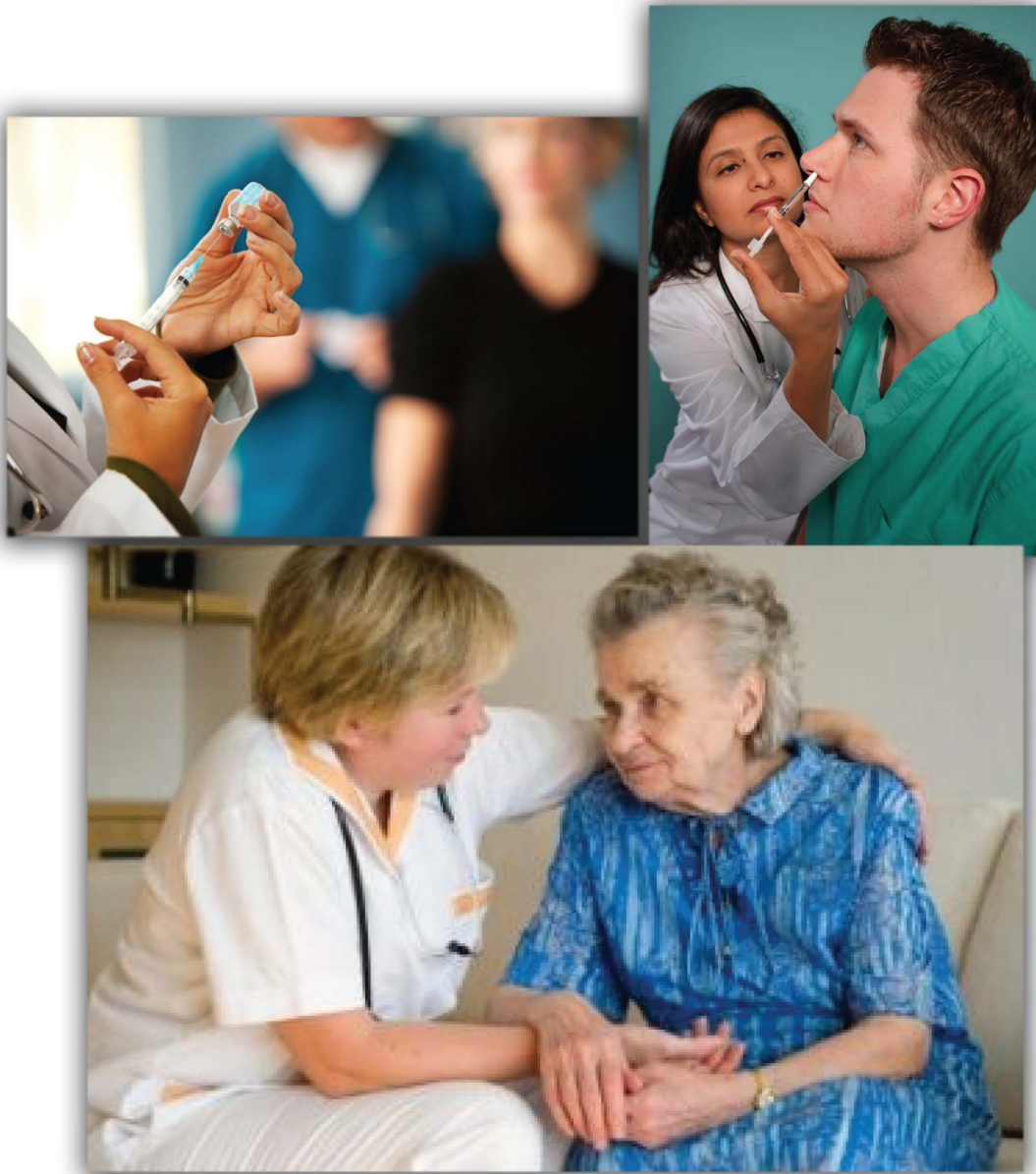


Healthcare Personnel Immunization Toolkit



Healthcare Personnel Immunization Toolkit

2012

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Healthcare Worker Immunization Toolkit

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Introduction to the Toolkit

Utilization of vaccines as a means to prevent disease transmission is a pillar of an effective infection prevention and control program. Often, this activity is provided through a separate and distinct employee/occupational health program within an individual healthcare facility with the infection preventionist either providing support or consultation. In smaller facilities, the individual may be responsible for the infection prevention and control as well as the employee/occupational health programs. Regardless, knowledge regarding program requirements, implementation, ongoing assessment and summative evaluation are critical as a means of ensuring the health and safety of the healthcare workforce. Ideally, the basis for the immunization program will be an integral part of a risk assessment process that links employee health and infection prevention and control.

The purpose of this toolkit is to provide infection preventionists and their employee/occupational health colleagues with a full spectrum of information, tools and resources that will assist them with the planning, development, implementation, evaluation and improvement of their healthcare personnel immunization program relevant in all healthcare settings.

The term “healthcare personnel” is used throughout this toolkit instead of the term “healthcare worker”, as healthcare personnel encompasses a broader group of workers. Healthcare personnel refers to individuals working in healthcare settings (paid and unpaid) who have the potential to be exposed to patients; infectious material; contaminated environmental surfaces; equipment and supplies; as well as contaminated air. Groups of healthcare personnel may include nurses, physicians, dentists, pharmacists, nursing assistants, therapists, technicians, laboratorians, emergency medical services personnel, dental hygienists, dental assistants, students and trainees, contract staff not employed by the facility, and licensed independent practitioners, among others. Healthcare personnel also include those without direct patient care responsibilities but with the potential for exposure to infectious agents that can be transmitted to them during their work time. These personnel include clerical, food services, environmental services, security, maintenance, finance and billing, and volunteers, among others. Consequently, the information contained in this toolkit must be considered to be relevant and applicable to all persons working in healthcare settings.

Resources critical for the immunization program have been provided via guidelines and recommendations from the Centers for Disease Control and Prevention (CDC) through the Advisory Committee on Immunization Practices (ACIP) and the Healthcare [formerly Hospital] Infection Control Practices Advisory Committee (HICPAC), with these documents focusing on which vaccines should be provided, to whom, and under what circumstances. Most recently, a summary document was released by the ACIP entitled *Immunization of Health-Care Personnel*

which pulled together current immunization recommendations for healthcare personnel and has essentially replaced the immunization guidelines provided in an ACIP/ HICPAC summary document from 1997 ^{1,2}. However, aspects of the healthcare personnel immunization program involve programmatic elements including safe handling of the vaccine supply, implementation of the immunization program, management of the immunization process, and overall program evaluation. Robust guidance for these aspects have been provided by the CDC and are included in the *Vaccine Storage and Handling Guide* that was revised in October 2011 as well as the *Pink Book* that provides comprehensive information regarding vaccine-preventable diseases as well as practical factors such as vaccination schedules, administration, contraindications and precautions, adverse reactions ^{3,4}. Additional information can be found in the 2008 *CDC Vaccine Storage and Handling Toolkit* that is currently under revision. Although the information provided in the aforementioned Vaccine Storage and Handling Guide and the Vaccine Storage and Handling Toolkit seem to target physician offices and clinics, they are relevant to practices in the employee/occupational health offices in hospitals, long term care facilities, ambulatory surgery settings, and any other facility that provides services to patients. Tools and resources to assist the employee/occupational health nurse and the infection preventionist are abundant and need only be gathered together and promoted. To that end, this document, the Healthcare Personnel Immunization Toolkit, has been compiled to provide assistance to the employee/occupational health and infection preventionists as they work to promote and improve healthcare personnel immunization through effective and evidence-based programs. Practical items, including sample policies and procedures, have been added to facilitate implementation of the recommendations and resources.

At present, the infection prevention and employee/occupational health fields lack clearly articulated competencies to guide professional development and practice with respect to healthcare personnel immunization programs outside those proposed for hospital-based healthcare personnel in 2008.⁵ The Toolkit therefore, addresses areas of specific practice expertise (instead of competencies) that are important for a safe, comprehensive and dynamic approach to immunization for healthcare personnel, recognizing the likelihood of healthcare personnel experiencing varying job roles and changes in physical status. These practice areas include: 1) vaccine storage and handling; 2) employee/occupational health provider roles; 3) vaccine selection; 4) vaccine administration; 5) management of vaccine reactions; 6) education of healthcare personnel receiving immunization; 7) documentation; 8) program evaluation; 9) performance improvement; and 10) practice expertise assessment for the employee/occupational health professional. In support of the practice areas, tools and resources for the immunization program including checklists, frequently asked questions, assessments, and sample policies are included.

Care should also be taken to review the package inserts of all vaccines to ensure the most up-to-date information regarding administration, indications, and contraindications. Frequent visits to the CDC and Immunization Action Coalition websites are important to ensure that printed materials provided to vaccine recipients (e.g., VIS) are the most current.

References:

1. CDC. Immunization of Health-Care Personnel: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR November 25, 2011; 60(No. RR-07); 1-45
2. CDC. Immunization of health-care workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). MMWR 1997;46(No. RR-18).
3. CDC. Vaccine Storage and Handling Guide 2011. Available at www.cdc.gov/vaccines/recs/storage/default.htm . Accessed November 25, 2011.
4. CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. The Pink Book 12th Edition (April 2011). Available at <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html> Accessed November 25, 2011.
5. Carrico R, Rebmann T, English JF, Mackey J, Cronin, SN. *Infection Prevention and Control Competencies for Hospital-Based Healthcare Personnel*. American Journal of Infection Control. 2008 Dec; 36(10):691-701.

Section 2 Vaccine Storage and Handling

This section addresses the basics of vaccine storage and handling. A general overview of the document and its web location, if available, are provided. The section includes the following:

- A major component of this section is the CDC Vaccine Storage & Handling Guide that was revised in October 2011. This document provides an overview of best practices that are relevant to the employee/occupational health office where vaccines are received, stored and maintained. In addition, this document includes specific information for the full range of vaccines that should be included in the healthcare personnel immunization program. The Guide addresses vaccines that are not part of healthcare personnel immunization programs, but that information may be helpful in addressing related questions.
<http://www.cdc.gov/vaccines/recs/storage/guide/default.htm>
- Temperature logs for the refrigerator and freezer and a troubleshooting record to note refrigeration incidents and action taken.
Celsius <http://www.immunize.org/catg.d/p3039a.pdf>
Fahrenheit <http://www.immunize.org/catg.d/p3039.pdf>
- Vaccine storage signage. <http://www.immunize.org/catg.d/p2090.pdf>
<http://www.immunize.org/catg.d/p2091.pdf>
- Frequently reported errors in vaccine storage and handling with explanations regarding those errors. <http://www.immunize.org/catg.d/p3036.pdf>
- Pictures and tips for use when transporting vaccine or when short-term storage is needed. <http://www.eziz.org/assets/docs/IMM-983.pdf>
- A worksheet for use when a power failure or other event occurs that results in exposure of the vaccine to temperatures outside the expected range.
<http://www.immunize.org/catg.d/p3051.pdf>
- A final component of this section is a checklist that can be used in any setting to ensure appropriate vaccine handling and management. The checklist is a summary of information that can be used to monitor the effectiveness of the program as well as provide a basis for training of personnel responsible for the program.

More detailed information is available at the CDC website www.cdc.gov and in the *Pink Book*.



Vaccine Storage & Handling Guide



Protect your vaccine ~ Protect your patients
October, 2011



**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION**



General Information

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Selected Biologicals

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Haemophilus influenzae type b-Containing Vaccines

Hib: ActHIB, Hiberix, PedvaxHIB	15
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Information contained in this document is based on the recommendations of the Advisory Committee on Immunization Practices (ACIP) and the manufacturer's product information.

A combination vaccine is defined as a product containing components that can be divided equally into independently available routine vaccines. A dash (-) between vaccine products indicates that products are supplied in their final form by the manufacturer and do not require mixing or reconstitution by the user. A slash (/) indicates that the products must be mixed or reconstituted by the user.

Vaccine Storage and Handling Best Practices

Vaccines must be stored properly from the time they are manufactured until they are administered. Immunization providers are responsible for proper storage and handling from the time vaccine arrives at the facility until the vaccine is given. Below is an outline of vaccine storage and handling best practices. CDC's Storage and Handling Toolkit contains detailed information on vaccine management. Immunization providers and staff are strongly encouraged to review the Storage and Handling Toolkit annually. Educate all staff, including temporary staff, as part of new staff orientation. In addition, Vaccines for Children (VFC) providers should follow VFC policy and work with their immunization program.

- **Vaccine Management** includes, but is not limited to, these three components.
 1. The **equipment** used for vaccine storage and temperature monitoring is **reliable and appropriate**.
 2. **Staff is knowledgeable** regarding proper vaccine storage and handling. At least 2 staff members should be responsible for vaccine management.
 3. Written storage and handling plans are updated at least annually for:
 - **routine storage and handling** of vaccines; and
 - **emergency vaccine retrieval and storage**.

Routine Vaccine Storage and Handling Plan should include the following four elements.

1. **Ordering and Accepting Vaccine Deliveries**
 - Store vaccines at the recommended temperatures IMMEDIATELY upon arrival.
 - Store refrigerated vaccines between 35°F and 46°F (2°C and 8°C).
 - Store frozen vaccines between -58°F and +5°F (-50°C and -15°C).
 - Ensure vaccines are delivered when the facility is open. Vaccine shipments should be delivered when staff is available to unpack and store the vaccine properly. Inform manufacturer/distributor when vaccine shipments can be delivered. VFC providers should also notify the immunization program. Consider holidays, vacations, changes in hours of operation, and staff schedules when ordering vaccines.
 - Educate all facility staff about vaccine storage. Vaccine shipments are often accepted by nonmedical staff. They should be aware that vaccine needs to be stored according to the manufacturer's guidelines immediately upon delivery.

- Order vaccines to maintain an adequate amount to meet the needs of the facility's patients. The amount of vaccine needed can vary throughout the year. Anticipate peak periods such as back-to-school appointments or influenza season and order accordingly.
- Order the vaccines and presentations that are appropriate for the ages and types of patients the facility serves. Influenza vaccine, for example, is available from many manufacturers with differing indications.
- Maintain a vaccine inventory log including:
 1. vaccine name and number of doses received;
 2. date vaccine received;
 3. condition of vaccine on arrival;
 4. vaccine manufacturer and lot number; and
 5. vaccine expiration date.

2. Storing and Handling Vaccines

- Store vaccines in refrigerator and freezer units which can maintain the appropriate temperature range and are large enough to maintain the year's largest inventory without crowding. Stand alone units are preferred but household combination units with separate exterior doors and thermostats can be used. Dormitory-style refrigerators should not be used. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door with an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.
- Store vaccine in storage units designated specifically for biologics. If biologic specimens must be stored in the same unit, these should be stored on a lower shelf to prevent contamination. Food and drinks should never be stored in the same unit with vaccines.
- Keep a calibrated thermometer with a Certificate of Traceability and Calibration* in the refrigerator and freezer. These thermometers should be recalibrated as recommended by the manufacturer.
- Post "Do Not Unplug" signs next electrical outlets and "Do Not Stop Power" signs near circuit breakers to maintain a consistent power source.
- Read and document refrigerator and freezer temperatures at least twice each workday- in the morning and before the end of the workday. Keep temperature logs for at least 3 years.

*Certificate of Traceability and Calibration thermometer with calibration measurements traceable to a testing laboratory accredited by the International organization of Standardization, to the standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency

- Store vaccine according to the manufacturer's instructions. Aim to maintain storage unit temperatures within the middle of the acceptable temperature range. This allows for the small temperature fluctuations that can occur in refrigerators and freezers without exposing vaccines to unacceptable temperatures.
- Ensure good air circulation around the vaccine in the storage unit. Proper air circulation is essential to maintaining the correct storage temperatures. Bins, baskets, or some other type of uncovered containers with slotted sides or openings should be used to store the vaccines. There should be space between the containers to promote air flow.
- Store vaccines on the shelves away from the walls, and vents in the part of the unit best able to maintain the required temperature. Vaccines should never be stored in the door of the freezer or refrigerator. The temperature here is not stable.
- Place frozen packs in the door of the freezer and water bottles in the door of the refrigerator to help the storage unit maintain a constant temperature. Frozen packs or water bottle should be placed securely so they do not dislodge and prevent the door from closing. In addition, caution must be taken to avoid weighing down the door so much that the seal is compromised when the door is closed.
- Store unopened and opened vaccines in their original box with the lid in place until administration. Several vaccines must be protected from light. This practice also helps to ensure different vaccines are not stored together in the same bins or containers which can lead to vaccine administration errors. And in the event of a power failure, studies have shown storing vaccines in the box helps to maintain the vaccine at the appropriate temperature.
- Prepare vaccines at the time the vaccine is administered. This includes reconstituting or "mixing" vaccine, if indicated. Use only the diluent supplied by the vaccine manufacturer. Store diluent according to the manufacturer's instructions.

3. Managing Inventory

- Rotate stock so vaccine and diluent with the shortest expiration date is used first. Place vaccine with the longest expiration date behind the vaccine that will expire the soonest. Remove expired vaccine and diluent from usable stock.
- Keep vaccine stock well organized. VFC providers should separate and identify VFC and other vaccines purchased with public funds within the storage unit. In addition, clearly label the space where the vaccine is placed to help staff choose the appropriate vaccine.

- Inspect the storage unit daily. A physical inspection helps to ensure vaccines and thermometers are placed appropriately within the unit. During a busy work day, vaccines and thermometers can be easily moved or displaced to an area inappropriate for vaccine storage.
 - Dispose of all vaccine materials using medical waste disposal procedures. Contact the immunization program for details and state specific guidance.
4. **Managing Potentially Compromised Vaccines**
- Identify and isolate all potentially compromised vaccines and diluents. Label these “DO NOT USE”. Store separately from uncompromised vaccines and diluents in the recommended temperature range. A clearly labeled paper bag can be used for this purpose. Do not automatically discard the vaccine or diluent.
 - Contact vaccine manufacturers and/or state immunization program for appropriate actions that should be followed for all potentially compromised vaccines and diluents.
 - Educate staff administering vaccines on correct handling and preparation procedures to decrease the likelihood of vaccine or diluent inadvertently being compromised. For example, each vaccine should be prepared just prior to administration.

Emergency Vaccine Retrieval and Storage Plan should include the following components.

1. Designate an alternate site where vaccines and diluents can be safely stored. Considerations when choosing a site include types of storage unit(s) available, temperature monitoring capabilities, and back-up generator. Potential back-up locations include local hospitals, another provider’s facility, retail or clinic pharmacies, long-term care facilities, or the Red Cross. Identify procedures that allow 24-hour access to alternate facilities.
2. Obtain and store an adequate number/amount of appropriate packing containers and materials (e.g., frozen and refrigerated gel packs, bubble wrap) in the facility that will be needed to pack vaccines for safe transport. Acceptable packing containers are described in the *Storage and Handling Toolkit*. Consider the year’s largest inventory when stocking supplies. Store these supplies with a copy of the emergency vaccine retrieval and storage plan. Communicate to staff where everything is kept.
3. Include written directions for packing vaccines and diluents for transport. A calibrated thermometer should be placed in each packing container near the vaccine or refrigerated diluent.

4. Develop a plan in which vaccine coordinators will be notified of power outages at the facility. Include instructions for gaining 24-hour access to where the vaccines are stored.
5. Incorporate written procedures for managing potentially compromised vaccines.
6. Include contact information for vaccine manufacturers and/or the immunization program.

For more detailed information on proper vaccine storage and handling please refer to CDC's *Vaccine Storage and Handling Toolkit*.

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Diphtheria Toxoid-, Tetanus Toxoid- and acellular Pertussis-Containing Vaccines

DTaP: DAPTACEL, Infanrix, Tripedia

DTaP-HepB-IPV: Pediarix

DTaP-IPV: KINRIX

DTaP-IPV/Hib: Pentacel

Condition upon Arrival

Diphtheria toxoid-, tetanus toxoid- and acellular pertussis-containing vaccines (DTaP, DTaP-HepB-IPV, DTaP-IPV, DTaP-IPV/Hib) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **DTaP-IPV/Hib (Pentacel) has 2 components.** The lyophilized Hib vaccine (ActHIB) and DTaP-IPV diluent vials should arrive packaged together in the same shipping container.

Storage Requirements

Refrigerate vaccine and diluent, if applicable, immediately upon arrival. Do not freeze or expose to freezing temperatures.

- **DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX): Refrigerate between 35°F* and 46°F (2°C and 8°C).**

- **DTaP-IPV/Hib (Pentacel): Refrigerate the lyophilized Hib vaccine (ActHIB) and the vaccine diluent (DTaP-IPV) together between 35°F* and 46°F (2°C and 8°C). Do not store them separately.**

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX), DTaP-IPV/Hib (Pentacel) vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX):** Just before use, shake vial or manufacturer-filled syringe well. After shaking, the vaccine should be a cloudy, white colored liquid. Do not use vaccine if it cannot be resuspended with thorough agitation.
- **DTaP-IPV/Hib (Pentacel):** This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute DTaP-IPV/Hib (Pentacel) prior to administering it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout "Vaccines with Diluents: How to Use Them".
 1. Just before use, shake the vial of DTaP/IPV diluent.
 2. Withdraw the entire contents of the diluent vial (blue capped vial) and inject it into the vial containing the lyophilized vaccine component (green capped vial).
 3. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.

4. The reconstituted vaccine is a cloudy, uniform, white to off-white (yellow tinged) liquid.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

DTaP-IPV/Hib (Pentacel): All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Administer immediately. Unused, reconstituted DTaP-IPV/Hib may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 30 minutes. Do not freeze or expose reconstituted vaccine to freezing temperatures. Agitate stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted DTaP-IPV/Hib (Pentacel) vaccine if it is not used within 30 minutes.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Diphtheria toxoid-, tetanus toxoid- and acellular pertussis-containing vaccines are easily confused increasing the risk for error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

Haemophilus influenzae type b-Containing Vaccines

Hib: ActHIB, Hiberix, PedvaxHIB

Hib-HepB: Comvax

Note: Information pertaining to DTaP/IPV-Hib (Pentacel) can be found on page 11

Condition upon Arrival

Haemophilus influenzae type b-containing vaccines (Hib, Hib-HepB) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacture and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **ActHIB and Hiberix vaccines each have 2 components.** The lyophilized Hib vaccine and diluent vials should arrive packaged together in the same shipping container.

Storage Requirements

Store the vaccine and diluent, if applicable, according to the manufacturer’s guidelines immediately upon arrival. Do not freeze or expose to freezing temperatures.

- **PedvaxHIB and Comvax vaccines: Refrigerate vaccine between 35°F* and 46°F (2°C and 8°C).**

- **ActHIB vaccine: Refrigerate lyophilized vaccine and diluent between 35°F and 46°F (2°C and 8°C).** Do not store them separately.
- **Hiberix vaccine:** If space allows, store the lyophilized vaccine and diluent together in the refrigerator.
Vaccine: Refrigerate the lyophilized vaccine between 35°F* and 46°F (2°C and 8°C). Protect vaccine from light at all times by storing in the original box.
Diluent: Store in the refrigerator between 35°F* and 46°F (2°C and 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C).

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at end of this document for information on vaccine administration.

- **PedvaxHIB and Comvax vaccines:** Just before use, shake the vial. The vaccine should be a slightly opaque, white liquid. Do not use vaccine if it cannot be resuspended with thorough agitation.
- **ActHIB and Hiberix vaccines:** These vaccines must be reconstituted before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute these vaccines. ActHIB and Hiberix diluents are not the same and they are NOT interchangeable. ActHIB is reconstituted with 0.4% sodium chloride diluent. Hiberix is reconstituted with 0.9% sodium chloride diluent. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for examples of labels and the educational handout "Vaccines with Diluents: How to Use Them".
 1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized Hib vaccine.

2. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. The reconstituted vaccine should be a clear and colorless liquid.

Beyond Use Date*: Shelf Life after Opening

PedvaxHIB and Comvax vaccines: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

ActHIB and Hiberix vaccines: All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Administer immediately. Unused, reconstituted ActHIB or Hiberix may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 24 hours. Do not freeze or expose reconstituted vaccines to freezing temperatures. Protect reconstituted Hiberix from light. Agitate stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted ActHIB or Hiberix vaccine if it is not used within 24 hours.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. For example, single antigen and combination vaccines. Vaccine products and presentations often have different approved indications (e.g., ages). Storing multiple products and presentations can be confusing to staff and increases the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

Hepatitis-Containing Vaccines

HepA: Havrix, VAQTA

HepB: Engerix-B, Recombivax HB

HepA-HepB: Twinrix

Note: Information pertaining to DTaP-IPV-HepB (Pediarix) can be found on page 11
Information pertaining to Hib-HepB (Comvax) can be found on page 15

Condition upon Arrival

Hepatitis-containing vaccines (HepA, HepB, HepA-HepB) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended with thorough agitation. After shaking, the vaccine should be white, slightly cloudy in color. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, single antigen HepA and HepB vaccines have different formulations based on age. Storing multiple products and presentations can be confusing to staff and increases the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

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Human Papillomavirus Vaccines

HPV2: Cervarix

HPV4: Gardasil

Condition upon Arrival

Human papillomavirus vaccine (HPV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

- **HPV4 (Gardasil):** Protect vaccine from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. After shaking, HPV vaccine is a white, cloudy liquid. Through agitation immediately before administration is needed to maintain suspension. Do not use vaccine if it cannot be resuspended with thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **HPV2 (Cervarix):** May separate to a fine, white deposit on the bottom of the vial with a clear, colorless liquid above during storage. This does not indicate deterioration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.

4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. There are two HPV products available from different manufacturers with different indications. HPV4 can be administered to males and females. HPV2 is approved for use in females only. Consider indications and the facility's patient population when ordering HPV vaccine.

Vaccines that sound alike are often confused. For example, HPV, HepB and Hib vaccines are often confused, increasing the risk for an error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Label the space where HPV is stored with name, gender and age indications to help decrease the likelihood of a vaccine administration error. Refer to the Resources section at the end of this document for examples of labels.

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Influenza Vaccines

LAIV: [FluMist](#)

Condition upon Arrival

Live, attenuated influenza vaccine (LAIV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

Shelf Life

Influenza vaccine is formulated for use during the current influenza season. Check expiration date on the nasal sprayer. Do not use after the expiration date shown on the label.

Preparation

This vaccine should not be combined or mixed with any other vaccines. Each nasal sprayer contains a single dose of LAIV. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Sprayer: The nasal sprayer should be removed from the refrigerator at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Often providers have different influenza presentations in the same storage unit. Influenza products and presentations have different approved indications (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

Influenza Vaccines

TIV: Afluria, Fluarix, FluLaval, Fluvirin, Fluzone, Fluzone High-Dose, Fluzone Intradermal

Condition upon Arrival

Trivalent influenza vaccine (TIV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

- **Afluria, Fluarix, FluLaval, and Fluvirin:** Protect vaccine from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Influenza vaccine is formulated for use during the current influenza season. Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Shake multidose vials each time before withdrawing a dose. Do not use vaccine if it cannot be resuspended with thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed or needle attached) at the time the vaccine is administered.

Intradermal Microinjection Syringe: Manufacturer-filled microinjection syringe should be activated (i.e., needle cap removed) at the time the vaccine is administered.

Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single age-appropriate dose of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

- **Once entered, a multidose vial of Afluria or FluLaval should be discarded after 28 days.**

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Vaccines, including TIV, should be drawn from the vial into the syringe at the time of administration. CDC strongly discourages providers from prefilling syringes in advance. If more than one dose of vaccine must be predrawn, only draw up a few syringes (no more than 10 doses or the contents of one multidose vial).

Provider prefilled syringes should be administered by the person who filled them. Any syringes prefilled by the provider must be stored within the recommended temperature range and used or discarded by the end of the workday.

CDC recommends manufacturer-filled syringes for large immunization events, such as community influenza vaccination clinics. Once a manufacturer-filled syringe is activated (e.g., syringe cap removed or needle attached) it must be stored within the recommended temperature range and used or discarded by the end of the workday.

Often providers have different TIV presentations in the same storage unit. Influenza products and presentations have different approved indications (e.g., ages, route). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, dosage and route of administration can help prevent vaccine administration errors. Refer to the Resources section of this document for examples of labels.

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Measles-, Mumps- and Rubella-Containing Vaccine

MMR: M-M-RII

Note: Information pertaining to MMRV (ProQuad) can be found on page 69

Condition upon Arrival

Measles, Mumps, Rubella vaccine (MMR) has 2 components: lyophilized vaccine and diluent. Both components should arrive together in the same shipping container. The vaccine and diluent should be in separate compartments. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the recommended storage between -58°F and +46°F (-50°C and +8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Store lyophilized vaccine and diluent according to the manufacturer’s guidelines immediately upon arrival.

Lyophilized vaccine: Store MMR lyophilized vaccine in the refrigerator or freezer between -58°F and +46°F (-50° and +8°C). Protect vaccine from light at all times by storing in the original box.

Diluent: Store diluent in the refrigerator between 35°F* and 46°F (2°C and 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C). Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use after the expiration date shown on the label.

Preparation

MMR is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout “Vaccines with Diluents: How to Use Them”. This vaccine should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
2. Shake the vial now containing the lyophilized vaccine and diluent to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. The reconstituted vaccine should be a yellow, clear liquid. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used.

Beyond Use Date*: Shelf Life after Opening

All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted MMR may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 8 hours. Do not freeze or expose reconstituted vaccine to freezing temperatures. Protect reconstituted vaccine from light at all times. Agitate stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted MMR vaccine if it is not used within 8 hours.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between -58°F and +46°F (-50°C and +8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

MMR vaccine can be stored in the refrigerator or freezer. Consider storing MMR in the freezer between -58°F and +5°F (-50°C and -15°C).

- Storing MMR in the freezer can free up storage space in the refrigerator. More vaccines must be stored in the refrigerator than in the freezer. Storing MMR in the freezer increases the space available for vaccines that should be stored in the refrigerator.
- In addition, storing MMR in the freezer can decrease confusion when stocking both MMR and MMRV (ProQuad). MMRV must be stored in the freezer. MMRV has been inadvertently moved to the refrigerator storage because staff confused it with MMR. Storing MMR and MMRV in the freezer decreases the likelihood of this happening.

MMR may be stored and/or transported in an insulated container between 35°F and 46°F (2°C and 8°C). Place a calibrated thermometer in the container with the vaccine. Monitor and record the temperature. **Use of dry ice is not recommended**, even for temporary storage. Dry ice may subject MMR vaccine to temperatures colder than -58°F (-50°C).

Providers can have different products or presentations containing the same vaccine in the storage unit, for example, MMR and MMRV (ProQuad) vaccines. Vaccine

products and presentations often have different approved indications and uses (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

Meningococcal Vaccines

MCV4: *Menactra*, *Menveo*

Condition upon Arrival

Meningococcal conjugate vaccine (MCV4) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from other uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **Menveo has 2 components.** The lyophilized Men A vaccine and the diluent (Men C, Y, W-135) vials should arrive packaged together in the same shipping container.

Storage Requirements

Refrigerate vaccine and diluent, if applicable, immediately upon arrival. Do not freeze or expose to freezing temperatures.

- **Menactra: Refrigerate between 35°F and 46°F (2°C and 8°C).**
- **Menveo: Refrigerate the lyophilized Men A vaccine and vaccine diluent (Men C, Y, W-135) together between 35°F* and 46°F (2°C and 8°C).** Do not store them separately. Protect Menveo from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **Menactra:** This vaccine is a clear to slightly cloudy liquid.
- **Menveo:** This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout “Vaccines with Diluents: How to Use Them”.
 1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
 2. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation
 3. The reconstituted vaccine should be a clear, colorless liquid.

Beyond Use Date*: Shelf Life after Opening

Menactra: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Menveo: All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted Menveo may be stored at or below 77°F (25°C) for up to 8 hours. Do not freeze or expose reconstituted vaccine to freezing temperatures. Protect from light. Agitate any stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted Menveo vaccine if it is not used within 8 hours.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, meningococcal vaccines (MCV4 and MPSV4) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, and/or route of administration can help prevent vaccine administration errors. Refer to the Resources sections at the end of this document for examples of labels.

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Meningococcal Vaccines

MPSV4: Menomune

Condition upon Arrival

Meningococcal polysaccharide vaccine (MPSV4) has 2 components: lyophilized vaccine and diluent. MPSV4 should arrive packed in an insulated container. Both components should arrive packaged together in the same shipping container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine and diluent in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from other uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate the lyophilized vaccine and diluent immediately upon arrival. **Store the lyophilized vaccine and diluent between 35°F and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

MPSV4 is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute

it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout “Vaccines with Diluents: How to Use Them”. This vaccine should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
2. Swirl the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. The reconstituted vaccine should be a clear, colorless liquid. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted MPSV4 vaccine may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 30 minutes. Agitate any stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted MPSV4 vaccine if it is not used within 30 minutes.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

Multidose Vials: Shake well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).**

- **Once entered, the multidose vial of MPSV4 should be discarded after 35 days.**

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages, route). For example, meningococcal vaccines (MCV4 and MPSV4) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Pneumococcal Vaccines

PCV13: Prevnar 13

PPSV23: Pneumovax 23

Condition upon Arrival

Pneumococcal vaccines (PCV13, PPSV23) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **PCV13:** During storage, the aluminum phosphate particles may settle, and this can result in a clear liquid solution above the aluminum phosphate particles. Just before use, shake **VIGOROUSLY**. After shaking, PCV13 is a white liquid. Do not use the vaccine if it cannot be resuspended with thorough agitation.
- **PPSV23:** Just before use, shake vial well. After shaking, PPSV23 should be a clear, colorless liquid. Do not use the vaccine if it cannot be resuspended with thorough agitation.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time of administration.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

PPSV23 Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, pneumococcal vaccines (PCV13 and PPSV23) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section of this document for examples of labels.

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Poliovirus-Containing Vaccine

IPV: IPOL

Note: Information pertaining to DTaP-IPV (KINRIX) can be found on page 11

Information pertaining to DTaP-IPV/HepB (Pediatrix) can be found on page 11

Information pertaining to DTaP-IPV-Hib (Pentacel) can be found on page 11

Condition upon Arrival

Inactivated polio vaccine (IPV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. This vaccine should not be

combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed or needle attached) at the time the vaccine is administered.

Multidose Vials: Withdraw a single dose (0.5 mL) of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date (time) the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. For example, single antigen and combination vaccines. Vaccine

products and presentations often have different approved indications and uses (e.g. ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Rotavirus Vaccines

RV1: ROTARIX

RV5: RotaTeq

Condition upon Arrival

Rotavirus vaccines (RV1, RV5) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

- **RV1 (ROTARIX) has 2 components.** The lyophilized vaccine and diluent should arrive packaged together in the same shipping container.

Storage Requirements

Store the vaccine and diluent, if applicable, according to the manufacturer’s guidelines immediately upon arrival. Do not freeze or expose to freezing temperatures. Protect vaccine from light at all times by storing in the original box.

- **RV1 (ROTARIX): Refrigerate lyophilized vaccine between 35°F and 46°F (2°C and 8°C). Store diluent separately at room temperature between 68°F and 77° F (20°C and 25°C).**
- **RV5 (RotaTeq): Refrigerate between 35°F* and 46°F (2°C and 8°C).**

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of vaccine AND diluent. Do not use vaccine or diluent, if applicable, after the expiration date shown on the label.

Preparation

RV1 and RV5 should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **RV1 (ROTARIX):** This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Reconstituted vaccine is a cloudy, white liquid. Refer to the Resources section at the end of this document for an educational handout “Vaccines with Diluents: How to Use Them”.
- **RV5 (RotaTeq):** This vaccine is supplied in a single dose squeezable plastic, latex-free dosing tube with a twist off cap. The dosing tube is contained in a pouch

Beyond Use Date*: Shelf Life after Opening

RV1 (ROTARIX): After reconstitution, **administer immediately.** Store unused, reconstituted RV1 in the oral applicator between 35°F and 46°F (2°C and 8°C) or at room temperature up to 77°F (25°C) for up to 24 hours. Agitate any stored, reconstituted vaccine prior to administration. Do not freeze reconstituted vaccine.

- **Do not administer reconstituted RV1 vaccine if it is not used within 24 hours.** Follow the immunization program guidance before discarding VFC or other publicly purchased vaccines. Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

RV5 (RotaTeq): This vaccine should be removed from the refrigerator and the screw cap removed at the time the vaccine is administered. Once the screw cap has been removed, the dosing tube should not be returned to the refrigerator. **Administer immediately.**

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers may have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

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Tetanus Toxoid Vaccine

TT: Tetanus Toxoid

Condition upon Arrival

Tetanus toxoid vaccine (TT) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container or vial. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial well. Do not use vaccine if it cannot be resuspended with thorough agitation. This vaccine should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) of vaccine into a sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

TT vaccine should only be used for tetanus immunization if the person has a severe, life-threatening allergy to the diphtheria component in other tetanus-containing vaccines. For persons 11 years of age and older who need a tetanus toxoid-containing vaccine, the Advisory Committee on Immunization Practices recommends the following:

- Tdap vaccine, if available, is preferred to TT or Td for those not previously vaccinated with Tdap.

- Td vaccine, if available, is preferred to TT for those previously vaccinated with Tdap.
- Tdap or Td vaccines, if neither available, TT should be administered.

Tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Tetanus Toxoid- and diphtheria toxoid-Containing Vaccines

Td: DECAVAC

DT: Diphtheria and Tetanus Toxoid

Condition upon Arrival

Tetanus toxoid- and diphtheria toxoid-containing vaccines (Td; DT) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or

manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended after thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- After shaking, Td vaccine is a cloudy, whitish-gray colored liquid.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Diphtheria toxoid- and tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines

in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

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Tetanus Toxoid-, diphtheria toxoid-, and acellular pertussis- Containing Vaccines

Tdap: [Adacel](#), [Boostrix](#)

Condition upon Arrival

Tetanus toxoid-, diphtheria toxoid- and acellular pertussis-containing vaccine (Tdap) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer’s guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended after thorough agitation. After shaking, Tdap should be a cloudy, white colored liquid. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Diphtheria toxoid- and tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

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Varicella-Containing Vaccines

VAR: Varivax (chickenpox)

ZOS: Zostavax (herpes zoster/shingles)

MMRV: ProQuad

Condition upon Arrival

Varicella-containing vaccines (VAR, MMRV and ZOS) have 2 components: lyophilized vaccine and diluent. Both components should arrive together in the same shipping container. The vaccine and diluent should be in separate compartments. Examine the shipping container and contents for damage during transport. If the interval between shipment from the manufacturer and arrival of the vaccine at the facility has been more than 3 days or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

1. Immediately place the vaccine in the freezer between -58°F and +5°F (-50°C and -15°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the manufacturer and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Store the lyophilized vaccine and diluent according to the manufacturer’s guidelines immediately upon arrival. Do not store lyophilized vaccine and diluent together.

Lyophilized vaccine: Store lyophilized vaccine in the freezer between -58°F and +5°F (-50°C and -15°C). Protect vaccine from light at all times by storing in the original box. Vaccine should only be stored in freezers or refrigerator/freezer units with separate compartments and exterior doors.

Diluent: Store separately from lyophilized vaccine in the refrigerator between 35°F* and 46°F (2°C to 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C). Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use after the expiration date shown on the labels.

Preparation

These vaccines must be reconstituted before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for examples of labels and the educational handout "Vaccines with Diluents: How to Use Them". These vaccines should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

1. Just before use, withdraw the entire contents of the diluent vial and inject it slowly into the vial containing the lyophilized vaccine vial.
2. Gently shake or agitate the vial now containing the lyophilized vaccine and diluent to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
3. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Reconstituted vaccine should have the following appearance:
 - VAR: Clear, colorless to pale yellow liquid.
 - ZOS: Semi-hazy to translucent, off white to pale, yellow liquid.
 - MMRV: Pale yellow to light pink, clear liquid.

Beyond Use Date*: Shelf Life after Opening

All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted varicella and MMRV vaccines may be stored at room temperature between 68°F and 77°F (20°C and 25°C) for up to 30 minutes. Protect from light. Do

not freeze or exposed reconstituted vaccine to freezing temperatures. Agitate any stored, reconstituted vaccine prior to administration.

- **Do not administer reconstituted varicella-containing vaccine (VAR, ZOS, MMRV) if it is not used within 30 minutes.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Varicella-containing vaccines exposed to temperatures outside the recommended range **require immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

1. Vaccine exposed to temperature above +5°F should be stored in the refrigerator between 35°F and 46°F (2°C and 8°C).
Vaccine exposed to temperatures below -58°F should be stored in a freezer between -58°F and +5°F (-50°C and -15°C).
2. Mark vaccine “Do Not Use” and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
3. Follow your immunization program policy and contact the manufacturer and/or the immunization program for further guidance.
4. Do not discard vaccine unless directed to by the immunization program and/or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

In order to maintain temperatures between -58°F and +5°F (-50°C and -15°C), it will be necessary in most combination refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperature will be necessary to avoid freezing vaccines stored in the refrigerator.

“Dormitory-style” refrigerator/freezer is not appropriate for the storage of varicella-containing vaccines. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

CDC and the vaccine manufacturer do not recommend transporting varicella-containing vaccines. If varicella-containing vaccines must be transported, CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some places. According to the manufacturer’s product information varicella-containing vaccines may be stored between 35°F and 46°F (2°C and 8°C) for up to 72 continuous hours prior to reconstitution. If varicella-containing vaccines must be transported between 35°F and 46°F (2°C and 8°C) complete the following actions:

1. Place a calibrated thermometer in the container as close as possible to the vaccine.
2. Record:
 - a. the time refrigerator storage began
 - b. the time refrigerator storage ended
 - c. storage temperature during transport
3. **Contact the manufacturer (1-800-9-VARIVAX) immediately upon arrival at the alternate storage facility for further guidance.**
4. **Do not discard vaccine without contacting the manufacturer and/or the immunization program for guidance.**

Use of dry ice is not recommended, even for temporary storage. Dry ice may subject varicella-containing vaccine to temperatures colder than -58°F (-50°C).

Providers can have different products or presentations containing the varicella-containing vaccines in the storage unit. For example, single antigen and combination vaccines. Vaccine products and presentations often have different approved indications and uses (e.g., ages, route). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors.

CDC Resources

Advisory Committee on Immunization Practices U.S. VACCINE ABBREVIATIONS

<http://www.cdc.gov/vaccines/recs/acip/downloads/vac-abbrev.pdf>

Epidemiology and Prevention of Vaccine-Preventable Diseases 12th Edition Storage and Handling Chapter 5

<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-storage.pdf>

Storage and Handling Resources Appendix C

<http://www.cdc.gov/vaccines/pubs/pinkbook/pink-appendx.htm#appc>

Vaccine Administration Appendix D

<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-d.pdf>

Epidemiology and Prevention of Vaccine-Preventable Disease Course Session 2 includes vaccine storage and handling information

<http://www.cdc.gov/vaccines/ed/epivac/default.htm>

General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)

<http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf>

Storage and Handling web page

<http://www.cdc.gov/vaccines/recs/storage/default.htm>

Storage and Handling ToolKit

<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>

Vaccine Label Examples

<http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf>

Vaccine Administration web page

<http://www.cdc.gov/vaccines/recs/vac-admin/default.htm>

Other Resources

Alliance for Immunization in Michigan (AIM) Provider ToolKit

www.aimtoolkit.org

Storage and Handling Materials

<http://www.aimtoolkit.org/vaccine.php>

Vaccine Administration Materials

Children

<http://www.aimtoolkit.org/children.php>

Adolescents

<http://www.aimtoolkit.org/adolescents.php>

Adults

<http://www.aimtoolkit.org/adults.php>

EZIZ- California Vaccines for Children (VFC) Program

www.eziz.org

Storage and Handling Educational Video

<http://eziz.org/eziz-training/>

Storage and Handling Job Aides

http://eziz.org/resources/materials_storageandhand.html

Vaccine Administration Educational Video

<http://eziz.org/eziz-training/>

Vaccine Administration Job Aides

<http://eziz.org/resources/vaccine-admin-job-aids/>

Immunization Action Coalition (IAC)

www.immunize.org

Handling and Storage Resources

<http://www.immunize.org/handouts/vaccine-storage-handling.asp>

Handling and Storage FAQ's

http://www.immunize.org/askexperts/experts_general.asp

Checklist for Safe Vaccine Storage and Handling

<http://www.immunize.org/catg.d/p3035.pdf>

Don't be Guilty of These Errors in Vaccine Storage and Handling

<http://www.immunize.org/catg.d/p3036.pdf>

Emergency Response Worksheet

<http://www.immunize.org/catg.d/p3051.pdf>

Skills Checklist for Immunization

<http://www.immunize.org/catg.d/p7010.pdf>

Temperature Logs for Refrigerator and Freezer:

Celsius <http://www.immunize.org/catg.d/p3039a.pdf>

Fahrenheit <http://www.immunize.org/catg.d/p3039.pdf>

Vaccines with Diluents: How to Use Them

<http://www.immunize.org/catg.d/p3040.pdf>

Vaccine Handling Tips

<http://www.immunize.org/catg.d/p3048.pdf>

Vaccine Administration Resources

<http://www.immunize.org/clinic/administering-vaccines.asp>

Vaccine Administration FAQ's

http://www.immunize.org/askexperts/experts_general.asp#admin

Administering Vaccines: Dose, Route, Site, and Needle Size

<http://www.immunize.org/catg.d/p3085.pdf>

How to Administer IM and SC Injections

<http://www.immunize.org/catg.d/p2020.pdf>

Manufacturer's Product Information

<http://www.immunize.org/packageinserts/>

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage

http://www.nist.gov/customcf/get_pdf.cfm?pub_id=904574

State Immunization Program Information**State Immunization Program Websites**

<http://www.cdc.gov/vaccines/spec-grps/prog-mgrs/grantee-imz-websites.htm>

Manufacturer / Distributor Websites	Telephone Number/E-mail	Products
Centers for Disease Control and Prevention www.cdc.gov/ncidod/srp/drugs/drug-service.html http://www.cdc.gov/laboratory/drugservice/index.html	404-639-3670/ drugservice@cdc.gov	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline (GSK) http://www.gskvaccines.com/	866-475-8222	DTaP, DTaP-HepB-IPV, DTaP-IPV, HepA, HepB, HepA-HepB, HPV2, RV1, Tdap, TIV
Massachusetts Biological Labs http://www.umassmed.edu/massbiolabs/index.aspx	617-474-3000	IGIM, Td, TT
MedImmune http://www.medimmune.com/	877-633-4411 medinfo@medimmune.com	LAIV
Merck & Co., Inc https://www.merckvaccines.com/	800-637-2590	HepA, HepB, Hib, Hib- HepB, HPV4, MMR, MMRV, PPSV23, Td, TIV, VAR, ZOS
Biotest Pharmaceuticals http://www.biotestpharma.com/products/nabiHB.html	800 458-4244 ma@biotestpharma.com	HBIG
Novartis http://www.novartisvaccines.com/us/index.shtml	877 683-4732 Vaccineinfo.us@novartis.com	TIV
Pfizer/Wyeth http://pfizerpro.com/	800-438-1985	PCV13
Sanofi Pasteur https://www.vaccineshoppe.com/	800-822-2463	DT, DTaP, DTaP-IPV/ Hib, Hib, IPV, MCV4, MPSV4, Rabies, RIG, Td, Tdap, TIV, TT
Talecris Biotherapeutics http://www.talecris.com/talecris-biotherapeutics-us-home.htm	800-520-2807 talecris@medcomsol.com	HBIG, IGIM, RIG, TIG

Temperature Log for Refrigerator and Freezer — Fahrenheit

Month/Year: _____ Days 1–15

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an “X” in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month’s completed form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents an unacceptable

temperature range. Follow these steps:

1. **Store the vaccine** under proper conditions as quickly as possible.
2. **Temporarily mark exposed vaccine “do not use”** until you have verified whether or not the vaccine may be used.
3. **Call the immunization program** at your state or local health department and/or the vaccine manufacturer to determine whether the vaccine is still usable: (____) ____.
4. **Document the action taken** on the reverse side of this log.

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Room Temp.															
Exact Time															
°F Temp	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm
Too warm*	≥49°														
	48°														
	47°														
	46°														
	45°														
	44°														
	43°														
	42°														
	41°														
	40°														
	39°														
	38°														
	37°														
	36°														
	35°														
	34°														
	33°														
	≤32°														
Too cold*															
	≥8°														
	7°														
	6°														
	5°														
	4°														
	≤3°†														

*Some frozen vaccines must not be stored colder than -58°F. Check the Prescribing Information on the vaccine manufacturer’s website for specific storage temperature instructions.

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

www.immunize.org/catg.d/p3039f.pdf • Item #P3039F (8/11)

Vaccine Storage Troubleshooting Record

Use this page to record the details of the vaccine storage incident, including the date and time of the last known temperature within the appropriate vaccine storage range.

Date	Time	Storage Unit Temp	Room Temp	Incident	Action Taken	Results	Initials

Temperature Log for Refrigerator and Freezer — Fahrenheit

Month/Year: _____ Days 16–31

Completing this temperature log: Check the temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an “X” in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month’s completed form for 3 years, unless state or local jurisdictions require a longer time period.

If the recorded temperature is in the shaded zone: This represents an unacceptable

temperature range. Follow these steps:

1. **Store the vaccine** under proper conditions as quickly as possible.
2. **Temporarily mark exposed vaccine “do not use”** until you have verified whether or not the vaccine may be used.
3. **Call the immunization program** at your state or local health department and/or the vaccine manufacturer to determine whether the vaccine is still usable: (____) ____.
4. **Document the action taken** on the reverse side of this log.

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Room Temp.																
Exact Time																
°F Temp	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm	am pm
Too warm*	≥49°															
	48°															
	47°															
	46°															
	45°															
	44°															
	43°															
	42°															
	41°															
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	38°															
	37°															
	36°															
	35°															
	34°															
	33°															
	≤32°															
Too cold*																
	≥8°															
	7°															
	6°															
	5°															
	4°															
	≤3°†															

†Some frozen vaccines must not be stored colder than -58°F. Check the Prescribing Information on the vaccine manufacturer’s website for specific storage temperature instructions.

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Technical content reviewed by the Centers for Disease Control and Prevention, August 2011.

Vaccine Storage Troubleshooting Record

Use this page to record the details of the vaccine storage incident, including the date and time of the last known temperature within the appropriate vaccine storage range.

Date	Time	Storage Unit Temp	Room Temp	Incident	Action Taken	Results	Initials

WARNING!

Expensive Vaccine in Storage!

¡AVISO! Contiene vacunas caras

DO NOT STOP POWER TO CIRCUIT BREAKER # _____
NO DESCONECTE LA ELECTRICIDAD A EL CIRCUITO # _____

In event of electrical problem, immediately contact:
Si hay un problema con la electricidad, comuníquese inmediatamente con



Don't Be Guilty of These Errors in Vaccine Storage and Handling

The following are frequently reported errors in vaccine storage and handling. Some of these errors are much more serious than others, but none of them should occur. Be sure your clinic or practice is not making errors such as these.

Error #1: Designating only one person, rather than at least two, to be responsible for storage and handling of vaccines

Since vaccines are both expensive and fragile, everyone in the office should know the basics of vaccine handling, including what to do when a shipment arrives and what to do in the event of an equipment failure or power outage. It's very important to train at least one back-up person in all aspects of proper storage and handling of vaccines. The back-up and primary persons should be equally familiar with all aspects of vaccine storage and handling, including knowing how to handle vaccines when they arrive, how to properly record refrigerator and freezer temperatures, and should be prepared to lead the response to an equipment problem or power outage.

Error #2: Refrigerating vaccine in a manner that could jeopardize its quality

The temperature in the vegetable bins, on the floor, next to the walls, in the door, and near the cold air outlet from the freezer may differ significantly from the temperature in the body of the refrigerator: do not store your vaccines or place thermometers in these locations. Always store vaccines in their original packaging in the body of the refrigerator away from these locations, and place your thermometer with the vaccines. Place vaccine packages in such a way that air can circulate around the compartment. Never overpack a refrigerator compartment.

Error #3: Storing food and drinks in the vaccine refrigerator

Frequent opening of the refrigerator door to retrieve food items can adversely affect the internal temperature of the unit and damage vaccines.

Error #4: Inadvertently leaving the refrigerator or freezer door open or having inadequate seals

Remind staff to close the unit doors tightly each time they open them. Also, check the seals on the doors on a regular schedule, and if there is any indication the door seal may be cracked or not sealing properly, have it replaced. Replacing a seal is much less costly than replacing a box of pneumococcal conjugate or varicella vaccine.

Error #5: Storing vaccine in a dorm-style refrigerator

All vaccines should be stored in a refrigerator and/or freezer unit that is designed specifically for the storage of biologics or, alternatively, in a separate free-standing unit. A dorm-style combination refrigerator-freezer unit with just one exterior door has been shown to be unacceptable no matter where the vaccine was placed inside the unit. Small stand-alone refrigerator or freezer units are best for short-term storage needs.

Error #6: Recording temperatures only once per day

Temperatures fluctuate throughout the day. Temperatures in the refrigerator and freezer should be checked at the beginning and end of the day to determine if the unit is getting too cold or too warm. Ideally, you should have continuous thermometers that record temperatures all day and all night; those with alarms can alert you when temperatures go out of range. A less expensive alternative is to purchase maximum/minimum thermometers. Only thermometers with a Current Certificate of Traceability and Calibration* should be used for vaccine storage. It's also a good idea to record the room temperature on your temperature log in case there is a problem with the storage unit. This information may

be helpful to the vaccine manufacturer and/or state immunization program in determining whether your vaccine is still usable.

Error #7: Recording temperatures for only the refrigerator or freezer, rather than both

It is essential to monitor and record temperatures in all refrigerators and freezers used to store vaccine. At all times you should have calibrated thermometers in the refrigerators as well as the freezers. Assure that your storage temperature monitoring is accurate by purchasing thermometers that have a Certificate of Traceability and Calibration* and recalibrate them according to the manufacturer's instructions. Your state immunization program may be able to provide more information on calibrated thermometers.

Error #8: Documenting out-of-range temperatures on vaccine temperature logs but not taking action

Documenting temperatures is not enough. Acting on the information is essential! So, what should you do? Notify your supervisor whenever you have an out-of-range temperature. Sometimes the solution is as simple as shutting a door left ajar or re-checking a freezer temperature that is slightly elevated as it goes through a normal, brief defrost cycle. Check the condition of the unit for problems. Are the seals on the door tight? Is there excessive lint or dust on the coils? After you have made any adjustment, document the date, time, temperature, the nature of the problem, the action you took, and the results of your action. Recheck the temperature every two hours. Call maintenance or a repair person if the temperature is still out of range. If the solution is not quick and easy, you will need to safeguard your vaccines by moving them to another storage unit that is functioning at the proper temperature. Label the affected vaccines "Do not use" and contact your state immunization program or vaccine manufacturer to find out if the affected vaccine is still usable. Be sure to notify your state's VFC Program Coordinator if VFC vaccine was involved.

Error #9: Discarding temperature logs at the end of every month

It's important that you keep your temperature logs for at least three years. As your refrigerator or freezer ages, you can track recurring problems. If out-of-range temperatures have been documented, you can determine how long and how often this has been happening and take appropriate action. It's also a great way to demonstrate why you need a new refrigerator or freezer.

Error #10: Discarding multi-dose vials 30 days after they are opened

Don't discard your multi-dose vials of vaccines prematurely. Almost all multi-dose vaccine vials contain a preservative and can be used until the expiration date on the vial unless there is actual contamination or the vials are not stored under appropriate temperatures. However, you must discard multi-dose vials of reconstituted vaccine (e.g., meningococcal polysaccharide, yellow fever) if they are not used within a defined period after reconstitution. Refer to the vaccine package inserts for detailed information.

Error #11: Not having emergency plans for a power outage or natural disaster

Every clinic should have a written Emergency Response Plan that identifies a refrigerator and freezer in another location (ideally, a storage unit with a back-up generator) in which to store vaccine in the event of a power outage or natural disaster. Consider arranging in advance for a local hospital or similar facility to be your back-up location if you should need it. Be sure back-up location staff understand vaccine storage and will allow you to supervise placement and verify storage temperatures so vaccine is not damaged.

*A calibrated thermometer with a Certificate of Traceability and Calibration with calibration measurements traceable to a testing laboratory accredited by the International Organization of Standardization, to the Standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency.

Transporting Refrigerated Vaccine

Guidelines for vaccine transport and short-term storage

- The procedure below for packing vaccine will keep all vaccines (**except varicella vaccine**) within recommended temperatures for 12 hours during transport and/or storage at room temperatures (inside a car, building, etc.). It will also maintain recommended temperatures if the cooler is exposed to outside temperatures as low as -4°F for one of those 12 hours.
- If the vaccine will be stored in refrigerators after transport, be sure those refrigerators have maintained temperatures between 35°F and 46°F for at least 3 to 5 days.

Assemble packing supplies

1. **Cooler.** Use hard plastic Igloo-type coolers. Attach a “Vaccines: Do Not Freeze” label to the cooler.
2. **“Conditioned” cold packs.** Condition frozen gel packs by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and packs look like they’ve been “sweating.” Cold packs that are not conditioned can freeze vaccine. **Do not use dry ice.**
3. **Thermometer.** Prepare the thermometer by placing it in the refrigerator at least 2 hours before you pack the vaccine.
4. **Packing material.** Use two 2-inch layers of bubble wrap. Not using enough bubble wrap can cause the vaccine to freeze.



Pack vaccine

1. Cold packs

Spread conditioned cold packs to cover only half of the bottom of the cooler.



2. Bubble wrap

& Thermometer

Completely cover the cold packs with a 2-inch layer of bubble wrap. Then, place the thermometer/probe on top of the bubble wrap directly above a cold pack.



3. Vaccine

Stack layers of vaccine boxes on the bubble wrap. Do not let the boxes of vaccine touch the cold packs.



4. Bubble wrap

Completely cover the vaccine with another 2-inch layer of bubble wrap.



5. Cold packs

Spread “conditioned” cold packs to cover only half of the bubble wrap. Make sure that the cold packs do not touch the boxes of vaccine.



6. Form & display

Fill the cooler to the top with bubble wrap. Place the thermometer’s digital display and the *Return or Transfer of Vaccines Report* form on top. It’s ok if temperatures go above 46°F while packing.



As soon as you reach the destination site, check the vaccine temperature. If the vaccine is:

- Between 35°F and 46°F, put it in the refrigerator.
- Below 35°F or above 46°F, contact your VFC Rep or the VFC program immediately at 1-877-243-8832. For H1N1 vaccine, call 1-888-867-6319. Then label the vaccine “Do Not Use” and put it in the refrigerator.

Emergency Response Worksheet

What to do in case of a power failure or another event that results in vaccine storage outside of the recommended temperature range

Follow these procedures:

1. Close the door tightly and/or plug in the refrigerator/freezer.
2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not discard the affected vaccines. Mark the vaccines so that the potentially compromised vaccines can be easily identified.
3. Notify the local or state health department or call the manufacturer (see manufacturers' phone numbers below).
4. Record action taken.

Record this information*:

1. Temperature of refrigerator: current _____ max. _____ min. _____
2. Temperature of freezer: current _____ max. _____ min. _____
3. Air temperature of room where refrigerator is located: _____
4. Estimated amount of time the unit's temperature was outside normal range:
refrigerator _____ freezer _____
5. Vaccines in the refrigerator/freezer during the event (use the table below)

* Using a recording thermometer is the most effective method of tracking the refrigerator and freezer temperatures over time. Visually checking thermometers twice a day is an effective method to identify inconsistent or fluctuating temperatures in a refrigerator and freezer.

Vaccines Stored in Refrigerator

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Vaccines Stored in Freezer

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Other Conditions

1. Prior to this event, was the vaccine exposed to temperatures outside the recommended range? Y N
2. Were water bottles in the refrigerator and ice packs in the freezer at the time of this event? Y N
3. Other: _____

Manufacturers

Crucell Vaccines Inc.	(800) 533-5899
CSL Biotherapies, Inc.	(888) 435-8633
GlaxoSmithKline	(888) 825-5249
MedImmune, Inc.	(877) 633-4411
Merck & Co., Inc.	(800) 672-6372
Novartis Vaccines	(800) 244-7668
Pfizer Inc.	(800) 438-1985
sanofi pasteur	(800) 822-2463

Other Resources

Local health department phone number _____ State health department phone number _____

Adapted by the Immunization Action Coalition, courtesy of the Michigan Department of Community Health

Technical content reviewed by the Centers for Disease Control and Prevention, October 2010.

www.immunize.org/catg.d/p3051.pdf • Item #P3051 (10/10)

Checklist: Importance of Vaccine Administration, Storage & Handling

<http://www.cdc.gov/vaccines/recs/vac-admin/providers-role-vacc-admin-storage.htm#storage>

The United States currently has the safest, most effective vaccines in its history. Federal regulations require that vaccines undergo years of testing before they can be licensed. Once in use, vaccines are monitored continually for safety and efficacy. As an immunization provider, you also play a key role in helping to ensure the safety and efficacy of vaccines through proper 1) Vaccine storage and handling; 2) Vaccine administration; 3) Timing and spacing of vaccine doses; 4) Observation of precautions and contraindications; 5) Management of vaccine side effects; 6) Reporting of suspected side effects; and 7) Communication about vaccine benefits and risks.

Additional information that addresses standards for immunization practices for children and adolescents and adults can be found in the 2003 American Journal of Preventive Medicine article by Poland et al available at <http://download.journals.elsevierhealth.com/pdfs/journals/0749-3797/PIIS074937970300120X.pdf> that supports the need to ensure that healthcare professionals review and administer vaccines in accordance with patient (in this instance, the healthcare personnel) needs.

Vaccine Storage

To achieve the best possible results from vaccines, carefully follow the recommendations for storage, handling, and administration found in each vaccine's package insert. Here are other steps you can take to help monitor and ensure vaccine safety:

Quality Monitoring Element	Yes	No	NA	Followup and/or corrective action
Proper vaccine storage unit(s) are available in which to store vaccines				
A properly calibrated thermometer or temperature recording device is inside each storage compartment				
Cold chain procedures are in place to ensure that vaccine storage and handling guidelines are being followed				
Vaccines are inspected upon delivery and refrigerator and freezer temperatures are monitored to assure maintenance of the cold chain.				
Vaccine stock is rotated so the oldest vaccines are used first.				
If errors in vaccine storage and administration occur, there is evidence that corrective action is immediately taken to prevent them from happening again				

Vaccine Administration

To achieve the best possible results from vaccines, carefully follow the recommendations for storage, handling, and administration found in each vaccine's package insert. Here are other steps you can take to monitor and help ensure vaccine safety:

Quality Monitoring Element	Yes	No	NA	Followup and/or corrective action
Administration of vaccine is performed to ensure that it is never administered later than the expiration date				
If reconstituted, the vaccine is administered within the prescribed time period following that reconstitution				
Vaccines are drawn into syringes immediately prior to administration (unless pre-drawn in the pharmacy under USP 797 standard conditions)				
If vaccines are mixed in the same syringe, it has been specifically approved for such mixing by the Food and Drug Administration (FDA)				
The vaccine and administration information, including lot numbers and injection sites, are noted in the employee's health record				
If errors in vaccine administration occur, appropriate notification is immediately performed to ensure patient safety				

Timing and Spacing

The timing and spacing of vaccine doses are two of the most important issues in the appropriate use of vaccines. To ensure optimal results from each immunization, follow the currently recommended immunization schedules. Use the following checklist to help monitor and ensure vaccine timing and spacing:

Quality Monitoring Element	Yes	No	NA	Followup and/or corrective action
All needed vaccines are administered as recommended, even if it means giving multiple doses at the same time				
Use of combination vaccines have been considered to minimize missed doses or timing errors (e.g., MMR, MMRV)				
Administration records are maintained in a manner that provides all necessary information (e.g., dates of administration) and are organized in a way that promotes				

adherence with followup dosing and scheduling				
An electronic process is utilized to maintain vaccine information and calculate next dose due dates				

Observe Valid Contraindications and Precautions

Contraindications and precautions to vaccination indicate when vaccines should not be given. A contraindication is a condition in a patient that increases the chance of a serious, adverse reaction. In general, a vaccine should not be administered when a contraindication is present. A precaution is a condition in a patient that may increase the chance of a serious side effect or render a vaccine less effective. Normally, vaccination is deferred when a precaution is present. However, situations may arise when the benefits of vaccination outweigh the risk of a side effect, and the provider may decide to vaccinate the patient. Most precautions and some contraindications are temporary and the vaccine may be given at a later time.

