

**OREGON HEALTH AUTHORITY
OREGON IMMUNIZATION PROGRAM
Optional**

Medical Management of Inadvertent Vaccine Misadministration	
Last Reviewed	17 April 2019
Last Revised	17 April 2019
This order expires	31 July 2020

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 the Oregon State Public Health Immunization Program’s model standing orders or pharmacy protocols, the Advisory Committee on Immunization Practices (ACIP) MMWR, the General Recommendations, the American Academy of Pediatrics’ (AAP) “Red Book,” and the vaccine manufacturers’ product guidelines.

1. Expired vaccine *New!*

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

A: Not necessarily:

“When an expired vaccine is inadvertently given, do not re-vaccinate without first checking with the Oregon Immunization Program, VFC Helpdesk at 971-673-4VFC (4823). We have recently learned that some lots of expired vaccines are fully potent after administration, based on internal testing at pharmaceutical companies. We are happy to check for you and advise on next steps.”

–OIP Program Medical Director and VFC Helpdesk. (17 April 2019)

2. Antipyretics *New!*

Q: Should we give Tylenol before a vaccine to prevent pain and fevers?

A: Here it is, from the new general recommendations:

Evidence does not support use of antipyretics before or at the time of vaccination; however, they can be used for the treatment of fever and local discomfort that might occur following vaccination. Studies of children with previous febrile seizures have not demonstrated antipyretics to be effective in the prevention of febrile seizures.

R: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.pdf> Page 95. Accessed 17 April 2019.

3. SIRVA *New!*

Q. What is SIRVA?

A. Shoulder injury related to vaccine administration (SIRVA). Here are the new phrases in the standing order and pharmacy protocols:

1. Verify needle length for **IM** injection into the vastus lateralis or deltoid muscles.
2. Avoid injecting in the upper third of the deltoid muscle.
3. Both client and vaccinator must be seated for vaccine administration.

R: <https://www.aappublications.org/news/2017/09/01/IDSnapshot082917> Accessed 17 April 2019.

R: <https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf> Accessed 17 April 2019.

4. Influenza *New!*

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 Fluarix or FluLaval Quadrivalent influenza vaccine (0.5mL for all ages). 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 Fluarix or FluLaval influenza vaccine should be administered as soon as the patient can return, or a 0.25mL dose of Fluzone can be administered as a full dose.
- The licensed 0.5mL of Fluarix, FluLaval, or Fluzone is **not** a double dose for babies 6-35 months.

A: If a larger dose (volume) of influenza vaccine (e.g. Fluzone 0.5mL for a 6 month old) is inadvertently administered, count the dose as valid. Revaccination with additional vaccine is not needed.

R: <https://www.cdc.gov/flu/about/qa/vaxadmin.htm> Accessed 17 April 2019.

Q. If inactivated influenza vaccine presentations for persons 3 years of age and older are not available, can a high-risk older child or adult receive the pediatric product (thimerosal preservative-free 0.25 ml dose) as long as they are given 0.5 mL?

A. Flu vaccine is available and recommended for almost everyone 6 months of age and older. If an adequate supply of adult formulation is available, CDC does not recommend that providers use pediatric formulations to vaccinate adults.

If there is not an adequate supply of adult formulation, providers may choose to administer pediatric presentations such as manufacturer-filled syringes (0.25 mL). Two manufacturer-filled syringes (0.25 mL) are needed to provide the correct dose (0.5 mL) for persons 3 years of age and older. Two separate injections should be administered. Providers should never attempt to transfer vaccine from one syringe to another for the purpose of administering only one injection. This is considered off-label use.

Giving two separate 0.25 ml shots of state-supplied flu vaccine to a single patient is *not* allowed *unless* an express exception is made during a general, state-wide vaccine shortage (VFC rules).

Accessed 18 April 2019.

R: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html> Accessed 17 April 2019.

R: http://www.immunize.org/askexperts/experts_zos.asp Accessed 17 April 2019.

5. Unexpected Loss of Vaccine Volume:

Q: If some portion of a vaccine leaks out of the syringe while it is injected into a patient, does the dose need to be repeated and if so, when?

A: When injectable vaccine volume is lost (patient moves, syringe leaks), it may be difficult to judge how much vaccine the patient actually received. In general, you should treat this as a nonstandard injectable dose and should not count it. If it was an inactivated vaccine, you should re-immunize the person as soon as possible. If it was a live vaccine, you can give another dose if you detect the error on the same clinic day; otherwise you should wait 28 days to give the next dose.

However, if part of a dose of an oral vaccine (rotavirus) was spit out, count the dose and do not administer a second dose.

Q. Do you repeat a dose of LAIV if the client sneezes after the full dose is given?

A. If the vaccine recipient sneezes after administration, the dose should not be repeated.

R: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html> Accessed 17 April 2019.

R: <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html> Accessed 17 April 2019.

