

## VCH Guidance Document on Inadvertent Immunization Errors and Deviations

**Overview:** Adequate vaccine dose and site of administration are important to ensuring optimal immune response and minimizing adverse events. The guidance for both are derived from clinical trials. Vaccine dose is a correlate of antigen dose; thus administration of vaccine volume less than recommended *may* result in inadequate protection. Site of vaccination can influence both vaccine response and adverse events. In particular, adjuvanted vaccines which when administered subcutaneously or intradermally can cause local reactions.

Errors in both dose and site do occur and questions are asked about whether a dose needs to be repeated. The answer to these is guided by data from clinical trials and expert guidance.

**Purpose:** The purpose of this document is to support PHNs in determining if repeat vaccine dose is necessary when the administered dose deviates from the recommended guidance.

### **Follow-up action after an immunization error has been identified:**

1. The PHN should inform the individual of the error and potential for local and/or systemic adverse events.\*
2. Report the immunization error to the CoC leader followed by documentation in Paris and [BC Patient Safety Learning System \(PSLS\)](#).
3. An [Adverse Event Following Immunization](#) form is to be completed if the vaccine administration error resulted in a reportable adverse reaction.

Type	Administration error	Recommended action*
Site	<b>IM rather than SC:</b> <ul style="list-style-type: none"> <li>• MMR<sup>2</sup></li> <li>• Varicella<sup>2</sup></li> <li>• MMRV<sup>2</sup></li> </ul>	<ul style="list-style-type: none"> <li>• <u>Consider this a <b>valid</b> dose.</u></li> <li>• Dose does not need to be repeated.</li> </ul>
	<b>SC rather than IM</b> where studies indicate immune response SC is similar to IM: <ul style="list-style-type: none"> <li>• DTaP<sup>2,6</sup></li> <li>• Hepatitis A vaccine<sup>1,6</sup></li> <li>• Meningococcal conjugate<sup>1,5</sup></li> <li>• PCV13<sup>3</sup></li> </ul>	<ul style="list-style-type: none"> <li>• <u>Consider this a <b>valid</b> dose.</u></li> <li>• Dose does not need to be repeated.</li> </ul>
	<b>SC rather than other than IM</b> where studies indicate immune response SC is inferior to IM: <ul style="list-style-type: none"> <li>• Hepatitis B vaccine<sup>1,2,6</sup></li> <li>• Influenza<sup>1,2,7</sup></li> </ul>	<ul style="list-style-type: none"> <li>• <u>This is an <b>invalid</b> dose.</u></li> <li>• Immune response is greater when administered IM rather than SC.</li> <li>• Administer a full repeat dose immediately in the opposite arm.</li> <li>• Inform the recipient about potential for local adverse events.</li> </ul>
	Rabies vaccine administered in gluteal site. <sup>1</sup>	<ul style="list-style-type: none"> <li>• <u>This is an <b>invalid</b> dose.</u></li> <li>• Administer a full repeat dose immediately.</li> <li>• Inform the recipient potential for local adverse events.</li> </ul>

	Vaccines such as HiB, Pediacel, HPV, or any other vaccines not listed.	<ul style="list-style-type: none"> <li>• There is no evidence related to immunogenicity.</li> <li>• Administer a full repeat dose immediately in the opposite arm.</li> <li>• Inform the recipient potential for local adverse events.</li> </ul>
<b>Dose volume</b>	If a partial dose is administered because of equipment failure (syringe or needle leaks) or recipient pulled away the before the injection was completed.	<ul style="list-style-type: none"> <li>• This is an <b>invalid</b> dose.</li> <li>• Administer a full repeat dose immediately in the opposite arm.</li> <li>• Inform the recipient potential for local adverse events.</li> </ul>
	Individual coughs, sneezes after nasal spray vaccine <sup>4</sup> or spits up after oral vaccines.	<ul style="list-style-type: none"> <li>• <u>Consider this a <b>valid</b> dose.</u></li> <li>• Repeat dose is NOT necessary.</li> </ul>
	Any vaccination using less than appropriate dose: Pediatric Hepatitis A or Hepatitis B vaccines given to adults. <sup>2</sup>	<ul style="list-style-type: none"> <li>• If 2 half doses given on the same day, consider as 1 valid dose.</li> <li>• If unable to administer half dose on same day, provide an adult dose.</li> </ul>
<b>Off label use of vaccine</b>	Vaccine products given off label for minimum or maximum age but meet the minimum age criteria for antigen: <ul style="list-style-type: none"> <li>• Flumist &lt; 2 years</li> <li>• Fluzone HD &lt; 65 years</li> <li>• MMRV ≥ 13 years</li> </ul>	<ul style="list-style-type: none"> <li>• <u>Consider this a <b>valid</b> dose</u></li> <li>• Dose does not need to be repeated.</li> </ul>
<b>Storage/Handling</b>	Dose administered past the expiration date.	<ul style="list-style-type: none"> <li>• <u>This is an <b>invalid</b> dose.</u></li> <li>• Administer a full repeat dose immediately in the opposite arm.</li> <li>• If the expired dose is a live virus vaccine, and it could not be repeated on the same day, wait at least 4 weeks after the previous (expired) dose was given before repeating it.</li> </ul>

**Referencing:**

1. <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html>
2. <https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html>
3. [https://journals.lww.com/pidj/Fulltext/2013/09000/Immunogenicity\\_and\\_Safety\\_of\\_a\\_13\\_valent.22.aspx](https://journals.lww.com/pidj/Fulltext/2013/09000/Immunogenicity_and_Safety_of_a_13_valent.22.aspx)
4. <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm>
5. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5537a2.htm>
6. [Tandfonline:Table 1. Adjuvanted vaccines and intramuscular compared with subcutaneous administration – reactogenicity and immunogenicity](#)
7. [Tandfonline:Table 3 Non-adjuvanted \(whole cell, split cell and subunit\) vaccines and intramuscular compared with subcutaneous administration – reactogenicity and immunogenicity](#)