Quality Monitoring Element	Yes	No	NA	Followup and/or corrective action
Every healthcare worker patient is screened for contraindications and precautions before being given a vaccine dose				
Documentation of the discussion regarding the contraindication/precaution is maintained				

Many conditions are often inappropriately regarded as contraindications to vaccination. In most cases, the following are not contraindications:

- Mild acute illness (e.g., diarrhea and minor upper-respiratory tract illnesses, including otitis media) with or without low grade fever
- Mild to moderate local reactions and/or low grade or moderate fever following a prior dose of the vaccine
- Current antimicrobial therapy
- Convalescent phase of illness
- Recent exposure to an infectious disease
- Breastfeeding

Communicate About Vaccine Benefits and Risks

Quality Monitoring Element	Yes	No	NA	Followup and/or corrective action
Assess reasons for refusal/declination of vaccines to determine educational opportunities				
Identify and collaborate with experts in immunization to identify concise communications regarding individual vaccines and their importance in disease prevention				
Develop targeted communications regarding vaccines that focus on the most common questions from personnel				
Coordinate communication methods so they include healthcare personnel who are employees as well as students, licensed independent professionals, and relevant external partners such as supply and pharmaceutical vendors and representatives				
A copy of the most current Vaccine Information Statement (VIS) is provided to all vaccines prior to the administration of each vaccine dose				
If English is the second language, the VIS in the employee's native language is provided, if available				

Be Prepared to Manage Vaccine Side Effects

Most people experience no side effects, or only mild ones, following immunization. Mild side effects may include soreness, swelling, or redness at the injection site or mild fever. Severe side effects, such as severe allergic reactions, following vaccination are extremely rare.

Quality Monitoring Element	Yes	No	NA	Followup and/or corrective action
Emergency protocols have been written and are regularly reviewed				
Personnel responsible for the immunization program are knowledgeable regarding the emergency protocols and have been deemed competent to apply those emergency interventions				
Epinephrine and equipment for maintaining an airway are available for immediate use				

Report Suspected Side Effects to VAERS

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety monitoring program. VAERS collects information about adverse events (possible side effects) that occur after administration of U.S. licensed vaccines.

Quality Monitoring Element	Yes	No	NA	Followup and/or corrective action
Those personnel responsible for the administration of vaccines are aware of the selected events that require reporting to VAERS				
Personnel are aware of the process for reporting vaccine events to VAERS				

More information about VAERS, including reporting forms, can be obtained by calling the VAERS information line at 800-822-7967, or by visiting <http://vaers.hhs.gov>

Section 3 Vaccine Selection and Administration

This section addresses the basics regarding the selection of vaccines appropriate for the targeted healthcare personnel groups and specifics regarding the administration of those vaccines. The following documents are included in this section:

- Healthcare Personnel Vaccination Recommendations in brief provided by the Immunization Action Coalition (IAC) <http://www.immunize.org/catg.d/p2017.pdf>
- Immunization of Health-Care Personnel, Recommendations of the Advisory Committee on Immunization Practices (ACIP) published on November 25, 2011 in the **MMWR**.
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm?s_cid=rr6007a1
- Basics of vaccine administration adapted from
http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/D/vacc_admin.pdf
- Administering Vaccines to Adults: Dose, Route, Site, Needle Size, and Preparation
<http://www.immunize.org/catg.d/p3084.pdf>
- How to Administer Intramuscular and Subcutaneous Vaccine Injections to Adults
<http://www.immunize.org/catg.d/p2020a.pdf>
- How to Administer Intramuscular, Intradermal, and Intranasal Influenza Vaccines
<http://www.immunize.org/catg.d/p2024.pdf>
- Vaccines with Diluents <http://www.immunize.org/catg.d/p3040.pdf>
- Guide to Contraindications and Precautions to Commonly Used Vaccines in Healthcare Personnel <http://www.immunize.org/catg.d/p3072a.pdf>

Healthcare Personnel Vaccination Recommendations

Vaccine	Recommendations in brief
Hepatitis B	Give 3-dose series (dose #1 now, #2 in 1 month, #3 approximately 5 months after #2). Give IM. Obtain anti-HBs serologic testing 1–2 months after dose #3.
Influenza	Give 1 dose of influenza vaccine annually. Give inactivated injectable influenza vaccine intramuscularly or live attenuated influenza vaccine (LAIV) intranasally.
MMR	For healthcare personnel (HCP) born in 1957 or later without serologic evidence of immunity or prior vaccination, give 2 doses of MMR, 4 weeks apart. For HCP born prior to 1957, see below. Give SC.
Varicella (chickenpox)	For HCP who have no serologic proof of immunity, prior vaccination, or history of varicella disease, give 2 doses of varicella vaccine, 4 weeks apart. Give SC.
Tetanus, diphtheria, pertussis	Give all HCP a Td booster dose every 10 years, following the completion of the primary 3-dose series. Give a 1-time dose of Tdap to HCP of all ages with direct patient contact. Give IM.
Meningococcal	Give 1 dose to microbiologists who are routinely exposed to isolates of <i>N. meningitidis</i> . Give IM or SC.

Hepatitis A, typhoid, and polio vaccines are not routinely recommended for HCP who may have on-the-job exposure to fecal material.

Hepatitis B

Healthcare personnel (HCP) who perform tasks that may involve exposure to blood or body fluids should receive a 3-dose series of hepatitis B vaccine at 0-, 1-, and 6-month intervals. Test for hepatitis B surface antibody (anti-HBs) to document immunity 1–2 months after dose #3.

- If anti-HBs is at least 10 mIU/mL (positive), the patient is immune. No further serologic testing or vaccination is recommended.
- If anti-HBs is less than 10 mIU/mL (negative), the patient is unprotected from hepatitis B virus (HBV) infection; revaccinate with a 3-dose series. Retest anti-HBs 1–2 months after dose #3.
 - If anti-HBs is positive, the patient is immune. No further testing or vaccination is recommended.
 - If anti-HBs is negative after 6 doses of vaccine, patient is a non-responder.

For non-responders: HCP who are non-responders should be considered susceptible to HBV and should be counseled regarding precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known or probable parenteral exposure to hepatitis B surface antigen (HBsAg)-positive blood.¹ It is also possible that non-responders are persons who are HBsAg positive. Testing should be considered. HCP found to be HBsAg positive should be counseled and medically evaluated.

Note: Anti-HBs testing is not recommended routinely for previously vaccinated HCP who were not tested 1–2 months after their original vaccine series. These HCP should be tested for anti-HBs when they have an exposure to blood or body fluids. If found to be anti-HBs negative, the HCP should be treated as if susceptible.¹

Influenza

All HCP, including physicians, nurses, paramedics, emergency medical technicians, employees of nursing homes and chronic care facilities, students in these professions, and volunteers, should receive annual vaccination against influenza. Live attenuated influenza vaccine (LAIV) may only be given to non-pregnant healthy HCP age 49 years and younger. Inactivated injectable influenza vaccine (TIV) is preferred over LAIV for HCP who are in close contact with severely immunosuppressed persons (e.g., stem cell transplant patients) when patients require protective isolation.

Measles, Mumps, Rubella (MMR)

HCP who work in medical facilities should be immune to measles, mumps, and rubella.

- HCP born in 1957 or later can be considered immune to measles, mumps, or rubella only if they have documentation of (a) laboratory confirmation

of disease or immunity (HCP who have an “indeterminate” or “equivocal” level of immunity upon testing should be considered nonimmune) or (b) appropriate vaccination against measles, mumps, and rubella (i.e., 2 doses of live measles and mumps vaccines given on or after the first birthday, separated by 28 days or more, and at least 1 dose of live rubella vaccine).

- Although birth before 1957 generally is considered acceptable evidence of measles, mumps, and rubella immunity, healthcare facilities should consider recommending 2 doses of MMR vaccine routinely to unvaccinated HCP born before 1957 who do not have laboratory evidence of disease or immunity to measles, mumps, and/or rubella. For these same HCP who do not have evidence of immunity, healthcare facilities should recommend 2 doses of MMR vaccine during an outbreak of measles or mumps and 1 dose during an outbreak of rubella.

Varicella

It is recommended that all HCP be immune to varicella. Evidence of immunity in HCP includes documentation of 2 doses of varicella vaccine given at least 28 days apart, history of varicella or herpes zoster based on physician diagnosis, laboratory evidence of immunity, or laboratory confirmation of disease.

Tetanus/Diphtheria/Pertussis (Td/Tdap)

All adults who have completed a primary series of a tetanus/diphtheria-containing product (DTP, DTaP, DT, Td) should receive Td boosters every 10 years. HCP of all ages with direct patient contact should be given a 1-time dose of Tdap, with priority given to those having contact with infants younger than age 12 months.

Meningococcal

Vaccination is recommended for microbiologists who are routinely exposed to isolates of *N. meningitidis*. Use of MCV4 is preferred for persons younger than age 56 years; give IM. Use MPSV4 only if there is a permanent contraindication or precaution to MCV4. Use of MPSV4 (not MCV4) is recommended for HCP older than age 55; give SC.

References

1. See Table 3 in “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis,” *MMWR*, June 29, 2001, Vol. 50, RR-11.

For additional specific ACIP recommendations, refer to the official ACIP statements published in *MMWR*. To obtain copies, visit CDC’s website at www.cdc.gov/vaccines/pubs/ACIP-list.htm; or visit the Immunization Action Coalition (IAC) website at www.immunize.org/acip.

Adapted from the Michigan Department of Community Health

Immunization of Health-Care Personnel

Recommendations of the Advisory Committee on Immunization Practices (ACIP)



Continuing Education Examination available at <http://www.cdc.gov/mmwr/cme/conted.html>.



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Disclosure of Relationship

CDC, our planners, and our content experts wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. This report will not include any discussion of the unlabeled use of a product or a product under investigational use with the exception of the following situations:

1. For varicella postexposure prophylaxis for persons without evidence of immunity who have contraindications for vaccination and who are at risk for severe disease and complications, the product currently used in the United States, VariZIG (Cangene Corporation, Winnipeg, Canada), is available under an Investigational New Drug Application Expanded Access Protocol.
2. The interval between administration of Td and Tdap might be <5 years as indicated in package insert.
3. One Tdap product, Adacel (sanofi pasteur, Toronto, Canada), is labeled for use in persons aged 11–64 years. The other Tdap product, Boostrix (GlaxoSmithKline Biologicals, Rixensart, Belgium), is labeled for use in persons aged ≥10 years. Until ACIP reviews the current recommendations on use of Tdap in persons aged ≥65 years, either Tdap product may be used in persons aged ≥65 years.
4. Meningococcal conjugate vaccines are licensed only as a single dose. The 2-dose series of meningococcal conjugate vaccine is recommended for persons with certain medical risk factors, and the booster dose of meningococcal conjugate vaccine is recommended for persons who remain at increased risk for a prolonged period.

On the cover: An adult female health-care professional receiving an intramuscular vaccination into her left shoulder muscle from a nurse.

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Immunization of Health-Care Personnel

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

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Summary

This report updates the previously published summary of recommendations for vaccinating health-care personnel (HCP) in the United States (CDC. Immunization of health-care workers: recommendations of the Advisory Committee on Immunization Practices [ACIP] and the Hospital Infection Control Practices Advisory Committee [HICPAC]. MMWR 1997;46[No. RR-18]). This report was reviewed by and includes input from the Healthcare (formerly Hospital) Infection Control Practices Advisory Committee. These updated recommendations can assist hospital administrators, infection-control practitioners, employee health clinicians, and HCP in optimizing infection prevention and control programs. The recommendations for vaccinating HCP are presented by disease in two categories: 1) those diseases for which vaccination or documentation of immunity is recommended because of risks to HCP in their work settings for acquiring disease or transmitting to patients and 2) those for which vaccination might be indicated in certain circumstances. Background information for each vaccine-preventable disease and specific recommendations for use of each vaccine are presented. Certain infection-control measures that relate to vaccination also are included in this report. In addition, ACIP recommendations for the remaining vaccines that are recommended for certain or all adults are summarized, as are considerations for catch-up and travel vaccinations and for work restrictions. This report summarizes all current ACIP recommendations for vaccination of HCP and does not contain any new recommendations or policies.

The material in this report originated in the National Center for Immunization and Respiratory Diseases, Anne Schuchat, MD, Director.

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The recommendations provided in this report apply, but are not limited, to HCP in acute-care hospitals; long-term-care facilities (e.g., nursing homes and skilled nursing facilities); physician's offices; rehabilitation centers; urgent care centers, and outpatient clinics as well as to persons who provide home health care and emergency medical services.

Introduction

This report updates the previously published summary of recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Healthcare (formerly Hospital) Infection Control Practices Advisory Committee (HICPAC) for vaccinating health-care personnel (HCP) in the United States (1). The report, which was reviewed by and includes input from HICPAC, summarizes all current ACIP recommendations for vaccination of HCP and does not contain any new recommendations or policies that have not been published previously. These recommendations can assist hospital administrators, infection-control practitioners, employee health clinicians, and HCP in optimizing infection prevention and control programs.

HCP are defined as all paid and unpaid persons working in health-care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients (2).

Because of their contact with patients or infective material from patients, many HCP are at risk for exposure to (and possible transmission of) vaccine-preventable diseases. Employers and HCP have a shared responsibility to prevent occupationally acquired infections and avoid causing harm to patients by taking reasonable precautions to prevent transmission of vaccine-preventable diseases. Vaccination programs are therefore an essential part of infection prevention and control for HCP. Optimal use of recommended vaccines helps maintain immunity and safeguard HCP from infection, thereby helping protect patients from becoming infected; pertinent ACIP statements on various individual vaccines and diseases have been published (Table 1). Nationwide, ongoing implementation of these vaccine recommendations through well-managed vaccination programs could substantially reduce both the number of susceptible HCP in any setting in which they interact with patients and their risks for transmitting vaccine-preventable diseases to patients, other HCP, and other contacts (3).

HICPAC and CDC have recommended that secure, preferably computerized, systems should be used to manage

vaccination records for HCP so records can be retrieved easily as needed (3). Each record should reflect immunity status for indicated vaccine-preventable diseases (i.e., documented disease, vaccination history, or serology results) as well as vaccinations administered during employment and any documented episodes of adverse events after vaccination (4). For each vaccine, the record should include date of vaccine administration (including for those vaccines that might have been received prior to employment), vaccine manufacturer and lot number, edition and distribution date of the language-appropriate Vaccine Information Statement (VIS) provided to the vaccinee at the time of vaccination, and the name, address, and title of the person administering the vaccine (4). Accurate vaccination records can help to rapidly identify susceptible HCP (i.e., those with no history of vaccination or lack of documentation of immunity) during an outbreak situation and can help reduce costs and disruptions to health-care operations (5–7). HCP should be provided a copy of their vaccination records and encouraged to keep it with their personal health records so they can readily be made available to future employers.

HICPAC has encouraged any facility or organization that provides direct patient care to formulate a comprehensive vaccination policy for all HCP (3). The American Hospital Association has endorsed the concept of vaccination programs for both hospital personnel and patients (8). To ensure that all HCP are up to date with respect to recommended vaccines, facilities should review HCP vaccination and immunity status at the time of hire and on a regular basis (i.e., at least annually) with consideration of offering needed vaccines, if necessary, in conjunction with routine annual disease-prevention measures (e.g., influenza vaccination or tuberculin testing). These recommendations (Tables 2 and 3) should be considered during policy development. Several states and health-care facilities have established requirements relating to assessment of vaccination status and/or administration of one or more vaccines for HCP (9,10). Disease-specific outbreak control measures are described in this report and elsewhere (3,11,12). All HCP should adhere to all other recommended infection-control guidelines, whether or not they are individually determined to have immunity to a vaccine-preventable disease.

Methods

In 2008, the ACIP Immunization of Health-Care Personnel Work Group (the Work Group) was formed as a subgroup of the ACIP Adult Immunization Work Group to update the previously published recommendations for immunization of HCP. The Work Group comprised professionals from

academic medicine (pediatrics, family medicine, internal medicine, occupational and environmental medicine, and infectious disease); federal and state public health professionals; and liaisons from the Society for Healthcare Epidemiology of America and HICPAC. The Work Group met monthly, developed an outline for the report, worked closely with subject matter experts at CDC (who developed, revised, and updated sections of the report), and provided subsequent critical review of the draft documents. The approach of the Work Group was to summarize previously published ACIP recommendations and not to make new recommendations or policies; a comprehensive list of publications containing the various vaccine-specific recommendations is provided (Table 1). In February 2011, the updated report was presented to ACIP, which voted to approve it.

The recommendations for vaccination of HCP are presented below by disease in two categories: 1) those diseases for which routine vaccination or documentation of immunity is recommended for HCP because of risks to HCP in their work settings and, should HCP become infected, to the patients they serve and 2) those diseases for which vaccination of HCP might be indicated in certain circumstances. Vaccines recommended in the first category are hepatitis B, seasonal influenza, measles, mumps, and rubella, pertussis, and varicella vaccines. Vaccines in the second category are meningococcal, typhoid, and polio vaccines. Except for influenza, all of the diseases prevented by these vaccines are notifiable at the national level (13). Main changes from the 1997 ACIP recommendations have been summarized (Box).

Diseases for Which Vaccination Is Recommended

On the basis of documented nosocomial transmission, HCP are considered to be at substantial risk for acquiring or transmitting hepatitis B, influenza, measles, mumps, rubella, pertussis, and varicella. Current recommendations for vaccination are provided below.

Hepatitis B

Background

Epidemiology and Risk Factors

Hepatitis B is an infection caused by the hepatitis B virus (HBV), which is transmitted through percutaneous (i.e., breaks in the skin) or mucosal (i.e., direct contact with mucous membranes) exposure to infectious blood or body fluids. The virus is highly infectious; for nonimmune persons,

disease transmission from a needlestick exposure is up to 100 times more likely for exposure to hepatitis B e antigen (HBeAg)-positive blood than to HIV-positive blood (14). HBV infection is a well recognized occupational risk for U.S. HCP and globally. The risk for HBV is associated with degree of contact with blood in the work place and with the hepatitis B e-antigen status of the source persons (15). The virus is also environmentally stable, remaining infectious on environmental surfaces for at least 7 days (16).

In 2009 in the United States, 3,371 cases of acute HBV infection were reported nationally, and an estimated 38,000 new cases of HBV infection occurred after accounting for underreporting and underdiagnosis (17). Of 4,519 persons reported with acute HBV infection in 2007, approximately 40% were hospitalized and 1.5% died (18). HBV can lead to chronic infection, which can result in cirrhosis of the liver, liver failure, liver cancer, and death. An estimated 800,000–1.4 million persons in the United States are living with chronic HBV infection; these persons serve as the main reservoir for continued HBV transmission (19).

Vaccines to prevent hepatitis B became available in the United States in 1981; a decade later, a national strategy to eliminate HBV infection was implemented, and the routine vaccination of children was recommended (20). During 1990–2009, the rate of new HBV infections declined approximately 84%, from 8.5 to 1.1 cases per 100,000 population (17); the decline was greatest (98%) among persons aged <19 years, for whom recommendations for routine infant and adolescent vaccination have been applied. Although hepatitis B vaccine coverage is high in infants, children, and adolescents (91.8% in infants aged 19–35 months and 91.6% in adolescents aged 13–17 years) (21,22), coverage remains lower (41.8% in 2009) for certain adult populations, including those with behavioral risks for HBV infection (e.g., men who have sex with men and persons who use injection drugs) (23).

Hepatitis B in Health-Care Settings

During 1982, when hepatitis B vaccine was first recommended for HCP, an estimated 10,000 infections occurred among persons employed in a medical or dental field. By 2004, the number of HBV infections among HCP had decreased to an estimated 304 infections, largely resulting from the implementation of routine preexposure vaccination and improved infection-control precautions (24–26).

The risk for acquiring HBV infection from occupational exposures is dependent on the frequency of percutaneous and mucosal exposures to blood or body fluids (e.g., semen, saliva, and wound exudates) containing HBV, particularly fluids containing HBeAg (a marker for high HBV replication and viral load) (27–31). The risk is higher during the professional

BOX. Summary of main changes* from 1997 Advisory Committee on Immunization Practices/Hospital (now Healthcare) Infection Control Practices Advisory Committee recommendations for immunization of health-care personnel (HCP)

Hepatitis B

- HCP and trainees in certain populations at high risk for chronic hepatitis B (e.g., those born in countries with high and intermediate endemicity) should be tested for HBsAg and anti-HBc/anti-HBs to determine infection status.

Influenza

- Emphasis that all HCP, not just those with direct patient care duties, should receive an annual influenza vaccination
- Comprehensive programs to increase vaccine coverage among HCP are needed; influenza vaccination rates among HCP within facilities should be measured and reported regularly.

Measles, mumps, and rubella (MMR)

- History of disease is no longer considered adequate presumptive evidence of measles or mumps immunity for HCP; laboratory confirmation of disease was added as acceptable presumptive evidence of immunity. History of disease has never been considered adequate evidence of immunity for rubella.
- The footnotes have been changed regarding the recommendations for personnel born before 1957 in routine and outbreak contexts. Specifically, guidance is provided for 2 doses of MMR for measles and mumps protection and 1 dose of MMR for rubella protection.

Pertussis

- HCP, regardless of age, should receive a single dose of Tdap as soon as feasible if they have not previously received Tdap.
- The minimal interval was removed, and Tdap can now be administered regardless of interval since the last tetanus or diphtheria-containing vaccine.
- Hospitals and ambulatory-care facilities should provide Tdap for HCP and use approaches that maximize vaccination rates.

Varicella

Criteria for evidence of immunity to varicella were established. For HCP they include

- written documentation with 2 doses of vaccine,
- laboratory evidence of immunity or laboratory confirmation of disease,
- diagnosis of history of varicella disease by health-care provider, or diagnosis of history of herpes zoster by health-care provider.

Meningococcal

- HCP with anatomic or functional asplenia or persistent complement component deficiencies should now receive a 2-dose series of meningococcal conjugate vaccine. HCP with HIV infection who are vaccinated should also receive a 2 dose series.
- Those HCP who remain in groups at high risk are recommended to be revaccinated every 5 years.

Abbreviations: HBsAg = Hepatitis B surface antigen; anti-HBc = hepatitis B core antibody; anti-HBs = hepatitis B surface antibody; Tdap = tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine; HIV = human immunodeficiency virus.

* Updated recommendations made since publication of the 1997 summary of recommendations (CDC Immunization of health-care workers: recommendations of the Advisory Committee on Immunization Practices [ACIP] and the Hospital Infection Control Practices Advisory Committee [HICPAC]. MMWR 1997;46[No. RR-18]).

training period and can vary throughout a person's career (1). Depending on the tasks performed, health-care or public safety personnel might be at risk for HBV exposure; in addition, personnel providing care and assistance to persons in outpatient settings and those residing in long-term-care facilities (e.g., assisted living) might be at risk for acquiring or facilitating transmission of HBV infection when they perform procedures that expose them to blood (e.g., assisted blood-glucose monitoring and wound care) (32–34).

A Federal Standard issued in December 1991 under the Occupational Safety and Health Act mandates that hepatitis B vaccine be made available at the employer's expense to all health-care personnel who are exposed occupationally to blood or other potentially infectious materials (35). The Federal Standard defines occupational exposure as reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that might result from the performance of an employee's duties (35). Occupational Safety and Health Administration

(OSHA) vaccination practice requirements (e.g., preexposure and postexposure antibody testing) are based on current ACIP recommendations. OSHA regulations might have accelerated the use of hepatitis B vaccine in HCP (36).

Data from a national, cross-sectional survey demonstrated that during 2002–2003, an estimated 75% of HCP had received the 3-dose hepatitis B vaccination series (37). Since 2002, rates of 1-dose and 3-dose vaccination coverage have remained stable. Data obtained through the National Health Interview Survey (NHIS) in 2009 demonstrated a ≥ 1 -dose coverage rate of 75%–77% and a ≥ 3 -dose rate of 67%–68% among HCP aged 18–49 years (23). Similarly, data obtained through the National Immunization Survey–Adult (NIS-Adult) in 2007 demonstrated a ≥ 3 -dose coverage of 62% among HCP aged 18–64 years (38). The Healthy People 2020 goal (objective no. IID-15.3) of a hepatitis B vaccination coverage rate of 90% among HCP (39) has not been achieved.

Vaccine Effectiveness, Duration of Immunity, and Vaccine Safety

Vaccine Effectiveness

The 3-dose vaccine series administered intramuscularly at 0, 1, and 6 months produces a protective antibody response in approximately 30%–55% of healthy adults aged ≤ 40 years after the first dose, 75% after the second dose, and $>90\%$ after the third dose (40–42). After age 40 years, $<90\%$ of persons vaccinated with 3 doses have a protective antibody response, and by age 60 years, protective levels of antibody develop in approximately 75% of vaccinated persons (43). Smoking, obesity, genetic factors, and immune suppression also are associated with diminished immune response to hepatitis B vaccination (43–46).

Duration of Immunity

Protection against symptomatic and chronic HBV infection has been documented to persist for ≥ 22 years in vaccine responders (47). Immunocompetent persons who achieve hepatitis B surface antibody (anti-HBs) concentrations of ≥ 10 mIU/mL after preexposure vaccination have protection against both acute disease and chronic infection. Anti-HBs levels decline over time. Regardless, responders continue to be protected, and the majority of responders will show an anamnestic response to vaccine challenge (47–51). Declines might be somewhat faster among persons vaccinated as infants rather than as older children, adolescents, or adults and among those administered recombinant vaccine instead of plasma vaccine (which has not been commercially available in the United States since the late 1980s). Although immunogenicity is lower among immunocompromised persons, those who achieve

and maintain a protective antibody response before exposure to HBV have a high level of protection from infection (52).

Among persons who do not respond to a primary 3-dose vaccine series (i.e., those in whom anti-HBs concentrations of ≥ 10 mIU/mL were not achieved), 25%–50% respond to an additional vaccine dose, and 44%–100% respond to a 3-dose revaccination series using standard or high dosage vaccine (43,53–58). Persons who have measurable but low (i.e., 1–9 mIU/mL) levels of anti-HBs after the initial series have better response to revaccination than persons who have no anti-HBs (49,53,54). Persons who do not have protective levels of anti-HBs 1–2 months after revaccination either are infected with HBV or can be considered primary nonresponders; for the latter group, genetic factors might be associated with nonresponse to hepatitis B vaccination (54,58,59). ACIP does not recommend more than two vaccine series in nonresponders (52).

Vaccine Safety

Hepatitis B vaccines have been demonstrated to be safe when administered to infants, children, adolescents, and adults (52,60,61). Although rare cases of arthritis or alopecia have been associated temporally with hepatitis B vaccination, recent data do not support a causal relationship between hepatitis B vaccine and either arthritis or alopecia (61–63). During 1982–2004, an estimated 70 million adolescents and adults and 50 million infants and children in the United States received ≥ 1 dose of hepatitis B vaccine (52). The most frequently reported side effects in persons receiving hepatitis B vaccine are pain at the injection site (3%–29%) and temperature of $>99.9^{\circ}\text{F}$ ($>37.7^{\circ}\text{C}$) (1%–6%) (64–67). However, in placebo-controlled studies, these side effects were reported no more frequently among persons receiving hepatitis B vaccine than among persons receiving placebo (40,41,64–67). Revaccination is not associated with an increase in adverse events.

Hepatitis B vaccination is contraindicated for persons with a history of hypersensitivity to yeast or any vaccine component (4,64–66). Persons with a history of serious adverse events (e.g., anaphylaxis) after receipt of hepatitis B vaccine should not receive additional doses. As with other vaccines, vaccination of persons with moderate or severe acute illness, with or without fever, should be deferred until illness resolves (4). Vaccination is not contraindicated in persons with a history of multiple sclerosis, Guillain-Barré Syndrome, autoimmune disease (e.g., systemic lupus erythematosus and rheumatoid arthritis), or other chronic diseases. Pregnancy is not a contraindication to vaccination; limited data suggest that developing fetuses are not at risk for adverse events when hepatitis B vaccine is administered to pregnant women (4,68). Available vaccines contain noninfectious hepatitis B surface antigen (HBsAg) and do not pose any risk for infection to the fetus.

Recommendations

Two single-antigen hepatitis B vaccines, Recombivax HB (Merck & Co., Inc., Whitehouse Station, New Jersey) and Engerix-B (GlaxoSmithKline Biologicals, Rixensart, Belgium) and one combination hepatitis A and hepatitis B vaccine, Twinrix (GlaxoSmithKline Biologicals), are available in the United States. Primary vaccination consists of ≥ 3 intramuscular doses of hepatitis B vaccine or of the combined hepatitis A and hepatitis B vaccine. The hepatitis vaccine series does not need to be restarted if the second or third dose is delayed. Detailed vaccination recommendations are available in previously published guidelines (52). Vaccine schedules are available at <http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm#HCWs>. In adults, hepatitis B vaccine always should be administered into the deltoid muscle. Longer needles (up to 1.5 inches in length) might be required for obese adults (4).

Preexposure

Unvaccinated and Incompletely Vaccinated HCP and Trainees: Pre- and Postvaccination Serologic Testing

- Prevaccination serologic testing for previous infection is not indicated for the majority of persons being vaccinated because of occupational risk unless the hospital or health-care organization considers such testing cost-effective (3,52,69–72). However, such testing is indicated for HCP and is cost-effective in certain high-risk populations (see HCP and Trainees at Additional Risk), regardless of vaccination status (71,73).
- All unvaccinated persons whose work- and training-related activities involve reasonably anticipated risk for exposure to blood or other infectious body fluids (e.g., HCP, long-term-care facility staff, and public safety workers) should be vaccinated with the complete, ≥ 3 -dose hepatitis B vaccine series.
- Persons with an incomplete series are not considered protected and should complete the ≥ 3 -dose series.
- Because higher risk has been reported during the professional training period, the vaccination series should be completed before trainees have contact with blood; vaccination should be offered in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions.
- To determine the need for revaccination and to guide postexposure prophylaxis, postvaccination serologic testing should be performed for all HCP at high risk for occupational percutaneous or mucosal exposure to blood or body fluids. Postvaccination serologic testing is performed 1–2 months after administration of the last dose of the vaccine series using a method that allows

detection of the protective concentration of anti-HBs (≥ 10 mIU/mL). Persons determined to have anti-HBs concentrations of ≥ 10 mIU/mL after receipt of the primary vaccine series are considered immune, and the result should be documented. Immunocompetent persons have long-term protection and do not need further periodic testing to assess anti-HBs levels. Postvaccination testing for persons at low risk for mucosal or percutaneous exposure to blood or body fluids (e.g., public safety workers and HCP without direct patient contact) likely is not cost effective (52); however, persons who do not undergo postvaccination testing should be counseled to seek immediate testing if exposed.

- Persons determined to have anti-HBs concentrations of < 10 mIU/mL soon after receipt of the primary vaccine series should be revaccinated. For these persons, administration of a second complete 3-dose series on an appropriate schedule, followed by anti-HBs testing 1–2 months after the third dose, usually is more practical than conducting serologic testing after each additional dose of vaccine.
- Persons who do not have a protective concentration of anti-HBs (≥ 10 mIU/mL) after revaccination (i.e., after receiving a total of 6 doses) should be tested for HBsAg and anti-HBc to determine infection status. Those determined not to be infected but who have anti-HBs < 10 mIU/mL (nonresponders) should be considered susceptible to HBV infection and should be counseled about precautions to prevent HBV infection and the need to obtain hepatitis B immune globulin (HBIG) postexposure prophylaxis for any known or likely exposure to HBsAg-positive blood (72). Persons determined to be infected (anti-HBc-positive) and positive for HBsAg should be provided counseling regarding how to prevent HBV transmission to others and referred for further evaluation (e.g., HBV viral load testing), care, treatment, and other services, as appropriate (69–71). Persons who are HBsAg-positive and who perform exposure-prone procedures should seek counsel from a review panel comprised of experts with a balanced perspective (e.g., HCPs' personal physicians and infectious disease specialists) regarding the procedures that they can perform safely. They should not be excluded from work (69). Persons who were infected in the past (anti-HBc-positive but negative for HBsAg) require no vaccination or treatment.

Postexposure

The need for postexposure prophylaxis should be evaluated immediately after HCP experience any percutaneous, ocular, mucous-membrane or nonintact skin exposure to blood or body fluid in the workplace. Decisions to administer

postexposure prophylaxis should be based on the HBsAg status of the source and the vaccination history and vaccine-response status of the exposed HCP (Table 4) (72).

Unvaccinated and Incompletely Vaccinated HCP and Trainees

- Unvaccinated or incompletely vaccinated persons who experience a workplace exposure from persons known to be HBsAg-positive should receive 1 dose of hepatitis B immune globulin HBIG (i.e., passive vaccination) as soon as possible after exposure (preferably within 24 hours). The effectiveness of HBIG when administered >7 days after percutaneous or permucosal exposures is unknown (Table 4).
- Hepatitis B vaccine should be administered in the deltoid muscle as soon as possible after exposure; HBIG should be administered at the same time at another injection site. The 3-dose hepatitis B vaccine series should be completed for previously unvaccinated and incompletely vaccinated persons who have needlestick or other percutaneous exposures, regardless of the HBsAg status of the source and whether the status of the source is known. To document protective levels of anti-HBs (≥ 10 mIU/mL), postvaccination testing of persons who received HBIG for postexposure prophylaxis should be performed after anti-HBs from HBIG is no longer detectable (4–6 months after administration).

Vaccinated HCP and Trainees

- Vaccinated HCP with documented immunity (anti-HBs concentrations of ≥ 10 mIU/mL) require no postexposure prophylaxis, serologic testing, or additional vaccination.
- Vaccinated HCP with documented nonresponse to a 3-dose vaccine series should receive 1 dose of HBIG and a second 3-dose vaccine series if the source is HBsAg-positive or known to be at high risk for carrying hepatitis. If the source is known or determined to be HBsAg-negative, these previously nonresponding HCP should complete the revaccination series and undergo postvaccination testing to ensure that their response status is documented (Table 4). Postvaccination testing of persons who received HBIG for PEP should be performed after anti-HBs from HBIG is no longer detectable (4–6 months after administration).
- Vaccinated HCP with documented nonresponse to two 3-dose vaccine series should receive 2 doses of HBIG, 1 month apart if the source is HBsAg-positive or known to be at high risk for carrying hepatitis; no additional vaccination is necessary. If the source is known or determined to be HBsAg-negative, these previously

nonresponding HCP need no additional testing or treatment (Table 4).

- Vaccinated HCP with no documentation of postvaccination serologic response who are exposed to an HBsAg-positive source should have serum obtained for anti-HBs testing immediately. Those determined to have protective levels of antibody (anti-HBs ≥ 10 mIU/mL) require no additional treatment; those with concentrations < 10 mIU/mL should receive 1 dose of HBIG, along with a booster dose of hepatitis B vaccine. To document protective levels of anti-HBs (≥ 10 mIU/mL), postvaccination testing of persons who received HBIG for postexposure prophylaxis should be performed after anti-HBs from HBIG is no longer detectable (4–6 months after administration).
- Vaccinated HCP with no documentation of postvaccination serologic response who are exposed to a source with unknown infection status should be tested for anti-HBs. Those determined to have protective levels of antibody require no additional treatment; those with concentrations < 10 mIU/mL should receive a booster dose of hepatitis B vaccine and serologic testing 1–2 months later.
- Vaccinated HCP with no documentation of postvaccination serologic response who are exposed to a source known to be HBsAg-negative require no testing or treatment (Table 4).

HCP and Trainees at Additional Risk

- Regardless of vaccination history, HCP and trainees in certain high-risk populations, including those born in geographic regions with high HBsAg prevalence ($\geq 8\%$) and intermediate (2%–7%) prevalence (71), unvaccinated U.S.-born HCP whose parents were born in regions of high HBsAg prevalence, HIV-positive HCP, HCP who have disclosed having engaged or currently engaging in high-risk substance abuse or sexual behaviors, and HCP who require immunosuppressive therapy or who are on hemodialysis should be tested for HBsAg and anti-HBc/anti-HBs to determine infection status. For those who are unvaccinated, blood should be drawn for testing before the first dose of vaccine is administered, and vaccination should be administered during the same health-care visit. Persons testing negative for hepatitis B infection or immunity should be managed in the same manner as other uninfected HCP. Persons determined to be HBsAg-positive should be provided counseling regarding how to prevent HBV transmission to others and referred for further evaluation (e.g., HBV viral load testing), care, treatment, and other services as appropriate (69–71). Persons who are HBsAg-positive and who perform exposure-prone procedures should seek counsel from a review panel comprised of experts with a balanced perspective (e.g., personal physicians

of HCP and infectious disease specialists) regarding the procedures that they can perform safely. They should not be excluded from work (69). Additional information regarding prevaccination testing for HCP with other hepatitis B risk factors and for pregnant women has been published previously (52,71). HCP receiving hemodialysis should be provided annual anti-HBs testing and should be administered a booster dose of vaccine when anti-HBs levels decline to <10 mIU/mL (52).

- For other immunocompromised HCP (e.g., HIV-infected persons, hematopoietic stem-cell transplant recipients, and persons receiving chemotherapy), the frequency of postvaccination testing and the need for booster doses has not been determined (52).

Other Considerations

- Occupational health programs and others responsible for infection prevention and control should identify all staff whose work-related activities involve exposure to blood or other potentially infectious body fluids in a health-care, laboratory, public safety, or institutional setting (including employees, students, contractors, attending clinicians, emergency medical technicians, paramedics, and volunteers); provide education to staff to encourage vaccination; and implement active follow-up, with reminders to track completion of the vaccine series and postvaccination testing among persons receiving vaccination (72).
- In partnership with state and local health authorities, household, sex, or needle-sharing contacts of HBsAg-positive HCP and trainees should be identified, tested, vaccinated (if indicated), and provided with counseling and referral for needed services, when appropriate.

Influenza

Background

Epidemiology and Risk Factors

Influenza causes an estimated average of >200,000 hospitalizations and 3,000–49,000 deaths annually in the United States (74–76). The majority of influenza-related severe illnesses and deaths occur among persons with chronic medical conditions, infants and young children, seniors, and pregnant women (74–78). Reducing the risk for influenza among persons at higher risk for complications is a major focus of influenza prevention strategies (77).

Influenza Transmission in Health-Care Settings

HCP are exposed to patients with influenza in the workplace and are thus at risk of occupationally acquired influenza and of

transmitting influenza to patients and other HCP. In a cross-sectional survey of hospital house staff (physicians in training), 37% reported influenza-like illness during September–April, and 9% reported more than one respiratory illness. Length of illness varied (range: 1–10 days; mean: 7 days), as did days of work missed (range: 0–10 days; mean: 0.7 days) (79). Infected HCP who continue to work while ill might transmit influenza to patients, many of whom are at increased risk for severe outcomes from influenza. HCP are therefore recommended for routine annual influenza vaccination (77).

Few randomized trials of the effect that influenza vaccination has on illness in HCP have been conducted. In one randomized trial of 427 HCP, influenza vaccination of HCP failed to decrease episodes of respiratory infection or duration of illness but was associated with a 28% decrease in absenteeism (from 1.4 days to 1.0 day) attributable to respiratory infections (80). No laboratory confirmation of influenza was obtained in this study. In another randomized trial among HCP, vaccination was associated with a significantly lower rate of serological evidence of influenza infection, with a vaccine efficacy rate of 88% for influenza A and 89% for influenza B ($p < 0.05$) (81); however, no significant differences were noted in days of febrile respiratory illness or absenteeism.

Influenza can cause outbreaks of severe respiratory illness among hospitalized persons and long-term-care residents (82–90). Influenza outbreaks in hospitals (86–88) and long-term-care facilities (91) have been associated with low vaccination rates among HCP. One nonrandomized study demonstrated an increase in HCW vaccination rates and decrease in nosocomially acquired, laboratory-confirmed influenza in a hospital after a mobile cart-based HCP vaccination program was introduced (86). Several randomized controlled studies of the impact of HCP vaccination on morbidity and mortality in long-term care facilities have been performed (92–95). These studies have demonstrated substantial decreases in all-cause mortality (92–95) and influenza-like illness (92,94,95). However, studies which examine and demonstrate efficacy in preventing more specific outcomes (e.g., laboratory-confirmed influenza illness and mortality) are lacking. Recent systematic reviews suggest that vaccination of HCP in settings in which patients also were vaccinated provided significant reductions in deaths among elderly patients from all causes and deaths from pneumonia, but also note that additional randomized controlled trials are warranted (96,97), as are examination of more specific outcomes.

Preventing influenza among HCP who might serve as sources of influenza virus transmission provides additional protection to patients at risk for influenza complications. Vaccination of HCP can specifically benefit patients who cannot receive vaccination (e.g., infants aged <6 months or those with severe

allergic reactions to prior influenza vaccination), patients who respond poorly to vaccination (e.g., persons aged ≥ 85 years and immune-compromised persons), and persons for whom antiviral treatment is not available (e.g., persons with medical contraindications). Although annual vaccination has long been recommended for HCP and is a high priority for reducing morbidity associated with influenza in health-care settings (98–100), national survey data have demonstrated that the vaccination coverage level during the 2008–09 season was 52.9% (101).

Considerations Regarding Influenza Vaccination of HCP

Barriers to HCP acceptance of influenza vaccination have included fear of vaccine side effects (particularly influenza-like symptoms), insufficient time or inconvenience, perceived ineffectiveness of the vaccine, perceived low likelihood of contracting influenza, avoidance of medications, and fear of needles (79,102–109). Factors demonstrated to increase vaccine acceptance include a desire for self-protection, previous receipt of influenza vaccine, a desire to protect patients, and perceived effectiveness of vaccine (79,105,106,109–112). Strategies that have demonstrated improvement in HCP vaccination rates have included campaigns to emphasize the benefits of HCP vaccination for staff and patients, vaccination of senior medical staff or opinion leaders, removing administrative barriers (e.g., costs), providing vaccine in locations and at times easily accessible by HCP, and monitoring and reporting HCP influenza vaccination rates (99,113–120). Intranasally administered live attenuated influenza vaccine (LAIV) is an option for healthy, nonpregnant adults aged <50 years who dislike needles.

The practice of obtaining signed declinations from HCP offered influenza vaccination has been adopted by some institutions but has not yet been demonstrated to exceed coverage rates of $>70\%$ – 80% (99,115,121–123). Institutions that require declination statements from HCP who refuse influenza vaccination should educate and counsel these HCP about benefits of the vaccine.

Each health-care facility should develop a comprehensive influenza vaccination strategy that includes targeted education about the disease, including disease risk among HCP and patients, and about the vaccine. In addition, the program should establish easily accessible vaccination sites and inform HCP about their locations and schedule. Facilities that employ HCP should provide influenza vaccine at no cost to personnel (124). The most effective combination of approaches for achieving high influenza vaccination coverage among HCP likely varies by institution. Hospitals and health-care

organizations in the United States traditionally have employed an immunization strategy that includes one or more of the following components: education about influenza, easy access to vaccine, incentives to encourage immunization, organized campaigns, institution of declination policies, and legislative and regulatory efforts (e.g., vaccination requirements) (99,115,121–126).

Beginning January 1, 2007, the Joint Commission on Accreditation of Health-Care Organizations required accredited organizations to offer influenza vaccinations to staff, including volunteers and licensed independent practitioners and to report coverage levels among HCP (127). Standards are available for measuring vaccination coverage among HCP as a measure of program performance within a health-care setting (128). Beginning January 2013, the Centers for Medicaid Services will require acute care hospitals to report HCP influenza vaccine as part of its hospital inpatient quality reporting program.*

Vaccine Effectiveness, Duration of Immunity, and Vaccine Safety

Effectiveness of influenza vaccines varies from year to year and depends on the age and health status of the person getting the vaccine and the similarity or “match” between the viruses or virus in the vaccine and those in circulation. Vaccine strains are selected for inclusion in the influenza vaccine every year based on international surveillance and scientists’ estimations about which types and strains of viruses will circulate in a given year. Annual vaccination is recommended because the predominant circulating influenza viruses typically change from season to season and, because immunity declines over time postvaccination (77).

In placebo-controlled studies among adults, the most frequent side effect of vaccination was soreness at the vaccination site (affecting 10%–64% of patients) that lasted <2 days (129,130). These injection-site reactions typically were mild and rarely interfered with the recipient’s ability to conduct usual daily activities. The main contraindication to influenza vaccination is a history of anaphylactic hypersensitivity to egg or other components of the vaccine. A history of Guillain-Barré Syndrome within 6 weeks following a previous dose of influenza vaccine is considered to be a precaution for use of influenza vaccines (77).

*US Department of Health and Human Services. Medicare program; hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and FY2012 rates; hospitals’ FTE resident caps for graduate medical education payment; final rules. Federal Register 2011;76:51631–3.

Recommendations

Vaccination

Annual influenza vaccination is recommended for all persons aged ≥ 6 months who have no medical contraindication; therefore, vaccination of all HCP who have no contraindications is recommended. The influenza vaccine is evaluated annually with one or more vaccine strains updated almost every year. In addition, antibody titers decline during the year after vaccination. Thus, annual vaccination with the current season's formulation is recommended. Annual vaccination is appropriate and safe to begin as early in the season as vaccine is available. HCP should be among the groups considered for prioritized receipt of influenza vaccines when vaccine supply is limited.

Two types of influenza vaccines are available. LAIV is administered intranasally and is licensed for use in healthy nonpregnant persons aged 2–49 years. The trivalent inactivated vaccine (TIV) is administered as an intramuscular injection and can be given to any person aged ≥ 6 months. Both vaccine types contain vaccine virus strains that are selected to stimulate a protective immune response against the wild-type viruses that are thought to be most likely in circulation during the upcoming season. Use of LAIV for HCP who care for patients housed in protective inpatient environments has been a theoretic concern, but transmission of LAIV in health-care settings has not been reported. LAIV can be used for HCP who work in any setting, except those who care for severely immunocompromised hospitalized persons who require care in a protective environment. HCP who themselves have a condition that confers high risk for influenza complications, who are pregnant, or who are aged ≥ 50 years should not receive LAIV and should be administered TIV instead. An inactivated trivalent vaccine containing 60 mcg of hemagglutinin antigen per influenza vaccine virus strain (Fluzone High-Dose [sanofi pasteur]) is an alternative inactivated vaccine for persons aged ≥ 65 years. Persons aged ≥ 65 years may be administered any of the standard-dose TIV preparations or Fluzone High-Dose (77). The majority of TIV preparations are administered intramuscularly. An intradermally administered TIV was licensed in May 2011 and is an alternative to other TIV preparations for persons aged 18–64 years (131).

Use of Antiviral Drugs for Treating Exposed Persons and Controlling Outbreaks

Use of antiviral drugs for chemoprophylaxis or treatment of influenza is an adjunct to (but not a substitute for) vaccination. Oseltamivir or zanamivir are recommended currently for chemoprophylaxis or treatment of influenza (132,133). TIV

can be administered to exposed, unvaccinated HCP at the same time as chemoprophylaxis, but LAIV should be avoided because the antiviral medication will prevent viral replication needed to stimulate a vaccine response (77). Antivirals are used often among patients during outbreaks in closed settings such as long-term-care facilities but also can be administered to unvaccinated HCP during outbreaks, when an exposure to a person with influenza occurs, or after exposure when vaccination is not thought to be protective against the strain to which a vaccinated HCP was exposed. Chemoprophylaxis consists of 1 dose (of either antiviral drug) daily for 10 days, and treatment consists of 1 dose twice daily for 5 days. In many instances of HCP exposure, watchful waiting and early initiation of treatment if symptoms appear is preferred rather than use of antiviral chemoprophylaxis immediately after exposure. The intensity and duration of the exposure and the underlying health status of the exposed worker are important factors in clinical judgments about whether to provide chemoprophylaxis. If chemoprophylaxis is used, the provider should base choice of the agent on whether the circulating strain or strains of influenza have demonstrated resistance to particular antivirals.

Program Evaluation

- Health-care administrators should include influenza vaccination coverage among HCP as a measure of quality of care (124).
- Influenza vaccination rates among HCP within facilities should be regularly measured and reported, and ward-, unit-, and specialty-specific coverage rates should be provided to staff and administration (124). Such information might be useful to promote compliance with vaccination policies.

Measles

Background

Epidemiology and Risk Factors

Measles is a highly contagious rash illness that is transmitted by respiratory droplets and airborne spread. Severe complications, which might result in death, include pneumonia and encephalitis. Before the national measles vaccination program was implemented in 1963, almost every person acquired measles before adulthood; an estimated 3–4 million persons in the United States acquired measles each year (134). Approximately 500,000 persons were reported to have had measles annually, of whom 500 persons died, 48,000 were

hospitalized, and another 1,000 had permanent brain damage from measles encephalitis (134).

Through a successful 2-dose measles vaccination program (i.e., a first dose at age 12–15 months and a second dose between ages 4–6 years) (135) and better measles control throughout the region of the Americas (136), endemic transmission of measles was interrupted in the United States, and measles was declared eliminated from the country in 2000 (137). However, measles remains widespread in the majority of countries outside the Western Hemisphere, with an estimated 20 million measles cases occurring worldwide (138) and approximately 164,000 related deaths (139). Thus, the United States continues to experience international importations that might lead to transmission among U.S. residents and limited outbreaks, especially in unvaccinated populations (140–143).

During 2001–2008, a total of 557 confirmed measles cases were reported in the United States from 37 states and the District of Columbia (annual median: 56; range: 37 in 2004 to 140 in 2008), representing an annual incidence of less than one case per million population (144). Of the 557 reported case-patients, 126 (23%) were hospitalized (annual median: 16; range: 5–29); of these, at least five case-patients were admitted to intensive care. Two deaths were reported, both in 2003 (144).

Of the 557 reported case-patients during 2001–2008, a total of 223 (40%) were adults, including 156 (28%) aged 20–39 years and 67 (12%) aged ≥40 years. Of the 438 measles cases among U.S. residents, 285 (65%) cases were considered preventable (i.e., occurred among persons who were eligible for vaccination but were unvaccinated) (144). The remaining 153 (35%) cases were considered nonpreventable. Cases were defined as nonpreventable if they occurred among U.S. resident case-patients who had received ≥1 dose of measles-containing vaccine, if patients were vaccinated as recommended if traveling internationally, or if they were not vaccinated but had other evidence of immunity (i.e., were born before 1957 and therefore presumed immune from natural disease in childhood, had laboratory evidence of immunity, or had documentation of physician-diagnosed disease) or for whom vaccination is not recommended. During 2001–2008, a total of 12.5% (one of eight) of measles cases reported to CDC among HCP occurred in persons born before 1957; the other seven cases occurred among HCP born after 1957.

Measles-mumps-rubella (MMR) vaccination policies have been enforced with variable success in United States health-care facilities over the past decade. Even though medical settings were a primary site of measles transmission during the 1989–1991 measles resurgence (145,146), as of September

2011, only three states (New York, Oklahoma, and Rhode Island) had laws mandating that all hospital personnel have proof of measles immunity and did not allow for religious or philosophic exemptions (147).

Vaccine coverage in the United States is high; in 2010, a total of 91.5% of children aged 19–35 months had received 1 dose of MMR vaccine (21); during 2009–2010, a total of 94.8% of kindergartners had evidence of 2 doses (148); and in 2010, a total of 90.5% of adolescents had evidence of 2 doses (22). Nationally representative data on MMR vaccine coverage of U.S. HCP are not available.

Measles Transmission and the Costs of Mitigating Measles Exposures in Health-Care Settings

Health-care-associated cases of measles are of public health concern. Because of the severity of measles, infected persons are likely to seek medical care in primary health-care facilities, emergency departments, or hospitals (141,149,150). Medical settings played a prominent role in perpetuating outbreaks of measles transmission during the 1989–1991 measles resurgence (145,146) and were a primary site of measles transmission in a health-care-associated outbreak in 2008 (149). During 2001–2008, a total of 27 reported measles cases were transmitted in U.S. health-care facilities, accounting for 5% of all reported U.S. measles cases.

Because of the greater opportunity for exposure, HCP are at higher risk than the general population for becoming infected with measles. A study conducted in 1996 in medical facilities in a county in Washington state indicated that HCP were 19 times more likely to develop measles than other adults (151). During 2001–2008, in the 23 health-care settings in which measles transmission was reported, eight cases occurred among HCP, six (75%) of whom were unvaccinated or had unknown vaccination status. One health-care provider was hospitalized in an intensive care unit for 6 days from severe measles complications (142). During a health-care-associated measles outbreak in Arizona in 2008 with 14 cases, six cases were acquired in hospitals, and one was acquired in an outpatient setting. One unvaccinated health-care worker developed measles and infected a hospital emergency room patient who required intensive care following hospital admission for measles (149).

High costs also are involved in evaluating and containing exposures and outbreaks in health-care facilities, as well as a substantial disruption of regular hospital routines when control measures are instituted, especially if hospitals do not have readily available data on the measles immunity status

of their staff and others included in the facility vaccination program. In 2005 in Indiana, one hospital spent more than \$113,000 responding to a measles outbreak (142), and in 2008 in Arizona, two hospitals spent \$799,136 responding to and containing cases in their facilities (149). The Arizona outbreak response required rapid review of measles documentation of 14,844 HCP at seven hospitals and emergency vaccination of approximately 4,500 HCP who lacked documentation of measles immunity. Serologic testing at two hospitals among 1,583 HCP without documented history of vaccination or without documented laboratory evidence of measles immunity revealed that 138 (9%) of these persons lacked measles IgG antibodies (149).

Vaccine Effectiveness, Duration of Immunity and Seroprevalence Studies, and Vaccine Safety

Vaccine Effectiveness

MMR vaccine is highly effective in preventing measles with a 1-dose vaccine effectiveness of 95% when administered on or after age 12 months and a 2-dose vaccine effectiveness of 99% (135).

Duration of Immunity and Seroprevalence Studies

Two doses of live measles vaccine are considered to provide long-lasting immunity (135). Although antibody levels decline following vaccination, a study examining neutralizing antibody levels up to 10 years following the second dose of MMR vaccine in children indicates that antibodies remain above the level considered protective (152).

Studies among HCP in the United States during the measles resurgence in the late 1980s through early 1990s demonstrated that 4%–10% of all HCP lacked measles IgG antibodies (153–156). During the 2008 Arizona outbreak, of the 1,077 health-care providers born during or after 1957 without documented measles immunity, 121 (11%) were seronegative (149). In a study of measles seroprevalence among 469 newly hired HCP at a hospital in North Carolina who were born before 1957, and thus considered immune by age, who could not provide written evidence of immunity to measles, serologic testing indicated that six (1.3%) lacked measles IgG antibodies (157). Other serologic studies of hospital-based HCP indicate that 2%–9% of those born before 1957 lacked antibodies to measles (156,158–160).

A survey conducted during 1999–2004 found a seroprevalence of measles antibodies of 95.9% among persons in the U.S. population aged 6–49 years (161). The survey

indicated that the lowest prevalence, 92.4%, was among adults born during 1967–1976 (161). A 1999 study of U.S. residents aged ≥20 years determined that 93% had antibodies to measles virus (162).

Vaccine Safety

Measles vaccine is administered in combination with the mumps and rubella components as the MMR vaccine in the United States. Monovalent measles vaccine rarely has been used in the United States in the past 2 decades and is no longer available. After decades of use, evidence demonstrates that MMR vaccine has an excellent safety profile (134).

The majority of documented adverse events occur in children. In rare circumstances, MMR vaccination of adults has been associated with the following adverse events: anaphylaxis (approximately 1.0–3.5 occurrences per million doses administered) (134), thrombocytopenia from the measles component or rubella component (a rate of three to four cases for every 100,000 doses) (134), and acute arthritis from the rubella component (arthralgia develops among approximately 25% of rubella-susceptible postpubertal females after MMR vaccination, and approximately 10% have acute arthritis-like signs and symptoms) (135). When joint symptoms occur, they generally persist for 1 day–3 weeks and rarely recur (135). Chronic joint symptoms attributable to the rubella component of the MMR vaccine are reported very rarely, if they occur at all. Evidence does not support an association between MMR vaccination and any of the following: hearing loss, retinopathy, optic neuritis, Guillain-Barré Syndrome, type 1 diabetes, Crohn's disease, or autism (135,163–169).

A woman can excrete the rubella vaccine virus in breast milk and transmit the virus to her infant, but the infection remains asymptomatic (135). Otherwise, persons who receive MMR or its component vaccines do not transmit measles, rubella, or mumps vaccine viruses (135). No transmission of MMR vaccine virus in a health-care setting has been documented.

Recommendations

Vaccination

All persons who work in health-care facilities should have presumptive evidence of immunity to measles. This information should be documented and readily available at the work location. Recently vaccinated HCP do not require any restriction in their work activities.

Presumptive evidence of immunity to measles for persons who work in health-care facilities includes any of the following:

- written documentation of vaccination with 2 doses of live measles or MMR vaccine administered at least 28 days apart,[†]
- laboratory evidence of immunity,[§]
- laboratory confirmation of disease, or
- birth before 1957.[¶]

Prevaccination Testing

Prevaccination antibody screening before MMR vaccination for an employee who does not have adequate presumptive evidence of immunity is not necessary unless the medical facility considers it cost effective (134,170–172) although no recent studies have been conducted. For HCP who have 2 documented doses of MMR vaccine or other acceptable evidence of immunity to measles, serologic testing for immunity is not recommended. In the event that a HCP who has 2 documented doses of MMR vaccine is tested serologically and determined to have negative or equivocal measles titer results, it is not recommended that the person receive an additional dose of MMR vaccine. Such persons should be considered to have presumptive evidence of measles immunity. Documented age-appropriate vaccination supersedes the results of subsequent serologic testing. Because rapid vaccination is necessary to halt disease transmission, during outbreaks of measles, serologic screening before vaccination is not recommended.

Use of Vaccine and Immune Globulin for Treating Exposed Persons and Controlling Outbreaks

Following airborne infection–control precautions and implementing other infection–control measures are important to control the spread of measles but might fail to prevent all nosocomial transmission, because transmission to other susceptible persons might occur before illness is recognized. Persons infected with measles are infectious 4 days before rash onset through 4 days after rash onset.

When a person who is suspected of having measles visits a health-care facility, airborne infection–control precautions should be followed stringently. The patient should be asked immediately to wear a medical mask and should be placed

in an airborne-infection isolation room (i.e., a negative air-pressure room) as soon as possible. If an airborne-infection isolation room is not available, the patient should be placed in a private room with the door closed and be asked to wear a mask. If possible, only staff with presumptive evidence of immunity should enter the room of a person with suspect or confirmed measles. Regardless of presumptive immunity status, all staff entering the room should use respiratory protection consistent with airborne infection–control precautions (i.e., use of an N95 respirator or a respirator with similar effectiveness in preventing airborne transmission) (3,150).

Because of the possibility, albeit low (~1%), of measles vaccine failure in HCP exposed to infected patients (173), all HCP should observe airborne precautions in caring for patients with measles. HCP in whom measles occurs should be excluded from work until ≥4 days following rash onset. Contacts with measles-compatible symptoms should be isolated, and appropriate infection–control measures (e.g., rapid vaccination of susceptible contacts) should be implemented to prevent further spread (174).

If measles exposures occur in a health-care facility, all contacts should be evaluated immediately for presumptive evidence of measles immunity. HCP without evidence of immunity should be offered the first dose of MMR vaccine and excluded from work from day 5–21 following exposure (135). HCP without evidence of immunity who are not vaccinated after exposure should be removed from all patient contact and excluded from the facility from day 5 after their first exposure through day 21 after the last exposure, even if they have received postexposure intramuscular immune globulin of 0.25 mL/kg (40 mg IgG/kg) (135). Those with documentation of 1 vaccine dose may remain at work and should receive the second dose.

Case-patient contacts who do not have presumptive evidence of measles immunity should be vaccinated, offered intramuscular immune globulin of 0.25 mL/kg (40 mg IgG/kg), which is the standard dosage for nonimmunocompromised persons (135), or quarantined until 21 days after their exposure to the case-patient. Contacts with measles-compatible symptoms should be isolated, and appropriate infection–control measures should be implemented to prevent further spread. If immune globulin is administered to an exposed person, observations should continue for signs and symptoms of measles for 28 days after exposure because immune globulin might prolong the incubation period.

Available data suggest that live virus measles vaccine, if administered within 72 hours of measles exposure, will prevent, or modify disease (134). Even if it is too late to provide effective postexposure prophylaxis by administering MMR, the vaccine can provide protection against future exposure to all three infections. Identifying persons who lack evidence of measles immunity during

[†] The first dose of measles-containing vaccine should be administered on or after the first birthday; the second dose should be administered no earlier than 28 days after the first dose.

[§] Measles immunoglobulin (IgG) in the serum; equivocal results should be considered negative.

[¶] The majority of persons born before 1957 are likely to have been infected naturally and may be presumed immune, depending on current state or local requirements. For unvaccinated personnel born before 1957 who lack laboratory evidence of measles immunity or laboratory confirmation of disease, health-care facilities should consider vaccinating personnel with 2 doses of MMR vaccine at the appropriate interval. For unvaccinated personnel born before 1957 who lack laboratory evidence of measles immunity or laboratory confirmation of disease, health-care facilities should recommend 2 doses of MMR vaccine during an outbreak of measles.

contact investigations provides a good opportunity to offer MMR vaccine to protect against measles as well as mumps and rubella, not only for HCP who are part of an organization's vaccination program, but also for patients and visitors. If an exposed person is already incubating measles, MMR vaccination will not exacerbate symptoms. In these circumstances, persons should be advised that a measles-like illness occurring shortly after vaccination could be attributable either to natural infection or to the vaccine strain. In such circumstances, specimens should be submitted for viral strain identification.

Mumps

Background

Epidemiology and Risk Factors

Mumps is an acute viral infection characterized by fever and inflammation of the salivary glands (usually parotitis) (175). The spectrum of illness ranges from subclinical infection (20%–40%) to nonspecific respiratory illness, sialadenitis including classic parotitis, deafness, orchitis, and meningoencephalitis; severity increases with age (175). In the prevaccine era, mumps was a common childhood illness, with approximately 186,000 mumps cases reported in the United States per year (176). After the introduction of the Jeryl Lynn strain mumps vaccine in 1967 and the implementation of the 1-dose mumps vaccine policy for children in 1977 (177), reports of mumps cases in the United States declined 99% (178). During 1986–1987, an increase in reported mumps cases occurred, primarily affecting unvaccinated adolescents and young adults. In the late 1980s, sporadic outbreaks continued to occur that affected both unvaccinated and 1-dose vaccinated adolescents and young adults (178). In 1989, a second dose of MMR vaccine was recommended nationwide for better measles control among school-aged children (179). Historically low rates of mumps followed with only several hundred reported cases per year in the United States during 2000–2005.

