

Medical Management of Inadvertent Vaccine Misadministration March 2016

Appropriate vaccine administration is critical to vaccine effectiveness and safety. The recommended site, route, and dosage for each vaccine is based on clinical trials, practical experience and theoretical considerations.

The following Q and A information provides general guidelines for

- Preventing immunization administration errors, and
- Corrective measures to follow when inadvertent misadministration errors occur.

These guidelines should be used in conjunction with professional standards for medication administration, vaccine manufacturers' product guidelines, The Advisory Committee on Immunization Practices (ACIP) MMWR General Recommendations, The American Academy of Pediatrics' (AAP) "Red Book," and the Oregon State Public Health Immunization Program's model standing orders.

1. Expired vaccine

Q: Does a dose of expired vaccine have to be repeated?

A: Yes.¹

- If a dose of expired inactivated vaccine is given by accident to a patient, the dose should be repeated with viable vaccine. The repeat dose can be given on the same day or at any time after the date of the expired dose.
- If a dose of expired live virus vaccine is given, you must wait at least 28 days after the expired dose was administered before repeating it. For certain vaccines (e.g. MMR, MMRV, or varicella vaccine) serologic testing can be performed, and, if immunity can be documented for all antigens, revaccination is not necessary.)²

2. Injections given by the wrong route

Q: Do immunizations administered by the wrong route need to be repeated?

A: Not usually. Vaccines should always be given by the route recommended by the manufacturer because data regarding safety and efficacy of alternative routes is limited.

- However, ACIP recommends that vaccines given by the wrong route be counted as valid with two exceptions; Hepatitis B and Rabies vaccine must be given IM and in the deltoid or anterolateral thigh muscle in order to be counted as valid. If either is given in the gluteal site the immunization must be repeated.³

3. Viability of vaccine stored in a refrigerator in a syringe

Q: How long can a vaccine that has been drawn up into a syringe be stored in a refrigerator before it needs to be used or discarded?

A: ACIP recommends that vaccines drawn up into syringes be discarded at the end of the clinic day. Disposable syringes other than those filled by the manufacturer are designed for immediate administration of immunobiologics, and are not licensed by the FDA for vaccine storage.⁴

Manufactured pre-filled syringes that have had the caps removed and a needle attached to the syringe should also be discarded at the end of the clinic day if unused.⁴

4. Viability of opened vaccine or immune globulin (IG) vials stored in the refrigerator

Q: How long is an opened multi-dose vaccine vial viable in the refrigerator?

A: Once opened, the remaining doses from partially used multidose vaccine vials (e.g. influenza, IPV, and PPV23) can be administered until the expiration date (or the last day of the month) printed on the vial, provided that the vial has been stored correctly.¹

Q: How long is an opened single-use vaccine or immune globulin vial viable in the refrigerator?

A. A single-use vaccine vial that has been opened by either removing the cap or inserting a needle must be used within the time frame specified by the

manufacturer, typically no longer than the same clinic day. If not used the vial should be discarded.^{4, 6}

- A. Any leftover IG (GammaSTAN®) from a 2 ml or 10 ml **single-use, preservative-free vial** should be discarded after it has been opened and the rubber top penetrated by a needle. Per Grifoils Medical Information representative: 1-800-520-2807⁵

Acceptable volume for a single dose of immune globulin (IG) into the deltoid muscle or vastus lateralis muscle:⁶

Deltoid:

- Average 0.5 mL
- Range 0.5–2 mL

Vastus Lateralis:

- Average 1–4 mL
- Range 1–5 mL

Infants and toddlers would fall at the lower end of the range, whereas adolescents and adults would generally fall on the higher end of the range.

5. Vaccine storage and handling of vaccine

Q: What do I do if I find that any of my vaccines have been stored outside the recommended temperature range for any length of time?

- A: Immediately call your Oregon State Immunization Program health educator for assistance and directions at 971-673-0300. See health educator map at: <https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/vfc/Documents/HEMap.pdf>

6. Q: How soon after reconstitution should different vaccines be administered before they are considered no longer viable and therefore must be discarded?

A. There are a total of 14 vaccines that require diluents.

- **Please see the IAC handout: Vaccines with Diluents: How to Use Them**⁷
- If any **live vaccines** are mistakenly administered after these time lines, the immunization must be repeated ≥ 28 days after the misadministered dose.⁸
- The misadministered **inactivated vaccines** can be repeated anytime after they are initially given.¹

7. Q: Are vaccine diluents interchangeable?

A. No.

- As a general rule vaccine diluents are not interchangeable.
- One exception is that the diluent for MMR can be used to reconstitute varicella vaccine or MMRV vaccine, and vice versa. The diluents for these three vaccines use sterile water for injection (not just any sterile water!), and are produced by the same manufacturer-Merck.⁶
- If a diluent from one manufacturer is inadvertently used to reconstitute a vaccine from a different manufacturer, the immunization needs to be repeated.⁶

8. Q: What are the recommendations for the Mantoux tuberculin skin test (TST) for TB screening?

A: This particular TST should be placed within 20 minutes of being drawn up. More than a brief exposure to room temperature or light can make the skin test antigens less effective.

