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.
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 adults, 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.2

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 vaccination session. 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. 3

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. 3

4. Viability of opened vaccine 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 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.3

Q: How long is an opened immune globulin vial viable in the refrigerator?
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: 1-800-520-2807.

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

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: All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).
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
- If any live vaccines are mistakenly administered after these time lines, the immunization must be repeated \( \geq 28 \) days after the misadministered dose.\(^1\)
- The misadministered inactivated vaccines can be repeated any time 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, MMRV vaccine or zoster vaccine, and vice versa. The diluents for these four vaccines use sterile water for injection (not just any sterile water!), and are produced by the same manufacturer-Merck.\(^5\)
- If a diluent from one manufacturer is inadvertently used to reconstitute a vaccine from a different manufacturer, the immunization needs to be repeated.\(^5\)

Q: What should I do if I gave the liquid portion of Pentacel\(^\text{®}\) without reconstituting the Hib component?

A: Use of DTaP-IPV solution as the diluent for the Hib component is specifically written both on the Pentacel box AND on the DTaP-IPV vial label. The DTaP-IPV component will count as valid doses of DTaP and IPV vaccines. ActHib must ONLY be reconstituted with either the DTaP-IPV solution supplied with Pentacel, or with a specific ActHib saline diluent. If you have ActHib but neither diluent, you must contact the manufacturer (sanofi pasteur) and obtain ActHib diluent or discard the ActHib component.\(^17\)
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.9

- 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.8, 9


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.2

10. **Non-simultaneous administration of live vaccines**

**Q:** What is the minimum interval between two doses of different live vaccines not administered simultaneously? 7

**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. 7
11. **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?\(^{10}\)

   **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 4\(^{th}\) or 5\(^{th}\) dose in the tetanus-diphtheria-pertussis series, the **Tdap dose should be counted as valid** and does not need to be repeated.

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12. **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.\(^{11}\)
13. **Q. Why can’t we pre-fill syringes for a clinic?**

**A.**

- 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](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](http://vaers.hhs.gov/index)

• If you have misadministered a dose that must be repeated, and you submit to ALERT, please notify the Vaccines for Children (VFC) Program immediately at the Oregon Immunization Program at 971-673-4VFC (4823) so the dose can be flagged in our registry.

14. Spacing of Vaccine Doses
Q. For the purpose of vaccine spacing, what constitutes a month: 28 days (4 weeks), 30 days or 31 days? 13
A. For intervals of 3 months or less, you should use 28 days (4 weeks) as a “month”. For intervals of 4 months or longer, you should consider a month a “calendar month”: the interval from one calendar date to the next a month later. This is a convention that was introduced on the childhood schedule in 2002 and discussed in the paper “Evaluation of Invalid Doses” (Stokley S, Maurice E, Smith PJ, et. al. American Journal of Preventive Medicine, 2004: 26[1]: 34–40).

Q. We gave a dose of vaccine too soon after the previous dose. When can we give another (valid) dose?
A. If vaccines are given too close together, it can result in a less than optimal immune response. However, in most instances, a difference of a few days is unlikely to have a negative effect on immune response. With the exception of rabies vaccine, ACIP allows a grace period of 4 days (i.e., vaccine doses administered up to 4 days before the recommended minimum interval or age can be counted as valid). However, if a dose was administered 5 or more days earlier than the recommended minimum interval between doses, it is not valid and must be repeated. The repeat dose should be spaced after the invalid dose by the recommended minimum interval.

If the first dose in a series is given 5 days or more before the recommended minimum age, the dose should be repeated on or after the date when the child reaches at least the minimum age. If the vaccine is a live vaccine, ensuring that a minimum interval of 28 days has elapsed from the invalid dose is recommended. Avoid such errors by knowing the minimum intervals and ages for routinely given vaccines. You can look up such information [www.cdc.gov/mmwr/pdf/rr/rr6002.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf), pages 36-37.9
The 4-day "grace period" should not be used when scheduling future vaccination visits, and should not be applied to the 28-day interval between live parenteral vaccines not administered at the same visit. It should be used primarily when reviewing vaccination records (for example, when evaluating a vaccination record prior to entry to daycare or school).

Q: A staff member inadvertently administered the wrong dose of influenza vaccine. How do we correct this?

A: If a smaller than recommended dose (volume) of any IIV product is inadvertently administered, additional vaccine should be given so that the patient receives a full dose. The amount of vaccine that should be administered is based on when the patient is available to be revaccinated.

- If 0.25 mL of Fluzone Quadrivalent is inadvertently administered to someone 3 years of age or older, an additional 0.25 mL dose can be given on the same clinic day to provide a full 0.5 mL dose. If the patient cannot be revaccinated until the next day or later, a full dose of 0.5 mL of inactivated influenza vaccine should be administered as soon as the patient can return.
- The same guidance applies for substandard doses of FluLaval Quadrivalent influenza vaccine. If 0.25 mL is inadvertently administered, an additional 0.25 mL dose can be administered on the same clinic day to provide a full 0.5 mL dose. If the error is discovered later or the patient cannot return until the next day or later, a full dose of 0.5 mL of FluLaval influenza vaccine should be administered as soon as the patient can return.
- If a larger dose (volume) of influenza vaccine is inadvertently administered, count the dose as valid. Revaccination with additional vaccine is not needed.

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References


2. Ibid. Page 17.


12. CDC. Updated recommendations for the use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine from the Advisory Committee on Immunization Practices (ACIP). MMWR 2010; 60(01);13–15. Available at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm) Accessed 15 March 2017.


16. CDC. Seasonal Influenza Vaccine Dosage & Administration Q and A. Available at: https://www.cdc.gov/flu/about/qa/vaxadmin.htm Accessed 14 March 2017.