In 1998, a national goal to eliminate mumps was set for 2010 (180). However, in 2006, a total of 6,584 mumps cases were reported in the United States, the largest U.S. mumps outbreak in nearly 20 years (181–183). Whereas overall national mumps incidence was 2.2 per 100,000 population, eight states in the Midwest were the most affected, with 2.5–66.1 cases per 100,000 population (183). The highest incidence (31.1 cases per 100,000 population) was among persons aged 18–24 years (e.g., college-aged students), the majority of whom had received 2 doses of mumps-containing vaccine. Of the 4,017 case-patients for whom age and vaccination status were known, 1,786 (44%) were aged ≥ 25 years (incidence: 7.2 cases per 100,000 persons); of these 1,786 patients, 351 (20%) received

at least 2 doses, 444 (25%) received 1 dose, 336 (19%) were unvaccinated, and 655 (37%) had unknown vaccination status.

Since the 2006 resurgence, two additional large U.S. mumps outbreaks have occurred, both during 2009–2010, one among members of a religious community with cases occurring throughout the northeastern United States (184) and the other in Guam (185); both outbreaks primarily affected children and adolescents in crowded environments who had received 2 doses of vaccine.

Vaccine coverage in the United States is high; in 2010, approximately 91.5% of children aged 19–35 months had received 1 dose of MMR vaccine (21); during 2009–2010, a total of 94.8% of kindergartners had evidence of 2 doses (148). In 2010, a total of 90.5% of adolescents had evidence of 2 doses (22). Nationally representative data on MMR vaccine coverage of U.S. HCP are not available.

Mumps Transmission and the Costs of Mitigating Mumps Exposures in Health-care Settings

Although health-care-associated transmission of mumps is infrequent, it might be underreported because of the high percentage (~20%–40%) of infected persons who might be asymptomatic (186–189). In a survey of 9,299 adults in different professions conducted in 1968, before vaccine was used routinely, the rate of mumps acquisition was highest among dentists and HCP, with rates of 18% among dentists and 15% among physicians (37% for pediatricians), compared with 9% among primary and secondary school teachers and 2% among university staff members (190).

In the postvaccine era, mumps transmission also has been documented in medical settings (191–193). During a Tennessee mumps outbreak during 1986–1987, a total of 17 (12%) of 146 hospitals and three (50%) of six long-term-care facilities reported one or more practices that could contribute to the spread of mumps, including not isolating patients with mumps, assigning susceptible staff to care for patients with mumps, and not immunizing susceptible employees. Health-care-associated transmission resulted in six cases of mumps infections among health-care providers and nine cases of mumps infections among patients (191). In Utah in 1994, two health-care providers in a hospital developed mumps after they had contact with an infected patient (192). During the 2006 outbreak, one health-care facility in Chicago experienced ongoing mumps transmission lasting 4 weeks (193).

During the 2006 multistate U.S. outbreak, 144 (8.5%) of 1,705 adult case-patients in Iowa for whom occupation was known were health-care providers (Iowa Department of Public Health, unpublished data, 2006). Whether transmission occurred from patients, coworkers, or persons in

the community is unknown. During the 2009–2010 outbreak in the northeastern region of the United States, seven (0.2%) of the 3,400 case-patients were health-care providers, six of whom likely were infected by patients because they had no other known exposure.

Exposures to mumps in health-care settings also can result in added economic costs because of furlough or reassignment of staff members from patient-care duties or closure of wards (194). In 2006, a Kansas hospital spent \$98,682 containing a mumps outbreak (195). During a mumps outbreak in Chicago in 2006, one health-care facility spent \$262,788 controlling the outbreak (193).

Vaccine Effectiveness, Duration of Immunity and Seroprevalence Studies, and Vaccine Safety

Vaccine Effectiveness

MMR vaccine has a 1-dose vaccine effectiveness in preventing mumps of 80%–85% (range: 75%–91%) (175,196–199) and a 2-dose vaccine effectiveness of 79%–95% (199–202). In a study conducted on two Iowa college campuses during the 2006 mumps outbreak among a population that was primarily vaccinated with 2 doses, 2-dose vaccine effectiveness ranged from 79% to 88% (202).

Duration of Immunity and Seroprevalence Studies

Mumps antibody levels wane over time following the first or second dose of vaccination (203,204), but the correlates of immunity to mumps are poorly understood and the significance of these waning antibody levels is unclear. A study on a university campus in Nebraska in 2006 indicated lower levels of mumps neutralizing antibodies among students who had been vaccinated with a second MMR dose >15 years previously than among those who had been vaccinated 1–5 years previously, but the difference was not statistically significant ($p>0.05$) (205). In a 2006 study on a university campus in Kansas, students with mumps were more likely to have received a second dose of MMR vaccine ≥ 10 years previously than were their roommates without mumps (206). However, another 2006 study from an Iowa college campus identified no such association (202).

During 1999–2004, national seroprevalence for mumps antibodies for persons aged 6–49 years was 90% (95% confidence interval [CI]: 88.8–91.1) (207). In the Nebraska study, 414 (94%) of the 440 participants were seropositive for mumps antibodies (205). A study in Kansas in 2006 indicated that 13% of hospital employees lacked antibodies to the mumps virus (195). In a recent study on mumps seroprevalence among 381 newly hired health-care personnel at a hospital in North Carolina who were born before 1957 and thus considered

immune by age and who could not provide written evidence of immunity to mumps, serologic testing indicated that 14 (3.7%) lacked IgG antibodies to mumps (157).

Vaccine Safety

Mumps vaccine is administered in combination with the measles and rubella components as the MMR vaccine in the United States. Monovalent mumps vaccine has rarely been used in the United States in the past 2 decades and is no longer available. After decades of use, evidence demonstrates that MMR vaccine has an excellent safety profile. The most common adverse reactions to the mumps component of the MMR vaccine are parotitis 10–14 days after vaccination and low-grade fever (175). On the basis of biologic plausibility, orchitis, arthritis, or sensorineural deafness might rarely follow vaccination (175).

The majority of documented adverse events occur in children. In rare circumstances, MMR vaccination of adults has been associated with anaphylaxis (approximately 1.0–3.5 occurrences per million doses administered) (134), thrombocytopenia from the measles component or rubella component (rate: three to four cases for every 100,000 doses) (134), and acute arthritis from the rubella component (arthralgia develops among approximately 25% of rubella-susceptible postpubertal females after MMR vaccination, and approximately 10% have acute arthritis-like signs and symptoms) (135). When joint symptoms occur, they generally persist for 1 day–3 weeks and rarely recur (135). Chronic joint symptoms attributable to the rubella component of the MMR vaccine are reported rarely, if they occur at all. Evidence does not support a link between MMR vaccination and hearing loss, retinopathy, optic neuritis, Guillain-Barré Syndrome, type 1 diabetes, Crohn's disease, or autism (135,163–169).

A woman can excrete the rubella vaccine virus in breast milk and transmit the virus to her infant, but the infection remains asymptomatic (135). Otherwise, persons who receive MMR or its component vaccines do not transmit measles, rubella, or mumps vaccine viruses (135). No transmission of MMR vaccine virus in a health-care setting has been documented.

Recommendations

Vaccination

All persons who work in health-care facilities should have presumptive evidence of immunity to mumps. This information should be documented and readily available at the work location. Recently vaccinated HCP do not require any restriction in their work activities.

Presumptive evidence of immunity to mumps for persons who work in health-care facilities includes any of the following:

- written documentation of vaccination with 2 doses of live mumps or MMR vaccine administered at least 28 days apart,**
- laboratory evidence of immunity,††
- laboratory confirmation of disease, or
- birth before 1957.§§

Prevaccination Testing

For HCP who do not have adequate presumptive evidence of mumps immunity, prevaccination antibody screening before MMR vaccination is not necessary (135,175). For HCP who have 2 documented doses of MMR vaccine or other acceptable evidence of immunity to mumps, serologic testing for immunity is not recommended. In the event that a health-care provider who has 2 documented doses of MMR vaccine is tested serologically and determined to have negative or equivocal mumps titer results, it is not recommended that the person receive an additional dose of MMR vaccine. Such persons should be considered immune to mumps. Documented age-appropriate vaccination supersedes the results of subsequent serologic testing. Likewise, during outbreaks of mumps, serologic screening before vaccination is not recommended because rapid vaccination is necessary to halt disease transmission.

Controlling Mumps Outbreaks in Health-Care Settings

Placing patients in droplet precautions and implementing other infection-control measures is important to control the spread of mumps but might fail to prevent all nosocomial transmission, because transmission to other susceptible persons might occur before illness is recognized (208). When a person suspected of having mumps visits a health-care facility, only HCP with adequate presumptive evidence of immunity should be exposed to the person, and in addition to standard precautions, droplet precautions should be followed. The index case-patient should be isolated, and respiratory precautions

(gown and gloves) should be used for patient contact. Negative pressure rooms are not required. The patient should be isolated for 5 days after the onset of parotitis, during which time shedding of virus is likely to occur (209).

If mumps exposures occur in a health-care facility, all contacts should be evaluated for evidence of mumps immunity. HCP with no evidence of mumps immunity who are exposed to patients with mumps should be offered the first dose of MMR vaccine as soon as possible, but vaccine can be administered at any interval following exposure; they should be excluded from duty from day 12 after the first unprotected exposure through day 25 after the most recent exposure. HCP with documentation of 1 vaccine dose may remain at work and should receive the second dose. HCP with mumps should be excluded from work for 5 days from the onset of parotitis (209).

Antibody response to the mumps component of MMR vaccine generally is believed not to develop soon enough to provide effective prophylaxis after exposure to suspected mumps (191,210), but data are insufficient to rule out a prophylactic effect. Nonetheless, the vaccine is not recommended for prophylactic purposes after exposure. However, identifying persons who lack presumptive evidence of mumps immunity during contact investigations provides a good opportunity to offer MMR vaccine to protect against mumps as well as measles and rubella, not only for HCP who are part of an organization's vaccination program, but also for patients and visitors. If an exposed person already is incubating mumps, MMR vaccination will not exacerbate the symptoms. In these circumstances persons should be advised that a mumps-like illness occurring shortly after vaccination is likely to be attributable to natural infection. In such circumstances, specimens should be submitted for viral strain identification to differentiate between vaccine and wild type virus. Immune globulin is not routinely used for postexposure protection from mumps because no evidence exists that it is effective (135).

Rubella

Background

Epidemiology and Risk Factors

Rubella (German measles) is a viral disease characterized by rash, low-grade fever, lymphadenopathy, and malaise (211). Although rubella is considered a benign disease, transient arthralgia and arthritis are observed commonly in infected adults, particularly among postpubertal females. Chronic arthritis has been reported after rubella infection, but such reports are rare, and evidence of an association is weak (212). Other complications that occur infrequently

** The first dose of mumps-containing vaccine should be administered on or after the first birthday; the second dose should be administered no earlier than 28 days after the first dose.

†† Mumps immunoglobulin (IgG) in the serum; equivocal results should be considered negative.

§§ The majority of persons born before 1957 are likely to have been infected naturally between birth and 1977, the year that mumps vaccination was recommended for routine use, and may be presumed immune, even if they have not had clinically recognizable mumps disease. (This might vary depending on current state or local requirements.) For unvaccinated personnel born before 1957 who lack laboratory evidence of mumps immunity or laboratory confirmation of disease, health-care facilities should consider vaccinating personnel with 2 doses of MMR vaccine at the appropriate interval; for unvaccinated personnel born before 1957 who lack laboratory evidence of mumps immunity or laboratory confirmation of disease, health-care facilities should recommend 2 doses of MMR vaccine during an outbreak of mumps.

are thrombocytopenia and encephalitis (211). Infection is asymptomatic in 25%–50% of cases (213). Clinical diagnosis of rubella is unreliable and should not be considered in assessing immune status. Many rash illnesses might mimic rubella infection and many rubella infections are unrecognized. The only reliable evidence of previous rubella infection is the presence of serum rubella IgG antibody (211).

Of primary concern are the effects that rubella can have when a pregnant woman becomes infected, especially during the first trimester, which can result in miscarriages, stillbirths, therapeutic abortions, and congenital rubella syndrome (CRS), a constellation of birth defects that often includes blindness, deafness, mental retardation, and congenital heart defects (211,213). Postnatal rubella is transmitted through direct or droplet contact from nasopharyngeal secretions. The incubation period ranges from 12 to 23 days (214,215). An ill person is most contagious when the rash first appears, but the period of maximal communicability extends from a few days before to 7 days after rash onset (213). Rubella is less contagious than measles.

In the prevaccine era, rubella was an endemic disease globally with larger epidemics that occurred; in the United States, rubella epidemics occurred approximately every 7 years (211). During the 1964–1965 global rubella epidemic, an estimated 12.5 million cases of rubella occurred in the United States, resulting in approximately 2,000 cases of encephalitis, 11,250 fetal deaths attributable to spontaneous or surgical abortions, 2,100 infants who were stillborn or died soon after birth, and 20,000 infants born with CRS. The economic impact of this epidemic in the United States alone was estimated at \$1.5 billion in 1965 dollars (\$10 billion in 2010 dollars) (216).

After the rubella vaccine was licensed in the United States in 1969, reported rubella cases decreased from 57,686 in 1969 to 12,491 in 1976 (216), and CRS cases reported nationwide decreased from 68 in 1970 to 23 in 1976 (217). Declines in rubella age-specific incidence occurred in all age groups, including adolescents and adults, but the greatest declines were among children aged <15 years (216). During 1977–1978, a resurgence of rubella occurred, primarily among older adolescents and young adults, because the initial vaccination strategy targeted children (218). During this resurgence, 62% of reported rubella cases occurred among persons aged >15 years compared with 23% of cases during 1966–1968 (135). As a result of the change in the epidemiologic profile of rubella, in 1977, ACIP modified its recommendations to include the vaccination of susceptible postpubertal girls and women. In 1989, a second MMR vaccination dose was recommended in response to large measles outbreaks nationwide (179). During

2001–2004, the annual numbers of rubella and CRS cases were extremely low, with 23 reported rubella cases in 2001, a total of 18 in 2002, a total of 7 in 2003, and a total of 9 in 2004 (219).

Rubella was declared eliminated from the United States in 2004 (219,220). During 2005–2009, a total of 54 cases of rubella were reported; the majority of the cases occurred among persons aged >20 years. Of the reported cases, 23 (43%) were import-associated; only two outbreaks of rubella were reported during this time, and both involved only three cases (CDC, unpublished data, 2009). Since 2005, only four cases of CRS have been reported, with two cases reported in 2009; three (75%) cases were acquired internationally, and the other had an unknown source (CDC, unpublished data, 2009). Rubella importations are expected to continue in the immediate future.

As of September 2011, only three states (i.e., New York, Oklahoma, and Rhode Island) had laws mandating that all hospital personnel have proof of rubella immunity and did not allow for religious or philosophical exemptions (147). Additional states had requirements for specific types of facilities or for certain employees within those facilities, but they did not have universal laws mandating proof of rubella immunity for all hospital personnel (147).

MMR vaccine coverage in the United States is high; in 2010, an estimated 91.5% of children aged 19–35 months had received 1 dose of MMR vaccine (21); during 2009–2010, a total of 94.8% of kindergarteners had evidence of 2 doses (148); and in 2010, a total of 90.5% of adolescents had evidence of 2 doses (22). Nationally representative data on MMR vaccine coverage of U.S. HCP are not available.

Rubella Transmission and the Costs of Mitigating Rubella Exposures in Health-Care Settings

No documented transmission of rubella to HCP or other hospital staff or patients in U.S. health-care facilities has occurred since elimination was declared. However, in the decades before elimination, rubella transmission was documented in at least 10 U.S. medical settings (221–231) and led to outbreaks with serious consequences, including pregnancy terminations, disruption of hospital routine, absenteeism from work, expensive containment measures, negative publicity, and the threat of litigation (232). In these outbreaks, transmission occurred from HCP to susceptible coworkers and patients, as well as from patients to HCP and other patients. No data are available on whether HCP are at increased risk for acquiring rubella compared with other professions.

Vaccine Effectiveness, Duration of Immunity and Seroprevalence Studies, and Vaccine Safety

Vaccine Effectiveness

Vaccine effectiveness of the RA 27/3 rubella vaccine against clinical rubella is 95% (85%–99% CI) and >99% for clinical laboratory confirmed rubella (211,233). Antibody responses to rubella as part of MMR vaccine are equal (i.e., >99%) to those seen after the single-antigen RA 27/3 rubella vaccine (211,234).

Duration of Immunity and Seroprevalence Studies

In clinical trials, 97%–99% of susceptible persons who received a single dose of the RA 27/3 rubella vaccine when they were aged ≥ 12 months developed antibody (211,235,236). Two studies have demonstrated that vaccine-induced rubella antibodies might wane after 12–15 years (237,238); however, rubella surveillance data do not indicate that rubella and CRS are increasing among vaccinated persons.

National seroprevalence for rubella antibodies among persons aged 6–49 years during 1999–2004 was 91% (239). During 1986–1990, serologic surveys in one hospital indicated that 5% of HCP (including persons born in 1957 or earlier) did not have detectable rubella antibody (240). Earlier studies indicated that up to 14%–19% of U.S. hospital personnel, including young women of childbearing age, lacked detectable rubella antibody (225,241,242). In a recent study on rubella seroprevalence among 477 newly hired HCP at a hospital in North Carolina who were born before 1957, and thus considered immune by age, who could not provide written evidence of immunity to rubella, serologic testing revealed that 14 (3.1%) lacked detectable levels of antibody to rubella (157).

Because of the potential for contact with pregnant women in any type of health-care facility, all HCP should have documented presumptive evidence of immunity to rubella. History of disease is not considered adequate evidence of immunity.

Vaccine Safety

Rubella vaccine is administered in combination with the measles and mumps components as the MMR vaccine in the United States. Monovalent rubella vaccine has been used rarely in the United States in the past 2 decades and is no longer available. After decades of use, evidence demonstrates that MMR vaccine has an excellent safety profile. The most common adverse reactions to the rubella component of the MMR vaccine are transient rashes, which usually appear 7–10 days after vaccination in approximately 5% of vaccinated persons, or transient lymphadenopathy, fever, sore throat, and headache (135,211).

The majority of documented adverse events occur in children. In rare circumstances, MMR vaccination of adults has been associated with the following adverse events: anaphylaxis (approximately 1.0–3.5 occurrences per million doses administered) (134), thrombocytopenia from the measles component or rubella component (rate: three to four cases for every 100,000 doses) (134), and acute arthritis from the rubella component (arthralgia develops among approximately 25% of rubella-susceptible postpubertal females after MMR vaccination, and approximately 10% have acute arthritis-like signs and symptoms from the rubella component of the vaccine) (135). When joint symptoms occur, they generally persist for 1 day–3 weeks and rarely recur (135). Chronic joint symptoms attributable to the rubella component of the MMR vaccine are very rarely reported, if they occur at all.

As a result of the theoretic risk to the fetus, women should be counseled to avoid becoming pregnant for 28 days after receipt of a rubella-containing vaccine (243). However, receipt of rubella-containing vaccine during pregnancy should not be a reason to consider termination of pregnancy; data from 18 years of following to term 321 known rubella-susceptible women who were vaccinated within 3 months before or 3 months after conception indicated that none of the 324 infants born to these mothers had malformations compatible with congenital rubella syndrome, but five had evidence of subclinical rubella infection (244). The estimated risk for serious malformations to fetuses attributable to the mother receiving RA 27/3 vaccine is considered to range from zero to 1.6% (135,244).

Evidence does not support a link between MMR vaccination and any of the following: hearing loss, retinopathy, optic neuritis, Guillain-Barré Syndrome, type 1 diabetes, Crohn's disease, or autism (135,163–169).

A woman can excrete the rubella vaccine virus in breast milk and transmit the virus to her infant, but the infection remains asymptomatic (135). Otherwise, persons who receive MMR or its component vaccines do not transmit measles, rubella, or mumps vaccine viruses (135). No transmission of MMR vaccine virus in a health-care setting has been documented.

Recommendations

Vaccination

All persons who work in health-care facilities should have presumptive evidence of immunity to rubella. Adequate rubella vaccination for HCP consists of 1 dose of MMR vaccine. However, because of the 2-dose vaccination requirements for measles and mumps, the use of the combined MMR vaccine will result in the majority of HCP receiving 2 doses of rubella-containing vaccine, which should provide an additional safeguard

against primary rubella vaccine failure. Recently vaccinated HCP do not require any restriction in their work activities.

Presumptive evidence of immunity to rubella for persons who work in health-care facilities includes any of the following:

- written documentation of vaccination with 1 dose of live rubella or MMR vaccine,
- laboratory evidence of immunity,^{¶¶}
- laboratory confirmation of rubella infection or disease, or
- birth before 1957^{***} (except women of childbearing potential who could become pregnant, although pregnancy in this age group would be exceedingly rare^{†††}).

Prevaccination Testing

For HCP who do not have adequate presumptive evidence of rubella immunity, prevaccination antibody screening before MMR vaccination is not necessary unless the medical facility considers it cost effective (135). For HCP who have 1 documented dose of MMR vaccine or other acceptable evidence of immunity to rubella, serologic testing for immunity is not recommended. In the event that a health-care provider who has at least 1 documented dose of rubella-containing vaccine is tested serologically and determined to have negative or equivocal rubella titer results, receipt of an additional dose of MMR vaccine for prevention of rubella is not recommended. Such persons should be considered immune to rubella. However, if the provider requires a second dose of measles or mumps vaccine, then a second dose of MMR should be administered. Documented age-appropriate vaccination supersedes the results of subsequent serologic testing. Likewise, during outbreaks of rubella, serologic screening before vaccination is not recommended because rapid vaccination is necessary to halt disease transmission.

Controlling Rubella Outbreaks

To prevent transmission of rubella in health-care settings, patients suspected to have rubella should be placed in private rooms. In addition to standard precautions, droplet precautions

should be followed until 7 days after onset of symptoms. Room doors can remain open, and special ventilation is not required.

Any exposed HCP who do not have adequate presumptive evidence of rubella immunity should be excluded from duty beginning 7 days after exposure to rubella and continuing through either 1) 23 days after the most recent exposure or 2) 7 days after rash appears if the provider develops rubella (213–215). Exposed HCP who do not have adequate presumptive evidence of immunity who are vaccinated postexposure should be excluded from duty for 23 days after the most recent exposure to rubella because no evidence exists that postexposure vaccination is effective in preventing rubella infection (244).

Neither rubella-containing vaccine (244) nor immune globulin (IG) (211,244) is effective for postexposure prophylaxis of rubella. Although intramuscular administration of 20 mL of immune globulin within 72 hours of rubella exposure might reduce the risk for rubella, it will not eliminate the risk (135,245); infants with congenital rubella have been born to women who received IG shortly after exposure (213). In addition, administration of IG after exposure to rubella might modify or suppress symptoms and create an unwarranted sense of security with respect to transmission.

If exposure to rubella does not cause infection, postexposure vaccination with MMR vaccine should induce protection against subsequent infection of rubella, as well as measles and mumps. If the exposure results in infection, no evidence indicates that administration of MMR vaccine during the presymptomatic or prodromal stage of illness increases the risk for vaccine-associated adverse events (213).

Pertussis

Background

Epidemiology and Risk Factors

Pertussis is a highly contagious bacterial infection. Secondary attack rates among susceptible household contacts exceed 80% (246,247). Transmission occurs by direct contact with respiratory secretions or large aerosolized droplets from the respiratory tract of infected persons. The incubation period is generally 7–10 days but can be as long as 21 days. The period of communicability starts with the onset of the catarrhal stage and extends into the paroxysmal stage. Symptoms of early pertussis (catarrhal phase) are indistinguishable from other upper respiratory infections.

Vaccinated adolescents and adults, whose immunity from childhood vaccinations wanes 5–10 years after the most recent dose of vaccine (usually administered at age 4–6 years), are an

^{¶¶} Rubella immunoglobulin (IgG) in the serum; equivocal results should be considered negative.

^{***} Depending on current state or local requirements, for unvaccinated personnel born before 1957 who lack laboratory evidence of rubella immunity or laboratory confirmation of infection or disease, health-care facilities should consider vaccinating personnel with one dose of MMR vaccine; for unvaccinated personnel born before 1957 who lack laboratory evidence of rubella immunity or laboratory confirmation of infection or disease, health-care facilities should recommend 1 dose of MMR vaccine during an outbreak of rubella.

^{†††} Because rubella can occur in some persons born before 1957 and because congenital rubella and congenital rubella syndrome can occur in the offspring of women infected with rubella virus during pregnancy, birth before 1957 is not acceptable evidence of rubella immunity for women who could become pregnant.

important source of pertussis infection for susceptible infants. Infants too young to be vaccinated are at greatest risk for severe pertussis, including hospitalization and death. The disease can be transmitted from adults to close contacts, especially unvaccinated children.

Vaccination coverage among infants and children for diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine remains high. In 2010, coverage for children aged 19–35 months who have received ≥ 4 doses of DTaP/diphtheria and tetanus toxoids and pertussis vaccine (DTP)/diphtheria and tetanus toxoids vaccine (DT) was 84% (21). Among children entering kindergarten for the 2009–2010 school year, DTaP coverage was 93% (148). Vaccination coverage for tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine was 68.7% among adolescents in 2010 and <7% among adults in 2009 (22,248). Tdap vaccination coverage among HCP was 17.0% in 2009 (248).

Disease in Health-Care Settings and Impact on Health-Care Personnel and Patients

In hospital settings, transmission of pertussis has occurred from hospital visitors to patients, from HCP to patients, and from patients to HCP (249–252). Although of limited size (range: 2–17 patients and 5–13 staff), documented outbreaks were costly and disruptive. In each outbreak, HCP were evaluated for cough illness and required diagnostic testing, prophylactic antibiotics, and exclusion from work.

During outbreaks that occur in hospitals, the risk for contracting pertussis among patients or staff is often difficult to quantify because exposure is not well defined. Serologic studies conducted among hospital staff indicate that exposure to pertussis is much more frequent than suggested by attack rates of clinical disease (246,249–254). In one outbreak, seroprevalence of pertussis agglutinating antibodies among HCP correlated with the degree of patient contact and was highest among pediatric house staff (82%) and ward nurses (71%) and lowest among nurses with administrative responsibilities (35%) (251).

A model to estimate the cost of vaccinating HCP and the net return from preventing nosocomial pertussis was constructed using probabilistic methods and a hypothetical cohort of 1,000 HCP with direct patient contact followed for 10 years (255). Baseline assumptions, determined from data in the literature, included incidence of pertussis in HCP, ratio of identified exposures per HCP case, symptomatic percentage of seroconfirmed pertussis infections in HCP, cost of infection-control measures per exposed person, vaccine efficacy, vaccine coverage, employment turnover rate, adverse events, and cost of vaccine (255). In a 10-year period, the cost of infection

control would be \$388,000 without Tdap vaccination of HCP compared with \$69,000 with such a program (255). Introduction of a vaccination program would result in a net savings as high as \$535,000 and a benefit-cost ratio of 2.38 (i.e., for every dollar spent on the vaccination program, the hospital would save \$2.38 on control measures) (255).

Vaccine Effectiveness, Duration of Immunity, and Vaccine Safety

A prelicensure immunogenicity and safety study in adolescents and adults of a vaccine containing acellular pertussis estimated vaccine efficacy to be 92% (256). Recent postlicensure studies of Tdap demonstrate vaccine effectiveness at 78% and 66% (257,258). Duration of immunity from vaccination has yet to be evaluated. Data from pre- and postlicensure studies support the safety of Tdap in adolescents and adults (259–263).

Since the 2005 Tdap recommendations for HCP, one study tried to determine if postexposure prophylaxis following pertussis exposure was necessary for Tdap-vaccinated HCP (264). During the study period, 116 exposures occurred among 94 HCP. Pertussis infection occurred in 2% of those who received postexposure prophylaxis compared with 10% of those who did not, suggesting a possible benefit of postexposure prophylaxis among Tdap-vaccinated HCP (264). Because Tdap coverage is suboptimal among HCP, and the duration of protection afforded by Tdap is unknown, vaccination status does not change the approach to evaluate the need for postexposure prophylaxis in exposed HCP. Postexposure prophylaxis is necessary for HCP in contact with persons at risk for severe disease. Other HCP either should receive postexposure prophylaxis or be monitored for 21 days after pertussis exposure and treated at the onset of signs and symptoms of pertussis. Recommended postexposure prophylaxis antibiotics for HCP exposed to pertussis include azithromycin, clarithromycin, or erythromycin. HCP are not at greater risk for diphtheria or tetanus than the general population.

Recommendations

Vaccination

Regardless of age, HCP should receive a single dose of Tdap as soon as feasible if they have not previously received Tdap and regardless of the time since their most recent Td vaccination. Vaccinating HCP with Tdap will protect them against pertussis and is expected to reduce transmission to patients, other HCP, household members, and persons in the community. Tdap is not licensed for multiple administrations; therefore, after receipt of Tdap, HCP should receive Td for future booster vaccination against tetanus and diphtheria. Hospitals and ambulatory-care facilities should provide Tdap for HCP and

use approaches that maximize vaccination rates (e.g., education about the benefits of vaccination, convenient access, and the provision of Tdap at no charge).

Prevaccination Testing

Prevaccination serologic testing is not recommended.

Demonstrating Immunity

Immunity cannot be demonstrated through serologic testing because serologic correlates of protection are not well established.

Controlling Pertussis Outbreaks in Health-Care Settings

Prevention of pertussis transmission in health-care settings involves diagnosis and early treatment of clinical cases, droplet isolation of infectious patients who are hospitalized, exclusion from work of HCP who are infectious, and postexposure prophylaxis. Early diagnosis of pertussis, before secondary transmission occurs, is difficult because the disease is highly communicable during the catarrhal stage, when symptoms are still nonspecific. Pertussis should be considered in the differential diagnoses for any patient with an acute cough illness with severe or prolonged paroxysmal cough, particularly if characterized by posttussive vomiting, whoop, or apnea. Nasopharyngeal specimens should be taken, if possible, from the posterior nasopharynx with a calcium alginate or Dacron swab for cultures and/or polymerase chain reaction (PCR) assay.

Health-care facilities should maximize efforts to prevent transmission of *Bordetella pertussis*. Precautions to prevent respiratory droplet transmission or spread by close or direct contact should be employed in the care of patients admitted to hospital with suspected or confirmed pertussis (265). These precautions should remain in effect until patients are improved clinically and have completed at least 5 days of appropriate antimicrobial therapy. HCP in whom symptoms (i.e., unexplained rhinitis or acute cough) develop after known pertussis exposure might be at risk for transmitting pertussis and should be excluded from work until 5 days after the start of appropriate therapy (3).

Data on the need for postexposure prophylaxis in Tdap-vaccinated HCP are inconclusive (264). Certain vaccinated HCP are still at risk for *B. pertussis*. Tdap might not preclude the need for postexposure prophylaxis. Postexposure antimicrobial prophylaxis is recommended for all HCP who have unprotected exposure to pertussis and are likely to expose a patient at risk for severe pertussis (e.g., hospitalized neonates and pregnant women). Other HCP should either receive postexposure antimicrobial prophylaxis or be monitored daily

for 21 days after pertussis exposure and treated at the onset of signs and symptoms of pertussis.

Varicella

Background

Epidemiology and Risk Factors

Varicella is a highly infectious disease caused by primary infection with varicella-zoster virus (VZV). VZV is transmitted from person to person by direct contact, inhalation of aerosols from vesicular fluid of skin lesions of varicella or herpes zoster (HZ), a localized, generally painful vesicular rash commonly called shingles, or infected respiratory tract secretions that also might be aerosolized (266). The average incubation period is 14–16 days after exposure to rash (range: 10–21 days). Infected persons are contagious an estimated 1–2 days before rash onset until all lesions are crusted, typically 4–7 days after rash onset (266). Varicella secondary attack rates can reach 90% among susceptible contacts. Typically, primary infection with VZV results in lifetime immunity. VZV remains dormant in sensory-nerve ganglia and can reactivate at a later time, causing HZ. Before the U.S. childhood varicella vaccination program began in 1995, approximately 90% of varicella disease occurred among children aged <15 years (266). During 1997–2009, national varicella vaccine coverage among children aged 19–35 months increased from 27% to 90%, leading to dramatic declines of >85% in varicella incidence, hospitalizations, and deaths (267–269). The decline in disease incidence was greatest among children for whom vaccination was recommended; however, declines occurred in every age group including infants too young to be vaccinated and adults, indicating reduced communitywide transmission of VZV.

Current incidence of varicella among adults is low (<0.1/1,000 population), and adult cases represent <10% of all reported varicella cases (270). National seroprevalence data from 1999–2004 demonstrated that, in the early vaccine era, adults continued to have high immunity to varicella (271). In this study, 98% of persons aged 20–49 years had VZV-specific IgG antibodies. However, with declining likelihood of exposure to VZV, children and adolescents who did not receive 2 doses of varicella vaccine could remain susceptible to VZV infection as they age into adulthood, when varicella can be more severe.

The clinical presentation of varicella has changed since the implementation of the varicella vaccination program, with more than half of varicella cases reported in 2008 occurring among persons who were vaccinated previously, the majority of them children. Varicella disease in vaccinated children (breakthrough varicella) usually has a modified or atypical presentation; the rash is typically mild, with <50 lesions that are

more likely to be predominantly maculopapular than vesicular (266). Fever is less common, and the duration of illness is shorter. Nevertheless, breakthrough varicella is infectious. One study indicated that vaccinated children with varicella with <50 lesions were only one third as infectious as unvaccinated children whereas those with ≥ 50 lesions were as infectious as unvaccinated children (272). Because the majority of adults are immune and few need vaccination, fewer breakthrough cases have been reported among adults than among children, and breakthrough varicella in adults has tended to be milder than varicella in unvaccinated adults (273,274).

The epidemiology of varicella in tropical and subtropical regions differs from that in the United States. In these regions, a higher proportion of VZV infections are acquired later in life. Persons emigrating from these regions might be more likely to be susceptible to varicella compared to U.S.-born persons and, therefore, are at a higher risk for developing varicella if unvaccinated and exposed (275,276).

Disease in Health-Care Settings and Impact on Health-Care Personnel and Patients

Although relatively rare in the United States since introduction of varicella vaccine, nosocomial transmission of VZV is well recognized and can be life-threatening to certain patients (277–289). In addition to hospital settings, nosocomial VZV transmission has been reported in long-term-care facilities and a hospital-associated residential facility (290,291). Sources of nosocomial exposure that have resulted in transmission include patients, HCP, and visitors with either varicella or HZ. Both localized and disseminated HZ in immunocompetent as well as immunocompromised patients have been identified as sources of nosocomial transmission of VZV. Localized HZ has been demonstrated to be much less infectious than varicella; disseminated HZ is considered to be as infectious as varicella (266). Nosocomial transmission has been attributed to delays in the diagnosis or reporting of varicella or HZ and in failures to implement control measures promptly. In hospitals and other health-care settings, airborne transmission of VZV from patients with either varicella or HZ has resulted in varicella in HCP and patients who had no direct contact with the index case-patient (284–288,291). Although all susceptible patients in health-care settings are at risk for severe varicella disease with complications, certain patients without evidence of immunity are at increased risk: pregnant women, premature infants born to susceptible mothers, infants born at <28 weeks' gestation or who weigh $\leq 1,000$ grams regardless of maternal immune status, and immunocompromised persons of all ages (including persons who are undergoing immunosuppressive therapy, have malignant disease, or are immunodeficient).

VZV exposures among patients and HCP can be disruptive to patient care, time-consuming, and costly even when they do not result in VZV transmission (281,282,292). Studies of VZV exposure in health-care settings have documented that a single provider with unrecognized varicella can result in the exposure of >30 patients and >30 employees (292). Identification of susceptible patients and staff, medical management of susceptible exposed patients at risk for complications of varicella, and furloughing of susceptible exposed HCP are time-consuming and costly (281,282).

With the overall reduction in varicella disease attributable to the success of the vaccination program, the risk for exposure to VZV from varicella cases in health-care settings is likely declining. In addition, an increasing proportion of varicella cases occur in vaccinated persons who are less contagious. Diagnosis of varicella has become increasingly challenging as a growing proportion of cases occur in vaccinated persons in whom disease is mild, and HCP encounter patients with varicella less frequently. Although not currently routinely recommended for the diagnosis and management of varicella, laboratory testing of suspected varicella cases is likely to become increasingly useful in health-care settings, especially as the positive predictive value of clinical diagnosis declines.

Vaccine Effectiveness, Duration of Immunity, and Vaccine Safety

Vaccine Effectiveness

Formal studies to evaluate vaccine efficacy or effectiveness have not been performed among adults. Studies of varicella vaccine effectiveness performed among children indicated good performance of 1 dose for prevention of all varicella (80%–85%) and >95% effectiveness for prevention of moderate and severe disease (266,293). Studies have indicated that a second dose among children produces an improved humoral and cellular immune response that correlates with improved protection against disease (266,294).

Varicella vaccine effectiveness is expected to be lower in adults than in children. Adolescents and adults require 2 doses to achieve seroconversion rates similar to those seen in children after 1 dose (266). A study of adults who received 2 doses of varicella vaccine 4 or 8 weeks apart and were exposed subsequently to varicella in the household estimated an 80% reduction in the expected number of cases (295).

Duration of Immunity

Serologic correlates of protection against varicella using commercially available assays have not been established for adults (266). In clinical studies, detectable antibody levels have persisted for at least 5 years in 97% of adolescents and adults who were administered 2 doses of varicella vaccine

4–8 weeks apart, but boosts in antibody levels were observed following exposures to varicella, which could account for the long-term persistence of antibodies after vaccination in these studies (295). Studies have demonstrated that whereas 25%–31% of adult vaccine recipients who seroconverted lost detectable antibodies 1–11 years after vaccination (273,296), vaccine-induced VZV-specific T-cell proliferation (marker for cell-mediated immunity [CMI]) was maintained in 94% of adults 1 and 5 years postvaccination (297). Disease was mild in vaccinated persons who developed varicella after exposure to VZV, even among vaccinees who did not seroconvert or who lost detectable antibody (273,274). Severity of illness and attack rates among vaccinated adults did not increase over time. These studies suggest that VZV-specific CMI affords protection to vaccinated adults, even in the absence of detectable antibody response.

Vaccine Safety

The varicella vaccine has an excellent safety profile. In clinical trials, the most common adverse events among adolescents and adults were injection-site complaints (24.4% after the first dose and 32.5% after the second dose) (266,295). Varicella-like rash at the injection site occurred in 3% of vaccine recipients after the first dose and in 1% after the second. A nonlocalized rash occurred in 5.5% of vaccine recipients after the first dose and in 0.9% after the second, with a median number of lesions of five, at a peak of 7–21 and 0–23 days postvaccination, respectively (295). Data on serious adverse events among adults after varicella vaccination are limited, but the proportion of serious adverse events among all adverse events reported to the Vaccine Adverse Events Reporting System during 1995–2005 was low (5%) among both children and adults (298). Serious adverse events reported among children included pneumonia, hepatitis, HZ (some hospitalized), meningitis with HZ, ataxia, encephalitis, thrombocytopenic purpura. Not all adverse events reported after varicella vaccination have been laboratory confirmed to be attributable to the vaccine strain VZV (266,298).

Risk for transmission of vaccine virus was assessed in placebo recipients who were siblings of vaccinated children and among healthy siblings of vaccinated leukemic children (266). The findings suggest that transmission of varicella vaccine virus from healthy persons to susceptible contacts is very rare. The risk might be increased in vaccinees in whom a varicella-like rash develops after vaccination. However, this risk is also low. The benefits of vaccinating HCP without evidence of immunity outweigh this extremely low potential risk. Since implementation of the varicella vaccine program, transmission of vaccine virus has been documented from eight persons (all of whom had a rash after vaccination) resulting in nine

secondary infections among household and long-term-care facility contacts (299). No transmission has been documented from vaccinated HCP.

Recommendations

Vaccination

Health-care institutions should ensure that all HCP have evidence of immunity to varicella. This information should be documented and readily available at the work location. HCP without evidence of immunity to varicella should receive 2 doses of varicella vaccine administered 4–8 weeks apart. If >8 weeks elapse after the first dose, the second dose may be administered without restarting the schedule. Recently vaccinated HCP do not require any restriction in their work activities; however, HCP who develop a vaccine-related rash after vaccination should avoid contact with persons without evidence of immunity to varicella who are at risk for severe disease and complications until all lesions resolve (i.e., are crusted over) or, if they develop lesions that do not crust (macules and papules only), until no new lesions appear within a 24-hour period.

Evidence of immunity for HCP includes any of the following (266):

- written documentation of vaccination with 2 doses of varicella vaccine,
- laboratory evidence of immunity^{§§§} or laboratory confirmation of disease,
- diagnosis or verification of a history of varicella disease by a health-care provider,^{¶¶¶} or
- diagnosis or verification of a history of HZ by a health-care provider.

In health-care settings, serologic screening before vaccination of personnel without evidence of immunity is likely to be cost effective. Key factors determining cost-effectiveness include sensitivity and specificity of serologic tests, the nosocomial transmission rate, seroprevalence of VZV antibody in the personnel population, and policies for managing vaccine recipients developing postvaccination rash or who are

^{§§§} Commercial assays can be used to assess disease-induced immunity, but they often lack sensitivity to detect vaccine-induced immunity (i.e., they might yield false-negative results).

^{¶¶¶} Verification of history or diagnosis of typical disease can be provided by any health-care provider (e.g., a school or occupational clinic nurse, nurse practitioner, physician assistant, or physician). For persons reporting a history of, or reporting with, atypical or mild cases, assessment by a physician or their designee is recommended, and one of the following should be sought: 1) an epidemiologic link to a typical varicella case or to a laboratory-confirmed case or 2) evidence of laboratory confirmation if it was performed at the time of acute disease. When such documentation is lacking, persons should not be considered as having a valid history of disease because other diseases might mimic mild atypical varicella.

exposed subsequently to VZV. Institutions may elect to test all unvaccinated HCP, regardless of disease history, because a small proportion of persons with a positive history of disease might be susceptible. For the purpose of screening HCP, a less sensitive and more specific commercial ELISA should be considered. The latex agglutination test can produce false-positive results, and HCP who remained unvaccinated because of false test results subsequently contracted varicella (289).

Routine testing for varicella immunity after 2 doses of vaccine is not recommended. Available commercial assays are not sensitive enough to detect antibody after vaccination in all instances. Sensitive tests that are not generally available have indicated that 92%–99% of adults develop antibodies after the second dose (266). Seroconversion does not always result in full protection against disease and, given the role of CMI for providing long-term protection, absence of antibodies does not necessarily mean susceptibility. Documented receipt of 2 doses of varicella vaccine supersedes results of subsequent serologic testing.

Health-care institutions should establish protocols and recommendations for screening and vaccinating HCP and for management of HCP after exposures in the work place. Institutions also should consider precautions for HCP in whom rash occurs after vaccination, although they should also consider the possibility of wild-type disease in HCP with recent exposure to varicella or HZ.

A vaccine to prevent HZ is available and recommended for all persons aged ≥ 60 years without contraindications to vaccination. HZ vaccine is not indicated for HCP for the prevention of nosocomial transmission, but HCP aged ≥ 60 years may receive the vaccine on the basis of the general recommendation for HZ vaccination, to reduce their individual risk for HZ.

Varicella Control Strategies

Appropriate measures should be implemented to manage cases and control outbreaks (300).

Patient Care

Only HCP with evidence of immunity to varicella should care for patients who have confirmed or suspected varicella or HZ. Airborne precautions (i.e., negative air-flow rooms) and contact precautions should be employed for all patients with varicella or disseminated HZ and for immunocompromised patients with localized HZ until disseminated infection is ruled out. These precautions should be kept in place until lesions are dry and crusted. If negative air-flow rooms are not available, patients should be isolated in closed rooms and should not have contact with persons without evidence of immunity to varicella. For immunocompetent persons with localized HZ,

standard precautions and complete covering of the lesions are recommended.

Postexposure Management of HCP and Patients

Exposure to VZV is defined as close contact with an infectious person, such as close indoor contact (e.g., in the same room) or face-to-face contact. Experts differ regarding the duration of contact; some suggest 5 minutes, and others up to 1 hour; all agree that it does not include transitory contact (301).

All exposed, susceptible patients and HCP should be identified using the criteria for evidence of immunity. An additional criterion of evidence of immunity only for patients who are not immunocompromised or pregnant is birth in the United States before 1980. Postexposure prophylaxis with vaccination or varicella-zoster immunoglobulin, depending on immune status, of exposed HCP and patients without evidence of immunity is recommended (266).

HCP who have received 2 doses of vaccine and who are exposed to VZV (varicella, disseminated HZ, and uncovered lesions of a localized HZ) should be monitored daily during days 8–21 after exposure for fever, skin lesions, and systemic symptoms suggestive of varicella. HCP can be monitored directly by occupational health program or infection-control practitioners or instructed to report fever, headache, or other constitutional symptoms and any atypical skin lesions immediately. HCP should be excluded from a work facility immediately if symptoms occur. HCP who have received 1 dose of vaccine and who are exposed to VZV (varicella, disseminated HZ, and uncovered lesions of a localized HZ) (in the community or health-care setting/workplace) should receive the second dose within 3–5 days after exposure to rash (provided 4 weeks have elapsed after the first dose). After vaccination, management is similar to that of 2-dose vaccine recipients. Those who did not receive a second dose or who received the second dose >5 days after exposure should be excluded from work for 8–21 days after exposure.

Unvaccinated HCP who have no other evidence of immunity who are exposed to VZV (varicella, disseminated HZ, and uncovered lesions of a localized HZ) are potentially infective from days 8–21 after exposure and should be furloughed during this period. They should receive postexposure vaccination as soon as possible. Vaccination within 3–5 days of exposure to rash might modify the disease if infection occurred. Vaccination >5 days postexposure is still indicated because it induces protection against subsequent exposures (if the current exposure did not cause infection). For HCP at risk for severe disease for whom varicella vaccination is contraindicated (e.g., pregnant or immunocompromised HCP), varicella-zoster immune globulin after exposure is recommended. The varicella-zoster immune

globulin product currently used in the United States, VariZIG (Cangene Corporation, Winnipeg, Canada), is available under an Investigational New Drug Application Expanded Access protocol; a sample release form is available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/UCM176031.pdf>. Varicella-zoster immune globulin might prolong the incubation period by a week, thus extending the time during which personnel should not work from 21 to 28 days. In case of an outbreak, HCP without evidence of immunity who have contraindications to vaccination should be excluded from the outbreak setting through 21 days after rash onset of the last identified case-patient because of the risk for severe disease in these groups. If the VZV exposure was to localized HZ with covered lesions, no work restrictions are needed if the exposed HCP had previously received at least 1 dose of vaccine or received the first dose within 3–5 days postexposure. A second dose should be administered at the appropriate interval. HCP should be monitored daily during days 8–21 after exposure for fever, skin lesions, and systemic symptoms suggestive of varicella and excluded from a work facility if symptoms occur. If at least 1 dose was not received, restriction from patient contact is recommended.

Diseases for Which Vaccination Might Be Indicated in Certain Circumstances

Health-care facilities and other organizations should consider including in their vaccination programs vaccines to prevent meningococcal disease, typhoid fever, and polio for HCP who have certain health conditions or who work in laboratories or regions outside the United States where the risk for work-related exposure exists.

Meningococcal Disease

Background

Epidemiology and Risk Factors

Meningococcal disease is rare among adults in the United States and incidence has decreased to historic lows; during 1998–2007 the average annual incidence of meningococcal disease was 0.28 (range: 0.26–0.31) cases per 100,000 population among persons aged 25–64 years (302).

Routine vaccination with meningococcal conjugate vaccine is recommended by ACIP for adolescents aged 11–18 years, with the primary dose at age 11–12 years and the booster dose at age 16 years. In 2010, coverage with meningococcal conjugate vaccine among persons aged 13–17 years was 62.7% (22).

Nosocomial transmission of *Neisseria meningitidis* is rare, but HCP have become infected after direct contact with respiratory secretions of infected persons (e.g., managing of an airway during resuscitation) and in a laboratory setting. HCP can decrease the risk for infection by adhering to precautions to prevent exposure to respiratory droplets (303,304) and by taking antimicrobial chemoprophylaxis if exposed directly to respiratory secretions.

Vaccine Effectiveness, Duration of Immunity, and Vaccine Safety

Two quadrivalent (A, C, W-135, Y) conjugate meningococcal vaccines (MCV4) are licensed for persons aged through 55 years (305,306). Both protect against two of the three serogroups that cause the majority of meningococcal disease in the United States and against 75% of disease among adults. Available data indicate that the majority of persons do not have enough circulating functional antibody to be protected ≥ 5 years after a single dose of MCV4. Both vaccines had similar safety profiles in clinical trials. Quadrivalent (A, C, W-135, Y) meningococcal polysaccharide vaccine (MPSV4) is available for use in persons aged >55 years. No vaccine for serogroup B meningococcal disease is licensed in the United States.

Recommendations

Vaccination

MCV4 is not recommended routinely for all HCP.

HCP Recommended to Receive Vaccine to Prevent Meningococcal Disease

A 2-dose vaccine series is recommended for HCP with known asplenia or persistent complement component deficiencies, because these conditions increase the risk for meningococcal disease. HCP traveling to countries in which meningococcal disease is hyperendemic or epidemic also are at increased risk for infection and should receive vaccine. Those with known asplenia or persistent complement component deficiencies should receive a 2-dose vaccine series. All other HCP traveling to work to high-risk areas should receive a single dose of MCV4 before travel if they have never received it or if they received it >5 years previously. Clinical microbiologists and research microbiologists who might be exposed routinely to isolates of *N. meningitidis* should receive a single dose of MCV4 and receive a booster dose every 5 years if they remain at increased risk. Health-care personnel aged >55 years who have any of the above risk factors for meningococcal disease should be vaccinated with MPSV4 (305).

HCP Who May Elect to Receive Vaccine to Prevent Meningococcal Disease

HCP with known HIV infection are likely at increased risk for meningococcal disease and may elect vaccination. If these HCP are vaccinated, they should receive a 2-dose vaccine series (307).

Booster Doses

HCP who receive the 2-dose MCV4 vaccine series and/or remain in a group at increased risk should receive a booster dose every 5 years (306).

Postexposure Management of Exposed HCP

Postexposure prophylaxis is advised for all persons who have had intensive, unprotected contact (i.e., without wearing a mask) with infected patients (e.g., via mouth-to-mouth resuscitation, endotracheal intubation, or endotracheal tube management), including HCP who have been vaccinated with either the conjugate or polysaccharide vaccine (3).

Antimicrobial prophylaxis can eradicate carriage of *N. meningitidis* and prevent infections in persons who have unprotected exposure to patients with meningococcal infections (305). Rifampin, ciprofloxacin, and ceftriaxone are effective in eradicating nasopharyngeal carriage of *N. meningitidis*. In areas of the United States where ciprofloxacin-resistant strains of *N. meningitidis* have been detected (as of August 30, 2011, only parts of Minnesota and North Dakota), ciprofloxacin should not be used for chemoprophylaxis (308). Azithromycin can be used as an alternative. Ceftriaxone can be used during pregnancy. Postexposure prophylaxis should be administered within 24 hours of exposure when feasible; postexposure prophylaxis administered >14 days after exposure is of limited or no value (305). HCP not otherwise indicated for vaccination may be recommended to be vaccinated with meningococcal vaccine in the setting of a community or institutional outbreak of meningococcal disease caused by a serogroup contained in the vaccine.

Typhoid Fever

Background

Epidemiology and Risk Factors

The incidence of typhoid fever declined steadily in the United States during 1900–1960 and has since remained low. During 1999–2006, on average, 237 cases were reported annually to the National Typhoid and Paratyphoid Fever Surveillance System (309). The median age of patients was 22 years and 54% were male; 79% reported foreign travel during the 30 days before onset of symptoms. Among international

travelers, the risk for *Salmonella* Typhi infection appears to be highest for those who visit friends and relatives in countries in which typhoid fever is endemic and for those who visit (even for a short time) the most highly endemic areas (e.g., the Indian subcontinent) (310).

Increasing resistance to fluoroquinolones such as ciprofloxacin, which are used to treat multidrug-resistant *S. Typhi*, has been seen particularly among travelers to south and southeast Asia (311). Isolates with decreased susceptibility to ciprofloxacin (DCS) do not qualify as resistant according to current Clinical and Laboratory Standards Institute criteria but are associated with poorer clinical outcomes (311,312). Resistance to nalidixic acid, a quinolone, is a marker for DCS and increased from 19% in 1999 to 59% in 2008 (313). Nine isolates resistant to ciprofloxacin also were seen during this time period (313).

Although overall *S. Typhi* infections have declined in the United States, increased incidence and antimicrobial resistance including resistance to fluoroquinolones have been seen for paratyphoid fever caused by Paratyphi A (314). No vaccines that protect against Paratyphi A infection are available.

Transmission and Exposure in Health-Care Settings

During 1985–1994, seven cases of laboratory-acquired typhoid fever were reported among persons working in microbiology laboratories, only one of whom had been vaccinated (315). Additionally, *S. Typhi* might be transmitted nosocomially via the hands of infected persons (315).

Vaccine Effectiveness, Duration of Immunity, and Vaccine Safety

Two typhoid vaccines are distributed in the United States: oral live-attenuated Ty21a vaccine (one enteric-coated capsule taken on alternate days for a total of four capsules) and the capsular polysaccharide parenteral vaccine (1 0.5 mL intramuscular dose). Both vaccines protect 50%–80% of recipients. To maintain immunity, booster doses of the oral vaccine are required every 5 years, and booster doses of the injected vaccine are required every 2 years. Complication rates are low for both types of *S. Typhi* vaccines. During 1994–1999, serious adverse events requiring hospitalization occurred in an estimated 0.47 to 1.3 per 100,000 doses, and no deaths occurred (310). However, live-attenuated Ty21a vaccine should not be used among immunocompromised persons, including those infected with HIV (316). Theoretic concerns have been raised about the immunogenicity of live, attenuated Ty21a vaccine in persons concurrently receiving antimicrobials (including antimalarial chemoprophylaxis), viral vaccines, or immune globulin (317). A third type of vaccine, a parenteral heat-inactivated vaccine associated with higher reactogenicity, was discontinued in 2000 (310,318).

Recommendations

Vaccination

Microbiologists and others who work frequently with *S. Typhi* should be vaccinated with either of the two licensed and available vaccines. Booster vaccinations should be administered on schedule according to the manufacturers' recommendations.

Controlling the Spread of Typhoid Fever

Personal hygiene, particularly hand hygiene before and after all patient contacts, will minimize risk for transmitting enteric pathogens to patients. However, HCP who contract an acute diarrheal illness accompanied by fever, cramps, or bloody stools are likely to excrete substantial numbers of infective organisms in their feces. Excluding these HCP from care of patients until the illness has been evaluated and treated can prevent transmission (3).

Poliomyelitis

Background

Epidemiology and Risk Factors

In the United States, the last indigenously acquired cases of poliomyelitis caused by wild poliovirus occurred in 1979, and the Americas were certified to be free of indigenous wild poliovirus in 1994 (319,320). With the complete transition from use of oral poliovirus vaccine (OPV) to inactivated poliovirus vaccine (IPV) in 2000, vaccine-associated paralytic poliomyelitis (VAPP) attributable to OPV also has been eliminated (321,322), so the risk for exposure to any live poliovirus in the United States is limited. However, global eradication of poliomyelitis has not yet occurred, so reintroductions of poliovirus into the United States are possible. Two cases of paralytic polio from vaccine-derived poliovirus have occurred since 2000 (one imported case in 2005 and one case in an immunodeficient person in 2008), and evidence of limited circulating vaccine-derived poliovirus in an undervaccinated community was documented in 2005 (323–325).

Transmission and Exposure in Health-Care Settings

Poliovirus can be recovered from infected persons, including from pharyngeal specimens, feces, urine, and (rarely) cerebrospinal fluid. HCP and laboratory workers might be exposed if they come into close contact with infected persons (e.g., travelers returning from areas where polio is endemic) or with specimens that contain poliovirus.

Vaccine Effectiveness, Duration of Immunity, and Vaccine Safety

Both IPV and OPV are highly immunogenic and effective when administered according to their schedules. In studies conducted in the United States, 3 doses of IPV resulted in 100% seroconversion for types 2 and 3 poliovirus and 96%–100% for type 1 (326). Immunity is prolonged and might be lifelong. IPV is well tolerated, and no serious adverse events have been associated with its use. IPV is an inactivated vaccine and does not cause VAPP. IPV is contraindicated in persons with a history of hypersensitivity to any component of the vaccine, including 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, and polymyxin B. OPV is no longer available in the United States.

Recommendations

Vaccination

Because the majority of adults born in the United States are likely immune to polio as a result of vaccination during childhood, poliovirus vaccine is not routinely recommended for persons aged ≥ 18 years. The childhood recommendation for poliovirus vaccine consists of 4 doses at ages 2, 4, and 6–18 months and 4–6 years.

However, vaccination is recommended for HCP who are at greater risk for exposure to polioviruses than the general population, including laboratory workers who handle specimens that might contain polioviruses and HCP who have close contact with patients who might be excreting wild polioviruses, including HCP who travel to work in areas where polioviruses are circulating.

Unvaccinated HCP should receive a 3-dose series of IPV, with dose 2 administered 4–8 weeks after dose 1, and dose 3 administered 6–12 months after dose 2. HCP who have previously completed a routine series of poliovirus vaccine and who are at increased risk can receive a lifetime booster dose of IPV if they remain at increased risk for exposure. Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults.

Controlling the Spread of Poliovirus

Standard precautions always should be practiced when handling biologic specimens. Suspect cases require an immediate investigation including collection of appropriate laboratory specimens and control measures. All suspect or confirmed cases should be reported immediately to the local or state health department.

Other Vaccines Recommended for Adults

Certain vaccines are recommended for adults based on age or other individual risk factors but not because of occupational exposure (327). Vaccine-specific ACIP recommendations should be consulted for details on schedules, indications, contraindications, and precautions for these vaccines.

- **Pneumococcal polysaccharide vaccine (PPSV).** PPSV is recommended for healthy persons aged ≥ 65 years. PPSV is also recommended for persons aged < 65 years with certain underlying medical conditions, including anatomic or functional asplenia, immunocompromise (including HIV infection), chronic lung, heart or kidney disease, and diabetes.
- **Tetanus and diphtheria toxoids (Td).** All adults should have documentation of having received an age-appropriate series of Td-containing vaccine and a routine booster dose every 10 years. Persons without documentation of having received a Td series should receive a 3-dose series. The first dose of the series should be administered as Tdap (see Pertussis).
- **Human papillomavirus (HPV) vaccine.** Either quadrivalent HPV vaccine (Gardasil) or bivalent HPV vaccine (Cervarix) is recommended for females at age 11 or 12 years with catch-up vaccination recommended through age 26 years. Quadrivalent HPV vaccine (Gardasil) may be administered to males aged 9–26 years.
- **Zoster vaccine.** Zoster vaccine contains the same live attenuated varicella zoster virus as varicella vaccine but at a higher concentration (approximately 14 times more vaccine virus per dose). Zoster vaccine is recommended for the prevention of HZ (shingles) in persons aged ≥ 60 years. Transmission of vaccine virus from the recipient to a contact has not been reported. Consequently, limiting or restricting work activities for persons who recently received zoster vaccine is not necessary.
- **Hepatitis A vaccine.** HCP have not been demonstrated to be at increased risk for hepatitis A virus infection because of occupational exposure, including persons exposed to sewage. Hepatitis A vaccine is recommended for person with chronic liver disease, international travelers, and certain other groups at increased risk for exposure to hepatitis A.

Catch-Up and Travel Vaccination

Catch-Up Programs

Managers of health-care facilities should implement catch-up vaccination programs for HCP who already are employed, in addition to developing policies for achieving high vaccination coverage among newly hired HCP. HCP vaccination records could be reviewed annually during the influenza vaccination season or concurrent with annual TB testing. This strategy could help prevent outbreaks of vaccine-preventable diseases. Because education, especially when combined with other interventions such as reminder/recall systems and low or no out-of-pocket costs, enhances the success of many vaccination programs, informational materials should be available to assist in answering questions from HCP regarding the diseases, vaccines, and toxoids as well as the program or policy being implemented (120,328). Conducting educational workshops or seminars several weeks before the initiation of a catch-up vaccination program might promote acceptance of program goals.

Travel

Hospital personnel and other HCP who perform research or health-care work in foreign countries might be at increased risk for acquiring certain diseases that can be prevented by vaccines recommended in the United States (e.g., hepatitis B, influenza, MMR, Tdap, poliovirus, varicella, and meningococcal vaccines) and travel-related vaccines (e.g., hepatitis A, Japanese encephalitis, rabies, typhoid, or yellow fever vaccines) (329). Elevated risks for acquiring these diseases might stem from exposure to patients in health-care settings (e.g., poliomyelitis and meningococcal disease) but also might arise from circumstances unrelated to patient care (e.g., high endemicity of hepatitis A or exposure to arthropod-vector diseases [e.g., yellow fever]). All HCP should seek the advice of a health-care provider familiar with travel medicine at least 4–6 weeks before travel to ensure that they are up to date on routine vaccinations and that they receive vaccinations recommended for their destination (329). Although bacille Calmette-Guérin vaccination is not recommended routinely in the United States, HCP should discuss potential beneficial and other consequences of this vaccination with their health-care provider.

Work Restrictions

Work restrictions for susceptible HCP (i.e., no history of vaccination or documented lack of immunity) exposed to or infected with certain vaccine-preventable diseases can range from restricting individual HCP from patient contact to complete exclusion from duty (Table 5). A furloughed employee should be considered in the same category as an

employee excluded from the facility. Specific recommendations concerning work restrictions in these circumstances have been published previously (3,11).

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TABLE 1. Recommendations for immunization practices and use of immunobiologics applicable to disease prevention among health-care personnel* — Advisory Committee on Immunization Practices (ACIP), June 9, 1989–August 26, 2011

Subject	Publication in <i>MMWR</i>
General recommendations on immunization	2011;60(No. RR-2)
Diphtheria, tetanus, and pertussis	1991;40(No. RR-10) 1997;46(No. RR-7)
Hepatitis B	1991;40;(No. RR-8) [†] 1991;40(No. RR-13) 2001;50(No. RR-11) [†] 2006;55(No. RR-16) 2008;57(No. RR-8) [†]
Influenza [§]	2010;59(No. RR-8) 2011;60:1128–32
Measles, mumps, rubella (MMR)	1998;47(No. RR-8)
Meningococcal disease and outbreaks	2005;54(No. RR-7) 2011;60:72–6
Mumps (see also MMR and Measles)	1989;38:388–92, 397–400 2006;55:629–630
Pertussis, acellular (see also Diphtheria, tetanus, and pertussis)	2006;55(No. RR-3) 2006;55(No. RR-17) 2008;57(No. RR-4) 2011;60:13–15
Poliomyelitis	2000;49(No. RR-5) 2009;58:829–30
Rubella (see also MMR, Measles, and Mumps)	2001;50:1117
Typhoid	1994;43(No. RR-14)
Varicella	2007;56(No. RR-4)

* Persons who provide health care to patients or work in institutions that provide patient care (e.g., physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative and support staff in health-care institutions). **Source:** U.S. Department of Health and Human Services. Definition of health-care personnel (HCP). Available at <http://www.hhs.gov/ask/initiatives/vacctoolkit/definition.html>.

