must report this within seven days of becoming aware of the AEFI. This report can be submitted either in PHIMS or by using the PDF



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<u>reporting form</u> that is submitted to a Medical Officer of Health (MOH). More information can be found in the <u>User Guide for the Completion and Submission of the AEFI Reports</u>.

As per the CPhM's <u>Medication Incidents and Near-Miss Events Practice Direction</u>, once the pharmacist has ensured the immediate safety of the patient, staff must report medication incidents to their medication incident reporting platform. De-identified (anonymous) data is sent to the <u>National Incident</u>

<u>Data Repository for Community Pharmacies</u> where medication safety specialists conduct analysis and share learning with healthcare professionals across Canada to reduce the chances of patient harm from similar incidents.

For specific medication incidents related to COVID-19 vaccine administration, pharmacists can use the resources below to follow the recommended actions for each incident:

- COVID-19 vaccine guide for youth and adults (12 years and over): Managing COVID-19 vaccine administration errors or deviations
- Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers (appendix D)
- CPhM Resources Relevant to the Administration of Injections to Young Children (Ages 2-5)

#### Resources

- 1. Age-related COVID-19 Vaccine Mix-Ups. Institute For Safe Medication Practices Canada. <a href="https://www.ismp.org/alerts/age-related-covid-19-vaccine-mix-ups">https://www.ismp.org/alerts/age-related-covid-19-vaccine-mix-ups</a>. Published 2021. Accessed July 26, 2022.
- 2. Don't Be Guilty of These Preventable Errors in Vaccine Administration! Immunization Action Coalition. <a href="https://www.immunize.org/catg.d/p3033.pdf">https://www.immunize.org/catg.d/p3033.pdf</a>. Accessed July 26, 2022.
- 3. Safety Bulletin Preventing Pediatric COVID-19 Vaccine Errors at Mass Vaccination Sites. Institute for Safe Medication Practices Canada. <a href="https://www.ismp-canada.org/news/section/alert/">https://www.ismp-canada.org/news/section/alert/</a>. Published 2022. Accessed July 26, 2022.
- 4. COVID-19 vaccine guide for youth and adults (12 years and over): Managing COVID-19 vaccine administration errors or deviations. Government of Canada. <a href="https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/quick-reference-guide-covid-19-vaccines/managing-administration-errors-deviations.html">https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/quick-reference-guide-covid-19-vaccines/managing-administration-errors-deviations.html</a>. Published 2022. Accessed July 26, 2022.
- Preventing Errors with COVID-19 Vaccines: Learning from Vaccine Incidents. Institute for Safe Medication Practices Canada.
   <a href="https://ismpcanada.ca/wp-content/uploads/2021/11/ISMPCSB2021-i2-COVID19-Vaccine-Error-Prevention.pdf">https://ismpcanada.ca/wp-content/uploads/2021/11/ISMPCSB2021-i2-COVID19-Vaccine-Error-Prevention.pdf</a>. Published 2021. Accessed July 26, 2022.



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- 6. Vaccine Administration: Preventing Vaccine Administration Errors. Centers of Disease Control and Prevention. <a href="https://www.cdc.gov/vaccines/hcp/admin/resource-library.html">https://www.cdc.gov/vaccines/hcp/admin/resource-library.html</a>. Published 2021. Accessed July 26, 2022.
- 7. Don't Be Guilty of These Preventable Errors in Vaccine Storage and Handling! Immunization Action Coalition. <a href="https://www.immunize.org/catg.d/p3036.pdf">https://www.immunize.org/catg.d/p3036.pdf</a>. Accessed July 26, 2022.