- A TST can be safely given 2 or 3 days before or at the same visit as a live virus vaccine. However, if the TST is not given simultaneously with a live virus vaccine you must wait at least 28 days after the live vaccine is given to place the TST. This delay will remove the concern of any theoretical but transient suppression of TST reactivity from the live circulating vaccine.^{9, 10}

Oregon State TB Program: 971-673-0169.

9. Splitting or combining doses of the same vaccine

Q: What should I do if I have a parent who requests a reduced dose vaccine for their infant or child?

A: Splitting vaccine doses or using multiple reduced doses (at different visits) that together equal a full immunizing dose is not endorsed or recommended by ACIP. Therefore, any immunization given containing less than the standard dose should not be counted and needs to be repeated, unless serologic testing indicates an adequate response has been achieved.³

10. Q: My situation is that I have run out of the multi-dose vials of flu vaccine and only have single dose (0.25 ml) pediatric vials on hand. If an adult presents for a flu vaccine can I draw up two pediatric doses into the same syringe to equal the 0.5 ml volume of an adult dose?

A: **NO.** Individual vaccines should not be mixed in the same syringe unless FDA licensed for mixing.

Potential Exceptions:

- Administering **two separate doses** of the same kind of pediatric vaccine into two different anatomical sites in order to achieve a full adult dose volume at the same visit can only be recommended with prior approval from the FDA, ACIP or the State Public Health Immunization Medical Director. (Oregon State Public Health Division Immunization Program unwritten policy) 03 February 2016.

11. Non-simultaneous administration of live vaccines

Q: What is the minimum interval between two doses of different live vaccines not administered simultaneously?⁸

A: To minimize the potential risk for interference, injectable or nasally administered live vaccines not administered on the same day should be administered ≥ 4 weeks apart. If live vaccines are separated by < 4 weeks, the vaccine administered second is counted as invalid. The repeat dose should be administered ≥ 4 weeks after the invalid dose.

Exceptions:

- Oral vaccines (Ty21a typhoid vaccine and Rota virus vaccine) can be administered simultaneously or at any interval before or after other live vaccines if indicated.⁸

12. Inadvertent administration of Tdap or pediatric DTaP

Q. What should I do if I mistakenly administer Tdap instead of DTaP to a child < 7 years?¹¹

A. If the dose you misadminister is one of the first 3 doses of the tetanus-diphtheria-pertussis series, the Tdap dose should not be counted as valid, and a replacement dose of DTaP should be administered at any interval after the invalid dose. The Tdap has less antigen than the DTaP dose.

If the dose you misadminister is the 4th or 5th dose in the tetanus-diphtheria-pertussis series, the Tdap dose should be counted as valid and does not need to be repeated.

13. What should I do if I mistakenly administer DTaP to an individual ≥ 7 years instead of Td or Tdap?

A. If DTaP or Tdap is given to a child 7–10 years instead of Td as part of a catch-up vaccine or for wound management, this dose can be counted as the adolescent Tdap dose.

DTaP given to patients age 7 or older can be counted as valid for the one-time Tdap dose as DTaP has more antigen than Tdap.¹¹

The individual should then receive the next tetanus and diphtheria booster dose 10 years after this inadvertent DTaP dose.¹²

14. Q. Why can't we pre-fill syringes for a clinic?¹⁴

- Increased possibility of administration and dosing errors
- Increased risk of maintaining vaccine under inappropriate storage conditions (i.e. temperature or light)
- Possibility of bacterial contamination
- Possibility of reducing a vaccine's potency over time because of its interaction with the plastic syringe components

Prefilling syringes might also violate basic medication administration guidelines, which state that an individual should administer **only** those medications he or she has prepared and drawn up him or herself.

CDC recommends using manufacturer-supplied prefilled syringes, which are designed both for storage and administration. However, keep in mind that once you remove the syringe cap or attach a needle, the sterile seal is broken. You should either use the syringe or discard it at the end of the clinic day.

Potential Exceptions:

Although pre-drawing vaccine is discouraged, immunization staff may pre-draw a limited amount of vaccine in a mass-immunization clinic setting **if the following conditions apply:**

- Only a single type of vaccine (e.g., influenza) is administered
- Vaccine is not drawn up in advance of its arrival at the mass-immunization clinic location
- Prefilled syringe doses are stored at temperatures appropriate for the vaccine they hold
- No more than one vial or 10 doses (whichever is greater) is drawn into syringes
- Clinic staff monitor patient flow carefully, avoid drawing up unnecessary doses, and promptly administer pre-drawn doses.

At the end of the clinic day, discard any remaining syringes prefilled by staff. **Never** save these syringes for another day, and **never** attempt to put the vaccine dose back into the vial.

Prefilling syringes might also violate basic medication administration guidelines, which state that an individual should administer **only** those medications he or she has prepared and drawn up him or herself.

Note:

- Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at <https://vaers.hhs.gov/esub/step1> Save a copy of the report number for your records, and send copies of the report and VAERS ID number to the Oregon Immunization Program Vaccine Safety Coordinator via confidential email at ORVAERS.Reports@state.or.us or fax (971-673-0278). Private providers are to report events directly to VAERS and can read about options on how to do so at <http://vaers.hhs.gov/index>
- If you have misadministered a dose **that must be repeated**, and you submit to ALERT, please notify your Oregon State Immunization Program health educator at 971-673-0300 so the dose can be flagged in our registry.

Original provided courtesy of the Oregon State Public Health Division Immunization Program

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