[†] This report provides guidance from CDC and is not an ACIP statement.

[§] Each year influenza vaccine recommendations are reviewed and amended to reflect updated information concerning influenza activity in the United States for the preceding influenza season and to provide information on the vaccine available for the upcoming influenza season. These recommendations are published periodically in *MMWR*. The most current published recommendations should be consulted (available at <http://www.cdc.gov/vaccines/pubs/acip-list.htm>).

TABLE 2. Immunizing agents and immunization schedules for health-care personnel (HCP)*

Generic name	Primary schedule and booster(s)	Indications	Major precautions and contraindications	Special considerations
Immunizing agents recommended for all HCP				
Hepatitis B (HB) recombinant vaccine	2 doses 4 weeks apart; third dose 5 months after second; booster doses not necessary; all doses should be administered IM in the deltoid	Preexposure: HCP at risk for exposure to blood or body fluids; postexposure (see Table 4)	On the basis of limited data, no risk for adverse effects to developing fetuses is apparent. Pregnancy should not be considered a contraindication to vaccination of women. Previous anaphylactic reaction to common baker's yeast is a contraindication to vaccination.	The vaccine produces neither therapeutic nor adverse effects in HBV-infected persons. Prevacination serologic screening is not indicated for persons being vaccinated because of occupational risk but might be indicated for HCP in certain high-risk populations. HCP at high risk for occupational [†] contact with blood or body fluids should be tested 1–2 months after vaccination to determine serologic response.
Hepatitis B immune globulin (HBIG)	0.06 mL/kg IM as soon as possible after exposure, if indicated	Postexposure prophylaxis (see Table 4)	See package insert [§]	
Influenza vaccine (TIV and LAIV)	Annual vaccination with current seasonal vaccine. TIV is available in IM and ID formulations. LAIV is administered intranasally.	All HCP	History of severe (e.g., anaphylactic) hypersensitivity to eggs; prior severe allergic reaction to influenza vaccine	No evidence exists of risk to mother or fetus when the vaccine is administered to a pregnant woman with an underlying high-risk condition. Influenza vaccination is recommended for women who are or will be pregnant during influenza season because of increased risk for hospitalization and death. LAIV is recommended only for healthy, non-pregnant persons aged 2–49 years. Intradermal vaccine is indicated for persons aged 18–64 years. HCP who care for severely immunosuppressed persons who require a protective environment should receive TIV rather than LAIV.
Measles live-virus vaccine	2 doses SC; ≥28 days apart	Vaccination should be recommended for all HCP who lack presumptive evidence of immunity; [¶] vaccination should be considered for those born before 1957.	Pregnancy; immunocompromised persons,** including HIV-infected persons who have evidence of severe immunosuppression; anaphylaxis to gelatin or gelatin-containing products; anaphylaxis to neomycin; and recent administration of immune globulin.	HCP vaccinated during 1963–1967 with a killed measles vaccine alone, killed vaccine followed by live vaccine, or a vaccine of unknown type should be revaccinated with 2 doses of live measles virus vaccine.
Mumps live-virus vaccine	2 doses SC; ≥28 days apart	Vaccination should be recommended for all HCP who lack presumptive evidence of immunity. ^{††} Vaccination should be considered for those born before 1957.	Pregnancy; immunocompromised persons,** including HIV-infected persons who have evidence of severe immunosuppression; anaphylaxis to gelatin or gelatin-containing products; anaphylaxis to neomycin	HCP vaccinated before 1979 with either killed mumps vaccine or mumps vaccine of unknown type should consider revaccination with 2 doses of MMR vaccine.
Rubella live-virus vaccine	1 dose SC; (However, due to the 2-dose requirements for measles and mumps vaccines, the use of MMR vaccine will result in most HCP receiving 2 doses of rubella-containing vaccine.)	Vaccination should be recommended for all HCP who lack presumptive evidence of immunity. ^{§§}	Pregnancy; immunocompromised persons** including HIV-infected persons who have evidence of severe immunosuppression; anaphylaxis to gelatin or gelatin-containing products; anaphylaxis to neomycin	The risk for rubella vaccine-associated malformations in the offspring of women pregnant when vaccinated or who become pregnant within 1 month after vaccination is negligible. ^{¶¶} Such women should be counseled regarding the theoretical basis of concern for the fetus.

See table footnotes on page 41

TABLE 2. (Continued) Immunizing agents and immunization schedules for health-care personnel (HCP)*

Generic name	Primary schedule and booster(s)	Indications	Major precautions and contraindications	Special considerations
Tetanus and diphtheria (toxoids) and acellular pertussis (Tdap)	1 dose IM as soon as feasible if Tdap not already received and regardless of interval from last Td. After receipt of Tdap, receive Td for routine booster every 10 years.	All HCP, regardless of age.	History of serious allergic reaction (i.e., anaphylaxis) to any component of Tdap. Because of the importance of tetanus vaccination, persons with history of anaphylaxis to components in Tdap or Td should be referred to an allergist to determine whether they have a specific allergy to tetanus toxoid and can safely receive tetanus toxoid (TT) vaccine. Persons with history of encephalopathy (e.g., coma or prolonged seizures) not attributable to an identifiable cause within 7 days of administration of a vaccine with pertussis components should receive Td instead of Tdap.	Tetanus prophylaxis in wound management if not yet received Tdap***
Varicella vaccine (varicella zoster virus live-virus vaccine)	2 doses SC 4–8 weeks apart if aged ≥ 13 years.	All HCP who do not have evidence of immunity defined as: written documentation of vaccination with 2 doses of varicella vaccine; laboratory evidence of immunity ^{†††} or laboratory confirmation of disease; diagnosis or verification of a history of varicella disease by a health-care provider, ^{§§§} or diagnosis or verification of a history of herpes zoster by a health-care provider.	Pregnancy; immunocompromised persons;*** history of anaphylactic reaction after receipt of gelatin or neomycin. Varicella vaccination may be considered for HIV-infected adolescents and adults with CD4+ T-lymphocyte count ≥ 200 cells/uL. Avoid salicylate use for 6 weeks after vaccination.	Because 71%–93% of adults without a history of varicella are immune, serologic testing before vaccination is likely to be cost-effective.
Varicella-zoster immune globulin	125U/10 kg IM (minimum dose: 125U; maximum dose: 625U)	Persons without evidence of immunity who have contraindications for varicella vaccination and who are at risk for severe disease and complications ^{¶¶¶} known or likely to be susceptible who have direct, nontransient exposure to an infectious hospital staff worker or patient		Serologic testing may help in assessing whether to administer varicella-zoster immune globulin. If use of varicella-zoster immune globulin prevents varicella disease, patient should be vaccinated subsequently. The varicella-zoster immune globulin product currently used in the United States (VariZIG) (Cangene Corp. Winnipeg Canada) can be obtained 24 hours a day from the sole authorized U.S. distributor (FFF Enterprises, Temecula, California) at 1-800-843-7477 or http://www.fffenterprises.com .

Other immunobiologics that might be indicated in certain circumstances for HCP

Quadrivalent meningococcal conjugate vaccine (tetraivalent (A,C,Y,W) for HCP ages 19–54 years, Quadrivalent meningococcal polysaccharide vaccine for HCP age ≥ 55 years	1 dose; booster dose in 5 years if person remains at increased risk	Clinical and research microbiologists who might routinely be exposed to isolates of <i>Neisseria meningitidis</i>	The safety of the vaccine in pregnant women has not been evaluated; it should not be administered during pregnancy unless the risk for infection is high.
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See table footnotes on page 41

TABLE 2. (Continued) Immunizing agents and immunization schedules for health-care personnel (HCP)*

Generic name	Primary schedule and booster(s)	Indications	Major precautions and contraindications	Special considerations
Typhoid vaccine IM, and oral	IM vaccine: 1 dose, booster every 2 years. Oral vaccine: 4 doses on alternate days. Manufacturer recommends revaccination with the entire 4-dose series every 5 years.	Workers in microbiology laboratories who frequently work with <i>Salmonella typhi</i> .	Severe local or systemic reaction to a previous dose. Ty21a (oral) vaccine should not be administered to immunocompromised persons** or to persons receiving antimicrobial agents.	Vaccination should not be considered an alternative to the use of proper procedures when handling specimens and cultures in the laboratory.
Inactivated poliovirus vaccine (IPV)	For unvaccinated adults, 2 doses should be administered at intervals of 4–8 weeks; a third dose should be administered 6–12 months after the second dose.	Vaccination is recommended for adults at increased risk for exposure to polioviruses including health-care personnel who have close contact with patients who might be excreting polioviruses. Adults who have previously received a complete course of poliovirus vaccine may receive one lifetime booster if they remain at increased risk for exposure.	Hypersensitivity or anaphylactic reactions to IPV or antibiotics contained in IPV. IPV contains trace amounts of streptomycin, polymyxin B, and neomycin.	

Abbreviations: IM = intramuscular; HBV = hepatitis B virus; HBsAg = hepatitis B surface antigen; SC = subcutaneous; HIV = human immunodeficiency virus; MMR = measles, mumps, rubella vaccine; TB = tuberculosis; HAV = hepatitis A virus; IgA = immune globulin A; ID = intradermal; TIV = trivalent inactivated split-virus vaccines; LAIV = live attenuated influenza vaccine; BCG = bacille Calmette-Guérin; OPV = oral poliovirus vaccine.

* Persons who provide health care to patients or work in institutions that provide patient care (e. g., physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative and support staff in health-care institutions). **Source:** U.S. Department of Health and Human Services. Definition of health-care personnel (HCP). Available at <http://www.hhs.gov/ask/initiatives/vac toolkit/definition.html>.

† Health-care personnel and public safety workers at high risk for continued percutaneous or mucosal exposure to blood or body fluids include acupuncturists, dentists, dental hygienists, emergency medical technicians, first responders, laboratory technologists/technicians, nurses, nurse practitioners, phlebotomists, physicians, physician assistants, and students entering these professions. **Source:** CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices. Part II: immunization of adults. MMWR 2006;55(No. RR-16).

§ The package insert should be consulted to weigh the risks and benefits of giving HBIG to persons with IgA deficiency, or to persons who have had an anaphylactic reaction to an IgG containing biologic product.

¶ Written documentation of vaccination with 2 doses of live measles or MMR vaccine administered ≥ 28 days apart, or laboratory evidence of measles immunity, or laboratory confirmation of measles disease, or birth before 1957.

** Persons immunocompromised because of immune deficiency diseases, HIV infection (who should primarily not receive BCG, OPV, and yellow fever vaccines), leukemia, lymphoma or generalized malignancy or immunosuppressed as a result of therapy with corticosteroids, alkylating drugs, antimetabolites, or radiation.

†† Written documentation of vaccination with 2 doses of live mumps or MMR vaccine administered ≥ 28 days apart, or laboratory evidence of mumps immunity, or laboratory confirmation of mumps disease, or birth before 1957.

§§ Written documentation of vaccination with 1 dose of live rubella or MMR vaccine, or laboratory evidence of immunity, or laboratory confirmation of rubella infection or disease, or birth before 1957, except women of childbearing potential who could become pregnant; though pregnancy in this age group would be exceedingly rare.

¶¶ **Source:** CDC. Revised ACIP recommendation for avoiding pregnancy after receiving a rubella-containing vaccine. MMWR 2001;50:1117.

*** **Source:** CDC. Update on adult immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1991;40(No. RR-12).

††† Commercial assays can be used to assess disease-induced immunity, but they often lack sensitivity to detect vaccine-induced immunity (i.e., they might yield false-negative results).

§§§ Verification of history or diagnosis of typical disease can be provided by any health-care provider (e.g., school or occupational clinic nurse, nurse practitioner, physician assistant, or physician). For persons reporting a history of, or reporting with, atypical or mild cases, assessment by a physician or their designee is recommended, and one of the following should be sought: 1) an epidemiologic link to a typical varicella case or to a laboratory-confirmed case or 2) evidence of laboratory confirmation if it was performed at the time of acute disease. When such documentation is lacking, persons should not be considered as having a valid history of disease because other diseases might mimic mild atypical varicella.

¶¶¶ For example, immunocompromised patients or pregnant women.

TABLE 3. Summary of recommendations for immunization of health-care personnel* (HCP) with special certain conditions — Advisory Committee on Immunization Practices, United States, 2011

Vaccine	Pregnancy	HIV infection	Severe immunosuppression [†]	Asplenia	Renal failure	Diabetes	Alcoholism and alcoholic cirrhosis
Hepatitis B	R	R	R	R	R	R	R
Influenza	R [§]	R	R	R	R	R	R
Measles, mumps, rubella	C	R [¶]	C	R	R	R	R
Meningococcus IPV ^{††}	UI	UI	UI	R**	UI	UI	UI
Pertussis, tetanus, diphtheria	UI	UI	UI	UI	UI	UI	UI
Typhoid, inactivated Vi ^{§§}	R	R	R	R	R	R	R
Typhoid, Ty21a	UI	UI	UI	UI	UI	UI	UI
Varicella	UI	C	C	UI	UI	UI	UI
	C	UI ^{¶¶}	C	R	R	R	R

Abbreviations: R = recommended; C = contraindicated; UI = use if indicated; IPV = inactivated poliovirus vaccine.

* Persons who provide health care to patients or work in institutions that provide patient care (e. g., physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative and support staff in health-care institutions).

Source: U.S. Department of Health and Human Services. Definition of health-care personnel (HCP). Available at <http://www.hhs.gov/ask/initiatives/vacctoolkit/definition.html>.

[†] Severe immunosuppression can be caused by congenital immunodeficiency, leukemia, lymphoma, generalized malignancy or therapy with alkylating agents, antimetabolites, ionizing radiation, or large amounts of corticosteroids.

[§] Women who are or will be pregnant during the influenza season.

[¶] Contraindicated in HIV-infected persons who have evidence of severe immunosuppression.

** Recommendation is based on the person's underlying condition rather than occupation.

^{††} Vaccination is recommended for unvaccinated HCP who have close contact with patients who may be excreting wild polioviruses. HCP who have had a primary series of oral poliovirus vaccine (OPV) or IPV who are directly involved with the provision of care to patients who may be excreting poliovirus may receive another dose of either IPV or OPV. Any suspected case of poliomyelitis should be investigated immediately. If evidence suggests transmission of poliovirus, control measures to contain further transmission should be instituted immediately.

^{§§} Capsular polysaccharide parenteral vaccine.

^{¶¶} Varicella vaccine may be considered for HIV-infected adults without evidence of immunity and with CD4 T-lymphocyte count ≥ 200 cells/UI.

TABLE 4. Recommended postexposure prophylaxis for percutaneous or permucosal exposure to hepatitis B virus — Advisory Committee on Immunization Practices, United States

Vaccination and antibody response status of exposed person	Treatment		
	Source HBsAg-positive	Source HBsAg-negative	Source not tested or status unknown
Unvaccinated	HBIG x 1; initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated			
Known responder	No treatment	No treatment	No treatment
Known nonresponder			
After 3 doses	HBIG x 1 and initiate revaccination	No treatment	If known high-risk source, treat as if source were HBsAg-positive
After 6 doses	HBIG x 2 (separated by 1 month)	No treatment	If known high-risk source, treat as if source were HBsAg-positive
Antibody response unknown	Test exposed person for anti-HBs	No treatment	Test exposed person for anti-HBs
	If adequate,* no treatment		If adequate,* no treatment
	If inadequate,* HBIG x 1 and vaccine booster		If inadequate,* initiate revaccination

Abbreviations: HBsAg = Hepatitis B surface antigen; HBIG = hepatitis B immune globulin; anti-HBs = antibody to hepatitis B surface antigen; HB = hepatitis B.

Source: Adapted from CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). Part II: immunization of adults. MMWR 2006;55(No. RR-16).

* A seroprotective (adequate) level of anti-HBs after completion of a vaccination series is defined as anti-HBs ≥ 10 mIU/mL; a response < 10 mIU/mL is inadequate and is not a reliable indicator of protection.

TABLE 5. Advisory Committee on Immunization Practices work restrictions for health-care personnel* (HCP) exposed to or infected with certain vaccine-preventable diseases and conditions

Disease/Condition	Work restriction	Duration
Hepatitis B		
HCP positive for HBsAg (e.g., acute or chronic hepatitis B infection):		
HCP who do not perform exposure-prone invasive procedures	No restriction unless linked epidemiologically to transmission of hepatitis B virus infection	Standard precautions always should be observed
HCP who perform exposure-prone invasive procedures	These HCP should not perform exposure-prone invasive procedures until they have sought counsel from an expert review panel, which should review and recommend the procedures the worker can perform, taking into account the specific procedure as well as the skill and technique of the worker	Per recommendation of expert panel
Upper respiratory infections		
HCP in contact with persons at high risk for complications of influenza [†]	Exclude from duty	<p>Until afebrile ≥ 24 hours (without the use of fever-reducing medicines such as acetaminophen). Those with ongoing respiratory symptoms should be considered for evaluation by occupational health to determine appropriateness of contact with patients. If returning to care for patients in a protective environment (e.g., hematopoietic stem cell transplant patients), consider for temporary reassignment or exclusion from work for 7 days from symptom onset or until the resolution of symptoms, whichever is longer.</p> <p>Those who develop acute respiratory symptoms without fever should be considered for evaluation by occupational health to determine appropriateness of contact with patients and can be allowed to work unless caring for patients in a protective environment; these personnel should be considered for temporary reassignment or exclusion from work for 7 days from symptom onset or until the resolution of all noncough symptoms, whichever is longer. If symptoms such as cough and sneezing are still present, HCP should wear a facemask during patient care activities. The importance of performing frequent hand hygiene (especially before and after each patient contact) should be reinforced.</p>
Measles		
Active	Exclude from duty	4 days after rash appears
Postexposure (HCP without presumptive evidence of measles immunity)	Exclude from duty	5 days after first exposure through 21 days after last exposure and/or 4 days after the rash appears
Mumps		
Active	Exclude from duty	5 days after onset of parotitis
Postexposure (HCP without presumptive evidence of mumps immunity)	Exclude from duty	12 days after first exposure through 25 days after last exposure or 5 days after onset of parotitis
Pertussis		
Active	Exclude from duty	Beginning of catarrhal stage through third week after onset of paroxysms or until 5 days after start of effective antimicrobial therapy
Postexposure		
Symptomatic personnel	Exclude from duty	5 days after start of effective antimicrobial therapy
Asymptomatic personnel – HCP likely to expose a patient at risk for severe pertussis [§]	No restriction from duty; on antimicrobial prophylactic therapy	
Asymptomatic personnel – other HCP	No restriction from duty; can receive postexposure prophylaxis or be monitored for 21 days after pertussis exposure and treated at the onset of signs and symptoms of pertussis	

See table footnotes on page 44

TABLE 5. (Continued) Advisory Committee on Immunization Practices work restrictions for health-care personnel* (HCP) exposed to or infected with certain vaccine-preventable diseases and conditions

Disease/Condition	Work restriction	Duration
Rubella		
Active	Exclude from duty	7 days after the rash appears
Postexposure (personnel without evidence of rubella immunity)	Exclude from duty	7 days after first exposure through 23 days after last exposure and/or 7 days after rash appears
Varicella		
Active	Exclude from duty	Until all lesions dry and crust. If only lesions that do not crust (i.e., macules and papules), until no new lesions appear within a 24-hour period
Postexposure (HCP without evidence of varicella immunity)	Exclude from duty unless receipt of the second dose within 3-5 days after exposure	8th day after 1st exposure through 21st day (28th day if varicella-zoster immune globulin administered) after the last exposure; if varicella occurs, until all lesions dry and crust or, if only lesions that do not crust (i.e., macules and papules), until no new lesions appear within a 24-hour period
Herpes zoster		
Localized in immunocompetent person	Cover lesions; restrict from care of high-risk patients [¶]	Until all lesions dry and crust
Disseminated or localized in immunocompromised person until disseminated infection is ruled out	Exclude from duty	Until all lesions dry and crust
Postexposure (HCP without evidence of varicella immunity)		
Disseminated zoster or localized zoster with uncontained/uncovered lesions	Exclude from duty unless receipt of the second dose of varicella vaccine within 3–5 days after exposure	8th day after 1st exposure through 21st day (28th day if varicella-zoster immune globulin administered) after the last exposure; if varicella occurs, until all lesions dry and crust or, if only lesions that do not crust (i.e., macules and papules), until no new lesions appear within a 24-hour period
Localized zoster with contained/covered lesions	For HCP with at least 1 dose of varicella vaccine, no work restrictions. For HCP with no doses of varicella vaccine, restrict from patient contact	8th day after 1st exposure through 21st day (28th day if varicella-zoster immune globulin administered) after the last exposure; if varicella occurs, until all lesions dry and crust or, if only lesions that do not crust (i.e., macules and papules), until no new lesions appear within a 24-hour period

Abbreviation: HBsAg = hepatitis B surface antigen.

Sources: Adapted from CDC. Recommendations for preventing transmission of human immunodeficiency virus and hepatitis B virus to patients during exposure-prone invasive procedures. MMWR 1991;40(No. RR-8); CDC. Guideline for isolation precautions in hospitals: recommendations of the Hospital Infection Control Practices Advisory Committee (HICPAC) and the National Center for Infectious Diseases. Infect Control Hosp Epidemiol 1996;17:53–80; Williams WW. CDC guideline for infection control in hospital personnel. Infect Control 1983;4(Suppl):326–49; CDC. Immunization of health-care workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). MMWR 1997;46(No. RR-18).

* Persons who provide health care to patients or work in institutions that provide patient care (e. g., physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative and support staff in health-care institutions). **Source:** U.S. Department of Health and Human Services. Definition of health-care personnel (HCP). Available at <http://www.hhs.gov/ask/initiatives/vac Toolkit/definition.html>.

[†] Includes children aged <5 years, adults aged ≥65 years, pregnant women, American Indians/Alaska Natives, persons aged <19 years who are receiving long-term aspirin therapy, and persons with certain high-risk medical conditions (i.e., asthma, neurologic and neurodevelopmental conditions, chronic lung disease, heart disease, blood disorders, endocrine disorders, kidney disorders, liver disorders, metabolic disorders, weakened immune system due to disease or medication, and morbid obesity).

[§] Includes hospitalized neonates and pregnant women.

[¶] Includes patients who are susceptible to varicella and at increased risk for complications of varicella (i.e., neonates, pregnant women, and immunocompromised persons of any age).

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The Basics of Vaccine Administration

Adapted from

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/D/vacc_admin.pdf to focus information relevant to healthcare personnel immunization (e.g., information regarding pediatric patients has not been included). To minimize confusion when differentiating between the roles of the administering healthcare professional (e.g., employee/occupational health nurse or the infection preventionist) and the healthcare personnel receiving the immunization, the term “patient” refers to the healthcare personnel receiving the immunization. The term “provider” or “healthcare provider” refers to the employee/occupational health nurse or infection preventionist involved in the immunization process

Appropriate vaccine administration is a critical component of a successful immunization program. The following information provides general guidance for those who administer vaccines and should be used in conjunction with professional standards of medication administration and vaccine manufacturers' guidelines.

The “Rights of Medication Administration” should be applied to each encounter when vaccines are administered. These rights include:

- the right patient;
- the right vaccine or diluent;
- the right time*;
- the right dosage;
- the right route, needle length, and technique;
- the right site; and,
- the right documentation.

*(includes administering at the correct age, the appropriate interval, and before vaccine or diluent expires)

Staff Training and Education

All personnel who will administer vaccines should receive competency-based training and education on vaccine administration before providing vaccines to patients. Providers need to orient new staff to vaccines used in their office and validate staff’s knowledge and skills about vaccine administration with a skills checklist. Providers should remember to include temporary personnel who may be filling in on days when the clinic is short staffed or helping during peak times such as flu season. Continuing education should be provided for all staff on the use and administration of new vaccines, new schedules, and new or revised recommendations.

Patient Preparation and Care

- **Screening** - All patients should be screened for contraindications and precautions every time a vaccine is administered, even if the patient has previously received a dose of that vaccine. The patient’s status can change from one visit to the next or a new contraindication or precaution may have been added.
- **Vaccine Safety & Risk Communication** - There have been safety concerns about vaccines since the 18th century when the first smallpox vaccination campaigns began. Specific vaccine concerns have changed through time. An increasing number of individuals raise vaccine

safety concerns and are exposed to information about vaccines through the media, internet, family members, and friends. Some of this information is inaccurate and misleading.

A provider's recommendation for vaccination is a powerful motivator. Healthcare providers are consistently identified as the most trusted source of vaccine information by parents and patients. Immunization providers should be prepared to discuss the benefits and risks of vaccines, as well as the risks of vaccine-preventable diseases (VPD), using Vaccine Information Statements (VIS) and other reliable resources. Establishing an open dialogue promotes a safe, trust-building environment in which individuals can freely evaluate information, discuss vaccine concerns and make informed decisions regarding immunizations. Providers are also encouraged to discuss after care instructions with patients.

• **Atraumatic Care** - Vaccine safety issues and the need for multiple injections have increased the concerns and anxiety associated with immunizations. Healthcare providers need to display confidence and establish an environment that promotes a sense of security and trust for the patient, utilizing a variety of techniques to minimize the stress and discomfort associated with receiving injections. Although pain from immunizations is, to some extent, unavoidable, there are some things that healthcare providers can do when administering vaccines. Everyone involved should work to provide immunizations in the safest and least stressful way possible. Simple strategies that can be used by the employee/occupational health nurse to make the process of receiving vaccines easier include:

- displaying a positive attitude through facial expressions, body language, and comments;
- using a soft and calm tone of voice;
- making eye contact;
- explaining why vaccines are needed (e.g., "this medicine will protect you from getting sick" or "this shot is a shield to protect your body against infection"); and,
- being honest and explaining what to expect (e.g., do not say that the injection will not hurt).

• **Positioning & Comforting Restraint** - The healthcare provider should accommodate for the patient's comfort, safety, age, activity level, and the site of administration when considering patient positioning and restraint.

All providers who administer vaccines to older children, adolescents, and adults should be aware of the potential for syncope (fainting) after vaccination and take measures to prevent it. Clinicians should (1) make sure the person who is being vaccinated is always seated or lying down; (2) be aware of symptoms that precede fainting (weakness, dizziness, pallor, etc.); and (3) provide supportive care and take appropriate measures to prevent injuries if such symptoms occur. The Advisory Committee on Immunization Practices (ACIP) also recommends that providers consider observing the vaccine recipient (with the recipient seated or lying down) for 15 minutes after vaccination.

• **Comfort Measures** - Concern and anxiety about injections are common for all ages. Fear of injections and needlestick pain are often cited as reasons why children and adults, including healthcare personnel, refuse vaccines. Pain is a subjective phenomenon influenced by multiple factors, including an individual's age, anxiety level, previous healthcare experiences, and culture. Managing the pain associated with immunizations has the potential to improve satisfaction with the immunization experience. Consideration for these factors is important as

the provider develops a planned approach to management of injection pain. Immunization providers are encouraged to determine the patient's previous experiences with needlesticks.

Evidence-based strategies to ease the injection process include:

Antipyretics - An age-appropriate dose of a non-aspirin-containing pain reliever may be considered to decrease discomfort and fever if it should occur after vaccination. ACIP does not recommend the prophylactic use of analgesics before or at the time of vaccination.

Distraction techniques – Age-appropriate, non-pharmacologic techniques may provide distraction from pain associated with injections. Psychological interventions such as distraction have been demonstrated to be effective at reducing stress and the perception of pain during the injection process. Distraction can be accomplished through a variety of techniques (e.g., deep breathing techniques).

Order of injections – Injecting the most painful vaccine (e.g., MMR) last when multiple injections are being administered may also decrease the pain of injections.

Tactile stimulation – Rubbing or stroking the skin near the injection site with moderate intensity may decrease pain in adults.

Administration technique – Performing intramuscular injections rapidly without aspiration has also demonstrated a reduction in pain.

Topical analgesia may be applied to decrease pain at the injection site. These products (e.g., 5% lidocaine-prilocaine emulsion or refrigerant spray) should be used only for the ages recommended and as directed by the product manufacturer.

Infection Prevention and Control

Healthcare providers should follow Standard Precautions to minimize the risks of spreading disease during the administration of vaccines.

- **Hand hygiene** – Hand hygiene is critical to prevent the spread of illness and disease. Hands should be washed thoroughly with soap and water or cleansed with an alcohol-based waterless antiseptic before vaccine preparation, between recipients, and any time hands become soiled.

- **Gloves** - Occupational Safety and Health Administration (OSHA) regulations do not require gloves to be worn when administering vaccines unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on the hands. If gloves are worn, they should be changed between vaccine recipients. Gloves will not prevent needlestick injuries. Any needlestick injury should be reported immediately to the site supervisor, with appropriate care and follow-up given as directed by local/state guidelines.

- **Equipment Disposal** - Used needles should not be recapped, cut, or detached from the syringes before disposal. All used syringe/needle devices should be placed in puncture proof containers to prevent accidental needlesticks and reuse. Empty or expired vaccine vials are considered medical waste and should be disposed of according to state regulations.

Vaccine Preparation

Proper vaccine handling and preparation is critical in maintaining the integrity of the vaccine during transfer from the manufacturer's vial to the syringe and ultimately to the patient.

- **Equipment Selection**

- **Syringe Selection** - A separate needle and syringe should be used for each injection. A parenteral vaccine may be delivered in either a 1-mL or 3-mL syringe as long as the prescribed dosage is delivered. OSHA requires that safety-engineered injection devices (e.g., needle-shielding syringes or needle-free injectors) be used for injectable vaccination in all clinical settings to reduce risk for injury and disease transmission. Personnel who will be using these products should be involved in evaluation and selection of these products and should receive training with these devices before using them in the clinical area.

- **Needle Selection** - Vaccine must reach the desired tissue site for optimal immune response to occur. Therefore, needle selection should be based on the prescribed route, size of the individual, volume and viscosity of the vaccine, and injection technique. A supply of needles in varying lengths appropriate for the clinic's patient population should be available to staff. Typically, vaccines are not highly viscous so a fine gauge needle (22-25 gauge) can be used.

- **Inspecting Vaccine** - Each vaccine and diluent vial should be carefully inspected for damage or contamination prior to use. The expiration date printed on the vial or box should be checked. Vaccine can be used through the last day of the month indicated by the expiration date unless otherwise stated on the package labeling. The expiration date or time for some vaccines changes once the vaccine vial is opened or the vaccine is reconstituted. This information is available in the manufacturer's product information. Regardless of expiration date, vaccine and diluent should only be used as long as they are normal in appearance and have been stored and handled properly. Expired vaccine or diluent should never be used.

- **Reconstitution** - Several vaccines are prepared in a lyophilized (freeze-dried) form that requires reconstitution with a liquid diluent. Vaccines should be reconstituted according to manufacturer guidelines using only the specific diluent supplied by the manufacturer for that vaccine. Each diluent is specific to the corresponding vaccine in volume, sterility, pH, and chemical balance. If the wrong diluent is used, the vaccine dose is not valid and will need to be repeated using the correct diluent.

Reconstitute vaccine just before using. Use all of the diluent supplied for a single dose and then draw up all of the vaccine after it is thoroughly reconstituted. Once reconstituted, the vaccine must be either administered within the time guidelines specified in the manufacturer's product information or discarded. Changing the needle between drawing vaccine from the vial and administering the vaccine is not necessary unless the needle is contaminated or damaged.

- **Filling Syringes** - Agitate (shake) the vial to mix the vaccine thoroughly and obtain a uniform suspension prior to withdrawing each dose. Whenever solution and container permit, inspect vaccine visually for particulate matter and/or discoloration prior to administration. If problems are noted (e.g., vaccine cannot be resuspended), the vaccine should not be administered.

Standard medication preparation guidelines should be followed for drawing a dose of vaccine into a syringe. A vaccine dose should not be drawn into the syringe until it is to be administered. When syringes are filled, the type of vaccine, lot number, and date of filling should be labeled on each syringe and the doses should be administered as soon as possible after filling. Sometimes providers prefill many syringes themselves, outside of appropriately controlled environments. This practice is strongly discouraged by CDC. The facility pharmacy may prefill syringes, but it is expected that this be done in accordance with USP 797 and other relevant safety standards.

Single-dose vials and manufacturer-filled syringes are designed for single-dose administration and should be discarded if vaccine has been withdrawn or reconstituted and subsequently not used within the time frame specified by the manufacturer. Typically, the maximum time for inactivated vaccines is no longer than the same clinic day. CDC also recommends that when the rubber diaphragm on a single-dose vial is exposed, the vaccine in the vial should be used that clinic day or discarded. It is difficult to tell if a needle has punctured the rubber diaphragm and single-dose vials do not contain a preservative. The same guideline applies to manufacturer-filled syringes that have been activated (i.e., syringe cap removed or needle attached) because the sterile seal has been broken.

Vaccines should never be combined in a single syringe except when specifically approved by the FDA and packaged for that specific purpose. Most combination vaccines will be combined by the manufacturer.

Vaccine should never be transferred from one syringe to another. Partial doses from separate vials should not be combined into a single dose. Both of these practices increase the risk of contamination. Instilling air into a multidose vial prior to withdrawing a vaccine dose may not be necessary. It could cause a “spritz” of vaccine to be lost each time the air is injected, which through time can decrease the amount of vaccine in the vial and lead to the loss of a dose (e.g., obtaining only 9 full doses from a 10-dose vial).

Route and Site

The recommended route and site for each vaccine are based on clinical trials, practical experience and theoretical considerations. This information is included in the manufacturer’s product information for each vaccine. There are four routes used in the administration of vaccines; oral, intramuscular injection, subcutaneous injection, and intranasal. Oral administration will not be included in this administration information as there are no oral vaccines currently recommended for healthcare personnel. Deviation from the recommended route may reduce vaccine efficacy or increase local adverse reactions.

- **Intranasal (NAS) Route** - The live attenuated influenza vaccine (LAIV, FluMist) is currently the only vaccine administered by the nasal route. The vaccine dose (0.2 mL) is

inside a special sprayer device. A plastic clip on the plunger divides the dose into two equal parts. The patient should be seated in an upright position with head tilted back. Instruct the patient to breathe normally. The provider should gently place a hand behind the patient's head. The tip of the nasal sprayer should be inserted slightly into the naris. Half of the contents of the sprayer (0.1 mL) are sprayed into the nostril. The dose-divider clip is then removed and the procedure is repeated in the other naris. Detailed information on the nasal administration of LAIV is included in the manufacturer's product information. The dose does not need to be repeated if the patient coughs, sneezes, or expels the dose in any other way.

It is possible for the LAIV spray to cause low-level contamination of the environment with vaccine virus, but there have been no reports of vaccine virus transmission by this route. No instances have been reported of illness or attenuated vaccine virus infections among inadvertently exposed healthcare personnel or immunocompromised patients. Only healthcare personnel with severe immunosuppression (i.e., who require a protective environment, such as for hematopoietic cell transplant) should be restricted from receiving or administering LAIV. It is unlikely that healthcare personnel with this level of immunosuppression would be administering vaccines or working, but it is still a possibility. Other healthcare personnel at higher risk for influenza complications can administer LAIV. These include persons with underlying medical conditions placing them at higher risk or who are likely to be at risk, including pregnant women, persons with asthma, and persons aged 50 years and older.

- **Subcutaneous (SQ) Route.** Subcutaneous injections are administered into the fatty tissue found below the dermis and above muscle tissue.

- **Site** - The recommended subcutaneous site for vaccine administration in adults is the upper outer triceps of the arm.

- **Needle Gauge & Length** - 5/8-inch, 23- to 25-gauge needle

- **Technique**

- Follow standard medication administration guidelines for site assessment/selection and site preparation.

- To avoid reaching the muscle, pinch up the fatty tissue, insert the needle at a 45° angle and inject the vaccine into the tissue.

- Withdraw the needle and apply light pressure to the injection site for several seconds with dry cotton ball or gauze.

- **Intramuscular (IM) Route.** Intramuscular injections are administered into muscle tissue below the dermis and subcutaneous tissue.

- **Site** - All inactivated vaccines, with the exception of one formulation of meningococcal polysaccharide vaccine (MPSV4), are administered by the intramuscular route. Many inactivated vaccines contain an adjuvant, which is a vaccine component that enhances the immune response to the antigen. Adjuvants can cause an exaggerated local reaction (e.g., pain, swelling, redness) if not injected into the muscle, so proper technique is critical.

There are only two routinely recommended IM sites for administration of vaccines, the vastus lateralis muscle (anterolateral thigh) and the deltoid muscle (upper arm). Injection at these

sites reduces the chance of involving neural or vascular structures. The site depends on the age of the individual and the degree of muscle development.

Because there are no large blood vessels in the recommended sites, aspiration before injection of vaccines (i.e., pulling back on the syringe plunger after needle insertion but before injection) is not necessary. A study published in *Archives of Disease in Childhood* in 2007 found that when a vaccine was administered and withdrawn rapidly without aspiration there was less evidence of pain than when the vaccine was injected and withdrawn slowly with aspiration. Also, some safety-engineered syringes do not allow for aspiration.

-Needle Length- The needle should be long enough to reach the muscle mass and prevent vaccine from seeping into subcutaneous tissue, but not so long as to involve underlying nerves, blood vessels, or bone. The vaccinator should be familiar with the anatomy of the area into which the vaccine will be injected. Decisions on needle size and site of injection must be made for each person on the basis of the size of the muscle, the thickness of adipose tissue at the injection site, the volume of the material to be administered, and injection technique.

- Adults (19 Years and Older)

For adults, the deltoid muscle is recommended for routine intramuscular vaccinations. The anterolateral thigh also can be used. For men and women weighing less than 130 lbs (60 kg) a 5/8- to 1-inch needle is sufficient to ensure intramuscular injection into the deltoid muscle if a 90-degree angle is used and the tissue is not bunched. For men and women who weigh 130-152 lbs (60-70 kg), a 1-inch needle is sufficient. For women who weigh 152-200 lbs (70-90 kg) and men who weigh 152-260 lbs (70-118 kg), a 1- to 1½-inch needle is recommended. For women who weigh more than 200 lbs (more than 90 kg) or men who weigh more than 260 lbs (more than 118 kg), a 1½-inch needle is recommended.

- Technique

Follow standard medication administration guidelines for site assessment/selection and site preparation. To avoid injection into subcutaneous tissue, spread the skin of the selected vaccine administration site taut between the thumb and forefinger, isolating the muscle. Another technique, acceptable mostly for pediatric and geriatric patients, is to grasp the tissue and "bunch up" the muscle. Insert the needle fully into the muscle at a 90° angle and inject the vaccine into the tissue. Withdraw the needle and apply light pressure to the injection site for several seconds with a dry cotton ball or gauze.

Special Situations

- **Multiple Vaccinations** - If multiple vaccines are administered at a single visit, administration of each preparation at a different anatomic site is desirable. For adults, the deltoid muscle can be used for more than one intramuscular injection. The injections should be separated by 1 inch or more, if possible, so that any local reactions can be differentiated. Vaccines that are the most reactive (e.g., tetanus-containing) should be administered in different limbs if possible. Use of combination vaccines can reduce the number of injections.

If a vaccine and an immune globulin preparation are administered simultaneously (e.g., Td/Tdap and tetanus immune globulin [TIG] or hepatitis B vaccine and hepatitis B immune globulin [HBIG]), separate anatomic sites should be used.

The location of all injection sites should be documented in the employee's health record. Healthcare practices should consider using a vaccination site map so that all persons administering vaccines routinely use the same anatomic site for each different vaccine.

- **Vaccinating Persons with Bleeding Disorders** - Individuals with a bleeding disorder or who are receiving anticoagulant therapy may develop hematomas in IM injection sites. When any intramuscularly administered vaccine is indicated for a patient with a bleeding disorder, the vaccine should be administered intramuscularly if a physician familiar with the patient's bleeding risk determines that the vaccine can be administered by this route with reasonable safety. Prior to administration of IM vaccines the patient should be instructed about the risk of hematoma formation from the injection. If the person periodically receives antihemophilia or similar therapy, IM vaccine administration should be scheduled shortly after such therapy is administered. A 23-gauge or finer needle should be used and firm pressure applied to the site for at least 2 minutes after injection. The site should not be rubbed or massaged. Persons receiving anticoagulation therapy presumably have the same bleeding risk as those with clotting factor disorders and providers should follow the same guidelines for intramuscular administration.

- **Nonstandard Administration** - CDC discourages deviating from the recommended route, site, dosage, or number of doses for any vaccine. Deviation can result in reduced protection and increase the risk of an exaggerated local reaction. For certain vaccines, the ACIP recommends revaccination if a nonstandard route or site is used.

Larger than recommended dosages can be hazardous because of excessive local or systemic concentrations of antigens or other vaccine constituents deposited into the tissue.

Administering volumes smaller than recommended (e.g., inappropriately divided doses) might result in inadequate protection. Using reduced doses administered at multiple vaccination visits that equal a full dose or using smaller divided doses is not recommended. Any vaccination using less than the standard dose should not be counted, and the person should be revaccinated according to age unless serologic testing indicates that an adequate response has developed. If a partial dose of a parenteral vaccine is administered because the syringe or needle leaks or the patient jerks away, the dose should be repeated.

Hepatitis B vaccine administered by any route other than the intramuscular route, or in adults at any site other than the deltoid or anterolateral thigh, should not be counted as valid and should be repeated. All vaccines should be administered by the manufacturer's recommended route, but there are no ACIP recommendations to repeat doses of other vaccines administered by another route.

- **Managing Acute Vaccine Reactions** - Severe, life-threatening anaphylactic reactions following vaccination are rare. Thorough screening for contraindications and precautions prior to vaccination can often prevent reactions. Staff must have in place and be familiar with procedures for managing a reaction. Staff should be familiar with the signs and symptoms of anaphylaxis because they usually begin within minutes of vaccination. These signs and symptoms can include, but are not limited to: flushing, facial edema, urticaria, itching, swelling of the mouth or throat, wheezing, and difficulty breathing. Each staff member should know

their role in the event of an emergency and all vaccination providers should be certified in cardiopulmonary resuscitation (CPR). Epinephrine and equipment for maintaining an airway should be available for immediate use. Additional drugs may also be used.

Documentation

All vaccines administered should be fully documented in the healthcare personnel's employee health record. Best practice documentation guidelines for medications include the vaccine type (ACIP list of U.S. vaccine abbreviations, <http://www.cdc.gov/vaccines/recs/acip/vac-abbrev.htm>), route, dosage, and site. Accurate documentation can help prevent administration errors and curtail the number and costs of excess vaccine doses administered. Providers also should update the healthcare personnel records to reflect any documented episodes of adverse events after vaccination and any serologic test results related to vaccine-preventable diseases (e.g., those for rubella screening and antibody to hepatitis B surface antigen). Participation in immunization information systems is encouraged. The healthcare personnel should be provided with an immunization record that includes the vaccines administered, including the dates of administration.

Strategies to Prevent Administration Errors

Vaccine administration errors can result in a person receiving an ineffective immunization. This can leave the person vulnerable to infection. In addition to strict adherence to the "Rights of Medication Administration" and ongoing training and education of staff, listed below are other strategies that can be implemented to help prevent administration errors.

When possible, involve staff in the selection of vaccine products to be used in your facility. Different brands of the same vaccine can have different schedules, age indications, or other indications. Stocking multiple brands might lead to staff confusion and vaccine administration errors.

Keep current reference materials available for staff on each vaccine used in your facility. Keep reference sheets for timing and spacing, recommended sites, routes, and needle lengths posted for easy reference in your medication preparation area.

Rotate vaccines so that those with the shortest expiration dates are in the front of the storage unit. Use these first and frequently check the storage unit to remove any expired vaccine.

Consider the potential for product mix-ups when storing vaccines. Do not store sound-alike and look-alike vaccines next to each other (e.g., DTaP and Tdap). Consider color coding labels on vaccine storage containers and/or including the vaccine type and age indications.

Administer only vaccines that you have prepared for administration. **Triple check** your work before you administer a vaccine and ask other staff to do the same.

Counsel healthcare personnel about vaccines to be administered and on how important it is for them to maintain immunization records on all family members. Educated persons may notice a potential error and help prevent it.

Administering Vaccines to Adults: Dose, Route, Site, Needle Size, and Preparation

Vaccine	Dose	Route	Site	Needle Size	Vaccine Preparation
Tetanus, Diphtheria (Td) with Pertussis (Tdap)	0.5 mL	IM	Deltoid muscle	22–25g, 1–1½"	Shake vial vigorously to obtain a uniform suspension prior to withdrawing each dose. Whenever solution and container permit, inspect vaccine visually for particulate matter and/or discoloration prior to administration. If problems are noted (e.g., vaccine cannot be resuspended), the vaccine should not be administered.
Hepatitis A (HepA)	≤18 yrs.: 0.5 mL ≥19 yrs.: 1.0 mL	IM	Deltoid muscle	22–25g, 1–1½"	
Hepatitis B (HepB)	≤19 yrs.: 0.5 mL ≥20 yrs.: 1.0 mL	IM	Deltoid muscle	22–25g, 1–1½"	
HepA+HepB (Twinrix)	≥18 yrs.: 1.0 mL	IM	Deltoid muscle	22–25g, 1–1½"	
Human papillomavirus (HPV)	0.5 mL	IM	Deltoid muscle	22–25g, 1–1½"	
Influenza, trivalent inactivated (TIV)	0.5 mL	IM	Deltoid muscle	22–25g, 1–1½"	
Pneumococcal polysaccharide (PPSV)	0.5 mL	IM	Deltoid muscle	22–25g, 1–1½"	
		SC	Fatty tissue over triceps	23–25g, ⅝"	<p>Reconstitute just before using. Use only the diluent supplied with the vaccine. Inject the volume of the diluent shown on the diluent label into the vial of lyophilized vaccine and gently agitate to mix thoroughly. Withdraw the entire contents and administer immediately after reconstitution.</p> <p>Discard single dose MPSV, varicella, and zoster vaccines if not used within 30 minutes after reconstitution.</p> <p>Note: Unused reconstituted MMR vaccine and multidose MPSV vaccine may be stored at 35–46°F (2–8°C) for a limited time. The reconstituted MPSV vaccine must be used within 35 days; the reconstituted MMR vaccine must be used within 8 hours. Do not freeze either reconstituted vaccine.</p>
Meningococcal, conjugated (MCV)	0.5 mL	IM	Deltoid muscle	22–25g, 1–1½"	
Meningococcal, polysaccharide (MPSV)	0.5 mL	SC	Fatty tissue over triceps	23–25g, ⅝"	
Measles, mumps, rubella (MMR)	0.5 mL	SC	Fatty tissue over triceps	23–25g, ⅝"	
Zoster (Zos)	0.65 mL	SC	Fatty tissue over triceps	23–25g, ⅝"	
Varicella (Var)	0.5 mL	SC	Fatty tissue over triceps	23–25g, ⅝"	
Influenza, live, attenuated (LAIV)	0.2 mL (0.1 mL into each nostril)	Intranasal spray	Intranasal	NA	Consult package insert.

*When giving intramuscular injections, a ⅝" needle is sufficient in adults weighing <130 lbs (<60 kg); a 1" needle is sufficient in adults weighing 130–152 lbs (60–70 kg); a 1½" needle is recommended in women weighing 152–200 lbs (70–90 kg) and men weighing 152–260 lbs (70–118 kg); a 1½" needle is recommended in women weighing >200 lbs (>90 kg) or men weighing >260 lbs (>118 kg). A ⅝" (16mm) needle may be used only if the skin is stretched tight, the subcutaneous tissue is not bunched, and injection is made at a 90-degree angle.

Please note: Always refer to the package insert included with each biologic for complete vaccine administration information. CDC's Advisory Committee on Immunization Practices (ACIP) recommendations for the particular vaccine should be reviewed as well. Access the ACIP recommendations at www.immunize.org/acip.

How to Administer IM and SC Vaccine Injections to Adults

Intramuscular (IM) Injections

Administer these vaccines via IM route:

Tetanus, diphtheria (Td), or with pertussis (Tdap); hepatitis A; hepatitis B; human papillomavirus (HPV); trivalent inactivated influenza (TIV); and quadrivalent meningococcal conjugate (MCV4). Administer polio (IPV) and pneumococcal polysaccharide vaccine (PPSV23) either IM or SC.

Injection site:

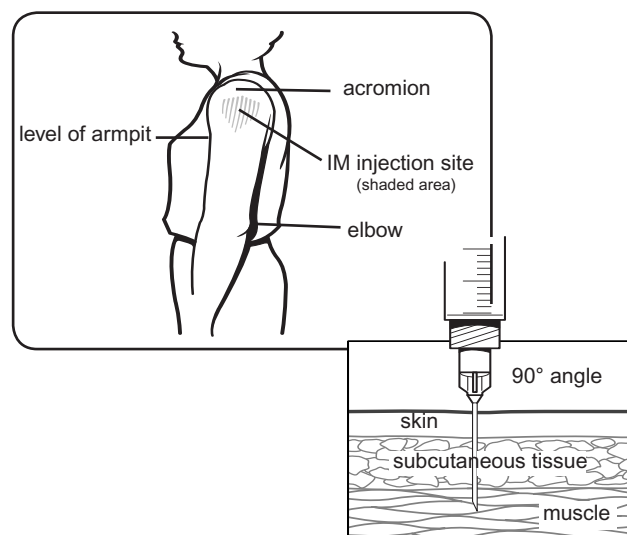
Give in the central and thickest portion of the deltoid—above the level of the armpit and below the acromion (see the diagram).

Needle size:

22–25 gauge, 1–1½" needle (see note at right)

Needle insertion:

- Use a needle long enough to reach deep into the muscle.
- Insert the needle at a 90° angle to the skin with a quick thrust.
- Separate two injections given in the same deltoid muscle by a minimum of 1".



Note: A 5/8" needle is sufficient in adults weighing <130 lbs (<60 kg); a 1" needle is sufficient in adults weighing 130–152 lbs (60–70 kg); a 1½" needle is recommended in women weighing 152–200 lbs (70–90 kg) and men weighing 152–260 lbs (70–118 kg); a 1½" needle is recommended in women weighing >200 lbs (>90 kg) or men weighing >260 lbs (>118 kg). A 5/8" (16mm) needle may be used only if the skin is stretched tight, the subcutaneous tissue is not bunched, and injection is made at a 90-degree angle.

Subcutaneous (SC) Injections

Administer these vaccines via SC route:

MMR, varicella, meningococcal polysaccharide (MPSV4), and zoster (shingles). Administer polio (IPV) and pneumococcal polysaccharide vaccine (PPSV23) either SC or IM.

Injection site:

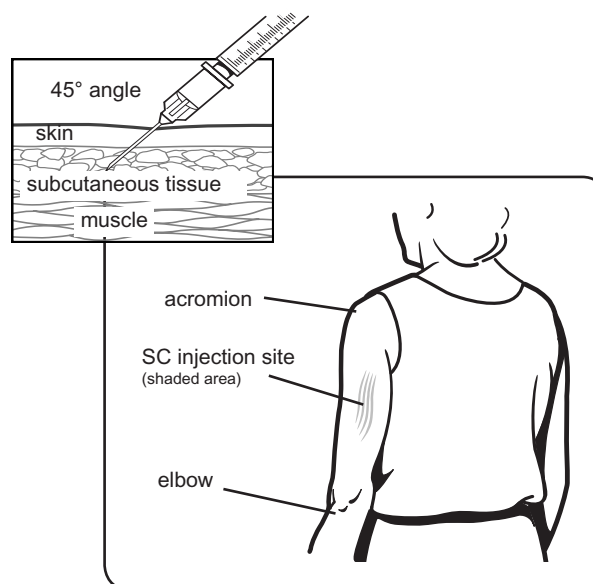
Give in fatty tissue over the triceps (see the diagram).

Needle size:

23–25 gauge, 5/8" needle

Needle insertion:

- Pinch up on the tissue to prevent injection into the muscle. Insert the needle at a 45° angle to the skin.
- Separate two injections given in the same area of fatty tissue by a minimum of 1".



Adapted by the Immunization Action Coalition, courtesy of the Minnesota Department of Health

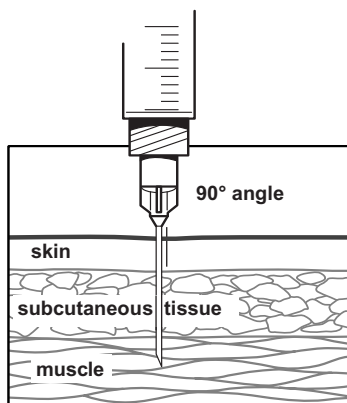
How to administer intramuscular, intradermal, and intranasal influenza vaccines

Intramuscular injection

Trivalent Inactivated Influenza Vaccines (TIV)

1. Use a needle long enough to reach deep into the muscle. Infants age 6 through 11 mos: 1"; 1 through 2 yrs: 1–1¼"; children and adults 3 yrs and older: 1–1½".
2. With your left hand*, bunch up the muscle.
3. With your right hand*, insert the needle at a 90° angle to the skin with a quick thrust.
4. Push down on the plunger and inject the entire contents of the syringe. There is no need to aspirate.
5. Remove the needle and simultaneously apply pressure to the injection site with a dry cotton ball or gauze. Hold in place for several seconds.
6. If there is any bleeding, cover the injection site with a bandage.
7. Put the used syringe in a sharps container.

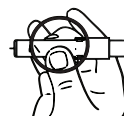
*Use the opposite hand if you are left-handed.



Intradermal administration

Trivalent Inactivated Influenza Vaccine (TIV)

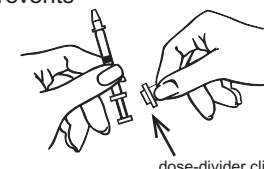
1. Gently shake the microinjection system before administering the vaccine.
2. Hold the system by placing the thumb and middle finger on the finger pads; the index finger should remain free.
3. Insert the needle perpendicular to the skin, in the region of the deltoid, in a short, quick movement.
4. Once the needle has been inserted, maintain light pressure on the surface of the skin and inject using the index finger to push on the plunger. Do not aspirate.
5. Remove the needle from the skin. With the needle directed away from you and others, push very firmly with the thumb on the plunger to activate the needle shield. You will hear a click when the shield extends to cover the needle.
6. Dispose of the applicator in a sharps container.



Intranasal administration

Live Attenuated Influenza Vaccine (LAIV)

1. FluMist (LAIV) is for intranasal administration only. Do not inject FluMist.
2. Remove rubber tip protector. Do not remove dose-divider clip at the other end of the sprayer.
3. With the patient in an upright position (i.e., head not tilted back), place the tip just inside the nostril to ensure LAIV is delivered into the nose. The patient should breathe normally.
4. With a single motion, depress plunger as rapidly as possible until the dose-divider clip prevents you from going further.
5. Pinch and remove the dose-divider clip from the plunger.
6. Place the tip just inside the other nostril, and with a single motion, depress plunger as rapidly as possible to deliver the remaining vaccine.
7. Dispose of the applicator in a sharps container.



Vaccines with Diluents: How to Use Them

The following vaccines must be reconstituted correctly before they are administered. Reconstitution means that the lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluent (liquid) in another. Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart. ALWAYS check the expiration date on the diluent and vaccine. NEVER use expired diluent or vaccine.

Vaccine product name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use*	Diluent storage environment
ActHIB (Hib)	sanofi pasteur	ActHIB	0.4% sodium chloride	24 hrs	Refrigerator
Hiberix (Hib)	GlaxoSmithKline	Hib	0.9% sodium chloride	24 hrs	Refrigerator or room temp
Imovax (RAB _{HDCV})	sanofi pasteur	Imovax	Sterile water	Immediately	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
Menomune (MPSV4)	sanofi pasteur	MPSV4	Distilled water	30 min (single-dose vial) 35 days (multi-dose vial)	Refrigerator
Menveo (MCV4)	Novartis	MenA	MenCWY	8 hrs	Refrigerator
Pentacel (DTaP-IPV/Hib)	sanofi pasteur	ActHIB	DTaP-IPV	Immediately†	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB _{PCECV})	Novartis	RabAvert	Sterile water	Immediately	Refrigerator
Rotarix (RV1)‡	GlaxoSmithKline	RV1	Sterile water, calcium carbonate, and xanthan*	24 hrs	Room temp
Varivax (VAR)	Merck	VAR	Sterile water	30 min	Refrigerator or room temp
YF-VAX (YF)	sanofi pasteur	YF-VAX	0.9% sodium chloride	60 min	Refrigerator or room temp
Zostavax (ZOS)	Merck	ZOS	Sterile water	30 min	Refrigerator or room temp

Always refer to package inserts for detailed instructions on reconstituting specific vaccines. In general, follow these steps:

- For single-dose vaccine products (exceptions are Menomune in the multi-dose vial and Rotarix[§]), select a syringe and a needle of proper length to be used for both reconstitution and administration of the vaccine. Following reconstitution, Menomune in a multi-dose vial will require a new needle and syringe for each dose of vaccine to be administered. For Rotarix, see the package insert.[‡]
- Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify the following:
 - that they are the correct two products to mix together
 - that the diluent is the correct volume (especially for Menomune in the multi-dose vial)
 - that neither vaccine nor diluent has expired
- Reconstitute (i.e., mix) vaccine *just prior to use*[‡] by
 - removing the protective caps and wiping each stopper with an alcohol swab
 - inserting needle of syringe into diluent vial and withdrawing entire contents
 - injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the lyophilized powder
- Check the appearance of the reconstituted vaccine.
 - Reconstituted vaccine may be used if the color and appearance match the description on the package insert.
 - If there is discoloration, extraneous particulate matter, obvious lack of resuspension, or cannot be thoroughly mixed, mark the vial as "DO NOT USE," return it to proper storage conditions, and contact your state or local health department immunization program or the vaccine manufacturer.
- If reconstituted vaccine is not used immediately or comes in a multi-dose vial (i.e., multi-dose Menomune),
 - clearly mark the vial with the date and time the vaccine was reconstituted
 - maintain the product at 35°–46°F (2°–8°C); do not freeze
 - protect reconstituted vaccines from light
 - use only within the time indicated on chart above

* If the reconstituted vaccine is not used within this time period, it must be discarded.

† Within 30 minutes or less.

‡ Rotarix vaccine is administered by mouth using the applicator that contains the diluent. It is not administered as an injection.

Guide to Contraindications and Precautions¹ to Commonly Used Vaccines* (Page 1 of 2)

Vaccine	Contraindications	Precautions ¹
Hepatitis B (HepB)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Infant weighing less than 2000 grams (4 lbs, 6.4 oz)²
Rotavirus (RV5 [RotaTeq], RV1 [Rotarix])	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Severe combined immunodeficiency (SCID) History of intussusception 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Altered immunocompetence other than SCID Chronic gastrointestinal disease³ Spina bifida or bladder exstrophy³
Diphtheria, tetanus, pertussis (DTaP) Tetanus, diphtheria, pertussis (Tdap)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP or DTaP (for DTaP); or of previous dose of DTP, DTaP, or Tdap (for Tdap) 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid-containing vaccine History of arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid containing vaccine Progressive or unstable neurologic disorder (including infantile spasms for DTaP), uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized <p>For DTaP only:</p> <ul style="list-style-type: none"> Temperature of 105° F or higher (40.5° C or higher) within 48 hours after vaccination with a previous dose of DTP/DTaP Collapse or shock-like state (i.e., hypotonic hyporesponsive episode) within 48 hours after receiving a previous dose of DTP/DTaP Seizure within 3 days after receiving a previous dose of DTP/DTaP Persistent, inconsolable crying lasting 3 or more hours within 48 hours after receiving a previous dose of DTP/DTaP
Tetanus, diphtheria (DT, Td)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever GBS within 6 weeks after a previous dose of tetanus toxoid-containing vaccine History of arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid containing vaccine
<i>Haemophilus influenzae</i> type b (Hib)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Age younger than 6 weeks 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever
Inactivated poliovirus vaccine (IPV)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Pregnancy
Pneumococcal (PCV or PPSV)	<ul style="list-style-type: none"> For PCV13, severe allergic reaction (e.g., anaphylaxis) after a previous dose (of PCV7, PCV13, or any diphtheria toxoid-containing vaccine) or to a vaccine component (of PCV7, PCV13, or any diphtheria toxoid-containing vaccine) For PPSV, severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR)⁴	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Known severe immunodeficiency (e.g., from hematologic and solid tumors, receiving chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy⁵ or patients with HIV infection who are severely immunocompromised)⁶ Pregnancy 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product)⁷ History of thrombocytopenia or thrombocytopenic purpura Need for tuberculin skin testing⁸

Vaccine	Contraindications	Precautions ¹
Varicella (Var)⁴	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Known severe immunodeficiency (e.g., from hematologic and solid tumors, receiving chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy⁵ or patients with HIV infection who are severely immunocompromised)⁶ Pregnancy 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product)⁷ Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination, if possible; delay resumption of these antiviral drugs for 14 days after vaccination.
Hepatitis A (HepA)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Pregnancy
Influenza, injectable trivalent (TIV)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any influenza vaccine or to a vaccine component, including egg protein 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever History of GBS within 6 weeks of previous influenza vaccine
Influenza, live attenuated (LAIV)⁴	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component, including egg protein Possible reactive airways disease in a child age 2 through 4 years (e.g., history of recurrent wheezing or a recent wheezing episode) Immune suppression Certain chronic medical conditions such as asthma, diabetes, heart or kidney disease⁹ Pregnancy 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever History of GBS within 6 weeks of previous influenza vaccine Receipt of specific antivirals (i.e., amantadine, rimantadine, zanamivir, or oseltamivir) 48 hours before vaccination, if possible; avoid use of these antiviral drugs for 14 days after vaccination.
Human papilloma-virus (HPV)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Pregnancy
Meningococcal: conjugate (MCV4); polysaccharide (MPSV4)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever
Zoster (Zos)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, or long-term immunosuppressive therapy⁴ or patients with HIV infection who are severely immunocompromised). Pregnancy 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination, if possible; delay resumption of these antiviral drugs for 14 days after vaccination.

Footnotes

- Vaccine package inserts and the full ACIP recommendations for these vaccines should be consulted for additional information on vaccine-related contraindications and precautions and for more information on vaccine excipients. Events or conditions listed as precautions should be reviewed carefully. Benefits of and risks for administering a specific vaccine to a person under these circumstances should be considered. If the risk from the vaccine is believed to outweigh the benefit, the vaccine should not be administered. If the benefit of vaccination is believed to outweigh the risk, the vaccine should be administered. Whether and when to administer DTaP to children with proven or suspected underlying neurologic disorders should be decided on a case-by-case basis.
- Hepatitis B vaccination should be deferred for preterm infants and infants weighing less than 2000 g if the mother is documented to be hepatitis B surface antigen (HBsAg)-negative at the time of the infant's birth. Vaccination can commence at chronological age 1 month or at hospital discharge. For infants born to women who are HBsAg-positive, hepatitis B immunoglobulin and hepatitis B vaccine should be administered within 12 hours of birth, regardless of weight.
- For details, see CDC. "Prevention of Rotavirus Gastroenteritis among Infants and Children: Recommendations of the Advisory Committee on Immunization Practices. (ACIP)" *MMWR* 2009;58(No. RR-2) at www.cdc.gov/vaccines/pubs/acip-list.htm.
- LAIV, MMR, and varicella vaccines can be administered on the same day. If not adminis-

tered on the same day, these vaccines should be separated by at least 28 days.

