

## Medically Managing Inadvertent Vaccine Errors

### July 2008



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

The following Q and A's provide general guidelines for

- Preventing immunization administration errors; and
- Correcting inadvertent errors when they 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), Morbidity and Mortality Weekly Report (MMWR) General Recommendations, Centers for Disease Control and Prevention (CDC) Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book), American Academy of Pediatrics' (AAP) Red Book and the Oregon Department of Human Services Public Health Division Immunization Program's model standing orders.

## 1. Expired vaccine

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

A: Yes. (MMWR General Recommendations on Immunization, Dec. 1, 2006, p. 23.)

- If a patient accidentally receives a dose of **expired inactivated vaccine**, 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 patient receives a dose of **expired live virus vaccine**, it must be repeated at least 28 days after the expired dose was administered. For certain vaccines (e.g., MMR, MMRV or varicella vaccine) serologic testing can be performed; if immunity can be documented for all antigens, revaccination is not necessary. (MMWR General Recommendations on Immunization, Dec. 1, 2006, p. 24.)



## 2. Vaccine reconstitution

Q: When reconstituting different vaccines, can I use any diluent I have on hand?

A: No. Diluent solutions vary; use only the specific diluent supplied with the vaccine you are reconstituting. (Pink Book, 10th ed, Appendix D-3.)

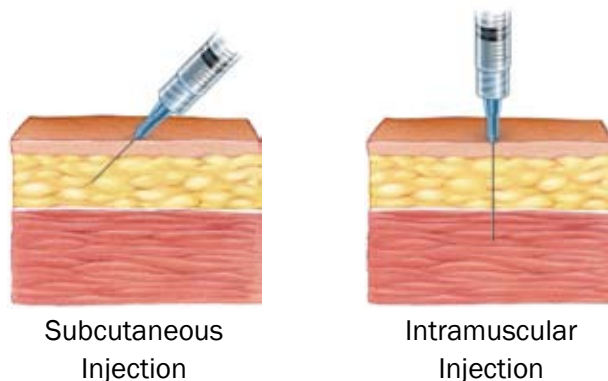
- As a general rule, vaccine diluents are not interchangeable. However, MMR's diluent can be used to reconstitute varicella vaccine or MMRV vaccine and vice versa. The diluents for these three vaccines use sterile water for injection and are produced by the same manufacturer, Merck. (Immunization Action Coalition, Ask the Experts: General Vaccine Questions, <[www.immunize.org/catg.d/p2021f.htm](http://www.immunize.org/catg.d/p2021f.htm). >)
- If a diluent from one manufacturer is inadvertently used to reconstitute a vaccine from a different manufacturer (e.g., MMR diluent used to reconstitute ACTHIB® vaccine), the immunization needs to be repeated. (National Immunization Program)

## 3. 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 vaccines must be given intramuscularly 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. (MMWR General Recommendations, Dec. 1, 2006, and Ask the Experts: General Vaccine Questions, <[www.immunize.org/catg.d/p2021f.htm](http://www.immunize.org/catg.d/p2021f.htm).>)



#### 4. Viability of vaccine stored in a refrigerator in a syringe

- Q: How long can a vaccine drawn up into a syringe be stored in a refrigerator before it needs to be used or discarded?
- A: The NIP 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, not for storage. (<[www.immunize.org/catg.d/p2021f.htm](http://www.immunize.org/catg.d/p2021f.htm)>, and Pink Book, 10th ed., January 2007, p. D-4.)
- Manufactured pre-filled syringes with the caps removed and a needle attached to the syringe should also be discarded at the end of the clinic day if unused.

#### 5. 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 if the vial has been stored correctly. (MMWR General Recommendations, Dec. 1, 2006, p. 23.)
- A 2 ml or 10 ml vial of IG (GamaSTAN) should be discarded after it has been opened and the rubber top penetrated once by a needle to withdraw a dose. These vials do not have a preservative to prevent contamination with future IG draws. They were produced to be used as a one-time dose. (Per telephone conversation with Telecris Biotherapeutics pharmacist, Nov. 27. 2007.)

#### 6. Vaccine 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: Immediately call your Oregon Immunization Program health educator for assistance and directions.
- Q: How soon after reconstitution should different vaccines be administered before they are considered no longer viable and therefore must be discarded?
- Varicella ≤30 minutes after reconstitution and protected from light until administered;
  - MMRV ≤30 minutes after reconstitution and protected from light until administered;
  - MMR ≤8 hours after reconstitution;
  - Zostavax® ≤30 minutes after reconstitution and protected from light until administered;
  - Yellow fever ≤1 hour after reconstitution;
  - Menomune® single dose vial ≤30 minutes after reconstitution;
  - TriHIBit® (ActHIB® reconstituted with Tripedia®) ≤30 minutes after reconstitution.

If any of the above **live vaccines** are mistakenly administered after these time lines, the immunization **must be repeated ≥28 days after the misadministered** dose. The **misadministered inactivated vaccines** Menomune®, and TriHIBit® **can be repeated anytime after they are initially given**. (MMWR General Recommendations on Immunization, Feb. 8, 2002.)