6. RZV (Shingrix®) *NEW!*

Q: What is the minimum age for administering RZV (Shingrix)?

A: The recommended and minimum age for RZV is 50 years. However, if a dose is inadvertently administered to an adult 18 through 49 years of age CDC does not recommend repeating the dose. The second RZV dose should not be administered until the 50th birthday. This guidance does not appear in the most recent zoster ACIP statement but is in the General Best Practice Guidelines (Table 3-1 in the Timing and Spacing of Immunobiologics section at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html) and is based on guidance from CDC's zoster subject matter experts.

R: Ask the Experts: CDC Experts Answer Your Questions

Issue 1378: August 3, 2018 <http://www.immunize.org/express/issue1378.asp> Accessed 17 April 2019.

Q: What is the minimum interval between doses of RZV (Shingrix)?

A: The minimum interval between doses of RZV is 4 weeks. The recommended interval between RZV doses is 2 to 6 months. If the second dose is given less than 4 weeks after the first dose, the second dose should be repeated at least 8 weeks after the invalid dose.

R: Ask the Experts: CDC Experts Answer Your Questions

Issue 1378: August 3, 2018 <http://www.immunize.org/express/issue1378.asp> Accessed 17 April 2019.

Q: Can we give Shingrix and Fludax at the same visit?

A: Shingrix (AS01_B) and Fludax (MF59) are individually more reactogenic than non-adjuvanted vaccines. There is no data on what happens if both Shingrix and Fludax are given at the same time. Try to avoid giving two adjuvants at the same time. Shingrix and non-adjuvanted IIV can be given together.

Q: We inadvertently gave Zostavax rather than Shingrix. Can the dose of Zostavax be counted as the first dose of the Shingrix series?

A: No. Shingrix and Zostavax are **not** interchangeable. Doses of ZVL cannot be counted towards completing the RZV series. The repeat dose of RZV should be given at least 8 weeks after the dose of ZVL.

Q: Patient was inadvertently given RZV by the subcutaneous rather than the intramuscular route. Does the dose need to be repeated?

A: RZV has been shown to be immunogenic when given by the subcutaneous route. A dose erroneously given by this route does not need to be repeated.

Q: When reconstituted, the volume of RZV is more than 0.5 mL. Should the entire volume of reconstituted vaccine be administered or just 0.5 mL as indicated in the package insert?

A: The RZV adjuvant solution may contain up to 0.75 mL of liquid. The entire volume of the adjuvant solution should be withdrawn and used to reconstitute

the lyophilized vaccine. After mixing, withdraw the recommended dose of 0.5 mL. Any reconstituted vaccine left in the vial should be discarded.

R: http://www.immunize.org/askexperts/experts_zos.asp Accessed 17 April 2019.

7. Pentacel® Issues: *New!*

Q: What should I do if I gave the liquid portion (DtaP-IPV) of Pentacel® without reconstituting the Hib (dry) 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.

R: http://www.immunize.org/askexperts/experts_combo.asp#DTaPIPVBib Accessed 17 April 2019.

Q: We gave 3 doses of Pentacel last week and discovered a left-over vial of diluent. What should we do?

A: The diluent part of the Pentacel dose is the DTaP-IPV component. The dry lyophilized powder is the Act-Hib component. This means that one patient likely received the ACT-Hib component but not the DTaP-IPV. The ACT-Hib was likely reconstituted with sterile water and none of the components are valid.

Unless you are able to identify the patient who received the incorrectly reconstituted ACT-Hib, all three patients should be contacted and offered revaccination.

OIP Program

8. Interferon gamma release assays (IGRAs) and TST values *New!*

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.^{8,9}

Interferon gamma release assays (IGRAs), such as the QuantiFERON-TB Gold In-Tube test and the T-Spot TB test, have the same timing guidelines that apply to the interval between a live vaccine and TST (i.e., 28 days between live vaccine and IGRA if they do not occur on the same day), because IGRA (like TST) might be suppressed through immunologic mechanisms. Oregon State TB Program: 971-673-0169.

R: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/special-situations.html>

Accessed 17 April 2019.

9. Tdap adolescent booster issues **NEW!**

Q. What should I do if I mistakenly administer DTaP to an individual ≥ 7 years instead of Td or Tdap? When should I give the next booster dose?

- 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 valid. An additional dose of Tdap should be administered at age 11 years.

For fully-vaccinated persons aged 7–10 years who inadvertently receive a dose of DTaP, this dose can be counted as the adolescent booster dose.

R: <https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6702a1-H.pdf>.

Accessed 17 April 2019.

❖ Inadvertent administration of Tdap for pediatric DTaP

Q. What should I do if I mistakenly administer Tdap instead of DTaP to a child <7 years? (page 29)

- 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.

R: <https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6702a1-H.pdf> Accessed 17 April 2019.