- Substantially immunosuppressive steroid dose is considered to be 2 weeks or more of daily receipt of 20 mg (or 2 mg/kg body weight) of prednisone or equivalent.
- HIV-infected children may receive varicella and measles vaccine if CD4+ T-lymphocyte count is >15%. (Source: Adapted from American Academy of Pediatrics. Passive Immunization. In: Pickering LK, ed. *Red Book: 2009 Report of the Committee on Infectious Diseases*. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics: 2009.)
- Vaccine should be deferred for the appropriate interval if replacement immune globulin products are being administered (see Table 5 in CDC. "General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" at www.cdc.gov/vaccines/pubs/acip-list.htm.)
- Measles vaccination might suppress tuberculin reactivity temporarily. Measles-containing vaccine can be administered on the same day as tuberculin skin testing. If testing cannot be performed until after the day of MMR vaccination, the test should be postponed for at least 4 weeks after the vaccination. If an urgent need exists to skin test, do so with the understanding that reactivity might be reduced by the vaccine.
- For details, see CDC. "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. *MMWR* 2010;59(No. RR-8), available at www.cdc.gov/vaccines/pubs/acip-list.htm.

*Adapted from "Table 6. Contraindications and Precautions to Commonly Used Vaccines" found in: CDC. "General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)." *MMWR* 2011; 60(No. RR-2), p. 40–41, and from Atkinson W, Wolfe S, Hamborsky J, eds. Appendix A. Epidemiology and Prevention of Vaccine-Preventable Diseases (www.cdc.gov/vaccines/pubs/pinkbook/index.html).

Section 4 Management of Vaccine Reactions

Included in this section is information regarding the management of acute reactions to immunization and the reporting responsibilities of those reactions as a reportable event in the Vaccine Adverse Event Reporting System (VAERS). As assistance to rapid intervention and improvement of basic knowledge regarding vaccines and vaccine-related events, this section also included frequently asked questions and several useful terms and definitions.

- Medical Management of Vaccine Reactions in Adult Patients
<http://www.immunize.org/catg.d/p3082.pdf>
- Vaccine Adverse Event Reporting System (VAERS) Table of Reportable Events Following Vaccine
[http://vaers.hhs.gov/resources/VAERS Table of Reportable Events Following Vaccination.pdf](http://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf)
- Frequently Asked Questions (FAQs), Vaccine Misadventures, and Glossary of Terms

Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

(continued on page 2)

- ☐ Aqueous epinephrine 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen). If EpiPens are stocked, at least three adult EpiPens (0.30 mg) should be available.
- ☐ Diphenhydramine (Benadryl) injectable (50 mg/mL solution) and 25 mg or 50 mg capsules or tablets and syrup (12.5 mg/5 mL suspension)
- ☐ Syringes: 1 and 3 cc, 22 and 25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl)
- ☐ Alcohol wipes
- ☐ Tourniquet
- ☐ Adult airways (small, medium, and large)
- ☐ Adult size pocket mask with one-way valve
- ☐ Oxygen (if available)
- ☐ Stethoscope
- ☐ Sphygmomanometer (blood pressure measuring device with adult-size and extra-large cuffs)
- ☐ Tongue depressors
- ☐ Flashlight with extra batteries (for examination of the mouth and throat)
- ☐ Wristwatch with ability to count seconds
- ☐ Cell phone or access to an onsite phone

Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (generalized hives); angioedema (swelling of the lips, face, or throat); bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.

- a. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- b. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.
- c. Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).
- d. In addition, for systemic anaphylaxis, administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg, up to 100 mg maximum single dose.
- e. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- f. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 10–20 minutes for up to 3 doses, depending on patient's response.
- g. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- h. Notify the patient's primary care physician.

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the _____ until rescinded or until _____.
name of clinic date

Effective date

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	Event and interval from vaccination
Tetanus in any combination; DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	<ul style="list-style-type: none"> A. Anaphylaxis or anaphylactic shock (7 days) B. Brachial neuritis (28 days) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pertussis in any combination; DTaP, DTP, DTP-Hib, Tdap, P, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	<ul style="list-style-type: none"> A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (7 days) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles, mumps and rubella in any combination; MMR, MR, M, MMRV, R	<ul style="list-style-type: none"> A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (15 days) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rubella in any combination; MMR, MMRV, MR, R	<ul style="list-style-type: none"> A. Chronic arthritis (42 days) B. Any acute complications or sequelae (including death) of above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles in any combination; MMR, MMRV, MR, M	<ul style="list-style-type: none"> A. Thrombocytopenic purpura (7-30 days) B. Vaccine-strain measles viral infection in an immunodeficient recipient (6 months) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Oral Polio (OPV)	<ul style="list-style-type: none"> A. Paralytic polio <ul style="list-style-type: none"> o in a non-immunodeficient recipient (30 days) o in an immunodeficient recipient (6 months) o in a vaccine-associated community case (interval - not applicable) B. Vaccine-strain polio viral infection <ul style="list-style-type: none"> o in a non-immunodeficient recipient (30 days) o in an immunodeficient recipient (6 months)

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	Event and interval from vaccination
	<ul style="list-style-type: none"> o in a vaccine-associated community case (interval - not applicable) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Inactivated Polio -IPV, DTaP-IPV, DTaP-IPV/HIB, DTaP-HepB-IPV	<ul style="list-style-type: none"> A. Anaphylaxis or anaphylactic shock (7 days) B. Any acute complication or sequelae (including death) of the above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hepatitis B in any combination- HepB, HepA-HepB, DTaP-HepB-IPV, Hib-HepB	<ul style="list-style-type: none"> A. Anaphylaxis or anaphylactic shock (7 days) B. Any acute complications or sequelae (including death) of the above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
<i>Hemophilus influenzae</i> type b in any combination (conjugate)- Hib, Hib-HepB, DTP-Hib, DTaP-IPV/Hib	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Varicella in any combination- VAR, MMRV	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rotavirus (monovalent or pentavalent) RV1, RV5	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pneumococcal conjugate (7-valent or 13-valent) PCV7, PCV13	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hepatitis A in any combination- HepA, HepA-HepB	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Influenza--trivalent inactivated influenza , live	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	Event and interval from vaccination
attenuated influenza-TIV, LAIV	
Meningococcal - MCV4, MPSV4	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Human Papillomavirus (Quadrivalent or Bivalent)- HPV4, HPV2	Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
<p>* Effective date: November 10, 2008. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturers package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if you are not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine.</p>	

A list of vaccine abbreviations is attached and is also located at:

<http://www.cdc.gov/vaccines/recs/acip/vac-abbrev.htm>

Vaccine	Abbreviation*
Diphtheria and tetanus toxoids adsorbed (children)	DT
Diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed	DTaP
Diphtheria and tetanus toxoids and whole cell pertussis vaccine	DTP
Diphtheria and tetanus toxoids and whole cell pertussis vaccine and <i>Haemophilus influenzae</i> type b conjugate vaccine	DTP-Hib
Tetanus and diphtheria toxoids adsorbed (adult)	Td
Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed	Tdap
Tetanus toxoid	TT
Diphtheria and tetanus toxoids and acellular pertussis adsorbed and <i>Haemophilus influenzae</i> type b conjugate vaccine	DTaP/Hib
Diphtheria and tetanus toxoids and acellular pertussis adsorbed, hepatitis B and inactivated poliovirus vaccine	DTaP-HepB-IPV
Diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine	DTaP-IPV
Diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and <i>Haemophilus influenzae</i> type b conjugate vaccine	DTaP-IPV/Hib
<i>Haemophilus influenzae</i> type b conjugate vaccine	Hib
<i>Haemophilus influenzae</i> type b conjugate and hepatitis B vaccine	Hib-HepB
Hepatitis A vaccine	HepA
Hepatitis B vaccine	HepB
Hepatitis A inactivated and hepatitis B vaccine	HepA-HepB
Human papillomavirus vaccine (quadrivalent)	HPV4
Human papillomavirus vaccine (bivalent)	HPV2
Trivalent inactivated influenza vaccine	TIV
Live attenuated influenza vaccine	LAIV
Measles vaccine	M
Measles and rubella vaccine	MR
Measles, mumps, and rubella vaccine	MMR
Measles, mumps, rubella, and varicella vaccine	MMRV

Meningococcal conjugate vaccine (quadrivalent)	MCV4
Meningococcal polysaccharide vaccine (quadrivalent)	MPSV4
Pertussis	P
Pneumococcal conjugate vaccine (7-valent)	PCV7
Pneumococcal conjugate vaccine (13-valent)	PCV13
Poliovirus vaccine (inactivated)	IPV
Poliovirus vaccine (live)	OPV
Rubella vaccine	R
Rotavirus vaccine (monovalent)	RV1
Rotavirus vaccine (pentavalent)	RV5
Varicella vaccine	VAR

*dash (-) indicates: products that are supplied in their final form by the manufacturer and do not require mixing or reconstitution by user; slash (/) indicates: products that are mixed or reconstituted by user.

Frequently Asked Questions (FAQs), Vaccine Misadventures and Glossary of Terms

The following questions represent some of the more common questions and scenario descriptions regarding vaccine misadventures that employee/occupational health departments may encounter when addressing immunization among employees. These questions and scenarios have been gathered from a variety of sources including the 4th edition of the Team-Based Manual provided by the American College of Physicians Guide to Adult Immunization, vaccine field representatives, infection preventionists and employee health/occupational health nurses. For additional information on how to best address these and other questions or situations, contact the local health department as well as review current APIC guidelines available at www.cdc.gov/vaccines/recs/acip/default.htm

Influenza

Q. Who can receive the live attenuated influenza vaccine (FluMist)?

FluMist is indicated for immunization of individuals 2 years to 49 years of age. It has not been adequately studied in persons 50 years of age and older.

Q. Can healthcare workers receive FluMist?

Yes, unless they are responsible for providing care for patients who are in protected environments due to their current receipt of a bone marrow transplant.

Q. Does FluMist cause the flu?

No. Flumist is engineered not to cause disease. It is attenuated (weakened) so it does not even cause influenza-like illness, although nasal stuffiness may occur following immunization. It is cold adapted so it replicates efficiently only in the cooler temperatures of the nasopharynx, and is temperature sensitive so it does not replicate efficiently in the warmer temperatures of the lower respiratory tract.

Q. Does FluMist need to be readministered if the recipient sneezes after vaccination?

No. Dripping, sneezing, or swallowing may occur after vaccination, but after administration, the spray effectively distributes the vaccine into the nasal cavity.

Q: Am I or others around me, at risk if the Live Attenuated Intranasal Vaccine (LAIV) is inadvertently sprayed into the air?

There have not been any reported cases of attenuated vaccine virus infections among patients or providers inadvertently exposed to the LAIV. However, prudent practice should include correct vaccine administration techniques and not arbitrary spraying into the environment.

Q: Can LAIV be administered to an employee if someone in the household is pregnant?

The Advisory Committee on Immunization Practices (ACIP) guidelines state that having a pregnant household member is not a contraindication to LAIV vaccination. Further, it is also acceptable for nursing mothers to receive LAIV. Pregnant women should receive the inactivated vaccine TIV (trivalent inactivated influenza).

Q: Can influenza vaccine be given with other vaccines?

Yes. ACIP says TIV can be given with other inactivated or live vaccines. However, vaccines should be administered at different site and in a different syringe. If administering the LAIV, another live virus vaccine can be administered at the same time (e.g., MMR), but if not given at the same time, let four weeks pass after administration of one live vaccine before administering another live vaccine.

Q: Can influenza vaccine be given to persons who are receiving antiviral medications?

The first thing to determine is what antivirals the recipient may be taking. If the antiviral agent(s) are for influenza (e.g., oseltamivir), TIV can be administered, but not LAIV. Those antiviral medications interfere with viral replication that is occurring in the nasal mucosa following LAIV administration. If the employee is currently taking an influenza antiviral (e.g., oseltamivir), do not administer LAIV until 48 hours after stopping antiviral medications. These antiviral medications should not be given until after two weeks after LAIV (unless medically necessary). Administering these antivirals before this two-week window may decrease vaccine effectiveness and repeat vaccination should be considered.

Q: Can influenza vaccine be given to an employee who is immunodeficient?

Yes. TIV inactivated influenza vaccine can and should be given to immunodeficient employees, but it is important for them, and their employer, to understand that they may not have as robust of an immunologic response after vaccination as do their immunocompetent counterparts.

Q: Is it safe for an employee to receive LAIV if someone in their household is immunocompromised?

It is important to ascertain the type of immunosuppression before deciding to vaccinate. In some cases it may be preferable for the household member to receive TIV instead.

Tetanus Toxoid/Td/Tdap

Q: Can an employee who has had pertussis get the disease again? Should you vaccinate someone with a history of pertussis infection?

Employees who have a history of pertussis disease generally should receive Tdap according to the routine recommendation. Vaccination, regardless of history of prior pertussis infection, is recommended because the duration of protection induced by natural disease is unknown. Waning of immunity can occur as early as seven years after infection. Administering pertussis vaccine to persons with a history of pertussis presents no theoretical risk so it should not be withheld.

Q: Upon occasion, an employee sustains a tetanus-prone injury and requires immunization. Which vaccine should be given, Td or Tdap?

Assuming that a primary series of the tetanus vaccine has been previously received (e.g., DTP/DTaP as childhood immunization) adolescents and adults ages 10 to 64 years who require a tetanus toxoid-containing vaccine as part of wound management should receive a single dose of Tdap instead of Td if they have not previously received Tdap. If Tdap is not available, then Td should be used. Adults generally over the age of 65 may receive Tdap if they have not received it, at the discretion of the provider.

Q: When should an employee receive tetanus toxoid alone?

Single antigen tetanus toxoid should only be used in the rare instance of a person with a documented prior severe allergic response to diphtheria toxoid.

Meningococcus

Q: How long does immunity last after vaccination?

Immunity following administration of the meningococcal conjugate quadrivalent (MCV4) vaccines wanes after about five years. A 2-dose series is recommended for some at-risk persons.

Hepatitis A

Q: I realize that Hepatitis A immunization is not a general recommendation for healthcare personnel, but what about the outbreaks that have involved food service workers? Should we make that group of employees an exception and provide them with the vaccine?

Food-borne hepatitis A outbreaks are relatively uncommon in the United States. Although food handlers have a critical role in common-source food borne outbreaks, they are not at increased risk of hepatitis A because of their occupation. Further, workers exposed to sewage (e.g., facilities maintenance) are not considered to be at increased risk. Routine infection prevention and control precautions are suitable for all healthcare personnel. In the event a community-wide outbreak was to occur, the state or local health department could request that certain groups be immunized. But immunizing this group as a part of your routine employee/occupational health program is outside the current ACIP recommendations.

Hepatitis B

Q: Can an employee receive the first dose of hepatitis B vaccine from one manufacturer and subsequent doses from another manufacturer?

Yes. No differences in immune response are observed when vaccines from different manufacturers are used to complete the series.

Q: Is it harmful to the employee to receive an extra dose(s) of hepatitis A or hepatitis B vaccine or to repeat the entire vaccine series if documentation of the vaccination history is unavailable?

No. If immunization history is unavailable, assume that the individual is susceptible and proceed with immunization.

Q: When should post-Hepatitis B vaccination testing be performed?

Post-vaccination testing for antibody to hepatitis B should generally be performed one to two months after completion of the vaccine series. If this is no evidence of sufficient response to the vaccine after two complete series, testing for chronic infection (testing for the antigen) should be the next step.

Q: Is there any benefit or risk in vaccinating a person who has been infected with HBV?

Persons who have already been infected with HBV will receive no benefit from vaccination. They will already have the antibody (immune) or the antigen (carrier). However, there is no risk to a previously infected person who receives vaccination.

Q: After receiving the hepatitis B vaccine series, what level of anti HBs is considered protective?

Following immunization, an anti-HBs level of >10mIU/mL is considered protective. Know what your laboratory reports mean so you understand the results.

Q: What should be done if hepatitis series is given but laboratory testing does not show seroconversion?

The entire three-dose Hepatitis B series should be repeated then re-testing done for anti-HBs in one to two months after completion of the second series. If the test is still negative, the person may be initially viewed as a non-responder and should be considered to be susceptible to Hepatitis B infection until further investigation can be completed. They may be chronically infected, and not simply a non-responder, and an antigen test should be done. If the antigen test is negative, that person should be classified as a non-responder and counseling should be done to ensure they know how to prevent transmission to others. In addition, their job responsibilities should be evaluated to ensure that patients are protected. A comprehensive plan should be in place to assist with this complex process.

Q: Do health care workers need to get additional Hepatitis B boosters if they demonstrated laboratory evidence of seroconversion after receiving the initial vaccine series even if current anti-HBs titer is less than 10 mIU/mL?

Individuals who have seroconverted after a 3 dose series do not need a booster. These individuals are still protected because immune memory maintains anamnestic anti-HBs response. There is one exception to this rule, however. If the healthcare worker is on hemodialysis, they should be retested each year. Generally this will be done as part of their medical care, so coordination of medical information will be important. Remember that healthcare personnel often experience the same health issues as the general public and may continue to work in order to maintain health insurance.

Measles-Mumps-Rubella

Q: Can MMR vaccine be administered on the same days as a tuberculin skin test (TST)?

Yes. However, live MMR vaccine may interfere with the immune response to tuberculin skin testing, if the TST test is administered more than one day following MMR administration. This effect is thought to last for only four to six weeks.

Q: If an employee is only susceptible to one of the three viruses in the MMR vaccine, can the vaccine be given?

There are no increased risks to giving the MMR vaccine even when the recipient is immune to one or more of its components.

Q: What about antibody testing?

Antibody testing is generally more expensive than the cost of the vaccine. Having an expectation that new employees provide immunization history is important to a cost efficient immunization program. Use of existing immunization registries can also provide rapid access to information.

Q: Can the live viruses in the MMR vaccine be transmitted to others?

There are no reports or evidence for transmission of MMR vaccine viruses. This means that healthcare personnel who are nursing mothers can safely receive MMR vaccine as can those who are close contacts/family members of immunocompromised individuals.

Q: Why is recent blood product administration a contraindication for receipt of MMR vaccine?

Immunogenicity, not safety, is the issue as the immune globulins in such products neutralize MMR vaccine viruses, preventing development of full immunity. Depending upon the blood product used, MMR vaccination should be delayed between three and 11 months.

Q: Since measles vaccine virus, like influenza virus, is grown in chicken eggs, why is egg allergy not a contraindication to MMR vaccination?

The quantities of any residual egg protein are so small that there has been no evidence of anaphylactic reaction in egg-allergic individuals directly challenged with MMR vaccine. In addition, the ACIP has issued new thoughts regarding egg allergy and influenza immunization so make sure policies reflect this rapidly changing ideology.

Q: Can MMR vaccine be given to HIV-positive healthcare workers?

MMR vaccine is indicated for all asymptomatic and symptomatic HIV-infected persons who do not have evidence of severe immunosuppression. For adolescents and adults, the total CD4+ T lymphocytes should be greater than 200/QL, or the CD4+ T lymphocytes should be greater than 14% of total lymphocytes. Administration of several vaccines is included in the care of HIV-infected individuals so coordination of medical treatment is important, if the healthcare worker will allow the sharing of that information.

Varicella

Q: Can a nursing healthcare worker receive the varicella vaccine?

Yes, varicella virus has not been observed to transmit through breast milk and passive transmission of antibodies through breast milk is not thought to occur.

Q: Can a healthcare worker with HIV/AIDS be given the varicella vaccine?

It depends on the CD4 counts. Adult patients with absolute CD4 counts below 200 cells/mm³ should not be given the vaccine. Patients whose CD4 cell count is above 200 cells/mm³ may receive the vaccine. Again, immunization is likely to be part of that healthcare worker's routine medical care, so coordination and shared information is important, if the healthcare worker will allow.

General information

Q: What live viral vaccines are currently licensed and used in the United States for healthcare personnel immunization?

Measles, mumps, rubella, varicella, herpes zoster, live attenuated influenza, smallpox, and yellow fever vaccines are live viral vaccines. Zoster, smallpox and yellow fever vaccines are not routine healthcare personnel immunizations, but it is important that the employee/occupational health personnel know what additional live virus vaccines might have been given to employees for other purposes.

Q: What live bacterial vaccines are licensed and used in the United States?

Oral typhoid vaccine (Ty21a) and Bacillus Calmette-Guerin (BCG) vaccine are live bacterial vaccines, but neither are included in routine healthcare personnel immunization programs.

Q: What dose of corticosteroid is considered immunosuppressive?

In general, the use of a steroid dose equivalent of either >2 mg/kg of body weight or 20 mg/day of prednisone or equivalent for persons who weigh >10 kg when administered for >2 weeks is thought to induce immunosuppression. ACIP states that "vaccination providers should wait at least one month after discontinuation of high-dose systemically-absorbed corticosteroid therapy administered for more than two weeks before administering a live virus vaccine."

Q: What if a healthcare worker has had their spleen removed? Are they at increased risk of a vaccine side effect?

No. The vaccine side effect profile for each vaccine is the same as that of non-asplenic.

Q: Are any vaccines contraindicated for patients with asplenia?

No. The only contraindications would be those otherwise true of any potential

Q: Can multiple vaccines be administered on the same day?

Yes. Multiple routine vaccines may be administered on the same day, but should be given using separate needles and at separate sites. If two vaccines are to be given in the same extremity, the injections should be given at sites separated by at least one inch to help the clinician administering the vaccines determine the cause if there is a local reaction.

Q: If a series of vaccines (e.g., hepatitis B or MMR) is initiated but not completed, does the series need to be started again?

If a vaccine series had not been completed, it does not have to be completely restarted. Pick up where it was left and continue according to the recommended schedule.

Glossary of Terms

Adjuvant: a chemical substance added to a vaccine in order to generate a stronger immune response

Arthus: a type III hypersensitivity reaction, mediated by the deposition of immune (antigen-antibody) complexes in the walls of blood vessels, especially in the kidney or in serosal linings (such as pleura, pericardium, synovium). It is named for [Nicolas Maurice Arthus](#) who, in the early 1900s, described the adverse reactions he noted when [horse serum](#) was injected subcutaneously into [rabbits](#).

Conjugate: a vaccine containing a chemical substance, frequently a protein, that is chemically bonded to the product in order to generate a more durable immune response.

Contraindication: a condition for which a vaccine or other product should not be given. Relative contraindications are those in which some exceptions can be made. Absolute contraindications are those in which no exceptions should be made under any circumstances.

IgG: a long-lasting type of immunoglobulin or antibody found either late in the course of a first infection or vaccine exposure or after repeated exposures to it.

IgM: a relatively short lived type of immunoglobulin or antibody found in persons with their first exposure to a microbe or vaccine.

Immunosuppressive therapy: Treatments such as radiation or chemotherapy that impair the normal antibody or cell-mediated response to an infection. When considering whether or not a vaccine recipient is taking immunosuppressive therapy, one accepted definition is two weeks or

more of daily receipt of 20 mg or more [or 2 mg/kg body weight or more] of prednisone or equivalent.

Polysaccharide: a chemical compound with several sugar molecules chemically bonded together.

Precaution: any measure taken to reduce the likelihood of an unwanted or potentially dangerous outcome.

Preservative: a chemical substance added to vaccine or other product to reduce the likelihood of microbial growth and thereby increase its shelf life.

Toxoid: a toxin that is chemically altered to eliminate direct hazard to the body but that is still capable of generating a protective immune response to a future exposure to the toxin.

Section 5 Healthcare Personnel (Vaccine Recipient) Information

Information included in this section focuses on knowledge necessary for the vaccine recipient. It is important that the healthcare personnel receiving immunization also receive information about the vaccine and its effects. Likewise, the information provided must also proactively address questions and dispel myths such as the misperceptions regarding vaccines and autism.

It is critical that the Vaccine Information Statements (VIS) provided to the receiving healthcare personnel be current, so immunization processes must include a method that routinely and regularly seeks to identify updated VIS.

This section includes the following documents:

- Vaccine Information Statements and Federal Law
<http://www.immunize.org/catg.d/p2027.pdf>
- Vaccine Information Statements (English)
 - Hepatitis B <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hep-b.pdf>
 - Influenza, LAIV <http://www.cdc.gov/flu/pdf/protect/vis-flulive.pdf>
 - Influenza, Inactivated <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-flu.pdf>
 - Measles, Mumps, Rubella (MMR)
<http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-mmr.pdf>
 - Tdap (tetanus, diphtheria and acellular pertussis vaccine)
<http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-td-tdap.pdf>
 - Varicella <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-varicella.pdf>
- Vaccines Recommended for Special Circumstances
 - Meningococcal (MCV4 and MPSV4)
<http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-mening.pdf>
 - Typhoid <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-typhoid.pdf>
 - Inactivated Polio Vaccine (IPV)
<http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-ipv.pdf>
- Vaccines and Autism: What you should know
<http://www.chop.edu/export/download/pdfs/articles/vaccine-education-center/autism.pdf>

It's federal law!

You must give your patients current Vaccine Information Statements (VISs)

As healthcare professionals understand, the risks of serious consequences following vaccination are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against. Most adverse reactions from vaccines are mild and self-limited. Serious complications are rare, but they can have a devastating effect on the recipient, family members, and the providers involved with the care of the patient. We must continue the efforts to make vaccines as safe as possible.

Equally important is the need to furnish vaccine recipients (or the parents/legal representatives of minors) with objective information on vaccine safety and the diseases that the vaccines protect against, so that they are actively involved in making decisions affecting their health or the health of their children. When people are not informed about vaccine adverse events, even common, mild events, they can lose their trust in healthcare providers and vaccines. Vaccine Information Statements (VISs) provide a standardized way to present objective information about vaccine benefits and adverse events.

What are VISs?

VISs are developed by the staff of the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccine recipient or the minor child's parent or legal representative about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should answer

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination.

Source: www.cdc.gov/vaccines/pubs/vis/vis-facts.htm

To obtain current VISs in more than 30 languages, visit the Immunization Action Coalition's website at www.immunize.org/vis

questions and address concerns that the recipient or the parent/legal representative may have.

Use of the VIS is mandatory!

Before a healthcare provider vaccinates a child or an adult with a dose of any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) vaccine, the provider is required by the National Childhood Vaccine Injury Act (NCVIA) to provide a copy of the VIS to either the adult recipient or to the child's parent/legal representative.

How to get VISs

All available VISs can be downloaded from the website of the Immunization Action Coalition at www.immunize.org/vis or from CDC's website at www.cdc.gov/vaccines/pubs/vis/default.htm. Ready-to-copy versions may also be available from your state or local health department.

You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis. To find VISs in alternative formats (e.g., audio, web-video), go to: www.immunize.org/vis/vis_sources.asp

Most current versions of VISs

As of November 2011, the most recent versions of the VISs are as follows:

DTaP/DT	5/17/07	MMR.....	3/13/08
Hepatitis A	10/25/11	MMRV.....	5/21/10
Hepatitis B	7/18/07	PCV13	4/16/10
Hib	12/16/98	PPSV	10/6/09
HPV (H. papillomavirus)		Polio	11/8/11
Cervarix	5/3/11	Rabies	10/6/09
Gardasil	5/3/11	Rotavirus	12/6/10
Influenza (inactive).....	7/26/11	Shingles	10/6/09
Influenza (live)	7/26/11	Td/Tdap	11/18/08
Japanese encephalitis....	3/1/10	Typhoid.....	5/19/04
Meningococcal	10/14/11	Varicella (chickenpox) ...	3/13/08
Multi-vaccine VIS		Yellow fever	3/30/11
(for 6 vaccines given to infants/children: DTaP, IPV, Hib, Hep B, PCV, RV)			

(Page 1 of 2)

Top 10 Facts about VISs

Fact 1 It's federal law!

Federal law requires that VISs must be used for the following vaccines when vaccinating patients of ALL ages:

- DTaP (includes DT)
- MMR and MMRV
- Td/Tdap
- meningococcal
- Hib
- pneumococcal conjugate
- hepatitis A
- polio
- hepatitis B
- rotavirus
- HPV
- varicella
- influenza (inactivated and live vaccines)

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination. There are also VISs for vaccines not covered by NCVIA: anthrax, Japanese encephalitis, pneumococcal polysaccharide, rabies, shingles, smallpox, typhoid, and yellow fever. CDC recommends the use of VISs whenever these vaccines are given. The VIS must always be used if vaccine was purchased under CDC contract.

Fact 2 VISs are required for both public and private sectors

Federal law requires use of VISs in both the public and private sector settings and regardless of the source of payment for the vaccine.

Fact 3 VIS must be provided BEFORE vaccine is administered to the patient

The VIS provides information about the disease and the vaccine and should be given to the patient before vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide the VIS right before administering vaccines.

Fact 4 You must provide a current VIS for each dose of vaccine

The most current VIS must be provided before each dose of vaccine is given, including vaccines given as a series of doses. If five doses of a single vaccine are required, the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

Fact 5 You must provide VISs for combination vaccines too

There is a VIS available for MMRV (ProQuad). An alternative VIS — the multi-vaccine VIS — is an option to providing single-vaccine VISs when administering one or more of these routine birth-through-6-month vaccines: DTaP, hepatitis B, Hib, pneumo-

coccal (PCV), polio (IPV), or rotavirus (RV). The multi-vaccine VIS can also be used when giving combination vaccines (e.g., Pediarix, Pentacel, Comvax) or when giving two or more routine vaccines at other pediatric visits (e.g., 12–15 months, 4–6 years). However, when giving combination vaccines for which no VIS exist (e.g., Twinrix), give out all relevant single VISs. For example, before administering Twinrix give your patient the VISs for both hepatitis A and hepatitis B vaccines.

Fact 6 VISs are available in other formats, including more than 30 languages

You may use laminated copies of VISs for patients and parents to read and return before leaving the clinic, but you must **also** offer the patient (parent/legal representative) a printed copy of the VIS to take home.

If they prefer to download the VIS onto a mobile device, direct them to CDC's VIS Mobile Downloads web page: www.cdc.gov/vaccines/Pubs/vis/vis-downloads.htm

To download VISs in other languages, visit www.immunize.org/vis

By using the VISs with your patients, you are helping to develop a better educated patient population and you are doing the right thing.

Fact 7 Federal law does not require signed consent in order for a person to be vaccinated

Signed consent is not required by federal law (although some states may require them).

Fact 8 To verify that a VIS was given, providers must record in the patient's chart (or permanent office log or file) the following information:

- The published date of the VIS
- The date the VIS is given to the patient
- Name, address (office address), and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number of each dose administered

Fact 9 VISs should not be altered before giving them to patients

Providers should not change a VIS or write their own VISs. It is permissible to add a practice's name, address, or phone number to an existing VIS. Providers are encouraged to supplement the VIS with additional patient-education materials.

Fact 10 Provide English-language VISs to all patients (even if the patient's first language is not English)

For patients who don't read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive the appropriate VIS, regardless of their ability to read English. If available, provide a translation of the VIS in the patient's language as well.

Translations of VISs in more than 30 languages are available from IAC. Go to www.immunize.org/vis for VISs in multiple languages as well as in other formats.

Hepatitis B Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages.
See www.immunize.org/vis.

Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite <http://www.immunize.org/vis>

1 What is hepatitis B?

Hepatitis B is a serious infection that affects the liver. It is caused by the hepatitis B virus.

- In 2009, about 38,000 people became infected with hepatitis B.
- Each year about 2,000 to 4,000 people die in the United States from cirrhosis or liver cancer caused by hepatitis B.

Hepatitis B can cause:

Acute (short-term) illness. This can lead to:

- loss of appetite
- diarrhea and vomiting
- tiredness
- jaundice (yellow skin or eyes)
- pain in muscles, joints, and stomach

Acute illness, with symptoms, is more common among adults. Children who become infected usually do not have symptoms.

Chronic (long-term) infection. Some people go on to develop chronic hepatitis B infection. Most of them do not have symptoms, but the infection is still very serious, and can lead to:

- liver damage (cirrhosis)
- liver cancer
- death

Chronic infection is more common among infants and children than among adults. People who are chronically infected can spread hepatitis B virus to others, even if they don't look or feel sick. Up to 1.4 million people in the United States may have chronic hepatitis B infection.

Hepatitis B virus is easily spread through contact with the blood or other body fluids of an infected person. People can also be infected from contact with a contaminated object, where the virus can live for up to 7 days.

- A baby whose mother is infected can be infected at birth;
- Children, adolescents, and adults can become infected by:
 - contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores;
 - contact with objects that have blood or body fluids on them such as toothbrushes, razors, or monitoring and treatment devices for diabetes;
 - having unprotected sex with an infected person;
 - sharing needles when injecting drugs;
 - being stuck with a used needle.

2 Hepatitis B vaccine: Why get vaccinated?

Hepatitis B vaccine can prevent hepatitis B, and the serious consequences of hepatitis B infection, including liver cancer and cirrhosis.

Hepatitis B vaccine may be given by itself or in the same shot with other vaccines.

Routine hepatitis B vaccination was recommended for some U.S. adults and children beginning in 1982, and for all children in 1991. Since 1990, new hepatitis B infections among children and adolescents have dropped by more than 95% – and by 75% in other age groups.

Vaccination gives long-term protection from hepatitis B infection, possibly lifelong.

3 Who should get hepatitis B vaccine and when?

Children and Adolescents

- Babies normally get 3 doses of hepatitis B vaccine:

- 1st Dose: Birth
- 2nd Dose: 1-2 months of age
- 3rd Dose: 6-18 months of age

Some babies might get 4 doses, for example, if a combination vaccine containing hepatitis B is used. (This is a single shot containing several vaccines.) The extra dose is not harmful.

- Anyone through 18 years of age who didn't get the vaccine when they were younger should also be vaccinated.

Adults

- All unvaccinated adults at risk for hepatitis B infection should be vaccinated. This includes:
 - sex partners of people infected with hepatitis B,
 - men who have sex with men,
 - people who inject street drugs,
 - people with more than one sex partner,
 - people with chronic liver or kidney disease,
 - people under 60 years of age with diabetes,
 - people with jobs that expose them to human blood or other body fluids,



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

- household contacts of people infected with hepatitis B,
 - residents and staff in institutions for the developmentally disabled,
 - kidney dialysis patients,
 - people who travel to countries where hepatitis B is common,
 - people with HIV infection.
- Other people may be encouraged by their doctor to get hepatitis B vaccine; for example, adults 60 and older with diabetes. Anyone else who wants to be protected from hepatitis B infection may get the vaccine.
 - Pregnant women who are at risk for one of the reasons stated above should be vaccinated. Other pregnant women who want protection may be vaccinated.

Adults getting hepatitis B vaccine should get 3 doses — with the second dose given 4 weeks after the first and the third dose 5 months after the second. Your doctor can tell you about other dosing schedules that might be used in certain circumstances.

4 Who should not get hepatitis B vaccine?

- Anyone with a life-threatening allergy to yeast, or to any other component of the vaccine, should not get hepatitis B vaccine. Tell your doctor if you have any severe allergies.
- Anyone who has had a life-threatening allergic reaction to a previous dose of hepatitis B vaccine should not get another dose.
- Anyone who is moderately or severely ill when a dose of vaccine is scheduled should probably wait until they recover before getting the vaccine.

Your doctor can give you more information about these precautions.

Note: You might be asked to wait 28 days before donating blood after getting hepatitis B vaccine. This is because the screening test could mistake vaccine in the bloodstream (which is not infectious) for hepatitis B infection.

5 What are the risks from hepatitis B vaccine?

Hepatitis B is a very safe vaccine. Most people do not have any problems with it.

The vaccine contains non-infectious material, and cannot cause hepatitis B infection.

Some mild problems have been reported:

- Soreness where the shot was given (up to about 1 person in 4).
- Temperature of 99.9°F or higher (up to about 1 person in 15).

Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses.

A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. More than 100 million people in the United States have been vaccinated with hepatitis B vaccine.

6 What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your doctor. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim)
Hepatitis B Vaccine

2/2/2012

42 U.S.C. § 300aa-26

LIVE, INTRANASAL INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2011-12

Vaccine Information Statements are available in Spanish and many other languages. See www.immunize.org/vis
Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Other illnesses can have the same symptoms and are often mistaken for influenza.

Young children, people 65 and older, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease, or a weakened immune system – can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from influenza and even more require hospitalization.

By getting flu vaccine you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Live, attenuated influenza vaccine - LAIV (nasal spray)

There are two types of influenza vaccine:

1. **Live, attenuated** influenza vaccine (LAIV) contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils.
2. **Inactivated** (killed) influenza vaccine, the “flu shot,” is given by injection with a needle. *This vaccine is described in a separate Vaccine Information Statement.*

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. Flu vaccine will not prevent disease from other viruses, including flu viruses not contained in the vaccine.

It takes up to 2 weeks for protection to develop after the vaccination. Protection lasts about a year.

LAIV does not contain thimerosal or other preservatives.

3 Who can receive LAIV?

LAIV is recommended for healthy people **2 through 49 years of age**, who are not pregnant and do not have certain health conditions (see #4, below).

4 Some people should not receive LAIV

LAIV is not recommended for everyone. The following people should get the inactivated vaccine (flu shot) instead:

- **Adults 50 years of age and older or children from 6 through 23 months of age.** (Children younger than 6 months should not get either influenza vaccine.)
- Children younger than 5 years with asthma or one or more episodes of wheezing within the past year.
- Pregnant women.
- People who have long-term health problems with:
 - heart disease
 - kidney or liver disease
 - lung disease
 - metabolic disease, such as diabetes
 - asthma
 - anemia, and other blood disorders
- Anyone with certain muscle or nerve disorders (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
- Anyone with a weakened immune system.
- Anyone in close contact with someone whose immune system is so weak they require care in a protected environment (such as a bone marrow transplant unit). *Close contacts of other people with a weakened immune system (such as those with HIV) may receive LAIV. Healthcare personnel in neonatal intensive care units or oncology clinics may receive LAIV.*
- Children or adolescents on long-term aspirin treatment.

Tell your doctor if you have any severe (life-threatening) allergies, including a severe allergy to eggs. A severe allergy to any vaccine component may be a reason not to get the vaccine. Allergic reactions to influenza vaccine are rare.

Tell your doctor if you ever had a severe reaction after a dose of influenza vaccine.

Tell your doctor if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your doctor will help you decide whether the vaccine is recommended for you.

Tell your doctor if you have gotten any other vaccines in the past 4 weeks.

Anyone with a nasal condition serious enough to make breathing difficult, such as a very stuffy nose, should get the flu shot instead.

People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 When should I receive influenza vaccine?

Get the vaccine as soon as it is available. This should provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur any time, but most influenza occurs from October through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your doctor.

Influenza vaccine may be given at the same time as other vaccines.

6 What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses very rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

Mild problems:

Some children and adolescents 2-17 years of age have reported:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.
- If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used

it. Millions of doses of LAIV have been distributed since it was licensed, and the vaccine has not been associated with any serious problems.

The safety of vaccines is always being monitored. For more information, visit:

www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html and

www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

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 - Visit CDC's website at www.cdc.gov/flu



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)
Live, Attenuated Influenza Vaccine (7/26/11) U.S.C. §300aa-26

INACTIVATED INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2011-12

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis
Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

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It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Other illnesses can have the same symptoms and are often mistaken for influenza.

Young children, people 65 and older, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease, or a weakened immune system – can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from influenza and even more require hospitalization.

By getting flu vaccine you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Inactivated influenza vaccine

There are two types of influenza vaccine:

1. **Inactivated** (killed) vaccine, the “flu shot,” is given by injection with a needle.
2. **Live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

A “high-dose” inactivated influenza vaccine is available for people 65 years of age and older. Ask your doctor for more information.

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. Flu vaccine will not prevent disease from other viruses, including flu viruses not contained in the vaccine.

It takes up to 2 weeks for protection to develop after the shot. Protection lasts about a year.

Some inactivated influenza vaccine contains a preservative called thimerosal. Thimerosal-free influenza vaccine is available. Ask your doctor for more information.

3 Who should get inactivated influenza vaccine and when?

WHO

All people **6 months of age and older** should get flu vaccine.

Vaccination is especially important for people at higher risk of severe influenza and their close contacts, including healthcare personnel and close contacts of children younger than 6 months.

WHEN

Get the vaccine as soon as it is available. This should provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur at any time, but most influenza occurs from October through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your doctor.

Influenza vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

4 Some people should not get inactivated influenza vaccine or should wait

- Tell your doctor if you have any severe (life-threatening) allergies, including a severe allergy to eggs. A severe allergy to any vaccine component may be a reason not to get the vaccine. Allergic reactions to influenza vaccine are rare.
- Tell your doctor if you ever had a severe reaction after a dose of influenza vaccine.
- Tell your doctor if you ever had Guillain-Barré

Syndrome (a severe paralytic illness, also called GBS). Your doctor will help you decide whether the vaccine is recommended for you.

- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from inactivated influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:

- soreness, redness, or swelling where the shot was given
- hoarseness; sore, red or itchy eyes; cough
- fever • aches • headache • itching • fatigue

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Moderate problems:

Young children who get inactivated flu vaccine and pneumococcal vaccine (PCV13) at the same time appear to be at increased risk for seizures caused by fever. Ask your doctor for more information.

Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, a type of inactivated influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

One brand of inactivated flu vaccine, called Afluria, **should not be given** to children 8 years of age or younger, except in special circumstances. A related vaccine was associated with fevers and fever-related seizures in young children in Australia. Your doctor can give you more information.

The safety of vaccines is always being monitored. For more information, visit:

www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html and
www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

6 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

People who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382**, or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your doctor. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/flu



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Vaccine Information Statement (Interim)
Inactivated Influenza Vaccine (7/26/11) 42 U.S.C. §300aa-26

MEASLES, MUMPS & RUBELLA (MMR) VACCINES

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 Why get vaccinated?

Measles, mumps, and rubella are serious diseases.

Measles

- Measles virus causes rash, cough, runny nose, eye irritation, and fever.
- It can lead to ear infection, pneumonia, seizures (jerking and staring), brain damage, and death.

Mumps

- Mumps virus causes fever, headache, and swollen glands.
- It can lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles or ovaries, and, rarely, death.

Rubella (German Measles)

- Rubella virus causes rash, mild fever, and arthritis (mostly in women).
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

You or your child could catch these diseases by being around someone who has them. They spread from person to person through the air.

Measles, mumps, and rubella (MMR) vaccine can prevent these diseases.

Most children who get their MMR shots will not get these diseases. Many more children would get them if we stopped vaccinating.

2 Who should get MMR vaccine and when?

Children should get 2 doses of MMR vaccine:

- The first at **12-15 months of age**
- and the second at **4-6 years of age**.

These are the recommended ages. But children can get the second dose at any age, as long as it is at least 28 days after the first dose.

Some **adults** should also get MMR vaccine:

Generally, anyone 18 years of age or older who was born after 1956 should get at least one dose of MMR vaccine,

unless they can show that they have had either the vaccines or the diseases.

Ask your provider for more information.

MMR vaccine may be given at the same time as other vaccines.

Note: A “combination” vaccine called **MMRV**, which contains both MMR and varicella (chickenpox) vaccines, may be given instead of the two individual vaccines to people 12 years of age and younger.

3 Some people should not get MMR vaccine or should wait

- People should not get MMR vaccine who have ever had a life-threatening allergic reaction to gelatin, the antibiotic neomycin, or to a previous dose of MMR vaccine.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting MMR vaccine.
- Pregnant women should wait to get MMR vaccine until after they have given birth. Women should avoid getting pregnant for 4 weeks after getting MMR vaccine.
- Some people should check with their doctor about whether they should get MMR vaccine, including anyone who:
 - Has HIV/AIDS, or another disease that affects the immune system
 - Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer.
 - Has any kind of cancer
 - Is taking cancer treatment with x-rays or drugs
 - Has ever had a low platelet count (a blood disorder)
- People who recently had a transfusion or were given other blood products should ask their doctor when they may get MMR vaccine

Ask your provider for more information.

4

What are the risks from MMR vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of MMR vaccine causing serious harm, or death, is extremely small.

Getting MMR vaccine is much safer than getting any of these three diseases.

Most people who get MMR vaccine do not have any problems with it.

Mild Problems

- Fever (up to 1 person out of 6)
- Mild rash (about 1 person out of 20)
- Swelling of glands in the cheeks or neck (rare)

If these problems occur, it is usually within 7-12 days after the shot. They occur less often after the second dose.

Moderate Problems

- Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses)
- Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)

Severe Problems (Very Rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been known to occur after a child gets MMR vaccine. But this happens so rarely, experts cannot be sure whether they are caused by the vaccine or not. These include:
 - Deafness
 - Long-term seizures, coma, or lowered consciousness
 - Permanent brain damage

Note: The first dose of **MMRV** vaccine has been associated with rash and higher rates of fever than MMR and varicella vaccines given separately. Rash has been reported in about 1 person in 20 and fever in about 1 person in 5. Seizures caused by a fever are also reported more often after MMRV. These usually occur 5-12 days after the first dose.

5

What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever, weakness, or behavior changes. Signs of a serious

allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

6

The National Vaccine Injury Compensation Program

A federal program has been created to help people who may have been harmed by a vaccine.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

7

How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO)
 - Visit CDC website at: www.cdc.gov/vaccines



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Vaccine Information Statement (Interim)
MMR Vaccine (3/13/08) 42 U.S.C. §300aa-26

Td or Tdap (Tetanus-Diphtheria or Tetanus-Diphtheria-Pertussis) Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas.
Visite <http://www.immunize.org/vis>

1 Why get vaccinated?

Tetanus, diphtheria and pertussis can be very serious diseases.

TETANUS (Lockjaw) causes painful muscle spasms and stiffness, usually all over the body.

- It can lead to tightening of muscles in the head and neck so the victim cannot open his mouth or swallow, or sometimes even breathe. Tetanus kills about 1 out of 5 people who are infected.

DIPHTHERIA can cause a thick membrane to cover the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and even death.

PERTUSSIS (Whooping Cough) causes severe coughing spells which can lead to difficulty breathing, vomiting, and disturbed sleep.

- It can lead to weight loss, incontinence, rib fractures and passing out from violent coughing. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, including pneumonia and death.

These three diseases are all caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts, scratches, or wounds.

The United States saw as many as 200,000 cases a year of diphtheria and pertussis before vaccines were available, and hundreds of cases of tetanus. Since then, tetanus and diphtheria cases have dropped by about 99% and pertussis cases by about 92%.

Children 6 years of age and younger get **DTaP** vaccine to protect them from these three diseases. But older children, adolescents, and adults need protection too.

2 Vaccines for adolescents and adults: Td and Tdap

Two vaccines are available to protect people 7 years of age and older from these diseases:

- **Td vaccine** has been used for many years. It protects against tetanus and diphtheria.
- **Tdap vaccine** was licensed in 2005. It is the first vaccine for adolescents and adults that protects against pertussis as well as tetanus and diphtheria.

A Td booster dose is recommended every 10 years. Tdap is given only once.

3 Which vaccine, and when?

Ages 7 through 18 years

- A dose of Tdap is recommended at age 11 or 12. This dose could be given as early as age 7 for children who missed one or more childhood doses of DTaP.

- Children and adolescents who did not get a complete series of DTaP shots by age 7 should complete the series using a combination of Td and Tdap.

Age 19 years and Older

- All adults should get a booster dose of Td every 10 years. Adults under 65 who have never gotten Tdap should get a dose of Tdap as their next booster dose. Adults 65 and older may get one booster dose of Tdap.
- Adults (including women who may become pregnant and adults 65 and older) who expect to have close contact with a baby younger than 12 months of age should get a dose of Tdap to help protect the baby from pertussis.
- Healthcare professionals who have direct patient contact in hospitals or clinics should get one dose of Tdap.

Protection After a Wound

- A person who gets a severe cut or burn might need a dose of Td or Tdap to prevent tetanus infection. Tdap should be used for anyone who has never had a dose previously. Td should be used if Tdap is not available, or for:
 - anybody who has already had a dose of Tdap,
 - children 7 through 9 years of age who completed the childhood DTaP series, or
 - adults 65 and older.

Pregnant Women

- Pregnant women who have never had a dose of Tdap should get one, after the 20th week of gestation and preferably during the 3rd trimester. If they do not get Tdap during their pregnancy they should get a dose as soon as possible after delivery. Pregnant women who have previously received Tdap and need tetanus or diphtheria vaccine while pregnant should get Td.

Tdap or Td may be given at the same time as other vaccines.

4 Some people should not be vaccinated or should wait

- Anyone who has had a life-threatening allergic reaction after a dose of any tetanus, diphtheria, or pertussis containing vaccine should not get Td or Tdap.
- Anyone who has a severe allergy to any component of a vaccine should not get that vaccine. Tell your doctor if the person getting the vaccine has any severe allergies.
- Anyone who had a coma, or long or multiple seizures within 7 days after a dose of DTP or DTaP should not get Tdap, unless a cause other than the vaccine was found. These people may get Td.



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- Talk to your doctor if the person getting either vaccine:
 - has epilepsy or another nervous system problem,
 - had severe swelling or severe pain after a previous dose of DTP, DTaP, DT, Td, or Tdap vaccine, or
 - has had Guillain Barré Syndrome (GBS).

Anyone who has a moderate or severe illness on the day the shot is scheduled should usually wait until they recover before getting Tdap or Td vaccine. A person with a mild illness or low fever can usually be vaccinated.

5

What are the risks from Tdap and Td vaccines?

With a vaccine, as with any medicine, there is always a small risk of a life-threatening allergic reaction or other serious problem.

Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls. Tell your doctor if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Getting tetanus, diphtheria or pertussis disease would be much more likely to lead to severe problems than getting either Td or Tdap vaccine.

Problems reported after Td and Tdap vaccines are listed below.

Mild Problems

(Noticeable, but did not interfere with activities)

Tdap

- Pain (about 3 in 4 adolescents and 2 in 3 adults)
- Redness or swelling at the injection site (about 1 in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents and 1 in 100 adults)
- Headache (about 4 in 10 adolescents and 3 in 10 adults)
- Tiredness (about 1 in 3 adolescents and 1 in 4 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents and 1 in 10 adults)
- Chills, body aches, sore joints, rash, swollen glands (uncommon)

Td

- Pain (up to about 8 in 10)
- Redness or swelling at the injection site (up to about 1 in 3)
- Mild fever (up to about 1 in 15)
- Headache or tiredness (uncommon)

Moderate Problems

(Interfered with activities, but did not require medical attention)

Tdap

- Pain at the injection site (about 1 in 20 adolescents and 1 in 100 adults)
- Redness or swelling at the injection site (up to about 1 in 16 adolescents and 1 in 25 adults)
- Fever over 102°F (about 1 in 100 adolescents and 1 in 250 adults)
- Headache (1 in 300)
- Nausea, vomiting, diarrhea, stomach ache (up to 3 in 100 adolescents and 1 in 100 adults)

Td

- Fever over 102°F (rare)

Tdap or Td

- Extensive swelling of the arm where the shot was given (up to about 3 in 100).

Severe Problems

(Unable to perform usual activities; required medical attention)

Tdap or Td

- Swelling, severe pain, bleeding and redness in the arm where the shot was given (rare).

A severe allergic reaction could occur after any vaccine. They are estimated to occur less than once in a million doses.

6

What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a severe allergic reaction or a high fever. If a severe allergic reaction occurred, it would be within a few minutes to an hour after the shot. Signs of a serious allergic reaction can include **difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat.**

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

8

How can I learn more?

- Your doctor can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim)

Td & Tdap Vaccines

1/24/2012

42 U.S.C. § 300aa-26

CHICKENPOX VACCINE

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 Why get vaccinated?

Chickenpox (also called varicella) is a common childhood disease. It is usually mild, but it can be serious, especially in young infants and adults.

- It causes a rash, itching, fever, and tiredness.
- It can lead to severe skin infection, scars, pneumonia, brain damage, or death.
- The chickenpox virus can be spread from person to person through the air, or by contact with fluid from chickenpox blisters.
- A person who has had chickenpox can get a painful rash called shingles years later.
- Before the vaccine, about 11,000 people were hospitalized for chickenpox each year in the United States.
- Before the vaccine, about 100 people died each year as a result of chickenpox in the United States.

Chickenpox vaccine can prevent chickenpox.

Most people who get chickenpox vaccine will not get chickenpox. But if someone who has been vaccinated does get chickenpox, it is usually very mild. They will have fewer blisters, are less likely to have a fever, and will recover faster.

2 Who should get chickenpox vaccine and when?

Routine

Children who have never had chickenpox should get 2 doses of chickenpox vaccine at these ages:

1st Dose: 12-15 months of age

2nd Dose: 4-6 years of age (may be given earlier, if at least 3 months after the 1st dose)

People 13 years of age and older (who have never had chickenpox or received chickenpox vaccine) should get two doses at least 28 days apart.

Catch-Up

Anyone who is not fully vaccinated, and never had chickenpox, should receive one or two doses of chickenpox vaccine. The timing of these doses depends on the person's age. Ask your provider.

Chickenpox vaccine may be given at the same time as other vaccines.

Note: A "combination" vaccine called **MMRV**, which contains both chickenpox and MMR vaccines, may be given instead of the two individual vaccines to people 12 years of age and younger.

3 Some people should not get chickenpox vaccine or should wait

- People should not get chickenpox vaccine if they have ever had a life-threatening allergic reaction to a previous dose of chickenpox vaccine or to gelatin or the antibiotic neomycin.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting chickenpox vaccine.
- Pregnant women should wait to get chickenpox vaccine until after they have given birth. Women should not get pregnant for 1 month after getting chickenpox vaccine.
- Some people should check with their doctor about whether they should get chickenpox vaccine, including anyone who:
 - Has HIV/AIDS or another disease that affects the immune system
 - Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer
 - Has any kind of cancer
 - Is getting cancer treatment with radiation or drugs
- People who recently had a transfusion or were given other blood products should ask their doctor when they may get chickenpox vaccine.

Ask your provider for more information.

What are the risks from chickenpox vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of chickenpox vaccine causing serious harm, or death, is extremely small.

Getting chickenpox vaccine is much safer than getting chickenpox disease. Most people who get chickenpox vaccine do not have any problems with it. Reactions are usually more likely after the first dose than after the second.

Mild Problems

- Soreness or swelling where the shot was given (about 1 out of 5 children and up to 1 out of 3 adolescents and adults)
- Fever (1 person out of 10, or less)
- Mild rash, up to a month after vaccination (1 person out of 25). It is possible for these people to infect other members of their household, but this is extremely rare.

Moderate Problems

- Seizure (jerking or staring) caused by fever (very rare).

Severe Problems

- Pneumonia (very rare)

Other serious problems, including severe brain reactions and low blood count, have been reported after chickenpox vaccination. These happen so rarely experts cannot tell whether they are caused by the vaccine or not. If they are, it is extremely rare.

Note: The first dose of **MMRV** vaccine has been associated with rash and higher rates of fever than MMR and varicella vaccines given separately. Rash has been reported in about 1 person in 20 and fever in about 1 person in 5. Seizures caused by a fever are also reported more often after MMRV. These usually occur 5-12 days after the first dose.

What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever, weakness, or behavior changes. Signs of a serious

allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

The National Vaccine Injury Compensation Program

A federal program has been created to help people who may have been harmed by a vaccine.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

How can I learn more?

- Ask your provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO)
 - Visit CDC website at: www.cdc.gov/vaccines



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Vaccine Information Statement (Interim)
Varicella Vaccine (3/13/08) 42 U.S.C. §300aa-26

Meningococcal Vaccines

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas.
Visite <http://www.immunize.org/vis>

1

What is meningococcal disease?

Meningococcal disease is a serious bacterial illness. It is a leading cause of bacterial meningitis in children 2 through 18 years old in the United States. Meningitis is an infection of the covering of the brain and the spinal cord.

Meningococcal disease also causes blood infections.

About 1,000 – 1,200 people get meningococcal disease each year in the U.S. Even when they are treated with antibiotics, 10-15% of these people die. Of those who live, another 11%-19% lose their arms or legs, have problems with their nervous systems, become deaf or mentally retarded, or suffer seizures or strokes.

Anyone can get meningococcal disease. But it is most common in infants less than one year of age and people 16-21 years. Children with certain medical conditions, such as lack of a spleen, have an increased risk of getting meningococcal disease. College freshmen living in dorms are also at increased risk.

Meningococcal infections can be treated with drugs such as penicillin. Still, many people who get the disease die from it, and many others are affected for life. This is why preventing the disease through use of meningococcal vaccine is important for people at highest risk.

2

Meningococcal vaccine

There are two kinds of meningococcal vaccine in the U.S.:

- Meningococcal conjugate vaccine (**MCV4**) is the preferred vaccine for people 55 years of age and younger.
- Meningococcal polysaccharide vaccine (**MPSV4**) has been available since the 1970s. It is the only meningococcal vaccine licensed for people older than 55.

Both vaccines can prevent 4 types of meningococcal disease, including 2 of the 3 types most common in the United States and a type that causes epidemics in Africa. There are other types of meningococcal disease; the vaccines do not protect against these.

3

Who should get meningococcal vaccine and when?

Routine Vaccination

Two doses of MCV4 are recommended for adolescents 11 through 18 years of age: the first dose at 11 or 12 years of age, with a booster dose at age 16.

Adolescents in this age group with HIV infection should get three doses: 2 doses 2 months apart at 11 or 12 years, plus a booster at age 16.

If the first dose (or series) is given between 13 and 15 years of age, the booster should be given between 16 and 18. If the first dose (or series) is given after the 16th birthday, a booster is not needed.

Other People at Increased Risk

- College freshmen living in dormitories.
- Laboratory personnel who are routinely exposed to meningococcal bacteria.
- U.S. military recruits.
- Anyone traveling to, or living in, a part of the world where meningococcal disease is common, such as parts of Africa.
- Anyone who has a damaged spleen, or whose spleen has been removed.
- Anyone who has persistent complement component deficiency (an immune system disorder).
- People who might have been exposed to meningitis during an outbreak.

Children between 9 and 23 months of age, and anyone else with certain medical conditions need 2 doses for adequate protection. Ask your doctor about the number and timing of doses, and the need for booster doses.

MCV4 is the preferred vaccine for people in these groups who are 9 months through 55 years of age. MPSV4 can be used for adults older than 55.



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4**Some people should not get meningococcal vaccine or should wait.**

- Anyone who has ever had a severe (life-threatening) allergic reaction to a previous dose of MCV4 or MPSV4 vaccine should not get another dose of either vaccine.
- Anyone who has a severe (life threatening) allergy to any vaccine component should not get the vaccine. *Tell your doctor if you have any severe allergies.*
- Anyone who is moderately or severely ill at the time the shot is scheduled should probably wait until they recover. Ask your doctor. People with a mild illness can usually get the vaccine.
- Meningococcal vaccines may be given to pregnant women. MCV4 is a fairly new vaccine and has not been studied in pregnant women as much as MPSV4 has. It should be used only if clearly needed. The manufacturers of MCV4 maintain pregnancy registries for women who are vaccinated while pregnant.

Except for children with sickle cell disease or without a working spleen, meningococcal vaccines may be given at the same time as other vaccines.

5**What are the risks from meningococcal vaccines?**

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of meningococcal vaccine causing serious harm, or death, is extremely small.

Brief fainting spells and related symptoms (such as jerking or seizure-like movements) can follow a vaccination. They happen most often with adolescents, and they can result in falls and injuries.

Sitting or lying down for about 15 minutes after getting the shot – especially if you feel faint – can help prevent these injuries.

Mild problems

As many as half the people who get meningococcal vaccines have mild side effects, such as redness or pain where the shot was given.

If these problems occur, they usually last for 1 or 2 days. They are more common after MCV4 than after MPSV4.

A small percentage of people who receive the vaccine develop a mild fever.

Severe problems

Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare.

6**What if there is a moderate or severe reaction?****What should I look for?**

Any unusual condition, such as a severe allergic reaction or a high fever. If a severe allergic reaction occurred, it would be within a few minutes to an hour after the shot. Signs of a serious allergic reaction can include **difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat.**

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7**The National Vaccine Injury Compensation Program**

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

8**How can I learn more?**

- Your doctor can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)

Meningococcal Vaccines

10/14/2011

42 U.S.C. § 300aa-26

TYPHOID VACCINE

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

1 What is typhoid?

Typhoid (typhoid fever) is a serious disease. It is caused by bacteria called *Salmonella Typhi*.

Typhoid causes a high fever, weakness, stomach pains, headache, loss of appetite, and sometimes a rash. If it is not treated, it can kill up to 30% of people who get it.

Some people who get typhoid become “carriers,” who can spread the disease to others.

Generally, people get typhoid from contaminated food or water. Typhoid is not common in the U.S., and most U.S. citizens who get the disease get it while traveling. Typhoid strikes about 21 million people a year around the world and kills about 200,000.



Typhoid vaccine can prevent typhoid.

2 Typhoid vaccines

There are two vaccines to prevent typhoid. One is an inactivated (killed) vaccine gotten as a shot, and the other is live, attenuated (weakened) vaccine which is taken orally (by mouth).

3 Who should get typhoid vaccine and when?

Routine typhoid vaccination is not recommended in the United States, but typhoid vaccine is recommended for:

- Travelers to parts of the world where typhoid is common. (NOTE: typhoid vaccine is not 100% effective and is not a substitute for being careful about what you eat or drink.)
- People in close contact with a typhoid carrier.
- Laboratory workers who work with *Salmonella Typhi* bacteria.

Inactivated Typhoid Vaccine (Shot)

- Should not be given to children younger than 2 years of age.
- One dose provides protection. It should be given at least 2 weeks before travel to allow the vaccine time to work.
- A booster dose is needed every 2 years for people who remain at risk.

Live Typhoid Vaccine (Oral)

- Should not be given to children younger than 6 years of age.
- Four doses, given 2 days apart, are needed for protection. The last dose should be given at least 1 week before travel to allow the vaccine time to work.
- A booster dose is needed every 5 years for people who remain at risk.

Either vaccine may be given at the same time as other vaccines.

4 Some people should not get typhoid vaccine or should wait

Inactivated Typhoid Vaccine (Shot)

- Anyone who has had a severe reaction to a previous dose of this vaccine should not get another dose.

Over . . .

Live Typhoid Vaccine (Oral)

- Anyone who has had a severe reaction to a previous dose of this vaccine should not get another dose.
- Anyone whose immune system is weakened should not get this vaccine. They should get the inactivated typhoid vaccine instead. These people include anyone who:
 - Has HIV/AIDS or another disease that affects the immune system.
 - Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer.
 - Has any kind of cancer.
 - Is taking cancer treatment with x-rays or drugs.
- Oral typhoid vaccine should not be given within 24 hours of certain antibiotics.

Ask your doctor or nurse for more information.

5 What are the risks from typhoid vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small. Serious problems from either of the two typhoid vaccines are very rare.

Inactivated Typhoid Vaccine (Shot)

Mild Reactions

- Fever (up to about 1 person per 100).
- Headache (up to about 3 people per 100).
- Redness or swelling at the site of the injection (up to 7 people per 100).

Live Typhoid Vaccine (Oral)

Mild Reactions

- Fever or headache (up to about 5 people per 100).
- Abdominal discomfort, nausea, vomiting, or rash (rare).