## 6. Vaccine storage and handling (continued)

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. (Tuberculosis Skin Test Procedures Manual, April 2000, National Health and Nutrition Examination Survey, p. 4-2.)

A TST can be safely given two or three 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 delay at least 28 days after the live vaccine is given before placing the TST. Waiting at least four weeks will remove any theoretical concern for temporary suppression of a positive skin test reaction. (MMWR General Recommendations on Immunization, Dec. 1, 2006, p. 30.)

## 7. Splitting or combining doses of the same vaccine

Q: What should I do if parents request a reduced dose vaccine for their infant or child?

A: The ACIP does not endorse or recommend **splitting vaccine doses** or using multiple reduced doses (at different visits) that together equal a full immunizing dose. 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. (MMWR General Recommendations on Immunization, Dec. 1, 2006, p. 19.)



Q: 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 they are licensed by the FDA for mixing.



### 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 Oregon Immunization Program Medical Director.
  - During the 2006 and 2007 influenza seasons, the Oregon Immunization Program's Medical Director did approve giving two 0.25 ml pediatric influenza doses of Fluzone® to individuals ≥3 years in two different anatomic sites to equal a recommended 0.5 ml dose. However, this approval would have to be written in each year's current standing order for influenza vaccine in order to be valid.
- Sanofi Pasteur's TriHIBit® (ActHIB® and Tripedia®) is licensed for mixing in the same syringe.

## 8. Non-simultaneous administration of live vaccines

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

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

### Exceptions:

- Yellow fever can be administered at any time after single antigen measles vaccine.
- 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. (MMWR General Recommendations on Immunization, Dec. 1, 2006, p.6, <[www.cdc.gov/mmwr/pdf/rr/rr5515.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5515.pdf)>.)

## 9. 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 of age?

A. **If the dose you misadminister is one of the first three 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.

**If you misadminister the fourth or fifth dose** in the tetanus-diphtheria-pertussis series, the **Tdap dose should be counted as valid** and does not need to be repeated.

Q. What should I do if I mistakenly administer DTaP instead of Td or Tdap to an individual  $\geq 7$  years of age?

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

If pediatric DTaP is mistakenly given to an adolescent 11–18 years of age, the dose should be counted as the adolescent Tdap booster. The individual should then receive the next tetanus and diphtheria booster dose 10 years after this inadvertent DTaP dose. (MMWR, March 24, 2006, Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccines, Vol. 55 (rr-3), p. 27.)

| Component         | Boostrix | Infanrix or Daptacel | Adacel |
|-------------------|----------|----------------------|--------|
| Tetanus Toxoid    | 5.0 Lf   | 10.0 vs 5.0          | 5.0 Lf |
| Diphtheria Toxoid | 2.5 Lf   | 25.0 vs 15.0         | 2.0 Lf |
| Pertussis Toxoid  | 8.0 ug   | 25.0 vs 10.0         | 2.5 ug |
| Preservative      | None     | No Thimerosal        | None   |

### Note:

- Whenever vaccine administration errors are made, the immunized adult or child's parent should be told and counseled about side effects or re-vaccination recommendations. An incident report should be completed, and follow-up with the family should be done to rule out adverse events.
- If you have misadministered a dose **that must be repeated** and you submit to ALERT, please notify your Oregon Immunization Program health educator at 971-673-0300 to flag the dose in our registry.

## Resources:

1. Atkinson W, Hamborsky J, Wolfe S, (eds.), Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book) 10th ed. Public Health Foundation Washington, DC: 2007, <<http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm>>.
2. MMWR, General Recommendations on Immunizations, Vol. 55, RR-15, Dec. 1, 2006, <<http://www.cdc.gov/mmwr/pdf/rr/rr5515.pdf>>.
3. Report of the Committee on Infectious Diseases (Red Book) 27th ed. Elk Grove Village, IL : 2006, <<http://www.aapredbook.aapublications.org>>.
4. Immunization Action Coalition. Ask the Experts, <<http://www.immunize.org/askexperts>>.
5. Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Reports (MMWR), <<http://www.cdc.gov/mmwr>>.
6. Oregon Department of Human Services Public Health Division, DHS Immunization Program standing orders, <<http://oregon.gov/dhs/ph/imm/provider/stdgorder.shtml>>.

Original provided courtesy of the Oregon Department of Human Services Immunization Program

Contact information: 971-673-0300.

Visit our website at: [www.oregon.gov/DHS/ph/imm/index.shtml](http://www.oregon.gov/DHS/ph/imm/index.shtml).

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Disclaimer: This guideline was prepared by the Oregon State Public Health Division Immunization Program. It is intended to serve as a general statement regarding appropriate practices to avoid vaccine errors based upon available and current medical literature and clinical expertise at the time of development. It should not be considered to be accepted protocol or policy, nor was it intended to replace clinical judgment or dictate care of individual patients.