10. Change needles after the dose is drawn up?

Q: Is it recommended to change needles after a vaccine dose has been drawn into a syringe?

A: No. It is also unnecessary to change the needle if it has passed through two stoppers, which is done when a lyophilized vaccine is reconstituted. Changing needles is a waste of resources and increase the risk of needle stick injury.

R: <http://www.immunize.org/askexperts/administering-vaccines.asp> Accessed 17 April 2019.

R: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html> Accessed 17 April 2019.

11. Timing and spacing of vaccine doses

Q: What does “Give Immediately” mean? How does CDC define “immediately”?

A: CDC considers “immediately” to be the reasonable time it takes to prepare and transport the vaccine to the patient to be administered. This would include any limited documentation that may be related to this process. It is up to the judgment of a provider to determine if a vaccine has not been used in the appropriate time. Some manufacturers have indicated to providers that “immediately” can be up to 30 minutes. The definition of “immediately” varies from manufacturer to manufacturer. Some do not have the data to put forth a general time frame as to what “immediately” means. CDC recommends that the provider contact the manufacturer any time (s)he has any question about whether or not the vaccine has been used in the appropriate time frame.

R: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html> Accessed 17 April 2019.

R: <http://www.immunize.org/express/issue1355.asp#IACX8> Accessed 17 April 2019.

❖ Definition of a Month

Q. For the purpose of vaccine spacing, what constitutes a month: 28 days (4 weeks), 30 days or 31 days?

- 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). See link below:
R: <https://www.ncbi.nlm.nih.gov/pubmed/14700710>

R: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html> Accessed 17 April 2019.

❖ Grace Period or 4–day Rule

- 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 at www.cdc.gov/mmwr/pdf/rr/rr6002.pdf , pages 36-37.

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).

❖ **Non-simultaneous administration of live vaccines**

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

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, Cholera and Rotavirus vaccine) can be administered simultaneously or at any interval before or after other live vaccines if indicated.

12. Injections given by the wrong route

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

A: Not usually. However, ACIP recommends that **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.

Vaccines should always be given by the route recommended by the manufacturer because data regarding safety and efficacy of alternative routes is limited.

13. Vaccine refrigerator, storage, and handling

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).

– Per OIP Policy. Verified 17 April 2019.

Clinics not enrolled in the VFC program should label the vaccine as not to be used, continue storage at the correct temperature, and contact the vaccine manufacturer for advice.

❖ **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.

R: <http://www.immunize.org/askexperts/storage-handling.asp#viability> Accessed 17 April 2019.

R: Vaccine Inventory Management, Transport, and Preparation.
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf> page 33.
Accessed 17 April 2019.

Q. How long is an opened single-use vaccine 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.

R: <http://www.immunize.org/askexperts/storage-handling.asp#viability> Accessed 17 April 2019.

❖ **Viability of vaccine *stored in a syringe*, in a refrigerator**

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.

R: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html>
Accessed 17 April 2019.

❖ Immune Globulin

Q Can a multi-dose vial of IG be used for more than one patient?

A. **Outbreak:** It is permissible to use a 10mL vial of GamaSTAN for more than one family member when the 2mL vial is not available. Separate syringes and needles must be used for each individual. Any IG left in the vial must be discarded. Vials of IG do not contain preservative and are not meant to be multi-dose vials. Per OIP Medical Director. 17 April 2019.

Acceptable volume for a single dose of immune globulin (IG) into the deltoid muscle or vastus lateralis muscle: ⁵

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.

R: IAC. Ask the Experts. Administering Vaccines. General Issues.

<http://www.immunize.org/askexperts/administering-vaccines.asp> Accessed 17 April 2019.

❖ Pre-filling syringes

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 (s)he has prepared and drawn up them self.

R: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>
Accessed 17 April 2019. Page 37.

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.

R: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>
Page 37 Accessed 17 April 2019.

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 <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf> Accessed 17 April 2019. Page 38.
- 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.

R: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf> Accessed 17 April 2019. Page 37.

14. Vaccine Reconstitution

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 13 vaccines that require diluents.

- Please see the IAC handout: Vaccines with Diluents: How to Use Them

R: <http://www.immunize.org/catg.d/p3040.pdf> Accessed 17 April 2019.

Q: Are vaccine diluents interchangeable?

A. No. As a general, rule vaccine diluents are not interchangeable. If a diluent from one manufacturer is inadvertently used to reconstitute a vaccine from a different manufacturer, the immunization needs to be repeated.

- One exception is that the diluent for MMR can be used to reconstitute varicella vaccine, MMRV vaccine or live zoster vaccine, and vice versa. The diluents for these four vaccines use sterile water for injection , and are produced by the same manufacturer-Merck.

R: <http://www.immunize.org/askexperts/administering-vaccines.asp> Accessed 17 April 2019.

15. 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.

R: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html> Accessed 17 April 2019.

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