6

What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7

How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Visit CDC's typhoid website at www.cdc.gov/ncidod/dbmd/diseaseinfo/typhoidfever_g.htm



Polio Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages.
See www.immunize.org/vis.

Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite <http://www.immunize.org/vis>

1 What is polio?

Polio is a disease caused by a virus. It enters the body through the mouth. Usually it does not cause serious illness. But sometimes it causes paralysis (can't move arm or leg), and it can cause meningitis (irritation of the lining of the brain). It can kill people who get it, usually by paralyzing the muscles that help them breathe.

Polio used to be very common in the United States. It paralyzed and killed thousands of people a year before we had a vaccine.

2 Why get vaccinated?

Inactivated Polio Vaccine (IPV) can prevent polio.

History: A 1916 polio epidemic in the United States killed 6,000 people and paralyzed 27,000 more. In the early 1950's there were more than 25,000 cases of polio reported each year. Polio vaccination was begun in 1955. By 1960 the number of reported cases had dropped to about 3,000, and by 1979 there were only about 10. The success of polio vaccination in the U.S. and other countries has sparked a world-wide effort to eliminate polio.

Today: Polio has been eliminated from the United States. But the disease is still common in some parts of the world. It would only take one person infected with polio virus coming from another country to bring the disease back here if we were not protected by vaccine. If the effort to eliminate the disease from the world is successful, some day we won't need polio vaccine. Until then, we need to keep getting our children vaccinated.

3 Who should get polio vaccine and when?

IPV is a shot, given in the leg or arm, depending on age. It may be given at the same time as other vaccines.

Children

Children get 4 doses of IPV, at these ages:

- A dose at 2 months
- A dose at 4 months
- A dose at 6-18 months
- A booster dose at 4-6 years

Some "combination" vaccines (several different vaccines in the same shot) contain IPV.

Children getting these vaccines may get one more (5th) dose of polio vaccine. This is not a problem.

Adults

Most adults 18 and older do not need polio vaccine because they were vaccinated as children. But some adults are at higher risk and should consider polio vaccination:

- (1) people traveling to areas of the world where polio is common,
- (2) laboratory workers who might handle polio virus, and
- (3) health care workers treating patients who could have polio.

Adults in these three groups:

- who have **never been vaccinated against polio** should get 3 doses of IPV:
 - Two doses separated by 1 to 2 months, and
 - A third dose 6 to 12 months after the second.
- who have had **1 or 2 doses** of polio vaccine in the past should get the remaining 1 or 2 doses.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

It doesn't matter how long it has been since the earlier dose(s).

- who have had **3 or more doses** of polio vaccine in the past may get a booster dose of IPV.

Your doctor can give you more information.

4

Some people should not get IPV or should wait.

These people should not get IPV:

- Anyone with a life-threatening allergy to any component of IPV, including the antibiotics neomycin, streptomycin or polymyxin B, should not get polio vaccine. Tell your doctor if you have any severe allergies.
- Anyone who had a severe allergic reaction to a previous polio shot should not get another one.

These people should wait:

- Anyone who is moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting polio vaccine. People with minor illnesses, such as a cold, may be vaccinated.

Ask your doctor for more information.

5

What are the risks from IPV?

Some people who get IPV get a sore spot where the shot was given. IPV has not been known to cause serious problems, and most people don't have any problems at all with it.

However, any medicine could cause a serious side effect, such as a severe allergic reaction or even death. The risk of polio vaccine causing serious harm is extremely small.

6

What if there is a moderate or severe problem?

What should I look for?

- Look for any unusual condition, such as a serious allergic reaction, high fever, or unusual behavior.

If a serious allergic reaction occurred, it would happen within a few minutes to a few hours

after the shot. Signs of a serious allergic reaction can include difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

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- Call your local or state health department.
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 - Call **1-800-232-4636 (1-800-CDC-INFO)** or visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)

Polio Vaccine

11/8/2011

42 U.S.C. § 300aa-26



Some parents of children with autism are concerned that vaccines are the cause. Their concerns center on three areas: the combination measles-mumps-rubella (MMR) vaccine; thimerosal, a mercury-containing preservative previously contained in several vaccines; and the notion that babies receive too many vaccines too soon.

Q. What are the symptoms of autism?

A. Symptoms of autism, which typically appear during the first few years of life, include difficulties with behavior, social skills and communication. Specifically, children with autism may have difficulty interacting socially with parents, siblings and other people; have difficulty with transitions and need routine; engage in repetitive behaviors such as hand flapping or rocking; display a preoccupation with activities or toys; and suffer a heightened sensitivity to noise and sounds. Autism spectrum disorders vary in the type and severity of the symptoms they cause, so two children with autism may not be affected in quite the same way.

Q. What causes autism?

A. The specific cause or causes of autism in all children are not known. But one thing is clear: autism spectrum disorders are highly genetic. Researchers figured this out by studying twins. They found that when one identical twin had autism, the chance that the second twin had autism was greater than 90 percent. But when one fraternal twin had autism, the chance that the second twin had autism was less than 10 percent. Because identical twins have identical genes and fraternal twins don't, these studies proved the genetic basis of autism. More recently, researchers have successfully identified some of the specific genes that cause autism.

Some parents wonder whether environmental factors – defined as anything other than genetic factors – can cause autism. It's possible. For example, researchers found that thalidomide, a sedative, can cause autism if used during early pregnancy. Also, if pregnant women are infected with rubella virus (German measles) during early pregnancy, their babies are more likely to have autism.

Q. Does the MMR vaccine cause autism?

A. No. In 1998, a British researcher named Andrew Wakefield raised the notion that the MMR vaccine might cause autism. In the medical journal *The Lancet*, he reported the stories of eight children who developed autism and intestinal problems soon after receiving the MMR vaccine. To determine whether Wakefield's suspicion was correct, researchers performed a series of studies comparing hundreds of thousands of children who had received the MMR vaccine with hundreds of thousands who had never received the vaccine. They found that the risk of autism was the same in both groups. The MMR vaccine didn't cause autism. Furthermore, children with autism were not more likely than other children to have bowel problems.

Q. Does thimerosal cause autism?

A. No. Multiple studies have shown that thimerosal in vaccines does not cause autism. Thimerosal is a mercury-containing preservative that was used in vaccines to prevent contamination. In 1999, professional groups called for thimerosal to be removed from vaccines as a precaution. Unfortunately, the precipitous removal of thimerosal from all but some multidose preparations of influenza vaccine scared some parents. Clinicians were also confused by the recommendation.

Since the removal of thimerosal, six studies have been performed to determine whether thimerosal causes autism. Again, hundreds of thousands of children who received thimerosal-containing vaccines were compared to hundreds of thousands of children who received the same vaccines free of thimerosal. The results were clear: The risk of autism was the same in both groups.

Vaccines and Autism: What you should know

Q. Are the studies showing that neither the MMR vaccine nor thimerosal causes autism sensitive enough to detect the problem in small numbers of children?

A. The studies showing that neither the MMR vaccine nor thimerosal causes autism, called epidemiological studies, are very sensitive. For example, epidemiological studies have shown that a rotavirus vaccine used between 1998 and 1999 in the United States caused intestinal blockage in 1 out of every 10,000 vaccine recipients; that measles vaccine caused a reduction in the number of cells needed to stop bleeding (platelets) in 1 out of every 25,000 recipients; and that an influenza (swine flu) vaccine used in the United States in 1976 caused a type of paralysis called Guillain-Barré Syndrome in 1 out of every 100,000 recipients.

About 1 out of every 150 children in the United States is diagnosed with an autism spectrum disorder. Even if vaccines caused autism in only 1 percent of those children – meaning 1 out of every 15,000 children – the problem would have easily been detected by epidemiological studies.

Q. Is autism caused by children receiving too many vaccines too soon?

A. Several facts make it very unlikely that babies are overwhelmed by too many vaccines given too early in life.

First, before they are licensed, new vaccines are always tested alone or in combination with existing vaccines. These studies determine whether new vaccines alter the safety and efficacy of existing vaccines and, conversely, whether existing vaccines affect the new vaccine. These studies, called concomitant use studies, are performed every time a new vaccine is added to the existing vaccination schedule.

Second, although the number of vaccines has increased dramatically during the past century, the number of immunological components in vaccines has actually decreased. One hundred years ago, children received just one vaccine, for smallpox. The smallpox vaccine contained about 200 immunological components. Today, with advances in protein purification and recombinant DNA technology, the 14 vaccines given to young children contain only about 150 immunological components.

Third, the immunological challenge from vaccines is minuscule compared to what babies typically encounter every day. The womb is sterile, containing no bacteria, viruses, parasites or fungi. But when babies leave the womb and enter the world, they are immediately colonized by trillions of bacteria that live on the linings of their nose, throat, skin and intestines. Each bacterium contains between 2,000 and 6,000

immunological components. And babies often make an immune response to these bacteria to prevent them from entering the bloodstream and causing harm. The challenge that vaccines present is tiny in comparison to that from the environment.

Fourth, children have an enormous capacity to respond to immunological challenges. Susumu Tonegawa, a molecular biologist who won a Nobel Prize for his work, showed that people have the capacity to make between 1 billion and 100 billion different types of antibodies. Given the number of immunological components contained in modern vaccines, a conservative estimate would be that babies have the capacity to respond to about 100,000 different vaccines at once. Although this sounds like a huge number, when you consider the number of challenges that babies face from bacteria in their environment, it's not.

Here's another way to understand the difference in scale between immunological challenges from vaccines and natural challenges from the environment. The quantity of bacteria that live on body surfaces is measured in grams (a gram is the weight of about one-fifth of a teaspoon of water). The quantity of immunological components contained in vaccines is measured in micrograms or nanograms (millionths or billionths of a gram).

Q. If I am concerned that vaccines cause autism, what is the harm in delaying or withholding vaccines for my baby?

A. All of the evidence shows that vaccines don't cause autism, so delaying or withholding vaccines will not lessen the risk of autism; it will only increase the period of time during which children are at risk for vaccine-preventable diseases. Several of these diseases, like chickenpox, pertussis (whooping cough) and pneumococcus (which causes bloodstream infections, pneumonia and meningitis) are still fairly common. Delaying or withholding vaccines only increases the time during which children are at unnecessary risk for severe and occasionally fatal infections.

All of the evidence shows that vaccines don't cause autism, so delaying or withholding vaccines will not lessen the risk of autism; it will only increase the period of time during which children are at risk for vaccine-preventable diseases.

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This information is provided by the Vaccine Education Center at The Children's Hospital of Philadelphia. The Center is an educational resource for parents and healthcare professionals and is composed of scientists, physicians, mothers and fathers who are devoted to the study and prevention of infectious diseases. The Vaccine Education Center is funded by endowed chairs from The Children's Hospital of Philadelphia. The Vaccine Education Center does not receive support from pharmaceutical companies.

Some of this material was excerpted from the book, *Vaccines: What You Should Know*, co-authored by Paul A. Offit, M.D., and Louis M. Bell, M.D.

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Vaccine Education Center at
The Children's Hospital of Philadelphia

vaccine.chop.edu

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The Children's Hospital of Philadelphia, the nation's first pediatric hospital, is a world leader in patient care and pioneering research.

Section 6 Documentation

Ensuring that documentation of all vaccines, response, and followup is a critical point in the responsibilities for the employee/occupational health component. This section focuses on providing some background information regarding the importance of electronic health records, including immunizations. In addition a sample document is provided that can be used to maintain a record of all healthcare personnel immunizations. Since improving influenza immunization rates remains a patient safety focus and the need to evaluate and improve healthcare personnel immunization rates, a sample influenza vaccination declination form is provided.

The following documents are provided in this section:

- Electronic Health Records and Immunization Registries
- Sample Healthcare Personnel Immunization Record
- Sample Adult Vaccine Record
- Example of a Lifetime Immunization Record
<http://www.immunize.org/images/LifetimeCard.pdf>
- Sample Influenza Vaccination Declination Form

Electronic Health Records and Immunization Registries

In the 2011 ACIP Immunization of Health-Care Personnel guideline update, there is a reminder statement that HICPAC and CDC have recommended that “secure, preferably computerized, systems should be used to manage vaccination records for healthcare personnel so records can be retrieved easily as needed”. The guideline goes on to describe what information should be included in the record, the use of records as a means of rapidly identifying susceptible healthcare personnel, and the importance of ensuring that every healthcare personnel have their immunization records so they can be made available to future employers and maintained as part of their own personal health records.

In order to ensure adequate immunization and quickly determine susceptibility, employee/occupational health records must be accessible, contain consistent information, be rapidly retrievable, and be maintained in a manner that enables the data to be aggregated for analysis. Clearly, the old method of paper and pen recordkeeping is no longer acceptable. Consequently, it is important that the individual(s) responsible for the healthcare personnel immunization program explore then utilize methods of maintaining these important health records in an electronic format.

At present, there exist a number of possibilities for accomplishing the goal of electronic employee/occupational health records. Proprietary software exists that can be customized to maintain records, generate reports and reminders. Most states also maintain immunization registries that, although not focused on healthcare personnel immunization recordkeeping, may allow for crossover use. Facilities may wish to utilize software that is currently available and in use within their facility such as Microsoft products (e.g., Excel or Access). The individual(s) responsible for the program should explore the alternatives and select a method that ensures records are accessible, consistent, retrievable and available for analysis.

To learn more about Immunization Information Systems (IIS), also known as Immunization Registries, go to the CDC website <http://www.cdc.gov/vaccines/programs/iis/default.htm>.

Sample Healthcare Personnel Immunization Record

(Please Print)

Name: _____ Birth Date: ____/____/____ Department: _____

Last First Middle

Required Immunizations and Testing																															
Tetanus-Diphtheria Acellular Pertussis (Tdap) Requirement: 1 dose of vaccine within last 10 years.		Booster Dose: ____/____/____ Booster Dose: ____/____/____																													
Measles-Mumps-Rubella (MMR) Requirement: Measles 2 doses of vaccine or positive titer Mumps 2 doses of vaccine or positive titer Rubella 1 dose of vaccine or positive titer		MMR Dose 1: ____/____/____ OR Measles Titer: ____/____/____ MMR Dose 2: ____/____/____ Mumps Titer: ____/____/____ Rubella Titer: ____/____/____																													
Hepatitis B Vaccine (HepB) Requirement: 3 doses of vaccine followed by positive titer (≥ 10 mlu)		Hepatitis B Dose 1: ____/____/____ Hepatitis B Dose 4: ____/____/____ Hepatitis B Dose 2: ____/____/____ Hepatitis B Dose 5: ____/____/____ Hepatitis B Dose 3: ____/____/____ Hepatitis B Dose 6: ____/____/____ AND AND Hepatitis B Titer: ____/____/____ Hepatitis B Titer: ____/____/____ Additional Hepatitis B Booster for special causes: Hepatitis B Dose: ____/____/____ Hepatitis B Titer: ____/____/____																													
Varicella (Chickenpox) Vaccine 2 doses of vaccine or positive antibody titer		Varicella Dose 1: ____/____/____ OR Varicella Titer: ____/____/____ Varicella Dose 2: ____/____/____																													
Tuberculosis Screening Requirement: (one of the following) 1. Tuberculin skin test (TST) within last 12 months, or 2. Documentation of reactive TST, CXR and treatment, or 3. Two (2) TSTs more than 2 weeks apart but less than 12 months if history of BCG, or 4. QuantiFERON-Gold TB blood test in last 12 months		<div> TST 1: ____/____/____ TST 2: ____/____/____ OR CXR: ____/____/____ INH From: ____/____/____ TO ____/____/____ OR QuantiFERON-Gold TB: ____/____/____ </div> <div> Annual Testing: <table> <thead> <tr> <th></th> <th>Date</th> <th>Result</th> </tr> </thead> <tbody> <tr><td>TST 1/QFTG</td><td>____/____/____</td><td>_____</td></tr> <tr><td>TST 1/QFTG</td><td>____/____/____</td><td>_____</td></tr> <tr><td>TST 1/QFTG</td><td>____/____/____</td><td>_____</td></tr> <tr><td>TST 1/QFTG</td><td>____/____/____</td><td>_____</td></tr> <tr><td>TST 1/QFTG</td><td>____/____/____</td><td>_____</td></tr> <tr><td>TST 1/QFTG</td><td>____/____/____</td><td>_____</td></tr> <tr><td>TST 1/QFTG</td><td>____/____/____</td><td>_____</td></tr> <tr><td>TST 1/QFTG</td><td>____/____/____</td><td>_____</td></tr> </tbody> </table> </div>				Date	Result	TST 1/QFTG	____/____/____	_____	TST 1/QFTG	____/____/____	_____	TST 1/QFTG	____/____/____	_____	TST 1/QFTG	____/____/____	_____	TST 1/QFTG	____/____/____	_____	TST 1/QFTG	____/____/____	_____	TST 1/QFTG	____/____/____	_____	TST 1/QFTG	____/____/____	_____
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Special Circumstances Immunizations and Testing

Meningococcal (MCV4)	MCV4 IM Dose 1: ____/____/____ Booster Dose: ____/____/____	
Typhoid	Oral Typhoid Dose 1: ____/____/____ Booster Dose: ____/____/____ Booster Dose: ____/____/____ OR IM Typhoid Dose 1: ____/____/____ Booster Dose: ____/____/____ Booster Dose: ____/____/____ Booster Dose: ____/____/____	
Inactivated Poliovirus (IPV)	IPV Dose 1: ____/____/____ IPV Dose 2: ____/____/____ IPV Dose 3: ____/____/____	
Changes in health conditions, adverse events, etc.	Note dates and conditions/events:	

Vaccine Administration Record for Adults

Patient name: _____

Birthdate: _____

Chart number: _____

Before administering any vaccines, give the patient copies of all pertinent Vaccine Information Statements (VISs) and make sure he/she understands the risks and benefits of the vaccine(s). Always provide or update the patient's personal record card.

Vaccine	Type of Vaccine ¹	Date given (mo/day/yr)	Funding source (F,S,P) ²	Site ³	Vaccine		Vaccine Information Statement (VIS)		Vaccinator ⁵ (signature or initials & title)
					Lot #	Mfr.	Date on VIS ⁴	Date given ⁴	
Tetanus, Diphtheria, Pertussis (e.g., Td, Tdap) Give IM. ⁶									
Hepatitis A⁷ (e.g., HepA, HepA-HepB) Give IM. ⁶									
Hepatitis B⁷ (e.g., HepB, HepA-HepB) Give IM. ⁶									
Human papillomavirus (HPV2, HPV4) Give IM. ⁶									
Measles, Mumps, Rubella (MMR) Give SC. ⁶									
Varicella (VAR) Give SC. ⁶									
Pneumococcal polysaccharide (PPSV23) Give SC or IM. ⁶									
Meningococcal (e.g., MCV4, conjugate; MPSV4, polysaccharide) Give MCV4 IM. ⁶ Give MPSV4 SC. ⁶									

See page 2 to record influenza, zoster, and other vaccines (e.g., travel vaccines).

How to Complete this Record

- Record the generic abbreviation (e.g., Tdap) or the trade name for each vaccine (see table at right).
- Record the funding source of the vaccine given as either F (federal), S (state), or P (private).
- Record the site where vaccine was administered as either RA (right arm), LA (left arm), RT (right thigh), LT (left thigh), or IN (intranasal).
- Record the publication date of each VIS as well as the date the VIS is given to the patient.
- To meet the space constraints of this form and federal requirements for documentation, a healthcare setting may want to keep a reference list of vaccinators that includes their initials and titles.
- IM is the abbreviation for intramuscular; SC is the abbreviation for subcutaneous.
- For combination vaccines, fill in a row for each antigen in the combination.

Abbreviation	Trade Name & Manufacturer
Tdap	Adacel (sanofi pasteur), Boostrix (GlaxoSmithKline [GSK])
Td	Decavac (sanofi pasteur), generic (MA Biological Labs)
HepA	Havrix (GSK); Vaqta (Merck)
HepB	Engerix-B (GSK), Recombivax HB (Merck)
HepA-HepB	Twinrix (GSK)
HPV2	Cervarix (GSK)
HPV4	Gardasil (Merck)
MMR	MMRII (Merck)
VAR	Varivax (Merck)
PPSV23	Pneumovax 23 (Merck)
MCV4	Menactra (sanofi pasteur); Menveo (Novartis)
MPSV4	Menomune (sanofi pasteur)

Vaccine Administration Record for Adults

Patient name: _____

Birthdate: _____

Chart number: _____

Before administering any vaccines, give the patient copies of all pertinent Vaccine Information Statements (VISs) and make sure he/she understands the risks and benefits of the vaccine(s). Always provide or update the patient's personal record card.

Vaccine	Type of Vaccine ¹	Date given (mo/day/yr)	Funding Source (F,S,P) ²	Site ³	Vaccine		Vaccine Information Statement (VIS)		Vaccinator ⁵ (signature or initials & title)
					Lot #	Mfr.	Date on VIS ⁴	Date given ⁴	
Influenza (e.g., TIV, inactivated; LAIV, live attenuated) Give TIV IM. ⁶ Give LAIV IN. ⁶									
Zoster (ZOS) Give SC. ⁶									
Other									

See page 1 to record Tdap/Td, hepatitis A, hepatitis B, HPV, MMR, varicella, pneumococcal, and meningococcal vaccines.

How to Complete this Record

- Record the generic abbreviation (e.g., Tdap) or the trade name for each vaccine (see table at right).
- Record the funding source of the vaccine given as either F (federal), S (state), or P (private).
- Record the site where vaccine was administered as either RA (right arm), LA (left arm), RT (right thigh), LT (left thigh), IN (intranasal), or .
- Record the publication date of each VIS as well as the date the VIS is given to the patient.
- To meet the space constraints of this form and federal requirements for documentation, a healthcare setting may want to keep a reference list of vaccinators that includes their initials and titles.
- IM is the abbreviation for intramuscular; SC is the abbreviation for subcutaneous; IN is the abbreviation for intranasal.

Abbreviation	Trade Name & Manufacturer
LAIV (Live attenuated influenza vaccine)	FluMist (MedImmune)
TIV (Trivalent inactivated influenza vaccine)	Afluria (CSL Biotherapies); Agriflu (Novartis); Fluarix (GSK); FluLaval (GSK); Fluvirin (Novartis); Fluzone (sanofi pasteur); Fluzone High-Dose (sanofi pasteur)
ZOS (shingles)	Zostavax (Merck)

Vaccine Administration Record for Adults

Patient name: Mohammed SharikBirthdate: 4/14/1981

Chart number: _____

Before administering any vaccines, give the patient copies of all pertinent Vaccine Information Statements (VISs) and make sure he/she understands the risks and benefits of the vaccine(s). Always provide or update the patient's personal record card.

Vaccine	Type of Vaccine ¹	Date given (mo/day/yr)	Funding source (F,S,P) ²	Site ³	Vaccine		Vaccine Information Statement (VIS)		Vaccinator ⁵ (signature or initials & title)
					Lot #	Mfr.	Date on VIS ⁴	Date given ⁴	
Tetanus, Diphtheria, Pertussis (e.g., Td, Tdap) Give IM. ⁶	<i>Td</i>	8/01/02	P	LA	U0376AA	AVP	6/10/94	8/1/2002	JTA
	<i>Td</i>	9/1/2002	P	LA	U0376AA	AVP	6/10/94	9/1/2002	PWS
	<i>Td</i>	3/1/2003	P	LA	U0376AA	AVP	6/10/94	3/1/2003	TAA
	<i>Tdap</i>	6/14/2010	P	LA	AC52B030AA	GSK	11/18/2008	6/14/2010	JTA
Hepatitis A⁷ (e.g., HepA, HepA-HepB) Give IM. ⁶	<i>HepA-HepB</i>	8/1/2002	P	RA	HAB239A4	GSK	8/25/1998	8/1/2002	JTA
	<i>HepA-HepB</i>	9/1/2002	P	RA	HAB239A4	GSK	8/25/1998	9/1/2002	PWS
	<i>HepA-HepB</i>	3/1/2003	P	RA	HAB239A4	GSK	8/25/1998	3/1/2003	TAA
Hepatitis B⁷ (e.g., HepB, HepA-HepB) Give IM. ⁶	<i>HepA-HepB</i>	8/1/2002	P	RA	HAB239A4	GSK	7/11/2001	8/1/2002	JTA
	<i>HepA-HepB</i>	9/1/2002	P	RA	HAB239A4	GSK	7/11/2001	9/1/2002	PWS
	<i>HepA-HepB</i>	3/1/2003	P	RA	HAB239A4	GSK	7/11/2001	3/1/2003	TAA
Human papillomavirus (HPV2, HPV4) Give IM. ⁶									
Measles, Mumps, Rubella (MMR) Give SC. ⁶	<i>MMR</i>	8/1/2002	P	RA	0025L	MRK	6/13/2002	8/1/2002	JTA
	<i>MMR</i>	11/1/2002	P	RA	0025L	MRK	6/13/2002	11/1/2002	TAA
Varicella (VAR) Give SC. ⁶	<i>VAR</i>	8/1/2002	P	LA	0799M	MRK	12/16/1998	8/1/2002	JTA
	<i>VAR</i>	11/1/2002	P	RA	0689M	MRK	12/16/1998	11/1/2002	TAA
Pneumococcal polysaccharide (PPSV23) Give SC or IM. ⁶									
Meningococcal (e.g., MCV4, conjugate; MPSV4, polysaccharide) Give MCV4 IM. ⁶ Give MPSV4 SC. ⁶	<i>Menveo</i>	7/12/2010	P	RA	28011	NOV	1/28/2008	7/12/2010	JTA

1 shot, 2 different VIS dates

See page 2 to record influenza, zoster, and other vaccines (e.g., travel vaccines).

How to Complete this Record

- Record the generic abbreviation (e.g., Tdap) or the trade name for each vaccine (see table at right).
- Record the funding source of the vaccine given as either F (federal), S (state), or P (private).
- Record the site where vaccine was administered as either RA (right arm), LA (left arm), RT (right thigh), LT (left thigh), or IN (intranasal).
- Record the publication date of each VIS as well as the date the VIS is given to the patient.
- To meet the space constraints of this form and federal requirements for documentation, a healthcare setting may want to keep a reference list of vaccinators that includes their initials and titles.
- IM is the abbreviation for intramuscular; SC is the abbreviation for subcutaneous.
- For combination vaccines, fill in a row for each antigen in the combination.

Abbreviation	Trade Name & Manufacturer
Tdap	Adacel (sanofi pasteur), Boostrix (GlaxoSmithKline [GSK])
Td	Decavac (sanofi pasteur), generic (MA Biological Labs)
HepA	Havrix (GSK); Vaqta (Merck)
HepB	Engerix-B (GSK), Recombivax HB (Merck)
HepA-HepB	Twinrix (GSK)
HPV2	Cervarix (GSK)
HPV4	Gardasil (Merck)
MMR	MMRII (Merck)
VAR	Varivax (Merck)
PPSV23	Pneumovax 23 (Merck)
MCV4	Menactra (sanofi pasteur); Menveo (Novartis)
MPSV4	Menomune (sanofi pasteur)

This is a record for a 29-year-old healthcare worker who is planning to travel to Saudi Arabia for the annual Hajj.

Vaccine Administration Record for Adults

Patient name: *Mohammed Sharik*

Birthdate: 4/14/1981

Chart number:

Before administering any vaccines, give the patient copies of all pertinent Vaccine Information Statements (VISs) and make sure he/she understands the risks and benefits of the vaccine(s). Always provide or update the patient's personal record card.

[illegible]

See page 1 to record Tdap/Td, hepatitis A, hepatitis B, HPV, MMR, varicella, pneumococcal, and meningococcal vaccines.

How to Complete this Record

1. Record the generic abbreviation (e.g., Tdap) or the trade name for each vaccine (see table at right).
2. Record the funding source of the vaccine given as either F (federal), S (state), or P (private).
3. Record the site where vaccine was administered as either RA (right arm), LA (left arm), RT (right thigh), LT (left thigh), or IN (intranasal).
4. Record the publication date of each VIS as well as the date the VIS is given to the patient.
5. To meet the space constraints of this form and federal requirements for documentation, a healthcare setting may want to keep a reference list of vaccinators that includes their initials and titles.
6. IM is the abbreviation for intramuscular; SC is the abbreviation for subcutaneous; IN is the abbreviation for intranasal.

Abbreviation	Trade Name & Manufacturer
LAIV (Live attenuated influenza vaccine)	FluMist (MedImmune)
TIV (Trivalent inactivated influenza vaccine)	Afluria (CSL Biotherapies); Agriflu (Novartis); Fluarix (GSK); FluLaval (GSK); Fluvirin (Novartis); Fluzone (sanofi pasteur); Fluzone High-Dose (sanofi pasteur)
ZOS (shingles)	Zostavax (Merck)

This is a record for a 29-year-old healthcare worker who is planning to travel to Saudi Arabia for the annual Hajj.

LIFETIME IMMUNIZATION RECORD

Always carry this record with you and have your healthcare professional or clinic keep it up to date.

Last name	First name	M.I.

Birthdate: (mo.) - (day) - (yr.)

Patient Number: _____

Printed by Immunization Action Coalition, Saint Paul, MN
www.immunize.org • www.vaccineinformation.org

Medical notes (e.g., allergies, vaccine reactions):
Healthcare provider: List the mo/day/yr for each vaccination given. Record the generic abbreviation (e.g., PCV13, DTaP-IPV/Hib), or the trade name. For combination vaccines, fill in a row for each separate antigen in the combination.

Vaccine	Type of vaccine	Date given mo/day/yr	Healthcare professional or clinic	Date next dose due
Hepatitis B (HepB, Hib-HepB, DTaP-HepB-IPV, HepA-HepB)				
Diphtheria, Tetanus, Pertussis (DTaP, DTP, DT, Td, Tdap, DTaP-HepB-IPV, DTaP-IPV/Hib, DTaP-IPV, DTaP/Hib)				

To learn more about vaccines, visit www.vaccineinformation.org and www.immunize.org

Declination of Influenza Vaccination

My employer or affiliated health facility, _____, has recommended that I receive influenza vaccination to protect the patients I serve.

I acknowledge that I am aware of the following facts:

- ♦ Influenza is a serious respiratory disease that kills thousands of people in the United States each year.
- ♦ Influenza vaccination is recommended for me and all other healthcare workers to protect this facility's patients from influenza, its complications, and death.
- ♦ If I contract influenza, I can shed the virus for 24 hours before influenza symptoms appear. My shedding the virus can spread influenza to patients in this facility.
- ♦ If I become infected with influenza, I can spread severe illness to others even when my symptoms are mild or non-existent.
- ♦ I understand that the strains of virus that cause influenza infection change almost every year and, even if they don't change, my immunity declines over time. This is why vaccination against influenza is recommended each year.
- ♦ I understand that I cannot get influenza from the influenza vaccine.
- ♦ The consequences of my refusing to be vaccinated could have life-threatening consequences to my health and the health of those with whom I have contact, including
 - all patients in this healthcare facility
 - my coworkers
 - my family
 - my community

Despite these facts, I am choosing to decline influenza vaccination right now for the following reasons: _____

I understand that I can change my mind at any time and accept influenza vaccination, if vaccine is still available.

I have read and fully understand the information on this declination form.

Signature: _____ Date: _____

Name (print): _____

Department: _____

Reference: CDC. Prevention and Control of Influenza with Vaccines—
Recommendations of ACIP at www.cdc.gov/flu/professionals/acip/index.htm

Section 7 Program Evaluation and Improvement

Developing strategies to evaluate and improving existing programs as well as identify gaps in current policies, procedures and services are critical to a well-designed program. This section provides a variety of tools and resources to assist in program evaluation and improvement including resources to improve the expertise of personnel involved in the administration of vaccines.

- Sample Monitoring Report for Immunization Rates
- Checklist for Safe Vaccine Handling and Storage
- Sample Policy for Vaccine Storage and Handling
- Checklist for Improving Immunization Rates Among Healthcare Personnel
- Safe Injection Practices Checklist
- Sample Improvement Strategies
 - Sample Standing Orders
 - Vaccine Excipient & Media Summary (vaccine ingredients)
- Sample Job Description
- Sample Practice Assessment Tools
 - Skills Validation for Intramuscular Seasonal Influenza Immunization Administration (adult)
 - Skills Validation for Intranasal Seasonal Influenza Immunization Administration (adult)
 - Administration of Intradermal Seasonal Influenza Immunization Administration (adult)
 - Skills Validation for Subcutaneous Immunization Administration (adult)
 - Vaccines with Diluents: How to Use Them

Sample Monitoring Report for Healthcare Personnel Immunization Rates. Year(s)_____

Immunization rate= number of healthcare personnel immunized with a specific vaccine /100 eligible healthcare personnel

Eligibility is determined by individuals needing immunization (susceptible) and able to be immunized without contraindication.

[illegible]

Sample Monitoring Report for Healthcare Personnel Influenza Immunization Rates. Year(s)_____

Immunization rate= number of healthcare personnel immunized against influenza /100 eligible healthcare personnel

Eligibility is determined by individuals needing immunization and able to be immunized without contraindication.

[illegible]

Checklist for Safe Vaccine Storage and Handling

Here are the most important things you can do to safeguard your vaccine supply. Are you doing them all? Review this list to see where you might make improvements in your vaccine management practices. Fill in each box with either **YES** or **NO**.

Establish Storage and Handling Policies

- ☐ YES ☐ NO 1. We have designated a primary vaccine coordinator and at least one back-up coordinator to be in charge of vaccine storage and handling at our facility.
- ☐ YES ☐ NO 2. Both the primary and back-up vaccine coordinator(s) have completely reviewed either CDC's online vaccine storage and handling guidance or equivalent training materials offered by our state health department's immunization program.
- ☐ YES ☐ NO 3. We have detailed, up-to-date, written policies for general vaccine management, including policies for routine activities and an emergency vaccine-retrieval-and-storage plan for power outages and other problems. Our policies are based on CDC's vaccine storage and handling guidance and/or on instruction from our state or local health department's immunization program.
- ☐ YES ☐ NO 4. We review these policies with all staff annually and with new staff, including temporary staff, when they are hired.

Log In New Vaccine Shipments

- ☐ YES ☐ NO 5. We maintain a vaccine inventory log that we use to document the following:
 - ☐ YES ☐ NO a. Vaccine name and number of doses received
 - ☐ YES ☐ NO b. Date we received the vaccine
 - ☐ YES ☐ NO c. Condition of vaccine when we received it
 - ☐ YES ☐ NO d. Vaccine manufacturer and lot number
 - ☐ YES ☐ NO e. Vaccine expiration date

Use Proper Storage Equipment

- ☐ YES ☐ NO 6. We store vaccines in refrigerator and freezer units designed specifically for storing biologics, including vaccines. Alternatively, we keep frozen and refrigerated vaccines in separate, free-standing freezer and refrigerator units. At a minimum, we use a household-style unit with a separate exterior door for the freezer and separate thermostats for the freezer and refrigerator. We do NOT use a dormitory-style unit (a small combination freezer-refrigerator unit with a freezer compartment inside the refrigerator).
- ☐ YES ☐ NO 7. We use only calibrated thermometers with a Certificate of Traceability and Calibration* that are recalibrated as recommended by the manufacturer.
- ☐ YES ☐ NO 8. We have planned back-up storage unit(s) in the event of a power failure or other unforeseen event. We perform regular maintenance to assure optimal functioning.

Ensure Optimal Operation of Storage Units

- ☐ YES ☐ NO 9. We have a "Do Not Unplug" sign next to the electrical outlets for the refrigerator and freezer and a "Do Not Stop Power" warning label by the circuit breaker for the electrical outlets. Both include emergency contact information.
- ☐ YES ☐ NO 10. We keep the storage unit clean, dusting the coils and cleaning beneath it every 3–6 months.

Maintain Correct Temperatures

- ☐ YES ☐ NO 11. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with the vaccines in the refrigerator; ideally, we have a continuous-temperature logger and/or temperature-sensitive alarm system.
- ☐ YES ☐ NO 12. We maintain the refrigerator temperature at 35–46°F (2–8°C), and we aim for 40°F (5°C).

(Maintain Correct Temperatures continued on page 2)

*Certificate of Traceability and Calibration with calibration measurements traceable to a testing laboratory accredited by the International Organization of Standardization, to the standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency.

(Maintain Correct Temperatures continued from page 1)

- ☐ YES ☐ NO 13. We keep extra containers of water in the refrigerator (e.g., in the door, on the floor of the unit where the vegetable bins were located) to help maintain cool temperatures.
- ☐ YES ☐ NO 14. We always keep at least one accurate calibrated thermometer (+/-1°C [+/-2°F]) with vaccines in the freezer.
- ☐ YES ☐ NO 15. We maintain the average temperature in the freezer at +5°F (-15°C), preferably colder but no colder than -58°F (-50°C).
- ☐ YES ☐ NO 16. We keep ice packs or ice-filled containers in the freezer to help maintain cold temperatures.

Store Vaccines Correctly

- ☐ YES ☐ NO 17. We post signs on the doors of the refrigerator and freezer that indicate which vaccines should be stored in the refrigerator and which in the freezer.
- ☐ YES ☐ NO 18. We do NOT store any food or drink in any vaccine storage unit.
- ☐ YES ☐ NO 19. We store vaccines in the middle of the refrigerator or freezer (never in the doors), with room for air to circulate.
- ☐ YES ☐ NO 20. We have removed all vegetable and deli bins from the storage unit.
- ☐ YES ☐ NO 21. If we are using a combination refrigerator-freezer unit, we do not store vaccines in front of the cold air outlet that leads from the freezer to the refrigerator (often near the top shelf).
- ☐ YES ☐ NO 22. We check vaccine expiration dates and rotate our supply of each type of vaccine so that we use the vaccines that will expire soonest.
- ☐ YES ☐ NO 23. We store vaccines in their original packaging in clearly labeled uncovered containers with slotted sides that allow air to circulate.

Maintain Daily Temperature Logs

- ☐ YES ☐ NO 24. On days when our practice is open, we document refrigerator and freezer temperatures on the daily log twice a day — first thing in the morning and right before our facility closes.
- ☐ YES ☐ NO 25. We consistently record temperatures on the log in either Fahrenheit or Celsius. We NEVER mix in any way how we record our temperatures. For example, if the log prompts us to insert an "x" by the temperature that's preprinted on the log, we do not attempt to write in the actual temperature.
- ☐ YES ☐ NO 26. The logs show whom to call if the temperature in the storage unit goes out of range.
- ☐ YES ☐ NO 27. When we change the thermostat setting, we document it in the daily log sheet's note section.
- ☐ YES ☐ NO 28. If out-of-range temperatures occur in the unit, we document in the daily log sheet's note section who responded and when.
- ☐ YES ☐ NO 29. Trained staff (other than staff designated to record the temperatures) review the logs weekly.
- ☐ YES ☐ NO 30. We keep the temperature logs on file for at least 3 years.

Take Emergency Action As Needed

31. In the event that vaccines are exposed to improper storage conditions, we take the following steps:
- ☐ YES ☐ NO a. We restore proper storage conditions as quickly as possible; if necessary, we move the vaccine to our planned back-up storage unit. We address the storage unit's mechanical or electrical problems according to guidance from the manufacturer or repair service.
- ☐ YES ☐ NO b. In responding to improper storage conditions, we do NOT make frequent or large changes in thermostat settings. After changing the setting, we give the unit at least a day to stabilize its temperature.
- ☐ YES ☐ NO c. We temporarily label exposed vaccines "Do not use" and keep them separate from any unexposed vaccines. We do not use exposed vaccines until our state health department's immunization program or the vaccine manufacturer gives us approval.
- ☐ YES ☐ NO d. We document exactly what happened, noting the temperature in the storage unit and the amount of time the vaccines were out of proper storage conditions. We contact our state health department's immunization program or the vaccine manufacturer to determine how to handle the exposed vaccines.
- ☐ YES ☐ NO e. We follow the health department or manufacturer's instructions and keep a record detailing the event. Where applicable, we mark the exposed vials with a revised expiration date provided by the manufacturer.

If we answer ☐ YES to all of the above, we give ourselves a pat on the back! If not, we assign someone to implement needed changes!

Vaccine Storage and Handling- Sample policy

1. Dormitory-style refrigerators are not used to stored vaccine.
2. Vaccines are stored at the recommended temperature immediately upon arrival in the Employee Health department.
3. Refrigerated vaccines are maintained at a temperature range of 35°F to 46° F at all times.
4. A temperature log that has the ability to identify out of range conditions is used to document refrigerator temperature.
5. If a temperature is noted to be out of range, immediate investigation and response will occur. If vaccine is felt to have been out of adequate temperature control, the vaccine will be immediately sequestered and determination regarding the disposition of the vaccine will be investigated.
6. Frozen vaccines are maintained in the pharmacy due to the inability to maintain adequate temperature control in the Employee Health department.
7. Frozen vaccines are obtained from the pharmacy and are administered within 30 minutes of removal from the pharmacy freezer.
8. Temperature of the refrigerator is monitored and documented at least twice daily, usually at the beginning and end of the work day.
9. A calibrated thermometer with a certificate of traceability and calibration is kept in the refrigerator.
10. Recalibration of the thermometer is done in accordance with manufacturer recommendation.
11. Signage is posted next to electrical outlines and circuit breakers (e.g., Do Not Unplug and Do Not Stop Power) to maintain a consistent power source.
12. Vaccines are stored in bins or baskets (uncovered) with slotted sides or opening.
13. Bins are arranged in the refrigerator so that air flow around the vaccine is promoted.
14. Bins are clearly labeled with the name of the vaccine. Bins are to contain only one type of vaccine.
15. Vaccines are never stored in the refrigerator door.
16. Water bottles are stored in the refrigerator door to help maintain a constant temperature. Care is taken to prevent too much water storage such that the ability for the refrigerator door to close is not compromised and the seals are maintained.
17. Food and drink (other than water for temperature control purposes) is not to be stored in the same refrigerator as vaccine.
18. Vaccines (opened and unopened) are stored in their original box with the lid in place.
19. Vaccines are prepared for administration at the time of their use.
20. Only the diluent supplied by the vaccine manufacturer is used to reconstitute a vaccine.

21. Vaccine stock is rotated weekly so the vaccine and diluent with the shortest expiration date can be used first. During this process, assessment for expired vaccine occurs.
22. Expired vaccine is disposed of in accordance with hazardous waste regulation unless specific arrangements have been made to return it to the manufacturer.
23. Vials are dated as soon as they are opened unless they are single dose and will be disposed of immediately upon single use.
24. Multidose vials are disposed of on the date of the manufacturers' expiration date, or sooner.
25. Unused reconstituted vaccine is disposed of in accordance with manufacturer recommendation.
26. If vaccine is removed from the department (e.g., mobile carts during influenza immunization campaigns) it is maintained in a manner that monitors and maintains the temperature requirements. A mobile vaccine refrigerator, with AC power capabilities, and a calibrated thermometer is the acceptable transport alternative when frequent entry into the refrigerated environment is expected.

Improving Immunization Rates Among Healthcare Personnel

Checklist for Improvement

- ☐ A statement is posted in my department that clearly shows the commitment we have to immunization.
- ☐ This department has done an assessment to identify obstacles to immunization that may be in place (on purpose or inadvertently).
- ☐ Written standing orders and protocols for immunization are in place.
- ☐ A process is in place so that immunization opportunities are assessed during every healthcare personnel encounter.
- ☐ An audit has been done within the prior 12 months that focuses on missed opportunities for immunization.
- ☐ Results of all audits have been shared with the department staff and others and a plan of improvement has been developed with clear metrics for success.
- ☐ This department knows what our immunization rates are for each vaccine (e.g., # of vaccine doses administered/100 healthcare personnel in whom the vaccine is appropriate).
- ☐ This department has determined and has set achievable goals including and timeframes to drive improvement.
- ☐ An action plan is in place to capture healthcare personnel needing followup on a routine basis either through emails, phone calls, or direct mail.
- ☐ Scripts addressing questions and/or concerns regarding immunization have been developed and reviewed by all personnel in this office.
- ☐ Material regarding immunization is available in the waiting area.
- ☐ Material regarding immunization is available in the examination room(s).
- ☐ All department personnel have been involved in discussions regarding immunization as a means of addressing their conflicting thoughts or opinions that may negatively influence immunization decision-making.

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Safe Injection Practice: A Comprehensive Checklist for Monitoring Practice

The transmission of pathogens to patients during routine care processes continues to occur primarily due to the use of unsafe and improper injection, infusion, and medical vial practices by healthcare workers. These unsafe practices occur in a variety of clinical settings and the results can be devastating for the patient. The areas of practice that are of greatest concern include:

1. Syringe and/or needle reuse
2. Contamination of medication vials
3. Contamination of intravenous bags
4. Failure to follow safety practices when preparing and administering parenteral medication
5. Inappropriate care/maintenance of single use medical devices
6. Inappropriate care/maintenance of reusable medical equipment
7. Lack of written policies/procedures/prevention protocols
8. Staff training and education
9. Monitoring of healthcare personnel practice
10. Feedback of results as a part of the improvement process

The following checklist has been developed by infection preventionists and can be used to evaluate care practices in any healthcare setting and may provide insight and guidance regarding care improvements. When using the checklist, all “Yes” responses indicate that the observed practice(s) follow safe injection practices. A “No” response indicates that immediate corrective action is indicated. A “Do Not Know” response indicates that further investigation is necessary to ensure patient and healthcare personnel safety.

Preventing syringe/needle reuse			
	Yes	No	Do not know
Sterile syringes are used for all medication administered in this setting, regardless of route medication is administered (e.g., intramuscular, intravenous, intradermal)			
Sterile needles are used for all medication administered in this setting, regardless of route medication is administered (e.g., intramuscular, intravenous, intradermal)			
Sterile syringes, needles, cannulas are removed from their packaging immediately before use			
Storage of syringes that have been removed from their packaging (even with capped needles) is prohibited			
New sterile syringes are used for each patient and are never reused or shared between patients			
Medication transfer from one syringe to another is prohibited (e.g., drawing up solution into one syringe then transferring into another syringe with the plunger removed or injected into the bevel or another syringe prior to administration)			
Storing or medication in syringes in pockets or clothing while awaiting administration is prohibited			
Preparation of medication in syringe occurs immediately prior to administration and not drawn up awaiting future administration			
Safety needles/syringes are used for administration of all injectable medication			

Preventing contamination of medication vial			
	Yes	No	Do not know
A new sterile syringe and sterile needle are used for every entry into a medication vial			
Single-use or single-dose vials are used whenever possible			
Single-dose vials are discarded after use.			
Medication left in a vial is never pooled, added to another vial, or added to another dose from another vial			
Access diaphragms of vials are cleansed with a sterile 70% alcohol, iodophor, or chlorhexidine/alcohol combination solution using friction immediately prior to entry			
For patients requiring repeated doses from a multi-dose vial (e.g., anesthetic agents), that multi-dose vial is used only for that individual patient			
Multiple entries into multi-dose vials are done using a new sterile syringe and a new sterile needle			
Multi-dose vials are maintained in a clean medication preparation area and not in the patient examination or treatment room			
Multi-dose vials placed on contaminated surfaces, used during a procedure or during an emergency situation are disposed of at the completion of that patient encounter			
The practice of inserting and leaving a needle or spike device in a multi-dose vial is prohibited			
Multi-dose vials are dated at the time of first use			
Multi-dose vials are discarded within 28 days after first use			
All medication vials are inspected prior to use and are disposed of if the contents are noted to be discolored, turbid, contain particulate matter, or if sterility has been compromised or is in doubt			

Preventing contamination of intravenous bags			
	Yes	No	Do not know
A new sterile syringe and sterile needle are used for every entry into an intravenous bag			
Use of “community” IV bags or bottles to obtain flu solutions or for any other use involving more than one patient is prohibited			
Use of infusion supplies (e.g., needles, syringes, IV bags/bottles, administration sets, flush solution) shared among more than one patient is prohibited			
Medication/solutions are drawn from the IV bag or bottle immediately prior to use			
Prefilling of syringes for storage and future use is prohibited			
The pooling of medication left in an IV/bag or bottle, adding to another vial/bag/bottle, or adding to another dose from another vial/bag/bottle is prohibited			
Access ports of IV bags/bottles are cleansed with a sterile 70% alcohol, iodophor, or chlorhexidine/alcohol combination solution using friction immediately prior to entry			
IV bags/bottles are maintained in a clean medication preparation area and not in the patient examination or treatment room			
The practice of inserting and leaving a needle or spike device in an IV bag/bottle is prohibited			
All IV bags/bottles are inspected prior to use and are disposed of if the contents are noted to be discolored, turbid, contain particulate matter, or if sterility has been compromised or is in doubt			

Ensuring safety practices when preparing and administering parenteral medication			
	Yes	No	Do not know
All staff having a role in medication preparation or administration have received the hepatitis B vaccination series			
All staff having received the hepatitis B vaccination series have been tested to ensure presence of hepatitis B antibodies			
All staff without documented seroconversion after hepatitis B vaccination series have been tested for the presence of hepatitis B surface antigen or other such test as recommended by the CDC			
Safety devices (e.g., retractable needs, retracting lancets, covered needles) are used for all patient encounters			
There is a process in place for recognition and reporting of occupational exposure to blood/body fluids including needlestick/sharps injury			
It is required that all medication preparation occur in a designated clean area			
Used items are disposed of in appropriate sharps containers immediately after use			
Preventing inappropriate use or reuse of single use medical devices			
Sharing of medical devices (e.g., finger stick devices, lancet holding devices, insulin pens, capillary blood sampling devices) is prohibited			
Reuse of finger stick devices is prohibited			
Used devices are disposed of in appropriate sharps containers immediately after use			

Preventing inappropriate care/maintenance of reusable medical equipment			
	Yes	No	Do not know
Durable medical equipment that must be shared among patients (e.g., glucosemeters, intravenous pumps) is cleaned and disinfected between patients prior to reuse using an EPA-registered disinfectant effective against HBV, HCV and HIV			
Manufacturer guidance is followed regarding processes for cleaning and disinfection of reusable medical equipment			
Providing written policies/procedures/prevention protocols			
Written policies and procedures are in place that outline the elements of safe injection practice relevant to the activities performed in the individual setting			
Written policies and procedures are available to all staff at all times during their work hours			
Written policies and procedures are reviewed at least annually and updated as needed			
There is an individual(s) directly assigned responsibility for writing and revising policies and procedures involving safe injection practices			
The individual(s) responsible for writing and revising policies and procedures involving safe injection practices is competent for this responsibility			

Providing staff training and education			
	Yes	No	Do not know
A process is in place that verifies all staff are provided with access to written policies and procedures regarding safe injection practice			
Safe injection practices are reviewed with each staff member, at least annually			
Written record of training is maintained for all staff members			
Staff input regarding safe injection practices are solicited and discussed, as appropriate			
A designated expert in infection prevention has been identified to assist with questions regarding safe injection practice			
Monitoring of practice and improving performance			
The injection practices of all staff are observed at least annually using a checklist or other such format			
Identified breaches in safe injection practice are reported to designated individual(s)			
Investigation of the root causes of breaches in safe injection practices are performed as soon as possible after the breach has been identified.			
Consultation occurs with designated infection prevention expert and/or local public health as a means of improving performance			

Providing feedback of results from practice/performance monitoring			
	Yes	No	Do not know
Results from staff monitoring of practice/performance are shared with staff members at least annually			
Measurable goals for performance improvement are identified and shared with staff members at least annually			
Data are collected for the identified measurable goals and results shared with staff members at least annually			
Identified breaches in safe injection practice are shared with staff members as a means of preventing reoccurrence and improving performance			
Consultation with local public health officials occurs in the event unsafe injection practices are discovered and there is evidence or suspicion of bloodborne pathogen transmission			

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Ruth Carrico PhD RN FSHEA CIC. Used with permission. Ruth.carrico@louisville.edu

Sample Standing Orders Healthcare Personnel Immunization: Hepatitis B virus

Purpose: To reduce morbidity and mortality associated with Hepatitis B among healthcare personnel through an effective and efficient immunization and infection prevention and control process.

Policy Statements:

1. Identify all healthcare personnel at occupational risk of infection through exposure to blood or other potentially infectious materials at the time of hire and at least annually to ensure inclusion in the HBV immunization program of the facility
2. Review, at least annually, changes in occupational status (e.g., job category and responsibilities) and health status (e.g., hemodialysis) that may influence immunization of reimmunization.
3. Maintain immunization records in a manner that facilitates rapid retrieval, analysis, and programmatic improvement (e.g., electronic registries)
4. Incorporate basic infection prevention and control strategies including hand hygiene, use of safety devices, personal protective equipment, proper waste disposal, and exposure prevention and response into work practices for all healthcare personnel.
5. Screen all healthcare personnel targeted for immunization for contraindications and precautions to Hepatitis B vaccine (For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf):
 - **Contraindication:** history of serious reactions (e.g., anaphylaxis) following a previous dose of Hepatitis B vaccine or to a component of the vaccine
 - **Precaution:** moderate or severe acute illness with or without fever
6. If the healthcare personnel is identified as HBsAg-positive, immunization is not necessary.
7. Provide all vaccine recipients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speakers with the VIS in their native language, if available; these can be found at www.immunize.org/vis.
8. Administer Hepatitis B vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle. For persons age 20 years or older, give 1.0 mL dosage; for persons age 19 years or younger, give 0.5 mL dosage.
9. Provide subsequent doses of Hepatitis B vaccine to complete each recipient's 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 8

weeks between the second and third doses, and at least 4 months (16 weeks) between the first and third doses.

10. Follow immunization with an evaluation of response to the vaccine by obtaining serology for HBsAb within 30-60 days after completion of the first series. Positive response is demonstrated by anti-HBs of $\geq 10\text{mIU/ml}$.

11. For non-respondents, repeat entire three dose series in accordance with spacing of vaccine doses as previously noted. Administration of more than two complete 3-dose series is not to be done.

12. Repeat serology (HBsAb) 30-60 days after second 3-dose series. If negative, test for presence of the Hepatitis B surface antigen (ABsAg) and anti-HBc to determine if chronic infection is present.

13. Administration of booster doses of Hepatitis B vaccine is not currently recommended. However, if the healthcare personnel is receiving hemodialysis, they should be provided annual anti-HBs testing and should be administered a booster dose of vaccine if/when the anti-HBs levels decline to $<10\text{ mIU/ml}$. This monitoring should generally occur as part of their hemodialysis treatment, but if not, the healthcare personnel should be immunized through the employee/occupational health function to ensure patient and healthcare personnel safety.

14. Counsel non-respondent healthcare personnel to ensure their safety as well as the safety of their patients. Counseling should include at least the following:

- Modes of bloodborne pathogen transmission
- Use of personal protective equipment
- Use of safety devices
- Use of hand hygiene
- Avoidance of exposure prone procedures and situations
- Ethical responsibilities for known or potential patient exposure
- Prompt post-exposure reporting
- Documentation of expert counseling

15. Documentation regarding vaccine administration should include:

- Date the vaccine was administered
- Manufacturer and lot number
- Administration dose, site and route
- Name and title of person administering the vaccine
- If dose not given (e.g., contraindication, refusal), record the reason for non-receipt
- Publication date of the VIS and the date given to the vaccine recipient
- Name and location of the administering site (e.g., employee/occupational health department; off site clinic)

16. Maintain a written emergency response protocol as well as equipment and medication.
17. Report all adverse events to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling 800-822-7967. VAERS report forms are available at www.vaers.hhs.gov
18. Complete a facility occurrence report in the event an adverse event(s) is identified.
19. Maintain a continuous report regarding Hepatitis B immunization that includes:
 - Rate of eligible healthcare personnel immunized x 1000 (number of eligible immunized/number eligible for immunization) for each month
 - Reasons for non-receipt of vaccine
 - Rate of adverse events (number of adverse event episodes/total number of doses administered x 1000) for each month
 - Response rate (number of recipients demonstrating positive titer/total number of recipients) for each month
 - Additional information as indicated (e.g., rate of HBsAg-positive among non-respondents)

Effective Date: _____ Revision Date(s): _____

Medical Director Signature: _____ Date: _____

Sample Standing Orders Healthcare Personnel Immunization: Seasonal Influenza Vaccine

Purpose: To reduce morbidity and mortality associated with influenza among healthcare personnel through an effective and efficient immunization and infection prevention and control process.

Policy Statements:

1. Identify all healthcare personnel without history of influenza immunization for the current influenza season.
2. Maintain immunization records in a manner that facilitates rapid retrieval, analysis, and programmatic improvement (e.g., electronic registries)
3. Incorporate basic infection prevention and control strategies including hand hygiene, use of personal protective equipment, and exposure prevention and response into work practices for all healthcare personnel.
4. Screen all healthcare personnel targeted for immunization for contraindications and precautions to influenza vaccine (For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf):
 - **Contraindication:** serious reaction (e.g., anaphylaxis) after ingesting eggs or after receiving a previous dose of influenza vaccine or an influenza vaccine component; do not give live attenuated influenza vaccine (LAIV; nasal spray) to an adult who is pregnant, is age 50 years or older, or who has chronic pulmonary (including asthma), cardiovascular (excluding hypertension), renal, hepatic, neurologic/neuromuscular, hemotologic, or metabolic (including diabetes) disorders; immunosuppression, including that caused by medications or HIV.
 - **Precaution:** moderate or severe acute illness with or without fever; history of Guillain Barre syndrome within 6 weeks of a previous influenza vaccine. For LAIV only, close contact with an immunosuppressed person requiring protective isolation, receipt of influenza antivirals (e.g., amantadine, rimantadine, zanamivir, or oseltamivir) within the previous 48 hours or possibility of use within 14 days after vaccination.
5. Provide all vaccine recipients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speakers with the VIS in their native language, if available; these can be found at www.immunize.org/vis.
6. Administer 0.5 mL injectable trivalent inactivated influenza vaccine (TIV) intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle. (Note: A 5/8" needle may be used for adults weighing less than 130 lbs (<60 kg) for injection in the deltoid muscle *only* if the skin is stretched tight,

subcutaneous tissue is not bunched, and the injection is made at a 90 degree angle.)
Alternatively, healthy adults younger than age 50 years without contraindications may be given 0.2 mL of intranasal LAIV; 0.1 mL is sprayed into each nostril while the patient is in an upright position.

7. Documentation regarding vaccine administration should include:

- Date the vaccine was administered
- Manufacturer and lot number
- Administration dose, site and route
- Name and title of person administering the vaccine
- If dose not given (e.g., contraindication, refusal), record the reason for non-receipt
- Publication date of the VIS and the date given to the vaccine recipient
- Name and location of the administering site (e.g., employee/occupational health department; influenza site clinic)

8. Maintain a written emergency response protocol as well as equipment and medication.

9. Report all adverse events to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling 800-822-7967. VAERS report forms are available at www.vaers.hhs.gov

10. Complete a facility occurrence report in the event an adverse event(s) is identified.

11. Maintain a continuous report regarding influenza immunization that includes:

- Rate of eligible healthcare personnel immunized x 1000 (number of eligible immunized/number eligible for immunization) for each month stratified by type of vaccine (e.g., TIV or LAIV).
- Reasons for non-receipt of vaccine
- Rate of adverse events (number of adverse event episodes/total number of doses administered x 1000) for each month

Effective Date:_____ Revision Date(s):_____

Medical Director Signature:_____ Date:_____

Sample Standing Orders Healthcare Personnel Immunization: Meningococcal

Purpose: To reduce morbidity and mortality associated with meningococcal disease among healthcare personnel through an effective and efficient immunization and infection prevention and control process.

Policy Statements:

1. Identify all healthcare personnel in need of vaccination against meningococcal disease including those whose job responsibilities involve routine exposure to isolates of *N. meningitidis*. This primarily focuses on healthcare personnel working in a microbiology laboratory.
2. Two quadrivalent (A, C, W-135, Y) conjugate meningococcal vaccines (MCV4) are licensed for persons aged through 55 years. Both protect against two of the three serogroups that cause the majority of meningococcal disease in the United States and against 75% of disease among adults. Available data indicate that the majority of persons do not have enough circulating functional antibody to be protected ≥5 years after a single dose of MCV4 so a 2-dose series is indicated. Quadrivalent (A, C, W-135, Y) meningococcal polysaccharide vaccine (MPSV4) is available for use in persons aged >55 years.
3. Maintain immunization records in a manner that facilitates rapid retrieval, analysis, and programmatic improvement (e.g., electronic registries).
4. Incorporate basic infection prevention and control strategies including hand hygiene, personal protective equipment, and exposure prevention and response into work practices for all healthcare personnel.
5. Screen all healthcare personnel targeted for immunization for contraindications and precautions to meningococcal vaccine (For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf):
 - **Contraindication:** history of a serious reaction (e.g., anaphylaxis) after a previous dose of meningococcal vaccine or vaccine component, including diphtheria toxoid.
 - **Precaution:** moderate or severe acute illness with or without fever.
6. Provide all vaccine recipients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speakers with the VIS in their native language, if available; these can be found at www.immunize.org/vis.
7. Administer 0.5 ml MCV4 vaccine intramuscularly (22–25g, 1-1 ½ " needle) in the deltoid muscle. (Note: A 5/8" needle may be used for adults weighing less than 130 lbs (<60 kg) for injection in the deltoid muscle *only* if the skin is stretched tight, subcutaneous tissue is not bunched, and the injection is made at a 90 degree angle.). For adults older than age 55 years,

administer 0.5 mL MPSV4 via the subcutaneous route (23-25 g, 5/8" needle) in the posterolateral fat of the upper arm. Adults who remain at high risk should receive subsequent vaccination 5 years after the previous dose.

8. Administer a single booster dose after 5 years if job responsibilities indicate risk of meningococcal exposure.

8. Documentation regarding vaccine administration should include:

- Date the vaccine was administered
- Manufacturer and lot number
- Administration dose, site and route
- Name and title of person administering the vaccine
- If dose not given (e.g., contraindication, refusal), record the reason for non-receipt
- Publication date of the VIS and the date given to the vaccine recipient
- Name and location of the administering site (e.g., employee/occupational health department; off site clinic)

9. Maintain a written emergency response protocol as well as equipment and medication.

10. Report all adverse events to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling 800-822-7967. VAERS report forms are available at www.vaers.hhs.gov

11. Complete a facility occurrence report in the event an adverse event(s) is identified.

12. Maintain a continuous report regarding meningococcal immunization that includes:

- Rate of eligible healthcare personnel immunized x 1000 (number of eligible immunized/number eligible for immunization) for each month
- Reasons for non-receipt of vaccine
- Rate of adverse events (number of adverse event episodes/total number of doses administered x 1000) for each month
- Additional information as indicated

Effective Date:_____ Revision Date(s):_____

Medical Director Signature:_____ Date:_____

Sample Standing Orders Healthcare Personnel Immunization: Measles, Mumps & Rubella

Purpose: To reduce morbidity and mortality associated with measles, mumps and rubella among healthcare personnel through an effective and efficient immunization and infection prevention and control process.

Policy Statements:

1. Identify all healthcare personnel without presumptive evidence of immunity to measles, mumps and rubella.
2. Those without presumptive evidence should receive serologic testing and those without positive IgG should be immunized.
3. Presumptive evidence of immunity to measles includes any of the following:
 - Written documentation of vaccination (at age 12 months or older) with 2 doses of live measles or MMR vaccine administered at least 28 days apart
 - Laboratory evidence of immunity (Measles immunoglobulin [IgG] in serum; equivocal results should be considered negative)
 - Laboratory confirmation of disease, or
 - Birth before 1957
4. Presumptive evidence of immunity to mumps includes any of the following:
 - Written documentation of vaccination (at age 12 months or older) with 2 doses of live mumps or MMR vaccine administered at least 28 days apart
 - Laboratory evidence of immunity (Mumps immunoglobulin [IgG] in serum; equivocal results should be considered negative)
 - Laboratory confirmation of disease, or
 - Birth before 1957
5. Presumptive evidence of immunity to rubella includes any of the following:
 - Written documentation of vaccination with 1 dose of live rubella or MMR vaccine
 - Laboratory evidence of immunity (Rubella immunoglobulin [IgG] in serum; equivocal results should be considered negative)
 - Laboratory confirmation of disease, or
 - Birth before 1957, except women of childbearing potential who could become pregnant

6. Maintain immunization records in a manner that facilitates rapid retrieval, analysis, and programmatic improvement (e.g., electronic registries)

7. Incorporate basic infection prevention and control strategies including hand hygiene, personal protective equipment, and exposure prevention and response into work practices for all healthcare personnel.

8. Screen all healthcare personnel targeted for immunization for contraindications and precautions to MMR vaccine (For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf):

- **Contraindication:** history of a serious reaction (e.g., anaphylaxis) after a previous dose of MMR vaccine or vaccine component; pregnant now or may become pregnant within one month; known severe immunodeficiency, hematologic and solid tumors; receiving long-term immunosuppressive therapy, severely immunocompromised from HIV infection (including CD₄ T-lymphocyte count of less than 200 cells per μ L)
- **Precaution:** moderate or severe acute illness with or without fever; recent (within the past 11 months) receipt of antibody-containing blood product (specific interval depends upon the product); history of thrombocytopenia or thrombocytopenic purpura.

9. Provide all vaccine recipients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speakers with the VIS in their native language, if available; these can be found at www.immunize.org/vis.

10. Administer 0.5 mL of reconstituted MMR vaccine subcutaneously (23–25g, 5/8" needle) in the posterolateral fat of the upper arm. For adults in need of a second dose of MMR, observe a minimum interval of 4 weeks between the first and second doses. Use only the diluent provided and use immediately after reconstitution. Discard if not administered within 8 hours of reconstitution.

11. No need for post-immunization testing.

12. Documentation regarding vaccine administration should include:

- Date the vaccine was administered
- Manufacturer and lot number
- Administration dose, site and route
- Name and title of person administering the vaccine
- If dose not given (e.g., contraindication, refusal), record the reason for non-receipt
- Publication date of the VIS and the date given to the vaccine recipient

- Name and location of the administering site (e.g., employee/occupational health department; off site clinic)

13. Maintain a written emergency response protocol as well as equipment and medication.

14. Report all adverse events to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling 800-822-7967. VAERS report forms are available at www.vaers.hhs.gov

15. Complete a facility occurrence report in the event an adverse event(s) is identified.

16. Maintain a continuous report regarding MMR immunization that includes:

- Rate of eligible healthcare personnel immunized x 1000 (number of eligible immunized/number eligible for immunization) for each month
- Reasons for non-receipt of vaccine
- Rate of adverse events (number of adverse event episodes/total number of doses administered x 1000) for each month
- Additional information as indicated

Effective Date: _____ Revision Date(s): _____

Medical Director Signature: _____ Date: _____

Sample Standing Orders Healthcare Personnel Immunization: Td/Tdap

Purpose: To reduce morbidity and mortality associated with tetanus, diphtheria, and pertussis among healthcare personnel through an effective and efficient immunization and infection prevention and control process.

Policy Statements:

1. Identify all healthcare personnel in need of vaccination against tetanus, diphtheria, and pertussis.
2. Maintain immunization records in a manner that facilitates rapid retrieval, analysis, and programmatic improvement (e.g., electronic registries)
3. Incorporate basic infection prevention and control strategies including hand hygiene, personal protective equipment, and exposure prevention and response into work practices for all healthcare personnel.
4. Screen all healthcare personnel targeted for immunization for contraindications and precautions to Td/Tdap vaccine (For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf):
 - **Contraindication:** history of a serious reaction (e.g., anaphylaxis) after a previous dose of Td or to a Td or Tdap vaccine component; for Tdap, a history of encephalopathy within 7 days following DTP/Dtap not attributable to another identifiable cause. Note: Use of Td or Tdap is not contraindicated in pregnancy. Either vaccine may be administered during the 2nd or 3rd trimester.
 - **Precaution:** history of Guillain-Barre syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine; history of an Arthus reaction following a previous dose of tetanus-containing and/or diphtheria-containing vaccine, including meningococcal conjugate vaccine; moderate or severe acute illness with or without fever; for Tdap only, progressive or unstable neurologic disorder, uncontrolled seizures or progressive encephalopathy.
5. Provide all vaccine recipients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speakers with the VIS in their native language, if available; these can be found at www.immunize.org/vis.
6. Administer one time 0.5 mL Tdap vaccine intramuscularly (22–25g, 1-1 ½ " needle) in the deltoid muscle. There is no minimum time interval between Td and Tdap doses

7. Documentation regarding vaccine administration should include:

- Date the vaccine was administered
- Manufacturer and lot number
- Administration dose, site and route
- Name and title of person administering the vaccine
- If dose not given (e.g., contraindication, refusal), record the reason for non-receipt
- Publication date of the VIS and the date given to the vaccine recipient
- Name and location of the administering site (e.g., employee/occupational health department; off site clinic)

8. Maintain a written emergency response protocol as well as equipment and medication.

9. Report all adverse events to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling 800-822-7967. VAERS report forms are available at www.vaers.hhs.gov

10. Complete a facility occurrence report in the event an adverse event(s) is identified.

11. Maintain a continuous report regarding MMR immunization that includes:

- Rate of eligible healthcare personnel immunized x 1000 (number of eligible immunized/number eligible for immunization) for each month
- Reasons for non-receipt of vaccine
- Rate of adverse events (number of adverse event episodes/total number of doses administered x 1000) for each month
- Additional information as indicated

Effective Date:_____ Revision Date(s):_____

Medical Director Signature:_____ Date:_____

Sample Standing Orders Healthcare Personnel Immunization: Varicella

Purpose: To reduce morbidity and mortality associated with varicella among healthcare personnel through an effective and efficient immunization and infection prevention and control process.

Policy Statements:

1. Identify all healthcare personnel without presumptive evidence of immunity to varicella.
2. If screening is done, utilize a commercial ELISA as it is less sensitive but more specific and therefore less likely to report false negative results.
3. Presumptive evidence of immunity to varicella includes any of the following:
 - Written documentation of vaccination with 2 doses of live varicella vaccine
 - Laboratory evidence of immunity or laboratory confirmation of disease;
 - Diagnosis or verification of a history of varicella disease by a healthcare provider; or
 - Diagnosis or verification of a history of herpes zoster by a healthcare provider
4. Maintain immunization records in a manner that facilitates rapid retrieval, analysis, and programmatic improvement (e.g., electronic registries)
5. Incorporate basic infection prevention and control strategies including hand hygiene, personal protective equipment, and exposure prevention and response into work practices for all healthcare personnel.
6. Screen all healthcare personnel targeted for immunization for contraindications and precautions to varicella vaccine (For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf):
 - **Contraindication:** history of a serious reaction (e.g., anaphylaxis) after a previous dose of varicella vaccine or vaccine component; pregnant now or may become pregnant within one month; having any malignant condition including blood dyscrasias, leukemia, lymphoma or any time, or other malignant neoplasms affecting the bone marrow or lymphatic systems; receiving high-dose systemic immunosuppressive therapy (e.g., two weeks or more of daily receipt of 20 mg or more [or 2 mg/kg body weight or more] of prednisone or equivalent); an adult or adolescent with CD4 = T-lymphocytes count < 200 cells/ μ L
 - **Precaution:** moderate or severe acute illness with or without fever; recent (within the past 11 months) receipt of antibody-containing blood product (specific interval depends upon the product).

7. Provide all vaccine recipients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speakers with the VIS in their native language, if available; these can be found at www.immunize.org/vis.

8. Administer 0.5 mL varicella vaccine subcutaneously (23–25g, 5/8" needle) in the posterolateral fat of the upper arm. Administer a second dose 4-8 weeks after the first dose.

9. No need for post-immunization testing.

10. Documentation regarding vaccine administration should include:

- Date the vaccine was administered
- Manufacturer and lot number
- Administration dose, site and route
- Name and title of person administering the vaccine
- If dose not given (e.g., contraindication, refusal), record the reason for non-receipt
- Publication date of the VIS and the date given to the vaccine recipient
- Name and location of the administering site (e.g., employee/occupational health department; off site clinic)

11. Maintain a written emergency response protocol as well as equipment and medication.

12. Report all adverse events to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling 800-822-7967. VAERS report forms are available at www.vaers.hhs.gov

13. Complete a facility occurrence report in the event an adverse event(s) is identified.

14. Maintain a continuous report regarding varicella immunization that includes:

- Rate of eligible healthcare personnel immunized x 1000 (number of eligible immunized/number eligible for immunization) for each month
- Reasons for non-receipt of vaccine
- Rate of adverse events (number of adverse event episodes/total number of doses administered x 1000) for each month
- Additional information as indicated

Effective Date: _____ Revision Date(s): _____

Medical Director Signature: _____ Date: _____

Vaccine Excipient & Media Summary, Part 2

Excipients Included in U.S. Vaccines, by Vaccine

Includes vaccine ingredients (e.g., adjuvants and preservatives) as well as substances used during the manufacturing process, including vaccine-production media, that are removed from the final product and present only in trace quantities.
In addition to the substances listed, most vaccines contain Sodium Chloride (table salt).

Vaccine	Contains
Anthrax (BioThrax)	Aluminum Hydroxide, Amino Acids, Benzethonium Chloride, Formaldehyde or Formalin, Inorganic Salts and Sugars, Vitamins
BCG (Tice)	Asparagine, Citric Acid, Lactose, Glycerin, Iron Ammonium Citrate, Magnesium Sulfate, Potassium Phosphate
DTaP (Daptacel)	Aluminum Phosphate, Ammonium Sulfate, Casamino Acid, Dimethyl-beta-cyclodextrin, Formaldehyde or Formalin, Glutaraldehyde, 2-Phenoxyethanol
DTaP (Infanrix)	Aluminum Hydroxide, Bovine Extract, Formaldehyde or Formalin, Glutaraldehyde, 2-Phenoxyethanol, Polysorbate 80
DTaP (Tripedia)	Aluminum Potassium Sulfate, Ammonium Sulfate, Bovine Extract, Formaldehyde or Formalin, Gelatin, Polysorbate 80, Sodium Phosphate, Thimerosal*
DTaP/Hib (TriHIBit)	Aluminum Potassium Sulfate, Ammonium Sulfate, Bovine Extract, Formaldehyde or Formalin, Gelatin, Polysorbate 80, Sucrose, Thimerosal*
DTaP-IPV (Kinrix)	Aluminum Hydroxide, Bovine Extract, Formaldehyde, Lactalbumin Hydrolysate, Monkey Kidney Tissue, Neomycin Sulfate, Polymyxin B, Polysorbate 80
DTaP-HepB-IPV (Pediarix)	Aluminum Hydroxide, Aluminum Phosphate, Bovine Protein, Lactalbumin Hydrolysate, Formaldehyde or Formalin, Glutaraldehyde, Monkey Kidney Tissue, Neomycin, 2-Phenoxyethanol, Polymyxin B, Polysorbate 80, Yeast Protein
DtaP-IPV/Hib (Pentacel)	Aluminum Phosphate, Bovine Serum Albumin, Formaldehyde, Glutaraldehyde, MRC-5 DNA and Cellular Protein, Neomycin, Polymyxin B Sulfate, Polysorbate 80, 2-Phenoxyethanol,
DT (sanofi)	Aluminum Potassium Sulfate, Bovine Extract, Formaldehyde or Formalin, Thimerosal (multi-dose) or Thimerosal* (single-dose)
DT (Massachusetts)	Aluminum Hydroxide, Formaldehyde or Formalin
Hib (ACTHib)	Ammonium Sulfate, Formaldehyde or Formalin, Sucrose
Hib (Hiberix)	Formaldehyde or Formalin, Lactose
Hib (PevaxHib)	Aluminum Hydroxyphosphate Sulfate
Hib/Hep B (Comvax)	Amino Acids, Aluminum Hydroxyphosphate Sulfate, Dextrose, Formaldehyde or Formalin, Mineral Salts, Sodium Borate, Soy Peptone, Yeast Protein
Hep A (Havrix)	Aluminum Hydroxide, Amino Acids, Formaldehyde or Formalin, MRC-5 Cellular Protein, Neomycin Sulfate, 2-Phenoxyethanol, Phosphate Buffers, Polysorbate
Hep A (Vaqta)	Aluminum Hydroxyphosphate Sulfate, Bovine Albumin or Serum, DNA, Formaldehyde or Formalin, MRC-5 Cellular Protein, Sodium Borate
Hep B (Engerix-B)	Aluminum Hydroxide, Phosphate Buffers, Thimerosal*, Yeast Protein

Vaccine	Contains
Hep B (Recombivax)	Aluminum Hydroxyphosphate Sulfate, Amino Acids, Dextrose, Formaldehyde or Formalin, Mineral Salts, Potassium Aluminum Sulfate, Soy Peptone, Yeast Protein
HepA/HepB (Twinrix)	Aluminum Hydroxide, Aluminum Phosphate, Amino Acids, Dextrose, Formaldehyde or Formalin, Inorganic Salts, MRC-5 Cellular Protein, Neomycin Sulfate, 2-Phenoxyethanol, Phosphate Buffers, Polysorbate 20, Thimerosal*, Vitamins, Yeast Protein
Human Papillomavirus (HPV) (Cervrix)	3- <i>O</i> -desacyl-4'-monophosphoryl lipid A (MPL), Aluminum Hydroxide, Amino Acids, Insect Cell Protein, Mineral Salts, Sodium Dihydrogen Phosphate Dihydrate, Vitamins
Human Papillomavirus (HPV) (Gardasil)	Amino Acids, Amorphous Aluminum Hydroxyphosphate Sulfate, Carbohydrates, L-histidine, Mineral Salts, Polysorbate 80, Sodium Borate, Vitamins
Influenza (Afluria)	Beta-Propiolactone, Calcium Chloride, Neomycin, Ovalbumin, Polymyxin B, Potassium Chloride, Potassium Phosphate, Sodium Phosphate, Sodium Taurodeoxychoalate
Influenza (Agriflu)	Cetyltrimethylammonium Bromide (CTAB), Egg Protein, Formaldehyde or Formalin, Kanamycin, Neomycin Sulfate, Polysorbate 80
Influenza (Fluarix)	Egg Albumin (Ovalbumin), Egg Protein, Formaldehyde or Formalin, Gentamicin, Hydrocortisone, Octoxynol-10, α -Tocopheryl Hydrogen Succinate, Polysorbate 80, Sodium Deoxycholate, Sodium Phosphate, Thimerosal*
Influenza (Flulaval)	Egg Albumin (Ovalbumin), Egg Protein, Formaldehyde or Formalin, Sodium Deoxycholate, Phosphate Buffers, Thimerosal
Influenza (Fluvirin)	Beta-Propiolactone , Egg Protein, Neomycin, Polymyxin B, Polyoxyethylene 9-10 Nonyl Phenol (Triton N-101, Octoxynol 9), Thimerosal (multidose containers), Thimerosal* (single-dose syringes)
Influenza (Fluzone)	Egg Protein, Formaldehyde or Formalin, Gelatin, Octoxinol-9 (Triton X-100), Thimerosal (multidose containers)
Influenza (FluMist)	Chick Kidney Cells, Egg Protein, Gentamicin Sulfate, Monosodium Glutamate, Sucrose Phosphate Glutamate Buffer
IPV (Ipol)	Calf Serum Protein, Formaldehyde or Formalin, Monkey Kidney Tissue, Neomycin, 2-Phenoxyethanol, Polymyxin B, Streptomycin,
Japanese Encephalitis (JE-Vax)	Formaldehyde or Formalin, Gelatin, Mouse Serum Protein, Polysorbate 80, Thimerosal
Japanese Encephalitis (Ixiaro)	Aluminum Hydroxide, Bovine Serum Albumin, Formaldehyde, Protamine Sulfate, Sodium Metabisulphite
Meningococcal (Menactra)	Formaldehyde or Formalin, Phosphate Buffers
Meningococcal (Menomune)	Lactose, Thimerosal (10-dose vials only)
Meningococcal (Menveo)	Amino Acid, Formaldehyde or Formalin, Yeast
MMR (MMR-II)	Amino Acid, Bovine Albumin or Serum, Chick Embryo Fibroblasts, Human Serum Albumin, Gelatin, Glutamate, Neomycin, Phosphate Buffers, Sorbitol, Sucrose, Vitamins

Vaccine	Contains
MMRV (ProQuad)	Bovine Albumin or Serum, Gelatin, Human Serum Albumin, Monosodium L-glutamate, MRC-5 Cellular Protein, Neomycin, Sodium Phosphate Dibasic, Sodium Bicarbonate, Sorbitol, Sucrose, Potassium Phosphate Monobasic, Potassium Chloride, Potassium Phosphate Dibasic
Pneumococcal (Pneumovax)	Bovine Protein, Phenol
Pneumococcal (Prevnar)	Aluminum Phosphate, Amino Acid, Soy Peptone, Yeast Extract
Pneumococcal (Prevnar 13)	Aluminum Phosphate, Amino Acid, Polysorbate 80, Soy Peptone, Succinate Buffer, Yeast Extract
Rabies (Imovax)	Human Serum Albumin, Beta-Propiolactone, MRC-5 Cellular Protein, Neomycin, Phenol Red (Phenolsulfonphthalein), Vitamins
Rabies (RabAvert)	Amphotericin B, Beta-Propiolactone, Bovine Albumin or Serum, Chicken Protein, Chlortetracycline, Egg Albumin (Ovalbumin), Ethylenediamine-Tetraacetic Acid Sodium (EDTA), Neomycin, Potassium Glutamate
Rotavirus (RotaTeq)	Cell Culture Media, Fetal Bovine Serum, Sodium Citrate, Sodium Phosphate Monobasic Monohydrate, Sodium Hydroxide Sucrose, Polysorbate 80
Rotavirus (Rotarix)	Amino Acids, Calcium Carbonate, Calcium Chloride, D-glucose, Dextran, Ferric (III) Nitrate, L-cystine, L-tyrosine, Magnesium Sulfate, Phenol Red, Potassium Chloride, Sodium Hydrogenocarbonate, Sodium Phosphate, Sodium L-glutamine, Sodium Pyruvate, Sorbitol, Sucrose, Vitamins, Xanthan
Td (Decavac)	Aluminum Potassium Sulfate, Bovine Extract, Formaldehyde or Formalin, 2-Phenoxyethanol, Peptone, Thimerosal*
Td (Massachusetts)	Aluminum Hydroxide, Aluminum Phosphate, Formaldehyde or Formalin, Thimerosal (some multidose containers)
Tdap (Adacel)	Aluminum Phosphate, Formaldehyde or Formalin, Glutaraldehyde, 2-Phenoxyethanol
Tdap (Boostrix)	Aluminum Hydroxide, Bovine Extract, Formaldehyde or Formalin, Glutaraldehyde, Polysorbate 80
Typhoid (inactivated – Typhim Vi)	Disodium Phosphate, Monosodium Phosphate, Phenol, Polydimethylsiloxane, Hexadecyltrimethylammonium Bromide
Typhoid (oral – Ty21a)	Amino Acids, Ascorbic Acid, Bovine Protein, Casein, Dextrose, Galactose, Gelatin, Lactose, Magnesium Stearate, Sucrose, Yeast Extract
Vaccinia (ACAM2000)	Glycerin, Human Serum Albumin, Mannitol, Monkey Kidney Cells, Neomycin, Phenol, Polymyxin B
Varicella (Varivax)	Bovine Albumin or Serum, Ethylenediamine-Tetraacetic Acid Sodium (EDTA), Gelatin, Monosodium L-Glutamate, MRC-5 DNA and Cellular Protein, Neomycin, Potassium Chloride, Potassium Phosphate Monobasic, Sodium Phosphate Monobasic, Sucrose
Yellow Fever (YF-Vax)	Egg Protein, Gelatin, Sorbitol
Zoster (Zostavax)	Bovine Calf Serum, Hydrolyzed Porcine Gelatin, Monosodium L-glutamate, MRC-5 DNA and Cellular Protein, Neomycin, Potassium Phosphate Monobasic, Potassium Chloride, Sodium Phosphate Dibasic, Sucrose

Where “thimerosal” is marked with an asterisk () it indicates that the product should be considered equivalent to thimerosal-free products. This vaccine may contain trace amounts (<0.3 mcg) of mercury left after post-production thimerosal removal, but these amounts have no biological effect. *JAMA* 1999;282(18) and *JAMA* 2000;283(16)

Adapted from Grabenstein JD. *ImmunoFacts: Vaccines & Immunologic Drugs*. St. Louis, MO: Wolters Kluwer Health Inc.; 2009 and individual products' package inserts.

All reasonable efforts have been made to ensure the accuracy of this information, but manufacturers may change product contents before that information is reflected here.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf>

JOB DESCRIPTION PROFESSIONAL IMPLEMENTATION POSITIONS

POSITION TITLE:	Employee/Occupational Health Nurse Manager
DEPARTMENT:	Human Resources
SUPERVISED BY:	Vice President of Human Resources
SUPERVISES DIRECTLY:	Employee/Occupational Health Nurse & Wellness Manager
SUPERVISES INDIRECTLY:	None
PREPARED/REVIEWED/REVISED DATE:	
PREPARED/REVISED BY:	
DEPT. DIRECTOR APPROVAL:	
HUMAN RESOURCES APPROVAL:	

EDUCATION, EXPERIENCE, LICENSE AND CERTIFICATION REQUIREMENTS

EDUCATION & TRAINING:	RN, BSN, COHN-S
EXPERIENCE:	5 + years experience in an acute care facility. Prior experience in Occupational Health preferred.
LICENSE & CERTIFICATION:	Active RN, current license in good standing from Commonwealth of Kentucky, RN, Certified Occupational Health Nurse Specialist preferred.

JOB PURPOSE/SUMMARY

The Employee/Occupational Health Nurse will provide an ongoing health maintenance program encompassing pre-placement screening and current employees' job related health. Employee Health will also coordinate activities with Infection Control, Workers' Compensation and Safety Hospital functions. The employee shall present a pleasant and helpful manner to patients, physicians and other members of the Hospital staff and general public. Employee shall comply with all Department and Hospital policies/procedures. Employee shall support and contribute to Department objectives.

WORK ENVIRONMENT CHARACTERISTICS/REQUIREMENTS

PART 1: PHYSICAL REQUIREMENTS										
SECTION A PHYSICAL MOBILITY REQUIREMENTS			SECTION B PHYSICAL EFFORT REQUIREMENTS			SECTION C PHYSICAL DEXTERITY REQUIREMENTS				
<u>% OF DAY SPENT</u>			<u># OF POUNDS LIFTED</u>			<u>REQUIRED ABILITY TO OPERATE</u>				
30%	Sitting		25%	Waist High		x	Telephone			
20%	Standing		10%	Shoulder High		x	Computer			
40%	Walking		10%	Above the Head			Hand Tools			
5%	Kneeling		<u>POUNDS ARE</u>				Electric Tools			
5%	Stooping		x	Carried Alone		x	Electronic Equipment			
			x	With Someone		x	Calculator			
<u>JOB REQUIRES ABILITY TO CLIMB</u>			<u>POUNDS ARE</u>			x	Copy Machine			
	Using a Ladder		x	Pushed		x	Medical Equipment			
x	On an Incline		x	Pulled						
x	Using Stairs			Held						
PART 2: SENSORY ABILITIES			PART 4: MENTAL EFFORT			PART 5: WORK ENVIRONMENT				
<u>AN ABILITY TO</u>			<u>PERFORMS ON A DAILY BASIS</u>			<u>JOB REQUIRES THE ABILITY TO</u>				
		IS CRITICAL	IS USEFUL							
				x	Reading	x	Work Under Time Pressure			
Distinguish Color	x			x	Writing	x	Work at a Rapid Pace			
Hear or Listen	x			x	Basic Math	<u>% OF TIME SPENT</u>				
Taste			x	x	Weighing	100%	Working In Doors			
Smell	x			x	Analyzing Data	0%	Working Outdoors			
Touch	x			x	Finding Solutions		At a Desk or Bench			
Speak	x			x	Managing Resources		In an Office or Control Room			
PART 3: JOB HAZARDS			x	Supervising Others	<u>THE CONDITION OF THE AIR IS</u>					
			x	Evaluating Performance of Others	x	Clean and Controlled				
			x	Working with Confidential Information		Dusty or Dirty				
			PART 5: WORK ENVIRONMENT				Wet/Humid			
			<u>THE WORK SURFACE IS</u>				Affected by Fumes or Smoke			

<input checked="" type="checkbox"/>	Level	<input type="checkbox"/>	<u>THE NOISE LEVEL IS</u>	
<input type="checkbox"/>	Sloping	<input type="checkbox"/>		
<input type="checkbox"/>	Uneven	<input checked="" type="checkbox"/>		Normal
<input type="checkbox"/>	Slippery	<input type="checkbox"/>		Loud Requiring Ear Protection

WORK PERFORMED/ESSENTIAL FUNCTIONS

PATIENT POPULATIONS FOR WHICH CARE IS PROVIDED (CHECK ALL THAT APPLY)			
<input type="checkbox"/>	NEONATAL/INFANT (BIRTH TO 12 MONTHS)	<input type="checkbox"/>	PEDIATRIC (13 MONTHS TO 11 YEARS)
<input type="checkbox"/>	ADOLESCENT (12 TO 17 YEARS)	<input type="checkbox"/>	ADULT (18 YEARS TO 65 YEARS)
<input type="checkbox"/>	GERIATRIC (66 YEARS AND OLDER)	<input checked="" type="checkbox"/>	POSITION DOES NOT PROVIDE PATIENT CARE

LIST THE ESSENTIAL FUNCTIONS PERFORMED BY THIS POSITION	
1.	Performs pre-employment health assessments on all job applicants to determine physical ability to perform job desired.
2.	Treats, counsels, refers and performs follow-up of all job related illnesses/injuries following all relevant Employee Health/Hospital policies.
3.	Manages preventive health programs that are established and assesses needs of facility.
4.	Creates and implements new programs according to hospital needs.
5.	Maintains Employee Health files that accurately reflect all interaction. This includes personnel issues such as blood pressure monitoring, allergy injections, etc.
6.	Monitors and trends employee job-related injuries/illnesses for input into Hospital Safety Committee. Also trends illnesses for coordination with the Infection Control function.
7.	Works closely with the Claims Specialist, physicians and other appropriate individuals to monitor employee treatment/progress.
8.	Participates in educational in-service programs related to Employee Health. This includes CLUE in January as well as individual counselling and unit specific. This also includes educating new employees on the Needle Safety Devices biweekly.
9.	Maintains Employee Health office hours as scheduled.
10.	Responsible for Employee Health Newsletter on the Information Station.
11.	Monitors pre-employment and fitness for duty drug/alcohol screening. Monitors drug/alcohol screening as related to DOT Regulations.
12.	Monitors employees involved in the Decontamination Unit per OSHA Regulations.

13.	Provides appropriate referral and educational information for employees with non-work related injuries/illnesses. Works closely with managers, physicians and employees regarding light duty/restrictions for non work related injuries/illnesses.
14.	Monitors employees involved in chemotherapeutic drugs per ONS and NIOSH recommendations.
15.	Works closely with Human Resources, physicians and other appropriate individuals to ensure FMLA concerns are addressed.
16.	Ensures reminder memos are sent to employees every two weeks for required immunizations and labs.
17.	Ensures all data keyed in Respond is up to date and accurate.
18.	Managers the Influenza program for hospital employees.
19.	Co-Chairs the Safety Subcommittee.
20.	Administrator for the Respiratory Protection Program.
21.	Perform annual evaluations and oversee the job responsibilities for the PRN Nurse Practitioner, PRN Employee Health Nurse, the full time Wellness Manager, and full time Employee Health Nurse.

VALUE BASED COMPETENCY EXPECTATIONS

COMPETENCY	DEFINITION & STANDARDS
ANALYTICAL THINKING VALUES: Learning & Continuous Improvement, Personal Responsibility	Analytical Thinking means breaking down problems or tasks; scanning ones own knowledge and experience to identify causes and consequences of events. <u>Anticipates Trends</u> Forecasts the future by analyzing present situations and past events. Brainstorms alternative resources and directions using multiple problem-solving methods. <u>Uses Multiple Approaches</u> Uses multiple approaches to understand the key issues in a complex situation. Thinks of multiple possible causes and consequences of events. Tests multiple possible scenarios. <u>Breaks Down Complex Tasks</u> Breaks down complex tasks into manageable parts in a systematic, detailed way and considers input from several sources.
CUSTOMER SERVICE ORIENTATION VALUES: Respect	Customer Service Orientation is a desire to help or serve others. The focus is on first discovering and understanding the customer=s needs and then taking action to help the customer and meet his or her needs. Customers include co-workers, workers in other departments that use your services, external customers, patients, families, or anyone we are trying to serve. <u>Addresses Underlying Needs</u> Understands customer relationships and seeks information about the real, underlying needs of the customer beyond those initially expressed and matches these needs to available or customized products or

COMPETENCY	DEFINITION & STANDARDS
	<p>services.</p> <p><u>Acts to Make Things Better</u> Anticipates customer needs and makes concrete attempts to add value to the customer, to make things better for the customer in some way.</p> <p><u>Makes Self Fully Available</u> Makes self fully available, especially when customer is going through a critical period. May give patient a pager number or other means of easy access or may spend extra time with the customer.</p>
<p>EXCELLENCE ORIENTATION</p> <p><u>VALUES:</u> Personal Responsibility, Learning & Continuous Improvement</p>	<p>Excellence Orientation refers to one's desire and commitment to do the best job he or she can; to find better, more efficient ways of doing his or her job. It involves a continuous effort to improve one's skills and abilities at every opportunity. It is striving for continuous improvement.</p> <p><u>Far Surpasses Established Standards</u> Commits significant effort and/or time to improve performance or reach a challenging goal. Creates an environment which encourages others to surpass their own standards of performance.</p> <p><u>Sets Own Standards</u> Follows own high standards, not just those set by others. Works to exceed existing quality standards at U of L Health Care.</p> <p><u>Meets Established Goals</u> Meets established goals by producing high quality work even for small requests. Challenges established practices or processes as necessary to ensure work is done in the most efficient way possible.</p>
<p>FLEXIBILITY</p> <p><u>VALUES:</u> Constancy of Purpose, Respect</p>	<p>Flexibility means one can handle change easily, sees the value of differing opinions, and adapt one's own approach or position in response to new information or changing needs in the organization.</p> <p><u>Explores Alternatives</u> Continually looks for ways to make changes work rather than only identifying why things cannot be accomplished. Performs tasks outside of the realm of his or her job to expedite projects and react to the changing needs at U of L Health Care.</p> <p><u>Modifies Own Opinion</u> Modifies a strongly held opinion in response to contrary evidence. Demonstrates a positive outlook toward job change. Is willing to adapt to the changing needs of the organization (i.e., changes in duties, shifts, etc.).</p> <p><u>Modifies Approach to Others</u> Adapts own style to fit personalities of different people. Recognizes individuals with different styles and the merits of different approaches to doing things.</p>
<p>PROFESSIONALISM</p> <p><u>VALUES:</u> Personal Responsibility, Respect, Cooperation & Team Work</p>	<p>Professionalism is shown by the manner in which we conduct ourselves and interact with others. It refers to our attitude toward our jobs, our co-workers, and the public; the way we treat and respond to others and the image we project.</p> <p><u>Uses Tact When Communicating</u> Considers how others will respond before communicating sensitive issues. Uses mature judgement when deciding what and how to communicate. Maintains professional confidences of others and encourages them to do the same in appropriate situations.</p>

COMPETENCY	DEFINITION & STANDARDS
	<p><u>Treats Co-Workers with Respect and Consideration</u> Does not allow personal opinions and issues with others to interfere with proper conduct of business. Takes noticeable pride in his or her work.</p> <p><u>Focuses on Assigned Work</u> Conducts work assignments effectively and without distracting others or letting others distract him or her from accomplishing work requirements. Reacts to others in a calm, rational manner. Uses appropriate, non-offensive language with others. Observes policies and procedures of the organization.</p>
<p>TEAMWORK AND COOPERATION</p> <p><u>VALUES:</u> Collaboration and Teamwork</p>	<p>Teamwork and Cooperation implies the intention to work cooperatively with others, to work together as opposed to working separately or competitively.</p> <p><u>Builds Team Spirit</u> Looks for ways to promote a friendly climate, good morale, and cooperation. Promotes team cooperation. Wants all members of a team to contribute to a process. Projects and promotes a good reputation with outsiders to the organization.</p> <p><u>Encourages Others</u> Publicly credit others who have performed well. Encourages, compliments and empowers others to make them feel they provide value and importance.</p> <p><u>Solicits Input</u> Genuinely values others' input and expertise. Is willing to learn from others (especially subordinates and peers). Solicits ideas and opinions to help form specific decisions or plans.</p>
<p>LISTENING & RESPONDING</p> <p><u>VALUES:</u> Respect, Trust, Collaboration & Teamwork</p>	<p>Listening and Responding refers to the way people share information</p> <p><u>Predicts Others' Responses</u> Employee thinks before he or she speaks. Thinks ahead and tries to figure out how others will react to things before talking or sharing information to ensure things are handled appropriately.</p> <p><u>Offers Help to Others</u> Offers help to others who appear in need of assistance. Is sensitive to the signals they may send. Looks for ways to help others solve problems.</p> <p><u>Makes Self Available</u> Employee is willing to listen. Is approachable and responds in a way that shows others he or she understands their concerns or issues and offers support.</p>

JOB DESCRIPTION PROFESSIONAL IMPLEMENTATION POSITIONS

POSITION TITLE:	Employee Health Nurse
DEPARTMENT:	Human Resource
SUPERVISED BY:	Vice President of Human Resources
SUPERVISES DIRECTLY:	None
SUPERVISES INDIRECTLY:	None
PREPARED/REVIEWED/REVISED DATE:	11/23/09
PREPARED/REVISED BY:	Occupational Health Nurse Manager
DEPT. DIRECTOR APPROVAL:	
HUMAN RESOURCES APPROVAL:	

EDUCATION, EXPERIENCE, LICENSE AND CERTIFICATION REQUIREMENTS

EDUCATION & TRAINING:	RN, BSN. COHN-S preferred
EXPERIENCE:	5 + years experience in an acute care facility. Prior experience in Occupational Health preferred.
LICENSE & CERTIFICATION:	Active RN, current license in good standing from Commonwealth of Kentucky, RN, Certified Occupational Health Nurse Specialist preferred.

JOB PURPOSE/SUMMARY

The Employee/Occupational Health Nurse will provide an ongoing health maintenance program encompassing pre-placement screening and current employee's job related health. Employee Health will also coordinate activities with Infection Control, Workers' Compensation and Safety Hospital functions. The employee shall present a pleasant and helpful manner to patients, physicians and other members of the Hospital staff and general public. Employee shall comply with all Department and Hospital policies/procedures. Employee shall support and contribute to Department objectives.

WORK ENVIRONMENT CHARACTERISTICS/REQUIREMENTS

PART 1: PHYSICAL REQUIREMENTS									
SECTION A PHYSICAL MOBILITY REQUIREMENTS			SECTION B PHYSICAL EFFORT REQUIREMENTS			SECTION C PHYSICAL DEXTERITY REQUIREMENTS			
% OF DAY SPENT			# OF POUNDS LIFTED			REQUIRED ABILITY TO OPERATE			
30%	Sitting		25%	Waist High		x	Telephone		
20%	Standing		10%	Shoulder High		x	Computer		
40%	Walking		10%	Above the Head			Hand Tools		
5%	Kneeling		POUNDS ARE				Electric Tools		
5%	Stooping		x	Carried Alone		x	Electronic Equipment		
			x	With Someone		x	Calculator		
JOB REQUIRES ABILITY TO CLIMB			POUNDS ARE			x	Copy Machine		
	Using a Ladder		x	Pushed		x	Medical Equipment		
x	On an Incline		x	Pulled					
x	Using Stairs			Held					
PART 2: SENSORY ABILITIES			PART 4: MENTAL EFFORT			PART 5: WORK ENVIRONMENT			
AN ABILITY TO			PERFORMS ON A DAILY BASIS			JOB REQUIRES THE ABILITY TO			
	IS CRITICAL	IS USEFUL							
			x	Reading		x	Work Under Time Pressure		
Distinguish Color	x		x	Writing		x	Work at a Rapid Pace		
Hear or Listen	x		x	Basic Math		% OF TIME SPENT			
Taste		x	x	Weighing		100%	Working In Doors		
Smell	x		x	Analyzing Data		0%	Working Outdoors		
Touch	x		x	Finding Solutions			At a Desk or Bench		
Speak	x		x	Managing Resources			In an Office or Control Room		
PART 3: JOB HAZARDS			x	Supervising Others		THE CONDITION OF THE AIR IS			
			x	Evaluating Performance of Others		x	Clean and Controlled		
			x	Working with Confidential Information			Dusty or Dirty		
			PART 5: WORK ENVIRONMENT				Wet/Humid		
			THE WORK SURFACE IS				Affected by Fumes or Smoke		
			x	Level					

		Sloping	<u>THE NOISE LEVEL IS</u>	
		Uneven	x	Normal
		Slippery		Loud Requiring Ear Protection

WORK PERFORMED/ESSENTIAL FUNCTIONS

PATIENT POPULATIONS FOR WHICH CARE IS PROVIDED (CHECK ALL THAT APPLY)			
	NEONATAL/INFANT (BIRTH TO 12 MONTHS)		PEDIATRIC (13 MONTHS TO 11 YEARS)
	ADOLESCENT (12 TO 17 YEARS)		ADULT (18 YEARS TO 65 YEARS)
	GERIATRIC (66 YEARS AND OLDER)	x	POSITION DOES NOT PROVIDE PATIENT CARE

LIST THE ESSENTIAL FUNCTIONS PERFORMED BY THIS POSITION	
1.	Performs pre-employment health assessments on all job applicants to determine physical ability to perform job desired.
2.	Treats, counsels, refers and performs follow-up of all job related illnesses/injuries following all relevant Employee Health/Hospital policies.
3.	Maintains Employee Health files that accurately reflect all interaction.
4.	Monitors and trends employee job-related injuries/illnesses for input into Hospital Safety Committee. Also trends illnesses for coordination with the Infection Control function.
5.	Works closely with the Claims Specialist, physicians and other appropriate individuals to monitor employee treatment/progress.
6.	Participates in educational in-service programs related to Employee Health.
7.	Maintains Employee Health office as scheduled.
8.	Assist with quarterly Employee Health newsletter.
9.	Monitors pre-employment and fitness for duty drug/alcohol screening. Monitors drug/alcohol screening as related to DOT Regulations.
10.	Notifies employees regarding required immunizations and annual tuberculosis testing.
11.	Monitors employees involved in the Decontamination Unit per OSHA Regulations
12.	Provides appropriate referral and educational information for employees with non-work related injuries/illnesses.
13.	Performs other duties as assigned.

VALUE BASED COMPETENCY EXPECTATIONS

COMPETENCY	DEFINITION & STANDARDS
<p>ANALYTICAL THINKING</p> <p>VALUES: Learning & Continuous Improvement, Personal Responsibility</p>	<p>Analytical Thinking means breaking down problems or tasks; scanning ones own knowledge and experience to identify causes and consequences of events.</p> <p><u>Anticipates Trends</u> Forecasts the future by analyzing present situations and past events. Brainstorms alternative resources and directions using multiple problem-solving methods.</p> <p><u>Uses Multiple Approaches</u> Uses multiple approaches to understand the key issues in a complex situation. Thinks of multiple possible causes and consequences of events. Tests multiple possible scenarios.</p> <p><u>Breaks Down Complex Tasks</u> Breaks down complex tasks into manageable parts in a systematic, detailed way and considers input from several sources.</p>
<p>CUSTOMER SERVICE ORIENTATION</p> <p>VALUES: Respect</p>	<p>Customer Service Orientation is a desire to help or serve others. The focus is on first discovering and understanding the customer=s needs and then taking action to help the customer and meet his or her needs. Customers include co-workers, workers in other departments that use your services, external customers, patients, families, or anyone we are trying to serve.</p> <p><u>Addresses Underlying Needs</u> Understands customer relationships and seeks information about the real, underlying needs of the customer beyond those initially expressed and matches these needs to available or customized products or services.</p> <p><u>Acts to Make Things Better</u> Anticipates customer needs and makes concrete attempts to add value to the customer, to make things better for the customer in some way.</p> <p><u>Makes Self Fully Available</u> Makes self fully available, especially when customer is going through a critical period. May give patient a pager number or other means of easy access or may spend extra time with the customer.</p>
<p>EXCELLENCE ORIENTATION</p> <p>VALUES: Personal Responsibility, Learning & Continuous Improvement</p>	<p>Excellence Orientation refers to one=s desire and commitment to do the best job he or she can; to find better, more efficient ways of doing his or her job. It involves a continuous effort to improve one=s skills and abilities at every opportunity. It is striving for continuous improvement.</p> <p><u>Far Surpasses Established Standards</u> Commits significant effort and/or time to improve performance or reach a challenging goal. Creates an environment which encourages others to surpass their own standards of performance.</p> <p><u>Sets Own Standards</u> Follows own high standards, not just those set by others. Works to exceed existing quality standards at U of L Health Care.</p> <p><u>Meets Established Goals</u> Meets established goals by producing high quality work even for small requests. Challenges established practices or processes as necessary to ensure work is done in the most efficient way possible.</p>

COMPETENCY	DEFINITION & STANDARDS
<p>FLEXIBILITY</p> <p><u>VALUES:</u> Constancy of Purpose, Respect</p>	<p>Flexibility means one can handle change easily, sees the value of differing opinions, and adapt one's own approach or position in response to new information or changing needs in the organization.</p> <p><u>Explores Alternatives</u> Continually looks for ways to make changes work rather than only identifying why things cannot be accomplished. Performs tasks outside of the realm of his or her job to expedite projects and react to the changing needs at U of L Health Care.</p> <p><u>Modifies Own Opinion</u> Modifies a strongly held opinion in response to contrary evidence. Demonstrates a positive outlook toward job change. Is willing to adapt to the changing needs of the organization (i.e., changes in duties, shifts, etc.).</p> <p><u>Modifies Approach to Others</u> Adapts own style to fit personalities of different people. Recognizes individuals with different styles and the merits of different approaches to doing things.</p>
<p>PROFESSIONALISM</p> <p><u>VALUES:</u> Personal Responsibility, Respect, Cooperation & Team Work</p>	<p>Professionalism is shown by the manner in which we conduct ourselves and interact with others. It refers to our attitude toward our jobs, our co-workers, and the public; the way we treat and respond to others and the image we project.</p> <p><u>Uses Tact When Communicating</u> Considers how others will respond before communicating sensitive issues. Uses mature judgement when deciding what and how to communicate. Maintains professional confidences of others and encourages them to do the same in appropriate situations.</p> <p><u>Treats Co-Workers with Respect and Consideration</u> Does not allow personal opinions and issues with others to interfere with proper conduct of business. Takes noticeable pride in his or her work.</p> <p><u>Focuses on Assigned Work</u> Conducts work assignments effectively and without distracting others or letting others distract him or her from accomplishing work requirements. Reacts to others in a calm, rational manner. Uses appropriate, non-offensive language with others. Observes policies and procedures of the organization.</p>
<p>TEAMWORK AND COOPERATION</p> <p><u>VALUES:</u> Collaboration and Teamwork</p>	<p>Teamwork and Cooperation implies the intention to work cooperatively with others, to work together as opposed to working separately or competitively.</p> <p><u>Builds Team Spirit</u> Looks for ways to promote a friendly climate, good morale, and cooperation. Promotes team cooperation. Wants all members of a team to contribute to a process. Projects and promotes a good reputation with outsiders to the organization.</p> <p><u>Encourages Others</u> Publicly credit others who have performed well. Encourages, compliments and empowers others to make them feel they provide value and importance.</p> <p><u>Solicits Input</u> Genuinely values others' input and expertise. Is willing to learn from</p>

COMPETENCY	DEFINITION & STANDARDS
	others (especially subordinates and peers). Solicits ideas and opinions to help form specific decisions or plans.
<p>LISTENING & RESPONDING</p> <p><u>VALUES:</u> Respect, Trust, Collaboration & Teamwork</p>	<p>Listening and Responding refers to the way people share information</p> <p><u>Predicts Others= Responses</u> Employee thinks before he or she speaks. Thinks ahead and tries to figure out how others will react to things before talking or sharing information to ensure things are handled appropriately.</p> <p><u>Offers Help to Others</u> Offers help to others who appear in need of assistance. Is sensitive to the signals they may send. Looks for ways to help others solve problems.</p> <p><u>Makes Self Available</u> Employee is willing to listen. Is approachable and responds in a way that shows others he or she understands their concerns or issues and offers support.</p>

**Skills Validation For
Intramuscular Seasonal Influenza Immunization Administration (adult)**

Measurement Criteria	Met	Not Met
1. Verifies correct medication (Subvirion influenza vaccine for the correct flu season)		
2. Assesses the recipient for contraindications		
3. Ensures vaccine cold chain		
4. Verifies correct dosage according to vaccine used and age of the recipient		
5. Utilizes 22-23 gauge x 1 inch as standard or 22-23 gauge x 1 ½ inch needle as adjustment needle length for larger patients to facilitate an intramuscular injection		
6. Able to correctly describe activation of safety device to prevent needlestick		
7. Sanitizes hands (alcohol-based hand rub or hand wash)		
8. Identifies deltoid muscle and is able to identify the triangular muscle region appropriate for use in the injection		
9. Insures that there is no constricting clothing around upper arm area		
10. Helps patient relax arm to decrease muscle tension and resultant soreness		
11. Cleanses injection area with alcohol swab		
12. Uses "press and spread" method to insure an intramuscular injection in the deltoid muscle		
13. Aspirates prior to injection		
14. After injection, gently massages area and applies latex safe band-aid		
15. Activates safety device and disposes of device and syringe in designated sharps container		
16. Instructs patient to move arm and periodically massage injection area during the next 24-48 hours to prevent soreness		
17. Provides patient education information (VIS) regarding influenza vaccine		
18. Maintains personal protective equipment and emergency pharmaceutical agents within easy reach		
19. Able to verbally demonstrate appropriate use of emergency protocols		

Validation for: _____

Date _____

Validation verified by: _____

Date _____

**Skills Validation For
Intranasal Seasonal Influenza Immunization Administration**

Measurement Criteria	Met	Not Met
1. Verifies correct medication (intranasal influenza vaccine for the correct flu season)		
2. Assesses recipient for vaccine contraindications		
3. Ensures adequate vaccine cold chain prior to administration		
4. Verifies correct dosage in syringe and ensures syringe has not been activated		
5. Performs hand hygiene using alcohol-based hand rub or soap and water hand wash. Helps vaccine recipient perform hand hygiene if he/she is self-administering		
6. Removes cap of syringe in a manner that minimizes the opportunity for contamination		
7. Provides vaccine recipient with tissue		
8. Inserts tip of syringe into the nares of the vaccine recipient or observes vaccine recipient as he/she inserts syringe into nares		
9. Administers vaccine into one nare of the recipient rapidly pushing plunger ensuring that the entire dose/portion is administered		
10. Instructs vaccine recipient to use tissue if needed		
11. Removes clip from syringe plunger so second portion of the dose can be administered		
12. Inserts tip of syringe into the other naris of the vaccine recipient or observes vaccine recipient as he/she inserts syringe into naris		
13. Administers vaccine into the naris of the recipient rapidly pushing plunger ensuring that the entire remaining dose/portion is administered		
14. Instructs vaccine recipient to use tissue, if needed		
15. Disposes of syringe in designated regulated waste container and other items into the general trash		
16. Completes documentation		
17. Provides patient education (VIS) regarding vaccine side effects and contact numbers for emergency		
18. Able to verbally demonstrate appropriate use of emergency equipment and procedure in the event it is necessary		

Validation for: _____

Date _____

Validation verified by: _____

Date _____

**Skills Validation For
Intradermal Seasonal Influenza Immunization Administration (adult)**

Measurement Criteria	Met	Not Met
1. Verifies correct medication (Subvirion influenza vaccine for the correct flu season)		
2. Assesses the recipient for contraindications		
3. Ensures vaccine cold chain		
4. Verifies correct dosage according to vaccine used and age of the recipient		
5. Utilizes the prefilled syringe for intradermal administration		
6. Able to correctly describe activation of safety device to prevent needlestick		
7. Sanitizes hands (alcohol-based hand rub or hand wash)		
8. Identifies deltoid region for intradermal administration		
9. Insures that there is no constricting clothing around upper arm (or thigh if appropriate) area		
10. Helps patient relax arm to decrease muscle tension and resultant soreness		
11. Cleanses injection area with alcohol swab		
12. Holds prefilled syringe between thumb and middle finger with the index finger used to inject		
13. Holds upper arm so the deltoid area is exposed. Presses 1.5 mm needle into the skin in the deltoid area		
14. Activates safety device and disposes of device and syringe in designated sharps container		
15. After injection, applies latex safe band-aid		
16. Instructs patient or family/caregiver regarding potential soreness at the injection site		
17. Provides patient/family/caregiver education information (VIS) regarding influenza vaccine		
18. Maintains personal protective equipment and emergency pharmaceutical agents within easy reach		
19. Able to verbally demonstrate appropriate use of emergency protocols		

Validation for: _____

Date _____

Validation verified by: _____

Date _____

**Skills Validation For
Subcutaneous Immunization Administration (adult)**

Measurement Criteria	Met	Not Met
1. Verifies correct medication		
2. Assesses the recipient for contraindications		
3. Ensures vaccine cold chain		
4. Verifies correct dosage according to vaccine used		
5. Utilizes appropriate diluent, if indicated		
6. Utilizes 23-25 gauge 5/8 inch needle to facilitate subcutaneous injection		
7. Able to correctly describe activation of safety device to prevent needlestick		
8. Sanitizes hands (alcohol-based hand rub or hand wash)		
9. Identifies injection area so vaccine is injected into fatty tissue below the dermis and above muscle tissue		
10. Insures that there is no constricting clothing around upper arm area		
11. Helps patient relax arm to decrease muscle tension and resultant soreness		
12. Cleanses injection area with alcohol swab		
13. Pinches up the fatty tissue and inserts needle at 45-degree angle injecting vaccine into the tissue		
14. After injection, applies light pressure to injection site for several seconds then applies latex free band-aid		
15. Activates safety device and disposes of device and syringe in designated sharps container		
16. Provides patient education information (VIS) regarding influenza vaccine		
17. Maintains personal protective equipment and emergency pharmaceutical agents within easy reach		
18. Able to verbally demonstrate appropriate use of emergency protocols		

Validation for: _____

Date _____

Validation verified by: _____

Date _____

Vaccines with Diluents: How to Use Them

The following vaccines must be reconstituted correctly before they are administered. Reconstitution means that the lyophilized (freeze-dried) vaccine powder or wafer in one vial must be reconstituted (mixed) with the diluent (liquid) in another. Only use the diluent provided by the manufacturer for that vaccine as indicated on the chart. ALWAYS check the expiration date on the diluent and vaccine. NEVER use expired diluent or vaccine.

Vaccine product name	Manufacturer	Lyophilized vaccine (powder)	Liquid diluent (may contain vaccine)	Time allowed between reconstitution and use*	Diluent storage environment
ActHIB (Hib)	sanofi pasteur	ActHIB	0.4% sodium chloride	24 hrs	Refrigerator
Hiberix (Hib)	GlaxoSmithKline	Hib	0.9% sodium chloride	24 hrs	Refrigerator or room temp
Imovax (RAB _{HDCV})	sanofi pasteur	Imovax	Sterile water	Immediately	Refrigerator
M-M-R II (MMR)	Merck	MMR	Sterile water	8 hrs	Refrigerator or room temp
Menomune (MPSV4)	sanofi pasteur	MPSV4	Distilled water	30 min (single-dose vial) 35 days (multi-dose vial)	Refrigerator
Menveo (MCV4)	Novartis	MenA	MenCWY	8 hrs	Refrigerator
Pentacel (DTaP-IPV/Hib)	sanofi pasteur	ActHIB	DTaP-IPV	Immediately†	Refrigerator
ProQuad (MMRV)	Merck	MMRV	Sterile water	30 min	Refrigerator or room temp
RabAvert (RAB _{PCECV})	Novartis	RabAvert	Sterile water	Immediately	Refrigerator
Rotarix (RV1)‡	GlaxoSmithKline	RV1	Sterile water, calcium carbonate, and xanthan*	24 hrs	Room temp
Varivax (VAR)	Merck	VAR	Sterile water	30 min	Refrigerator or room temp
YF-VAX (YF)	sanofi pasteur	YF-VAX	0.9% sodium chloride	60 min	Refrigerator or room temp
Zostavax (ZOS)	Merck	ZOS	Sterile water	30 min	Refrigerator or room temp

Always refer to package inserts for detailed instructions on reconstituting specific vaccines. In general, follow these steps:

- For single-dose vaccine products (exceptions are Menomune in the multi-dose vial and Rotarix[§]), select a syringe and a needle of proper length to be used for both reconstitution and administration of the vaccine. Following reconstitution, Menomune in a multi-dose vial will require a new needle and syringe for each dose of vaccine to be administered. For Rotarix, see the package insert.[‡]
- Before reconstituting, check labels on both the lyophilized vaccine vial and the diluent to verify the following:
 - that they are the correct two products to mix together
 - that the diluent is the correct volume (especially for Menomune in the multi-dose vial)
 - that neither vaccine nor diluent has expired
- Reconstitute (i.e., mix) vaccine *just prior to use*[‡] by
 - removing the protective caps and wiping each stopper with an alcohol swab
 - inserting needle of syringe into diluent vial and withdrawing entire contents
 - injecting diluent into lyophilized vaccine vial and rotating or agitating to thoroughly dissolve the lyophilized powder
- Check the appearance of the reconstituted vaccine.
 - Reconstituted vaccine may be used if the color and appearance match the description on the package insert.
 - If there is discoloration, extraneous particulate matter, obvious lack of resuspension, or cannot be thoroughly mixed, mark the vial as "DO NOT USE," return it to proper storage conditions, and contact your state or local health department immunization program or the vaccine manufacturer.
- If reconstituted vaccine is not used immediately or comes in a multi-dose vial (i.e., multi-dose Menomune),
 - clearly mark the vial with the date and time the vaccine was reconstituted
 - maintain the product at 35°–46°F (2°–8°C); do not freeze
 - protect reconstituted vaccines from light
 - use only within the time indicated on chart above

* If the reconstituted vaccine is not used within this time period, it must be discarded.

† Within 30 minutes or less.

‡ Rotarix vaccine is administered by mouth using the applicator that contains the diluent. It is not administered as an injection.

Section 8 Additional Resources

Items included in this toolkit are continuously under review and revision by federal agencies and individuals. Therefore, it is imperative that the individuals responsible for the healthcare personnel immunization program be cognizant of that and incorporate processes that will search for and identify updates and new information. There are, however, some basic pieces of information that provide foundations for safe and best practices that should also be part of the information compiled by the individuals responsible for the program. This section includes both a list of suggested resources as well as copies of some items that will likely be referenced and consulted on a regular basis.

Included in this section:

- An additional resource list
- Copies of open access publications
 - Poland GA, Shefer AM, McCauley M, et al. Standards for adult immunization practices. *Am J Prev Med* 2003;25:144—50.
 - CDC. Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation. *MMWR* March 24, 2011; 49(RR-1);1-39.
 - CDC. Use of Standing Orders Programs to Increase Adult Vaccination Rates. *MMWR* March 24, 2000; 49(RR-1);15-26
 - Henderson DK et al. SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus. *Infection Control and Hospital Epidemiology*. March 2010; 31(3);203-232.
 - Talbot TR et al. Revised SHEA Position Paper: Influenza Vaccination of Healthcare Personnel. *Infection Control and Hospital Epidemiology*. August 31, 2010. 31(10):987-995.
- Adult Immunization Schedule 2012

Additional Resources

There is a plethora of resources regarding immunization and those responsible for healthcare personnel immunization programs should be familiar with a variety of recommendations, landmark publications, and books that can improve both the efficiency and safety of the immunization program. In addition to those listed below, personnel at the local and state health department should be considered critical and valuable resources. When questions arise regarding vaccines, administration, adverse events, or other questions, contact your local health department and ask to speak with the individual responsible for the immunization program. They can direct you for more information as needed.

The following list of resources should not be considered comprehensive. Instead, the list offers you a variety upon which you can build your knowledge and understanding of vaccines and their benefit.

- CDC. Vaccine Storage and Handling Guide 2011. Available at www.cdc.gov/vaccines/recs/storage/default.htm . Accessed November 25, 2011.
- CDC. General Recommendations on Immunization. 2011. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm?s_cid=rr6002a1_e
- California Department of Public Health Immunization Training and Resources. Available at <http://eziz.org/eziz-training/>
- Poland GA, Shefer AM, McCauley M, et al. Standards for adult immunization practices. Am J Prev Med 2003;25:144—50. Available at <http://download.journals.elsevierhealth.com/pdfs/journals/0749-3797/PIIS074937970300120X.pdf> Accessed November 25, 2011.
- CDC. Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation. MMWR March 24, 2011; 49(RR-1);1-39. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4901a1.htm> . Accessed November 25, 2011.
- CDC Adult Immunization Schedule. MMWR February 4, 2011; 60(4);133-139. Available at <http://www.cdc.gov/mmwr/pdf/wk/mm6004.pdf> Accessed November 25, 2011.
- CDC. Vaccine Adverse Event Reporting System. Available at <http://vaers.hhs.gov/index>
- CDC. Advisory Committee on Immunization Practices Recommendations. Available at <http://www.cdc.gov/vaccines/recs/acip/default.htm#recs>
- CDC. Use of Standing Orders Programs to Increase Adult Vaccination Rates. MMWR March 24, 2000; 49(RR-1);15-26 <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4901a2.htm> Accessed November 25, 2011.
- Henderson DK et al. SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus. Infection Control and Hospital Epidemiology March 2010; 31(3);203-232. Available at http://www.shea-online.org/Assets/files/guidelines/BBPathogen_GL.pdf Accessed November 25, 2011.
- Talbot TR et al. Revised SHEA Position Paper: Influenza Vaccination of Healthcare Personnel. Infection Control and Hospital Epidemiology. August 31, 2010. 31(10):987-995. Available at <http://www.jstor.org/stable/pdfplus/10.1086/656558.pdf?acceptTC=true> . Accessed May 4, 2012.

- www.immunize.org

Reference Books

CDC Health Information for International Travel

Better known as the "Yellow Book," is published every two years by CDC as a reference to those who advise international travelers of health risks. It is written primarily for health care providers, although others might find it useful. The title links to the CDC website where you can freely download the text. You can purchase a hard copy from the Public Health Foundation by calling (877) 252-1200 or order online.

Epidemiology & Prevention of Vaccine-Preventable Disease

Better known as the "Pink Book," this easy-to-read reference book from the CDC includes both general principles of vaccination as well as the latest information on vaccine-preventable diseases. The book also serves as the text for CDC's immunization training course of the same name. The title links to the CDC website where you can freely download the text. You can purchase a hard copy from the Public Health Foundation by calling (877) 252-1200 or order online. Available at <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html> Accessed November 25, 2011.

Immunization Against Infectious Disease

Better known as the "Green Book," this new edition from the UK Department of Health presents the latest information on vaccines and vaccination procedures for all the vaccine-preventable infectious diseases that may occur in the UK. In particular, it deals with those immunizations that comprise the routine immunization program for all children from birth to adolescence. The title links to UK Department of Health website, where you can download the entire PDF document or by chapter.

ImmunoFacts

Written by J.D. Grabenstein, published by Facts and Comparisons, and updated quarterly. Comprehensive and updatable reference compendium on vaccines and immunologic drugs. Call (800) 223-0554 or order online.

International Travel and Health

Issued by the World Health Organization. Offers guidance on the full range of health risks likely to be encountered at specific destinations and associated with different types of travel - from business, humanitarian, and leisure travel, to backpacking and adventure tours. The book is only available online to allow for regular updates.

Red Book: Report of the Committee on Infectious Diseases

From the American Academy of Pediatrics (AAP). Revised every three years, contains AAP's recommendations for prevention and management of infectious diseases in children. The book comes in

hard cover, soft cover, immediate download, and CD-ROM format. For more information, call (866) 843-2271 or order online.

Safety and Health During International Travel

The Technical Information Bulletin from the U.S. Occupational Safety and Health Administration (OSHA) is designed to help international business travelers. Order by calling OSHA at (800) 321-6742, or download the pdf.

The Complete Idiot's Guide to Vaccinations

Written by L. Bouck L and Dr. Michael Smith, this book is an overview of vaccines with an emphasis on the pros and cons so you are equipped to address comments and questions from parents and others who need correct and complete information about vaccines.

Travel & Routine Immunization - A Practical Guide for the Medical Office

This guide contains extensive information on immunization recommendations for travel. For more information call Shoreland, Inc. at (800) 433-5256 or visit their website.

The Vaccine Handbook: A Practical Guide for Clinicians, fourth edition 2012 *(the purple book)*

Written by Gary Marshall, MD, (professor of Pediatrics, University of Louisville School of Medicine). The handbook is a practical guide for clinicians, containing practical advice and background for the practitioner on vaccine infrastructure, standards and regulations, business aspects of vaccine practice, general recommendations, schedules, special circumstances, and how to address a patient's concerns about vaccines. This book also represents a partnership with the Immunization Action Coalition (IAC) and is available by contacting info@pcibooks.com

Vaccines, 5th Edition--Expert Consult

The fifth edition by Stanley A. Plotkin, MD, Walter A. Orenstein, MD and Paul A. Offit, MD (2008); 1748 pages. Order online or call (800) 545-2522.

Institute of Medicine. Adverse Effects of Vaccines: Evidence and Causality

This book provides an overview of vaccines and reported adverse effects, The National Academies Press. August 2011. PDF Available for Download at http://www.nap.edu/catalog.php?record_id=13164

Standards for Adult Immunization Practices

Gregory A. Poland, MD, Abigail M. Shefer, MD, Mary McCauley, MTSC, Peggy S. Webster, MD, Patricia N. Whitley-Williams, MD, Georges Peter, MD, and the National Vaccine Advisory Committee, Ad Hoc Working Group for the Development of Standards for Adult Immunization Practices

Abstract: Since the Standards for Adult Immunization Practices were first published in 1990, healthcare researchers and providers have learned important lessons on how to better achieve and maintain high vaccination rates in adults. The success rate of childhood immunization far exceeds the success rate of adult immunization. Thus, information and practices that will produce higher success rates for adult vaccination are crucial, resulting in overall societal cost savings and substantial reductions in hospitalizations and deaths. The Standards, which were developed to encourage the best immunization practices, represent the collective efforts of more than 100 people from more than 60 organizations. The revised Standards are more comprehensive than the 1990 Standards and focus on the accessibility and availability of vaccines, proper assessment of patient vaccination status, opportunities for patient education, correct procedures for administering vaccines, implementation of strategies to improve vaccination rates, and partnerships with the community to reach target patient populations. The revised Standards are recommended for use by all healthcare professionals and all public and private sector organizations that provide immunizations for adults. All who are involved in adult immunization should strive to follow the Standards in order to create the same level of success achieved by childhood vaccination programs and to meet the *Healthy People 2010* goals. (Am J Prev Med 2003;25(2):144–150)

Introduction

In the United States, years of clinical and programmatic experience have been translated into successful childhood immunization practices. As a result, vaccination rates among infants and children are near or at all-time highs. Today, most childhood vaccine-preventable diseases rarely occur or are non-existent. However, similar success in vaccinating adults has not been achieved.

Goals for adult immunization feature prominently in *Healthy People 2010*,¹ a comprehensive, nationwide health promotion and disease prevention agenda from the U.S. Department of Health and Human Services. The target is 90% coverage for annual influenza immunization among adults aged ≥ 65 years and 90% for one dose of pneumococcal vaccine. Success will require a dramatic increase from rates in 2000, which were only

66% for influenza vaccine and 50% for pneumococcal vaccine.²

Increasing the use of these two vaccines among older adults could have tremendous health impacts. Influenza and its complications kill approximately 40,000 individuals every year in the United States.³ Another 100,000 individuals suffer so severely from influenza that hospitalization is required.⁴ The overwhelming majority of these deaths and hospitalizations occur in the elderly. When vaccine viruses are well matched to circulating viruses, vaccination lowers the risk of infection among healthy adults by up to 90%.^{4,5} Although influenza vaccination is somewhat less effective among the elderly, vaccination has been estimated to reduce their risk of influenza-related hospitalization and death by up to 70%.^{4,6–8} The Centers for Disease Control and Prevention (CDC)⁹ estimate that for each additional 1 million elderly people vaccinated each year, 900 deaths and 1300 hospitalizations would be averted. Furthermore, economic studies find overall societal cost savings and substantial reductions in hospitalizations and deaths if people aged ≥ 65 years receive the influenza vaccine.^{4,6,7}

In recent years, pneumococcal infections have accounted for >100,000 hospitalizations for pneumonia, >60,000 cases of bacteremia and other forms of invasive disease, and about 7000 deaths from invasive pneumococcal disease.^{10–12} In 1998, >50% of these deaths occurred among people aged ≥ 65 years. Over-

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all, vaccine effectiveness against invasive pneumococcal disease among immunocompetent people aged ≥ 65 years is 75%,¹³ and the vaccine has been shown to be cost effective for people in this age group as well.¹⁴ Based on 1998 projections, annually 76% of invasive pneumococcal disease cases and 87% of resulting deaths occurred in people who were eligible for pneumococcal vaccine in the United States.¹²

Additional health benefits could also be gained by reaching immunization targets for younger high-risk adults. *Healthy People 2010*¹ targets are 60% coverage with influenza and pneumococcal vaccines among high-risk adults aged 18 to 64 years. In 1999, only 31% of these adults reported receiving influenza vaccine, and only 17% received pneumococcal vaccine (Centers for Disease Control and Prevention, unpublished data, 1999). In 1998, 41% of deaths attributed to invasive pneumococcal disease occurred among individuals aged 18 to 64 years who had a medical indication for the pneumococcal vaccine.¹²

Despite the availability of a vaccine that is >95% effective in preventing hepatitis B, approximately 80,000 individuals, mostly adolescents and adults, are infected annually in the United States.^{15,16} About 6% of newly infected people become chronically infected and face a 15% to 25% lifetime risk of death from chronic liver disease. Annually, an estimated 4000 to 5000 chronically infected people die prematurely from chronic liver disease.¹⁷ Without an improvement in vaccinating adults at increased risk of hepatitis B infection, transmission of hepatitis B will continue for decades.

Vaccines also remain underutilized among other groups of adults, especially among certain racial/ethnic populations. For example, the rates of influenza and pneumococcal vaccination in African-American and Hispanic populations are significantly lower than those among whites.¹⁸ In addition, adult immunization is not limited to pneumococcal, influenza, and hepatitis B vaccines. All adults should be immune to measles, mumps, rubella, tetanus, diphtheria, and varicella, and adults who are susceptible to hepatitis A and polio should be vaccinated if they are at risk for exposure. Further, certain vaccines, such as travel vaccines or vaccines occupationally required, should be reviewed and provided if appropriate. The CDC's Advisory Committee on Immunization Practices (ACIP) has recently published an Adult Immunization Schedule (<http://cdc.gov/nip/recs/adult-schedule.htm>).

Revising the Standards

The Standards for Adult Immunization Practices, developed to encourage best practices, were first published in 1990.¹⁹ Since then, the healthcare system has changed dramatically. For example, there has been a shift toward managed care, resulting in a change in

Table 1. Standards for adult immunization practices

Make vaccinations available.

1. Adult vaccination services are readily available.
2. Barriers to receiving vaccines are identified and minimized.
3. Patient "out-of-pocket" vaccination costs are minimized.

Assess patients' vaccination status.

4. Healthcare professionals routinely review the vaccination status of patients.
5. Healthcare professionals assess for valid contraindications.

Communicate effectively with patients.

6. Patients are educated about risks and benefits of vaccination in easy-to-understand language.

Administer and document vaccinations properly.

7. Written vaccination protocols are available at all locations where vaccines are administered.
8. Persons who administer vaccines are properly trained.
9. Healthcare professionals recommend simultaneous administration of indicated vaccine doses.
10. Vaccination records for patients are accurate and easily accessible.
11. All personnel who have contact with patients are appropriately vaccinated.

Implement strategies to improve vaccination rates.

12. Systems are developed and used to remind patients and healthcare professionals when vaccinations are due and to recall patients who are overdue.
13. Standing orders for vaccinations are employed.
14. Regular assessments of vaccination coverage levels are conducted in a provider's practice.

Partner with the community.

15. Patient-oriented and community-based approaches are used to reach target populations.

provider incentives and reimbursement for preventive services. Also in the past decade, healthcare researchers and providers have learned many valuable lessons about what is needed to achieve and maintain high vaccination rates among adults.

This revision of the Standards for Adult Immunization Practices (Table 1) reflects the experience of the past 10 years. The Standards represent the collective efforts of more than 100 people from more than 60 organizations, including professional societies, state and local health departments, immunization programs, and immunization providers. The National Vaccine Advisory Committee (NVAC) led this effort. As the Federal Advisory Committee is charged by the Secretary of Health and Human Services to ensure the adequate delivery of safe and effective vaccination products in the United States, the NVAC itself is composed of people who represent the spectrum of those with an interest in immunization, including physicians, researchers, developers, manufacturers, state and public health agencies, and more than 20 federal agencies. The revised Standards also incorporate information from two important reports published by NVAC in the last decade on the status of adult immunization²⁰ and on adult immunization programs in nontraditional settings.²¹

Information published from the *Guide to Community Preventive Services* reviews strategies to improve immunization service delivery and provides a broader base of evidence to support the Standards.^{22,23} Based on research published in the 1990s concerning techniques proven to improve immunization rates among adults, three new standards were constructed and require the following: (1) systems that remind patients and providers when an immunization is due, (2) standing orders from physicians that enable other personnel to prescribe and deliver vaccinations, (3) regular assessments of coverage rates at clinics, and (4) pertinent information provided to clinic staff to ensure current patient immunizations.

The Standards supplement research with expert consensus in areas where research does not offer guidance but experience does. The revised Standards are more comprehensive than the previous version and organized to focus on the provider's ongoing process of minimizing barriers that prevent patients from receiving vaccines, assessing for valid indications and contraindications, keeping patients' immunizations current, and communicating effectively with patients about vaccines.

Today, more tools are available to support immunization providers. The revised Standards include links to websites that contain information on model standing-order policies, instructions for setting up reminder/recall systems, and templates for personal vaccination records. The tools are currently available free on CD-ROM, but will soon be available online. In addition, information about federal requirements and programs, including Vaccine Information Statements, the Vaccine Adverse Event Reporting System (VAERS), and the National Vaccine Injury Compensation Program (VICP) is current and has been made easily accessible in the Standards.

Applying the Standards

Once the revised Standards are implemented on a practice-by-practice or program-by-program basis, immediate results can be expected for improved adult immunization. Long-term sustainable improvement in adult immunization necessitates an infrastructure to organize immunization efforts by providers and federal agencies, as well as state and local health departments. Such an infrastructure is lacking.²⁴ Partnerships among healthcare professionals, state and local health departments, medical and nursing organizations, and insurance companies will need to be strengthened. Factors that cause low vaccination coverage among adults must be addressed. These factors include provider behaviors and practices that may affect accurate identification of patients in need of vaccination, attitudes toward the healthcare system that may impact adults seeking and accepting vaccines, and financial issues that may im-

pede appropriate vaccination of certain populations. For example, although Medicare ensures coverage benefits for vaccines for those aged ≥ 65 years, in 2001 an estimated 17% and 13% of adults aged 35 to 44 years and 45 to 64 years, respectively, did not have health insurance.² In addition, even though many adults may have insurance coverage, the medical insurance may not cover vaccination.

Overall improvement in our healthcare system will take time. However, we can do much now to improve the delivery of vaccination services for adults. The following Standards for Adult Immunization Practices and the accompanying discussion are intended to address these issues.

The Standards

Make Vaccinations Available

Standard 1: Adult vaccination services are readily available. Primary care healthcare professionals who serve adults should always include routinely recommended vaccinations as part of their care. Specialists, whose patients may be at increased risk of vaccine-preventable diseases, should also include routinely recommended vaccinations as part of their care. For selected vaccines (e.g., meningococcal vaccine for college entrants and vaccines for international travelers), patients may be referred to another provider.

Standard 2: Barriers to receiving vaccines are identified and minimized. Barriers to receiving vaccines may include requiring a physical examination before vaccination, requiring an additional visit for vaccination, long waiting periods, and lack of educational materials that are culturally appropriate. Prior to vaccine administration, simply observing the patient, asking if the patient is well and questioning the patient/guardian about vaccine contraindications is sufficient.

Standard 3: Patient "out-of-pocket" vaccination costs are minimized. Resources should be identified to keep patient vaccination costs as low as possible, specifically for those patients aged ≥ 65 years and for vaccines not covered by Medicare Part B. In the public sector, patient fees should include only the cost of vaccine and administration that cannot be funded through another source. In the private sector, routinely recommended vaccination services should be included in basic benefits packages. System and policy changes should be addressed to provide adequate reimbursement to providers for delivering vaccinations to their adult population.

Assess Patients' Vaccination Status

Standard 4: Healthcare professionals routinely review the vaccination status of patients. Healthcare professionals should review and document the vaccination

status of all new patients during initial office visits and also review vaccination status on an annual basis thereafter. Healthcare professionals should ascertain if the patient has medical risk factors, lifestyle risk factors, or an occupation for which certain vaccines may be indicated. Healthcare professionals should record this information in the patient's chart and preventive health summary. Healthcare professionals should also routinely review pneumococcal vaccination status at the time of influenza vaccination.

Standard 5: Healthcare professionals assess for valid contraindications. Failure to differentiate between valid and invalid contraindications often results in the needless deferral of indicated vaccinations. Healthcare professionals should ask about prior adverse events in connection with a vaccination and about any conditions or circumstances that might indicate vaccination should be withheld or delayed. Healthcare professionals should refer to current ACIP recommendations on valid and invalid contraindications as well as on valid indications for vaccine use (www.cdc.gov/nip).

Communicate Effectively with Patients

Standard 6: Patients are educated about risks and benefits of vaccination in easy-to-understand language. Healthcare professionals should discuss with the patient the benefits of vaccines, the diseases that the vaccines prevent, and any known risks from vaccines. These issues should be discussed in the patient's native language, whenever possible. Printed materials, accurately translated into the patient's language, should be provided. For most commonly used vaccines, the U.S. federal government has developed Vaccine Information Statements for use by both public and private healthcare professionals to give to potential vaccine recipients. For vaccines covered by the National Childhood Vaccine Injury Act, including those vaccines used in children, these forms are required. These statements are available in English and other languages. Healthcare professionals should allot ample time with patients to review written materials and address questions and concerns. Information and assistance can be obtained by calling the Immunization Hotline (1-800-232-2522) or accessing the website (www.cdc.gov/nip).

Healthcare professionals should respect each patient's right to make an informed decision to accept or reject a vaccine or to defer vaccination until more information is collected.

Administer and Document Vaccinations Properly

Standard 7: Written vaccination protocols are available at all locations where vaccines are administered. The medical protocol should detail procedures for vaccine storage and handling, vaccine schedules, contraindications, administration techniques, management and re-

porting of adverse events, and record maintenance and accessibility. These protocols should be consistent with established guidelines. CDC-recommended storage and handling procedures are available on the Internet at http://gravity.lmi.org/lmi_cdc/geninfo.htm.

Healthcare professionals should promptly report all clinically significant adverse events following vaccination to VAERS, even if the healthcare professional does not believe that the vaccine caused the event. Reporting is required for those vaccines given to adults and medical conditions covered by the National Childhood Vaccine Injury Act of 1986, as amended. Healthcare professionals should be aware that patients may report to VAERS; if they choose to do so, they are encouraged to seek the help of their healthcare professional. Report forms and assistance are available by calling 1-800-822-7967 or on the Internet at www.fda.gov/cber/vaers/vaers.htm.

The VICP is a no-fault system that compensates people of any age for injuries or conditions that may have been caused by a vaccine recommended by CDC for routine administration to children. Healthcare professionals should be aware of the VICP in order to address questions raised by patients. Information about the VICP is available on the Internet at www.hrsa.gov/bhpr/vicp.htm or by calling 1-800-338-2382.

Since VAERS and VICP are separate programs, a report of an event to VAERS does not result in the submission of a compensation claim to VICP. Such a claim must be filed independently in the U.S. Court of Federal Claims. A brief description and contact information for both programs are provided on each Vaccine Information Statement for vaccines covered by the VICP.

Standard 8: People who administer vaccines are properly trained. All people who administer vaccinations should be fully trained in vaccine storage and handling, vaccine schedules, contraindications, administration techniques, management and reporting of adverse events, and record maintenance and accessibility. Office staff should receive continuing education on these issues annually. With appropriate training, people other than physicians and nurses can administer vaccines. Healthcare professionals should contact public health authorities or other medical authorities in their state for more information concerning which individuals are permitted to administer vaccines.

Standard 9: Healthcare professionals recommend simultaneous administration of all indicated vaccine doses. Administering indicated vaccines simultaneously is safe and effective. Simultaneous administration decreases the number of required visits and the potential for missed doses. Measles, mumps, and rubella (MMR) vaccine and tetanus and diphtheria (Td) toxoids should always be administered in their combined product. Giving influenza and pneumococcal vaccine at the

same time (but in separate arms) is also safe and effective. Healthcare professionals should respect the choices of patients and their caregivers.

Standard 10: Vaccination records for patients are accurate and easily accessible. Patient vaccination histories should be recorded on a standard form in an easily accessible location in the medical record to facilitate rapid review of vaccination status. Accurate record keeping helps ensure that needed vaccinations are administered and unnecessary vaccinations are not administered. Records should indicate the vaccine, the date of administration, the vaccine manufacturer and lot number, the signature and title of the person administering the vaccine, and the address where the vaccine was administered. The medical record at the primary care provider's office, clinic, or worksite should include all vaccinations received (such as those received at a specialist's office, influenza vaccination clinic, or pharmacy).

Record keeping may be paper-based or computerized. Computer systems make record maintenance, retrieval, and review easier.

Healthcare professionals should give patients a personal record of vaccinations they have received, including the dates and places of administration. Patients should be encouraged to bring their vaccination records to all medical visits.

Information and a modifiable template of these forms and records are available at www.ahcpr.gov/ppip/adultflow.pdf and are also available on CD-ROM and can be ordered on the Internet at www.atpm.org/Immunization/whatworks.html.

Standard 11: All personnel who have contact with patients are appropriately immunized. Healthcare professionals and other personnel (including first responders) who have contact with patients should be appropriately immunized (e.g., annual influenza vaccination, hepatitis B vaccination). Institutions should have policies to review and maintain the appropriate vaccination of staff and trainees.

ACIP recommendations for vaccinating healthcare workers are available on the Internet at www.cdc.gov/nip/publications/ACIP-list.htm.

Implement Strategies to Improve Vaccination Rates

Standard 12: Systems are developed and used to remind patients and healthcare professionals when vaccinations are due and to recall patients who are overdue. Evidence shows that reminder/recall systems improve adult vaccination rates. Systems may be designed to alert patients who are due (reminder) or overdue (recall) for specific vaccine doses or they may alert patients to contact their provider to determine if vaccinations are needed. Reminders or recalls can be

mailed or communicated by telephone; an autodialer can be used to expedite telephone reminders. Patients who might be at high risk for not complying with medical recommendations may require more intensive follow-up.

Provider reminder/recall interventions inform those who administer vaccinations that individual patients are due or overdue for specific vaccinations. Reminders can be delivered in patient charts, by computer, and/or by mail or other means, and content of the reminders can be specific or general. Information about these strategies and resources to assist in their implementation are available on CD-ROM and can be ordered on the Internet at www.atpm.org/Immunization/whatworks.html. Model reminder recall templates are also available at www.ahcpr.gov/ppip/postcard.pdf.

Standard 13: Standing orders for vaccinations are employed. Evidence shows that standing orders improve vaccination coverage among adults in a variety of healthcare settings, including nursing homes, hospitals, clinics, doctor's offices, and other institutional settings. Standing orders enable nonphysician personnel such as nurses and pharmacists to prescribe or deliver vaccinations by approved protocol without direct physician involvement at the time of the interaction. Standing orders overcome administrative barriers such as lack of physician personnel to order vaccines. Further, the Centers for Medicare and Medicaid allow standing order exemption from Medicare rules (www.cms.hhs.gov/medicaid/ltcsp/sc0302.pdf).

Information about this strategy and its implementation is available on CD-ROM and can be ordered on the Internet at www.atpm.org/Immunization/whatworks.html.

Standard 14: Regular assessments of vaccination coverage rates are conducted in a provider's practice. Evidence shows that assessment of vaccination coverage and provision of the results to the staff in a practice improves vaccination coverage among adults. Optimally, such assessments are performed annually. Provider assessment can be performed by the staff in the practice or by other organizations, including state and local health departments. Effective interventions that include assessment and provision of results may also incorporate incentives or compare performance to a goal or standard. This process is commonly referred to as AFIX (assessment, feedback, incentives, and exchange of information). Coverage should be assessed regularly so that reasons for low coverage in the practice, or in a subgroup of the patients served, can be identified and interventions implemented to address them.

Information about this strategy and its implementation is available on CD-ROM and can be ordered on the Internet at www.atpm.org/Immunization/whatworks.html. Software to assist in conducting coverage rate

assessments and feedback is available at www.cdc.gov/nip.

Partner with the Community

Standard 15: Patient-oriented and community-based approaches are used to reach target populations. Vaccination services should be designed to meet the needs of the population served. For example, interventions that include community education, along with other components such as extended hours, have been demonstrated to improve vaccination coverage among adults. Vaccination providers can work with partners in the community, including other health professionals (e.g., pharmacists), vaccination advocacy groups, managed care organizations, service organizations, manufacturers, and state and local health departments to determine community needs and develop vaccination services to address them.

Conclusion

The revised Standards for Adult Immunization Practices provide a concise, convenient summary of the most desirable immunization practices. The Standards have been widely endorsed by major professional organizations. This revised version of the Standards for Adult Immunization Practices is recommended for use by all healthcare professionals and payers in the public and private sectors who provide immunizations for adults. Everyone involved in adult immunization should strive to follow these Standards. Not all practices and programs have the resources necessary to fully implement the Standards; nevertheless, those lacking the resources should find the Standards useful to guide current practice and to guide the process of defining immunization needs and obtaining additional resources in the future.

These Standards are approved by the National Vaccine Advisory Committee (NVAC), the National Coalition for Adult Immunization (NCAI), the Advisory Committee on Immunization Practices (ACIP), and the U.S. Public Health Service, and endorsed, as of December 1, 2001, by the American Medical Association, Infectious Diseases Society of America, American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, Society of Adolescent Medicine, Health Resources and Services Administration, National Medical Association, National Association of County and City Health Officials, Association of State and Territorial Health Officers, Council of State and Territorial Epidemiologists, Association of Professionals in Infection Control and Epidemiology, Inc., Chiron, State of Washington Department of Health, Society of Teachers of Preventive Medicine, Immunization Action Coalition, Partnership for Prevention, National Coalition for Adult Immunization, American Academy of Otolaryngology Head and Neck Surgery, American Health Care Association, Hepatitis B Foundation, American College of Preventive

Medicine, American Pharmaceutical Association, American Society for Health System Pharmacists, State of Maine Department of Health, National Alliance for Hispanic Health, American Academy of Physician Assistants, National Association of School Nurses, Memphis County Health Department, Maine Ambulatory Care Association, Institute for Advanced Studies in Aging and Geriatric Medicine, The Arizona Partnership for Adult Immunization, National Foundation for Infectious Diseases, and the National Partnership for Immunization.

The NVAC was chartered in 1988 to advise and make recommendations to the director of the National Vaccine Program and the assistant secretary for health, Department of Health and Human Services, on matters related to the prevention of infectious diseases through immunization and the prevention of adverse reactions to vaccines. The NVAC is composed of 15 members from public and private organizations representing vaccine manufacturers, physicians, parents, and state and local health agencies, and public health organizations. In addition, representatives from government agencies involved in health care of allied services serve as ex-officio members of the NVAC.

Members of the National Vaccine Advisory Committee in 2001 are listed below.

Regular members: Georges Peter, MD (chair), Brown Medical School, Providence RI; Bruce Gellin, MD, MPH, Executive Secretary (Martin G. Myers, MD, former Executive Secretary), National Vaccine Program Office, Atlanta GA; Jeffrey P. Davis, MD, State Epidemiologist, Wisconsin Division of Health, Madison WI; Michael D. Decker, MD, MPH, Vice President, Scientific and Medical Affairs, Aventis Pasteur, Swiftwater PA; Patricia Fast, MD, PhD, Director, Medical Affairs, International AIDS Vaccine Initiative, New York City NY; Mary desVignes-Kendrick, MD, Director, City of Houston Department of Health and Human Services, Houston TX; Amy Fine, Health Policy/Program Consultant, Washington DC; Jerome O. Klein, MD, Professor of Pediatrics and Vice Chairman for Academic Affairs, Boston University School of Medicine, Boston MA; Yvonne A. Maldonado, MD, Associate Professor, Department of Pediatrics, Stanford University School of Medicine, Stanford CA; Stanley Plotkin, MD, Aventis Pasteur, Doylestown PA; Peter R. Paradiso, PhD, Vice President, Scientific Affairs, Wyeth-Lederle Vaccines and Pediatric American Home Products, West Henrietta NY; Gregory A. Poland, MD, Chief, Mayo Vaccine Research Group, Mayo Clinic and Foundation, Rochester MN; Marian Sokol, PhD, Founding Executive Director, Any Baby Can, Inc., San Antonio TX; Donald E. Williamson, MD, State Health Officer, Alabama Department of Public Health, Montgomery AL; and Patricia N. Whitley-Williams, MD, Associate Professor of Pediatrics, University of Medicine and Dentistry of New Jersey–Robert Wood Johnson Medical School, New Brunswick NJ.

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**Adult Immunization Programs
in Nontraditional Settings:
Quality Standards and Guidance
for Program Evaluation**

**A Report of the National Vaccine
Advisory Committee**

and

**Use of Standing Orders Programs
to Increase Adult Vaccination Rates**

**Recommendations of the Advisory
Committee on Immunization Practices**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
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Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation

A Report of the National Vaccine Advisory Committee

Summary

This report provides a summary of the National Vaccine Advisory Committee's (NVAC) workshop on adult immunization programs in nontraditional settings, quality standards for such programs, and guidance for program evaluation. Throughout the United States, an increasing number of adults are receiving vaccine in nontraditional settings (e.g., pharmacies and churches). Immunization programs in nontraditional settings are often more accessible and convenient than a health-care provider's office or a public health clinic, especially for medically underserved adults (e.g., economically disadvantaged, inner city, and minority populations). Medically underserved adults might be at particular risk for undervaccination because they are often without a medical home (i.e., a regular point of contact where their health-care needs are met). Immunization programs in nontraditional settings might enhance the capacity of the health-care system to effectively deliver vaccine to adults by increasing the number and types of sites where adults can receive vaccine. NVAC has recognized that strategies need to be developed to make vaccines available to all adults and that the number of immunization programs in nontraditional settings is increasing. Therefore, the Committee issues the following report, including quality standards and guidance for program evaluation.

BACKGROUND

Approximately 45,000 adults in the United States die annually of complications from influenza, pneumococcal infections, and hepatitis B — the primary vaccine-preventable diseases affecting adults. The total economic cost of treating these vaccine-preventable diseases among adults, excluding the value of years of life lost, exceeds \$10 billion each year. Although effective vaccines to prevent these diseases are available, they are widely underutilized (1,2). This underutilization reflects a lack of emphasis on vaccines for adults in comparison with the more substantial emphasis on vaccines for children.

Influenza and pneumococcal vaccine coverage rates for adults aged ≥ 65 years vary by race and ethnicity (2). In 1997, influenza vaccine coverage rates ranged from 67.2% among non-Hispanic whites to 50.2% among non-Hispanic blacks (2). Pneumococcal vaccine coverage rates were even lower: 47.3% of white adults aged ≥ 65 years reported receiving pneumococcal vaccine compared with 34.1% of Hispanics and 29.7% of blacks (2). Disease burden also varies by race and ethnicity. Blacks have a threefold to fivefold increased risk for developing life-threatening invasive pneumococcal disease compared with whites (3–5).

A recommendation by a health-care provider is a key factor determining whether an adult patient will be vaccinated (6). Medically underserved adults (e.g., economically disadvantaged, inner city, and minority populations) might be at particular risk for underimmunization because they are often without a medical home (i.e., a regular point of contact where their health-care needs are met) and might not have regular access to a health-care provider (7–10). Therefore, to reach medically underserved adults, strategies to increase vaccine-seeking behavior are critically needed. One such strategy involves offering vaccine to adults in nontraditional settings (e.g., pharmacies and churches) that might be more accessible and convenient than the office of a health-care provider or a public health clinic. Immunization programs in nontraditional settings might enhance the capacity of the health-care system to effectively deliver vaccine to adults by increasing the number and types of settings in which adults can receive vaccine.

INTRODUCTION

Purpose of the National Vaccine Advisory Committee Workshop

The National Vaccine Program Office sponsored a public meeting of the National Vaccine Advisory Committee's (NVAC) Adult Immunization Working Group on December 1–2, 1997, to explore adult immunization programs in nontraditional settings. The purpose of the workshop was

- to gain a better understanding of programs currently offering vaccines to adults in nontraditional settings,
- to identify potential benefits and challenges associated with administering vaccines in nontraditional settings,
- to identify additional nontraditional settings that could be explored and potentially used,
- to define areas where additional research is needed,
- to develop an effective immunization strategy integrating immunization programs in nontraditional settings with those in traditional settings, and
- to develop quality standards for immunization programs in nontraditional settings.

The workshop was limited to discussion regarding vaccines for adults because national vaccine coverage estimates for adults are substantially lower than the national goals established for this population, whereas coverage estimates for children approach or exceed national goals (2,7,11).

The purpose of this report is to provide a summary of discussions at the NVAC workshop so that persons who conduct or plan to conduct immunization programs in a nontraditional setting will have guidance regarding how to safely operate such a program. This report also highlights the importance of evaluating these programs by collecting data regarding associated benefits (e.g., increases in the number of adults vaccinated) and challenges (e.g., preventing fragmentation of care by reporting administration of vaccine to the primary-care provider of the vaccinee).

Influenza and pneumococcal vaccines constitute the majority of vaccines administered in nontraditional settings; therefore, this report focuses on these vaccines. If the types of vaccines administered in nontraditional settings increase, both the benefits and challenges could change.

Workshop Participants

Workshop participants included members of the NVAC Adult Immunization Working Group and representatives from approximately 50 organizations, including federal and state governments, community and professional organizations, and private companies. Participants were identified through discussions with staff at CDC, the Health Resources and Services Administration, the National Coalition for Adult Immunization (NCAI), and other organizations. NCAI is composed of nearly 100 professional medical and health-care associations, advocacy groups, voluntary organizations, vaccine manufacturers, and government agencies. Workshop presenters were selected to ensure that a spectrum of viewpoints was represented.

SUMMARY OF WORKSHOP PRESENTATIONS

Information regarding the U.S. Department of Health and Human Services' Adult Immunization Action Plan (1), vaccine coverage rates, and incidence of morbidity and mortality attributable to vaccine-preventable diseases among adults was presented. The American College of Physicians (ACP) and the National Medical Association provided physicians' perspectives of administration of vaccine in nontraditional settings. The benefits and challenges highlighted by these physicians were similar to those of other workshop participants. Benefits included increased access and convenience, reduced cost for vaccination, and increased awareness of the importance of vaccination. Challenges included ensuring that trained staff are available to treat potential adverse reactions to vaccines, keeping effective records, protecting health-care providers from liability, preventing fragmentation of care, and removing restrictive legal regulations.

NCAI and the National Council on Aging emphasized the importance of collaboration between public and private sectors and community-based organizations. A panel of representatives from community-based organizations providing services to traditionally underserved populations presented ways in which their clients might be more adequately cared for by the health-care profession (e.g., providing culturally and linguistically appropriate materials and outreach programs). Organizations that currently provide vaccines to adults in several nontraditional settings (including pharmacies, nontraditional clinical settings, retail establishments, dental care facilities, churches, the workplace, and the home) provided examples of the benefits and challenges experienced in these programs.

Examples of Adult Immunization Programs in Nontraditional Settings

The Health Care Financing Administration's (HCFA) Horizons pilot project, a collaborative project between professional review organizations and nine historically black colleges and universities in eight southern states, was presented as an example of how the Federal government works with communities to provide vaccine in nontraditional settings. The goal of the Horizons project is to produce effective community-based

interventions for increasing vaccine coverage rates among black populations. Tennessee's Horizons project has provided vaccines to adults in approximately 14 non-traditional settings, including shopping malls, senior citizen centers, nutrition sites, mobile units, grocery stores, voting sites, parks, and public housing projects.

Pharmacies in the United States are increasing their participation in vaccination activities (12). Pharmacists are functioning as a) vaccine advocates, by educating their clients about the importance of vaccines; b) vaccine facilitators, by hosting vaccine clinics at pharmacies; and c) vaccine administrators, by vaccinating their clients. The American Pharmaceutical Association and CDC's National Immunization Program have developed a training course to prepare pharmacists for active participation in immunization programs (13). Twenty-six states have statutes that permit pharmacists to administer vaccine. Accessibility of pharmacists and the degree of trust between pharmacists and patients were suggested as factors that provide important opportunities for pharmacists to educate adults about the benefits of vaccines and, in some cases, administer vaccine.

Nurse practitioners, visiting nurses, and members of the National Black Nurses Association (NBNA) also are involved in immunization programs in nontraditional settings. Nurse practitioners, using mobile-community health centers, often provide care to traditionally underserved homeless and migrant workers and a large population of older adults who reside in rural or inner city areas. NBNA and the Visiting Nurses Association often staff immunization programs operating in nontraditional settings, including the workplace, pharmacies, and churches.

A representative from the American Association of Occupational Health Nurses noted that employers can be involved in workplace immunization activities on three levels: a) providing vaccines at the work site, administered by their own medical staff; b) contracting with health-care providers to administer vaccine at the work site; and/or c) including preventive care benefits (e.g., vaccinations) in health plans for employees. Employers generally are interested in increasing employee productivity; therefore, decreased employee absenteeism associated with receiving influenza vaccine should be highlighted (14). Potential barriers to workplace vaccination programs include employers being reluctant to disrupt work schedules or to offer vaccine to employees covered by health plans. Workplaces with a small number of employees might not be able to provide vaccination programs on their own but might be able to unite with other offices and provide vaccines in a centralized site within an office park.

New Settings and Incentives for Immunization Programs

Several additional nontraditional settings in which vaccines might be provided include soup kitchens, prisons, sheltered workshops for persons with disabilities, casinos, bingo halls, adult day care centers, major transit points, and polling stations on election days. Designation of mass immunization days (analogous to national immunization days for polio vaccination in endemic areas [15]) during which vaccinations are provided in several different settings was suggested. New incentive or endorsement programs that might increase the demand for vaccinations were also presented. For example, retail coupons and endorsement by sports teams were suggested as potential ways to enhance vaccine-seeking behavior among adults.

BENEFITS OF ADULT IMMUNIZATION PROGRAMS IN NONTRADITIONAL SETTINGS

Access and Convenience

The most common benefits of administering vaccine in nontraditional settings noted by workshop presenters are increased access and convenience. Providing vaccines in settings readily accessible to adults who are most in need of the services is critical. For many adults, the need to use transportation to reach a health-care provider is a barrier to receiving preventive services (7,9). This barrier might be eliminated by offering preventive services (e.g., administration of vaccines) in a neighborhood retail establishment, church, or other convenient location. Eliminating the need for making an appointment in advance and avoiding the waiting time often associated with a clinic or office visit are factors that also might increase the vaccine-seeking behavior of some adults (8,9).

Reduced Cost for Vaccinations

The reduced cost of receiving vaccines in nontraditional settings compared with traditional settings is another potential benefit. The current cost of administering influenza and pneumococcal vaccines in a nontraditional setting is \$10–\$15 and \$15–\$20, respectively. Adults without health insurance might be willing to pay for a vaccine administered in a nontraditional setting when they would be unwilling or unable to pay the greater cost associated with a physician's office visit (16,17). For adults who are covered by Medicare, HCFA has mandated reimbursement for health-care providers who administer influenza vaccine, regardless of the setting, even if the health-care provider is not a member of the vaccinee's health-care plan.

Increased Awareness for Vaccinations Among Adults

An indirect benefit of administering vaccine in nontraditional settings is increased public awareness of the need for adult immunization. This benefit is realized in two ways. First, many immunization programs operating in nontraditional settings use direct marketing to inform the community about their services and why they are important. Although marketing strategies might be directed toward promoting a specific site, the actual benefit is likely a general increase in public awareness regarding the importance and availability of vaccines for adults. Secondly, immunization programs in nontraditional settings often elicit media attention, which might increase community awareness of the need for vaccination of adults.

CHALLENGES OF ADULT IMMUNIZATION PROGRAMS IN NONTRADITIONAL SETTINGS

Adverse Reactions to Vaccines

Vaccine providers should be trained to manage adverse reactions that might occur. Concerns regarding postvaccination observation included: "Should direct observation

of vaccine recipients be routine? If so, what is the duration of observation? If a severe adverse reaction occurs, are trained and skilled personnel on site to respond appropriately?"

Recordkeeping

Important factors regarding recordkeeping include how to determine which adults are in need of vaccines and how to prevent inappropriate revaccination.* Immunization registries might play a role in resolving this issue; however, most existing immunization registries do not include information regarding adults. Until immunization registries routinely include this information, the primary-care provider and/or health department should be notified when a vaccine is administered in a nontraditional setting so that patient immunization records can be updated. In addition, vaccinees should be provided with wallet-sized vaccine records. These efforts will help ensure that adults are offered appropriately timed vaccines and that their vaccination status is accessible to their health-care provider in traditional or nontraditional settings and to other health-care providers who might offer them vaccines in nontraditional settings.

Liability of Health-Care Providers

Many workshop participants considered liability protection for health-care providers an important component of any adult immunization program. Health-care providers might be more likely to promote and administer vaccines if they could be assured of not being held liable for incidents of rare but serious adverse reactions to vaccines.

Legal Regulations

Workshop participants described several restrictive legal regulations regarding the administration of vaccines. In many states, legislation restricts who can administer vaccines and under what circumstances. In some areas, new immunization programs that might reach populations at high risk for disease could be hampered by restrictive legal regulations.

Integrating Vaccine Programs in Nontraditional and Traditional Settings

One challenge of offering vaccines in a setting that does not provide other preventive services is fragmentation of care. Workshop participants acknowledged the importance of having a medical home to ensure appropriate and comprehensive preventive care, early diagnosis, and optimal therapy. Immunization programs in nontraditional settings should facilitate identification of medical homes for medically underserved adults who need a health-care provider. To promote integration of preventive care

*Influenza vaccine should not be routinely administered more than once during an influenza season (18). Revaccination with pneumococcal vaccine one time, at least 5 years after initial vaccination, is recommended for persons at highest risk for pneumococcal infection (e.g., persons who are immunocompromised or who are asplenic) and those most likely to have a rapid decline in antibody concentrations. In addition, for persons vaccinated before age 65 years, a second dose should be administered at age ≥ 65 years, provided that ≥ 5 years have elapsed since the first dose (19).

services when an adult with a regular primary-care provider is vaccinated in a nontraditional setting, the primary-care provider should be notified by the vaccine provider of the patient's vaccination status. Vaccination status is often a marker for other health-care needs. Therefore, adults seeking vaccines in nontraditional settings also might need other preventive health services (e.g., mammograms and lipid screenings). In addition, these programs need systematic procedures (e.g., providing lists of nearby physicians and offering to schedule appointments) to ensure that referrals to primary-care providers are offered when appropriate and that relevant health promotion and disease prevention literature are available on site.

Quality of Services

The mission of an immunization program and the motivation of the health-care providers who operate the program might affect the quality of services provided. Important components of quality care when administering vaccines in nontraditional settings include a) ability to handle adverse reactions, b) notification of the primary-care provider or health department when vaccines are administered, c) physician referral services, and d) providing education regarding other key preventive health measures.

FUTURE CONSIDERATIONS AND PRIORITIES

The conclusions reached by workshop participants were based primarily on expert opinion and anecdotal information. Both workshop participants and NVAC recognize the need for research targeted at providing data that addresses the effectiveness of immunization programs in nontraditional settings in reaching previously unvaccinated adults.

NVAC recommends that program evaluation be conducted to determine the impact of immunization programs in nontraditional settings on vaccine coverage rates and vaccine-preventive disease rates among adults. Specifically, the following concerns should be addressed:

- Determine characteristics of persons receiving vaccine in nontraditional settings, including demographic characteristics, previous vaccine-seeking behavior, and previous and anticipated future use of the traditional medical system. A survey of persons using nontraditional settings for vaccination could provide these data.
- Determine characteristics of programs successfully reaching hard-to-reach, previously unvaccinated adults. Demonstration projects, including various types of programs (e.g., those operated by service versus for-profit organizations) in different locations, including churches, work sites, and pharmacies, need to be assessed to determine which combination of features creates the most successful program.
- Catalogue the types of services provided. The catalogue could include the following features: reporting to primary-care physician, referral to physician, provision of educational materials regarding the importance of other preventive care measures, the number of programs offering each service, and the effect of these services on program operating costs.

- Determine if the nontraditional settings in which vaccines are administered are accessible locations and settings in which medically underserved populations feel comfortable receiving vaccine. This information could be obtained by surveying these adults.
- Determine the potential effect of liability protection on physician practice patterns by surveying physicians.
- Determine reasons nonphysician providers in some states are not allowed to administer vaccines in nontraditional settings. These reasons could be addressed by surveying state legislators and health officials.

GUIDANCE FROM NVAC FOR CONDUCTING ADULT IMMUNIZATION PROGRAMS IN NONTRADITIONAL SETTINGS

Although no formalized, coordinated effort to provide vaccinations in nontraditional settings exists at the national level, many adults are already receiving vaccine in these settings. To ensure the safety of persons receiving vaccines in these settings, NVAC has established seven quality standards for vaccine providers conducting or planning to conduct adult immunization programs in nontraditional settings.

Quality standards for immunization programs in nontraditional settings generally coincide with the quality standards for programs in traditional settings. NVAC's quality standards for immunization programs in nontraditional settings are consistent with existing adult immunization standards of the Advisory Committee on Immunization Practices (ACIP) (20), ACP (21), the Infectious Disease Society of America (22), and NCAI (23), with additional caveats specific to nontraditional settings.

Standard 1: Information and Education for Vaccinees

Before receiving vaccine, the vaccinee must be given information about the risks and benefits associated with vaccination, including the CDC-developed Vaccination Information Statements that address the risks and benefits for 12 commonly administered vaccines, including influenza and pneumococcal vaccines. This information should be culturally and linguistically appropriate and written at a reading level that can be easily understood. The vaccine provider should be available to accurately address questions and concerns posed by the vaccinee.

Vaccinees should also be informed regarding the importance of having a medical home and receiving other preventive medical services. In addition, health promotion and disease prevention literature should be available on site and offered to the vaccinee.

Standard 2: Vaccine Storage and Handling

Adherence to vaccine handling and storage recommendations included in vaccine package inserts is critical because mishandling and inappropriate storage can render vaccines ineffective. Influenza and pneumococcal vaccines are the primary vaccines administered in nontraditional settings. These vaccines should be stored at temperatures between 2 C and 8 C (38 F and 48 F), and records of storage temperature should

be maintained. Temperatures below freezing destroy the potency of these vaccines (24). Vaccine providers are responsible for ensuring appropriate storage of vaccines and should be trained accordingly. Storage procedures will become more complex if the types of vaccine offered in nontraditional settings increase.

Standard 3: Immunization History

Prevaccination screening interviews should be conducted and immunization histories of vaccinees obtained before administering vaccines. At a minimum, the following information should be obtained from the vaccinee: vaccines previously received, pre-existing health conditions, allergies, and adverse events that occurred after previous vaccinations. Consulting the vaccinee's medical record is the most reliable method of determining immunization status; however, this is not always feasible, especially among adults receiving vaccines in nontraditional settings. In many cases, the medical record might not be available or, if available, might not contain the most recent information, particularly if a vaccine was not administered by the vaccinee's primary-care provider. Although repeated pneumococcal vaccination (especially within 24 months) might be associated with local adverse reactions more severe than those occurring after initial vaccination (19,25), ACIP and ACP recommend that the vaccine be offered when vaccination status cannot be determined (19,21).

Standard 4: Contraindications

Before administering vaccine, vaccine providers must assess the presence of contraindications. This assessment, part of the process of assessing the vaccinee's immunization history (Standard 3), should be made during the prevaccination screening interview. If a contraindication to immunization exists, this information should be provided to the primary-care provider or local health department and the vaccinee.

Severe systemic hypersensitivity reactions (including anaphylaxis) to egg protein, gelatin, neomycin, or streptomycin are contraindications for vaccines that contain these products (e.g., influenza vaccines). Live virus vaccines are generally contraindicated for adults who are immunocompromised and for women who are pregnant. These important contraindications affect only a small number of adults. Adults who need vaccine are more likely to not be offered it because of misconceptions concerning contraindications (see Box).

Standard 5: Recordkeeping

Each time an adult receives a dose of vaccine, the following information should be recorded: vaccinee's name, age, preexisting health conditions, type of vaccine, dose, site and route of administration, name of the vaccine provider, date vaccine was administered, manufacturer and lot number, and date that the next dose is due. If possible, this information should be recorded in the vaccinee's medical file, sent to their primary-care provider, and given to the vaccinee. Retrievable files also should be maintained by the vaccine provider in compliance with general medical practice and state requirements.

Many adults do not have a primary-care provider and, even if they do, vaccine is often not administered by their primary-care provider. Geographic and occupational

mobility, changes in sources of health care, and economic factors often cause adults to see several health-care providers throughout their lifetime. As a result, vaccination records are often dispersed among a number of health-care providers. When vaccine is administered by a health-care provider other than the vaccinee's primary-care provider (e.g., vaccine received in a nontraditional setting), a vaccine card with the information noted in this standard should be provided to the primary-care provider or local health department (if no such provider can be identified) and the vaccinee. When possible, reminder notices should be sent to adults alerting them of when they are due for another vaccination.

BOX. Contraindications to Immunization***True Contraindications
(Do Not Administer Vaccine)**

- Anaphylactic reaction to a vaccine.
- Anaphylactic reaction to a vaccine component.
- Moderate or severe illness with or without fever.
- Pregnancy.
- Compromised immune system.

**False Contraindications
(Vaccine May be Administered)**

- Mild to moderate local reaction following a dosage of an injectable antigen.
- Low-grade or moderate fever following a previous vaccine dosage.
- Mild acute illness with or without fever.
- Current antimicrobial therapy.
- Convalescent phase of illness.
- Prematurity.
- Recent exposure to an infectious disease.
- History of penicillin or other nonspecific allergies or fact that relatives have such allergies.
- Pregnancy of mother or household contact.
- Unvaccinated household contact.
- Breast-feeding.

*This table is a modified version of the National Vaccine Advisory Committee's Standards for Pediatric Immunization Practices (CDC. Standards for pediatric immunization practices: recommendations of the National Vaccine Advisory Committee. MMWR 1993;42[No. RR-5]). Please consult with CDC's National Immunization Program for updates.

Standard 6: Vaccine Administration

Health-care providers who administer vaccine must have the legal authority to do so and must be appropriately trained and licensed in all aspects of vaccine administration, including a) proper storage and handling of vaccines, b) information to be elicited from clients before vaccination (Standard 3), c) information to be given to clients before vaccination (Vaccine Information Statements), d) techniques for vaccine administration (20), and e) ability to handle adverse reactions.

Specific information regarding the recommended route of administration and appropriate dose is included in the package insert of each vaccine. Most vaccines are administered intramuscularly or subcutaneously. The dose indicated in the insert should be the dose administered. Administering one half of the recommended dose to potentially reduce the risk for adverse reaction has not been demonstrated to be an effective method of reducing adverse reactions and could result in inadequate protection against disease (26).

Standard 7: Adverse Events

Vaccine providers must be trained to recognize and treat adverse reactions, and the equipment needed to do so must be available on site. Vaccines are safe and effective; however, adverse events, ranging from minor, local reactions to severe systemic illness, occasionally occur following vaccination. Although severe, systemic reactions are rare, they can be life-threatening. Vaccine providers should be trained to use medications (epinephrine, atropine, and sodium bicarbonate) and conduct procedures necessary to maintain the airway and manage cardiovascular collapse (basic and advanced cardiopulmonary resuscitation [CPR], operation of a defibrillator, and use of a self-reinflating ventilating bag [Ambu bag] to provide positive pressure ventilation during resuscitation). Vaccine providers must be in close proximity to a telephone so that emergency medical personnel can be summoned immediately, if necessary.

Vaccinees should be monitored for adverse reactions after receiving vaccine. If a severe adverse reaction occurs while the vaccinee is on site or any time after receiving vaccine, the primary-care provider or local health department should be notified.

To improve knowledge about vaccines and vaccine-associated adverse reactions, all serious adverse events should be reported to the Vaccine Adverse Event Reporting System (VAERS) (21). VAERS reporting forms and assistance can be obtained by telephone (1-800-822-7967) or through the CDC Internet site at <<http://www.cdc.gov/nip/vaers.htm>>.

CONCLUSION

The ability of vaccines to save lives and prevent suffering extends beyond childhood. As with childhood vaccines, adult vaccines are a cost-effective means of preventing disease (27,28). To realize these benefits, vaccines must be made readily available to the public. Although rates of vaccine coverage among adults are increasing, many adults (especially among economically disadvantaged, inner city, and minority populations) are not receiving appropriate vaccinations (2). Enhancing educational efforts and increasing the number and types of programs (e.g., standing orders [29] and non-traditional settings) safely administering vaccine to adults might increase the number of adults receiving vaccines and the associated benefits.

Educating health-care providers and the public is the cornerstone of an effective vaccination strategy. The Adult Immunization Action Plan (1) emphasizes the need for physicians and other health-care providers to recognize both the severity of influenza and pneumococcal disease and the safety and effectiveness of vaccines so they consistently offer vaccines to their patients. Physicians' recommendations influence patients' decisions to receive vaccine, regardless of the patients' initial attitude (6). However, some adults who need vaccination receive medical care but are not offered vaccine, whereas others might not have regular contact with traditional health-care settings. For these reasons, increased efforts to educate the public as well as health-care providers are needed. The 1994 NVAC report on adult immunization concluded that "better public understanding of the seriousness of vaccine-preventable diseases and the benefits of vaccination will be essential if there are to be improvements in adult immunization" (30).

An essential step toward creating an effective immunization infrastructure integrating traditional and nontraditional immunization programs is to determine the role each type of program has in the overall immunization strategy. Data from immunization programs in traditional and nontraditional settings are needed to assess who receives vaccine in which settings and why they choose that setting. Data characterizing persons who do not receive vaccine and their reasons for not getting vaccinated also are needed. These data will facilitate the development of a comprehensive immunization strategy to increase immunization coverage in all segments of the adult population.

Integration of nontraditional immunization programs with the existing health-care infrastructure provides the potential to increase vaccine coverage rates and decrease vaccine-preventable diseases among adults. To do so most effectively, the specific contributions of immunization programs in traditional and nontraditional settings need to be established, and the quality standards in this report need to be implemented. The efforts that effectively lowered vaccine-preventable disease rates among children now need to be targeted toward developing new and effective immunization programs that will make appropriate vaccines readily accessible to adults.

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Use of Standing Orders Programs to Increase Adult Vaccination Rates

**Recommendations of the Advisory
Committee on Immunization Practices**

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Use of Standing Orders Programs to Increase Adult Vaccination Rates

Recommendations of the Advisory Committee on Immunization Practices

Summary

The Advisory Committee on Immunization Practices recognizes the need for evidence-based policy to improve the delivery and receipt of immunization services recommended for adults (i.e., persons aged ≥ 18 years). Two recent, systematic reviews of the health services research literature recommended standing orders programs as an effective organizational intervention to improve vaccination coverage rates among adults. This report briefly reviews the evidence on the effectiveness of standing orders programs, describes standards for program implementation, and recommends initiating these programs to improve immunization coverage in several traditional and nontraditional settings.

INTRODUCTION

Standing orders programs authorize nurses and pharmacists to administer vaccinations according to an institution- or physician-approved protocol without a physician's exam. These programs have documented improved vaccination rates among adults. Standing orders programs can be used in inpatient and outpatient facilities, long-term-care facilities, managed-care organizations, assisted living facilities, correctional facilities, pharmacies, adult workplaces, and home health-care agencies to vaccinate patient, client, resident, and employee populations. The Advisory Committee on Immunization Practices (ACIP) recommends standing orders for influenza and pneumococcal vaccinations (1,2). Recently, systematic literature reviews by the Task Force for Community Preventive Services (3) and the Southern California Evidence-Based Practice Center–RAND endorsed these programs for adult populations (4).

This report briefly reviews the evidence regarding the effectiveness of standing orders programs in improving adult vaccination coverage rates and recommends prioritizing these programs for influenza and pneumococcal vaccinations, to have the greatest impact on the burden of vaccine-preventable diseases in the United States. Standing orders programs are also recommended for other vaccines, including hepatitis B vaccine and diphtheria and tetanus toxoid vaccines, when feasible.

BACKGROUND

Epidemics of influenza occur during the winter months nearly every year and are responsible for an average of approximately 20,000 deaths per year in the United States (5,6). Influenza viruses cause disease in all age groups (7,8), but rates of serious morbidity and mortality are highest among persons aged ≥ 65 years and persons of any age who have medical conditions that place them at high risk for complications from influ-

enza (2,9–11). Pneumococcal disease accounts for approximately 3,000 cases of meningitis, 50,000 cases of bacteremia, and 500,000 cases of pneumonia each year (1) and is responsible for more deaths than any other vaccine-preventable bacterial disease (12). Despite antimicrobial therapy and intensive medical care, the overall case-fatality rate for pneumococcal bacteremia is 15%–20% among adults (i.e., persons aged ≥ 18 years) (1). Among persons aged ≥ 65 years, case-fatality rates can be as high as 40% (13).

In recent years, a rapid emergence of antimicrobial resistance among pneumococci, especially to penicillin, has occurred. Increasing pneumococcal vaccination rates could help prevent invasive pneumococcal disease caused by vaccine-type, multidrug-resistant pneumococci. Outbreaks of pneumococcal disease caused by a single drug-resistant pneumococcal serotype have occurred in institutional settings, including nursing homes (14,15). In 1999, because of concerns about pneumococcal antimicrobial resistance and underuse of pneumococcal vaccine, the American Medical Association and several partner organizations issued a Quality Care Alert that supports ACIP's recommendations for pneumococcal vaccination (16).

Health services research indicates that influenza and pneumococcal vaccines are underused in institutional settings, even after they became covered benefits of Medicare Part B (1981 for pneumococcal vaccine and 1993 for influenza vaccine) (17,18). Despite the availability of suitable vaccines, persons hospitalized with conditions for which influenza and pneumococcal vaccines are indicated are not usually assessed for vaccination status or vaccinated. Among persons who reported at least one hospitalization during the preceding year to the 1997 National Health Interview Survey, 83% of persons aged 18–64 years with medical conditions that put them at high risk and 55% of all persons aged ≥ 65 years reported not receiving pneumococcal vaccinations (CDC, unpublished data, 1999). Sixty-nine percent of persons aged 18–64 years with medical conditions that put them at high risk and 32% of all persons aged ≥ 65 years reported not receiving influenza vaccination (CDC, unpublished data, 1999). In 12 western states, 80% of Medicare beneficiaries hospitalized for pneumonia during September–December 1994 did not receive influenza vaccines; 65% did not receive pneumococcal vaccines (17). The 1995 National Nursing Home Survey estimated influenza and pneumococcal vaccination rates among residents in long-term-care facilities to be approximately 63% and 22%, respectively (18). These rates are far below the *Healthy People 2010* objective of 90% for both vaccines among all persons aged ≥ 65 years (objective 14-29) (19). Coverage estimates for 1997 were approximately 64% for influenza vaccines and 28% for pneumococcal vaccines (CDC, unpublished data, 1999). Many long-term-care facilities have inadequate policies and procedures to prevent vaccine-preventable diseases among their vulnerable populations (20).

Several studies suggest that standing orders programs are more effective than other institution-based strategies in improving vaccination services. In one New York hospital, instituting a standing orders program for pneumococcal vaccination among persons aged ≥ 65 years and other patients at high risk increased the pneumococcal vaccination rate from 0% to 78% (21). In another study, pharmacists increased pneumococcal vaccination rates from 4.2% to 94% in one nursing facility and from 1.9% to 83% in a second facility, whereas the rates at a control facility increased from 0.9% to 4.0% (22). In a study of six small community hospitals in northern Minnesota, standing orders programs achieved an influenza vaccination rate of 40.3% among patients, compared with 17% using physician reminders and 9.6% using educational programs (23).

A study conducted in an ambulatory care clinic compared the use of nurse standing orders combined with other interventions, including patient and health-care provider reminders, with the use of patient and provider reminders alone. Pneumococcal vaccination rates per total patient population were 22%–25% for the nurse standing orders programs, compared with 5% when patient and provider reminders were used alone (24).

Based on the scientific evidence of effectiveness in improving vaccination rates in institutions, the Task Force for Community Preventive Services and the Southern California Evidence-Based Practice Center–RAND recommend standing orders programs for the vaccination of adults in hospitals, clinics, and nursing homes (3,4). Standing orders policies are acceptable to most primary-care physicians (25) and have resulted in higher vaccination rates than other vaccination delivery methods (4,26).

IMPLEMENTATION GUIDELINES

Successful standing orders programs begin by documenting a plan for the program's infrastructure, key service-delivery components, and quality assurance. To ensure success, a committee should be formed that includes the organization's medical director, nursing director, infection-control and quality-control personnel, and medical or nursing staff representatives. This committee should write protocols for the following procedures:

- Identifying persons eligible for vaccination based on their age, their vaccination status (e.g., persons previously unvaccinated or due for vaccination according to the recommended schedule), or the presence of a medical condition that puts them at high risk.
- Providing adequate information to patients or their guardians regarding the risks for and benefits of a vaccine and documenting the delivery of that information.
- Recording patient refusals or medical contraindications.
- Recording administration of a vaccine(s) and any postvaccination adverse events, according to institution- or physician-approved protocol.
- Providing documentation of vaccine administration to patients and their primary-care providers.

Standing orders protocols should also specify that vaccines be administered by health-care professionals trained to a) screen patients for contraindications to vaccination, b) administer vaccines, and c) monitor patients for adverse events, in accordance with state and local regulations. Vaccine information statements developed by and available from CDC can be useful for risk/benefit counseling before administering a vaccine. All health-care personnel administering vaccines or providing care to vaccinated persons should be trained to report adverse outcomes to the Vaccine Adverse Events Reporting System (VAERS). The appropriate VAERS forms and contact information should be readily available in all facilities delivering vaccines.

The standards for adult immunization practice established by the National Coalition for Adult Immunization recommend that standing orders programs include a standard personal and institutional immunization record to verify the immunization status of

patients and staff members and to reduce the risk for inappropriate revaccination (27). A patient's primary-care provider should be able to override institutional standing orders when medically appropriate. Ongoing communication between the primary-care provider, vaccinee, and institutional staff members is recommended to reduce the possibility of inappropriate vaccinations.

None of the studies of standing orders programs for influenza and pneumococcal vaccination reported unnecessary or inappropriate vaccinations (3,4,21–23,26). If repeated pneumococcal vaccinations did occur, studies have indicated that the risk for adverse events beyond self-limited local reactions was minimal for a second dose administered 2–5 years after the primary dose (1,28). The risk for self-limited local injection site reactions does not represent a contraindication to revaccination with pneumococcal vaccine in recommended groups.

The policies and protocols for standing orders programs should include a quality assurance process to maintain appropriate standards of care. The feasibility and cost-effectiveness of standing orders programs in several settings need ongoing evaluation, with particular attention to safety and tracking of vaccinations (29). For example, preprinted admissions orders could improve the effectiveness of program staff members to assess the vaccination status of patients and to provide information about the risks for and benefits of administering vaccinations routinely upon admission to facilities.

Facility staff members should consider other potential benefits (e.g., sustainability over time) when developing standing orders programs (30). These programs could be adapted to other preventive services (e.g., mammography) to improve delivery of those services, and they could be used to improve clinic efficiency by reducing pressures on physicians' time (3).

CONCLUSION

ACIP recommends that standing orders programs be used in long-term-care facilities under the supervision of a medical director to ensure the administration of recommended vaccinations for adults. ACIP also encourages the introduction of standing orders programs for vaccination of adults in other settings (e.g., inpatient and outpatient facilities, managed-care organizations, assisted living facilities, correctional facilities, pharmacies, adult workplaces, and home health-care agencies). Implementation of standing orders programs alone or combined with other effective interventions can help improve vaccination coverage by institutional providers (3,4,31). Because of the societal burden of influenza and pneumococcal disease, implementation of standing orders programs to improve adult vaccination coverage for these diseases should be a national public health priority.

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SHEA GUIDELINE

SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus

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EXECUTIVE SUMMARY

This guideline provides the updated recommendations of the Society for Healthcare Epidemiology of America (SHEA) regarding the management of healthcare providers who are infected with hepatitis B virus (HBV), hepatitis C virus (HCV), and/or the human immunodeficiency virus (HIV). For the reasons cited in the guideline, SHEA continues to recommend that, although some aspects of the approach to and administrative management of each of these infectious syndromes in healthcare providers are similar, separate management strategies for healthcare workers who are infected with these unrelated viruses remain appropriate. As we did in both prior iterations of this document, SHEA emphasizes the use of appropriate infection control procedures to minimize exposure of patients or providers to blood, emphasizes that transfers of blood from patients to providers and from providers to patients should be avoided, and recommends that infected healthcare providers should not be totally prohibited from participating in patient-care activities solely on the basis of a bloodborne pathogen infection. The types of procedures assessed by the panel as associated with an increased risk for provider-to-patient transmission of these pathogens are discussed in detail. For each pathogen, recommendations are graduated according to the relative viral load level of the infected provider (Tables 1 and 2). However, SHEA emphasizes that, because of the complexity of these cases, each such case will be slightly different from the next, and each should be independently considered in context.

HBV

SHEA recommends that HBV-infected healthcare providers who test either positive for HBV “e” antigen (HBeAg) or

negative for HBeAg but who have circulating HBV burdens of greater than or equal to 10^4 genome equivalents (GE) per milliliter of blood routinely use double-gloving for all invasive procedures, for all contact with mucous membranes or non-intact skin, and for all instances in patient care for which gloving is recommended, and that they not perform those Category III activities identified as associated with a risk for provider-to-patient HBV transmission despite the use of appropriate infection control procedures (details of the procedures identified as associated with increased risk for transmission are given in Table 2).

SHEA recommends that a healthcare provider who has a circulating HBV burden of less than 10^4 GE/mL be allowed to perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogens, so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel (the function of the Expert Review Panel is discussed in more detail in Recommendation 8, below) about continued practice; (3) undergoes follow-up routinely by Occupational Medicine staff (or an appropriate public health official), who test the provider twice per year to demonstrate the maintenance of a viral burden of less than 10^4 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HBV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly

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TABLE 1. Summary Recommendations for Managing Healthcare Providers Infected with Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and/or Human Immunodeficiency Virus (HIV)

Virus, circulating viral burden	Categories of clinical activities ^a	Recommendation	Testing
HBV			
<10 ⁴ GE/mL	Categories I, II, and III	No restrictions ^b	Twice per year
≥10 ⁴ GE/mL	Categories I and II	No restrictions ^b	NA
≥10 ⁴ GE/mL	Category III	Restricted ^c	NA
HCV			
<10 ⁴ GE/mL	Categories I, II, and III	No restrictions ^b	Twice per year
≥10 ⁴ GE/mL	Categories I and II	No restrictions ^b	NA
≥10 ⁴ GE/mL	Category III	Restricted ^c	NA
HIV			
<5 × 10 ² GE/mL	Categories I, II, and III	No restrictions ^b	Twice per year
≥5 × 10 ² GE/mL	Categories I and II	No restrictions ^b	NA
≥5 × 10 ² GE/mL	Category III	Restricted ^d	NA

NOTE. These recommendations provide a framework within which to consider such cases; however, each such case is sufficiently complex that each should be independently considered in context by the expert review panel (see text). GE, genome equivalents; NA, not applicable.

^a See Table 2 for the categorization of clinical activities.

^b No restrictions recommended, so long as the infected healthcare provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine staff (or an appropriate public health official), who test the provider twice per year to demonstrate the maintenance of a viral burden of less than the recommended threshold (see text); (4) also receives follow-up by a personal physician who has expertise in the management of her or his infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]), and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (see text).

^c These procedures permissible only when viral burden is <10⁴ GE/mL.

^d These procedures permissible only when viral burden is <5 × 10² GE/mL.

if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below).

HCV

SHEA recommends that HCV-infected providers who have circulating HCV viral burdens of greater than or equal to 10⁴ GE/mL routinely use double-gloving for all invasive procedures, for all contact with mucous membranes or nonintact skin, and for all instances in patient care for which gloving is routinely recommended, and that they not perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogen infection despite the use of appropriate infection control procedures. SHEA also recommends that an HCV-infected provider who has a viral burden of less than 10⁴ GE/mL not be excluded from any aspect of patient care, including the performance of Category III procedures (Tables 1 and 2), so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert

Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine, who tests the provider twice annually to demonstrate the maintenance of a viral burden of less than 10⁴ GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HCV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an infection control expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving during Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below).

HIV

SHEA recommends that HIV-infected providers who have circulating HIV viral burdens of greater than or equal to

5×10^2 GE/mL routinely use double-gloving for all invasive procedures, for all contact with mucous membranes or non-intact skin, and for all instances in patient care for which gloving is recommended, and that they not perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogen infection despite the use of appropriate infection control procedures (Tables 1 and 2). SHEA recommends that an HIV-infected provider who has a viral burden of less than 5×10^2 GE/mL not be excluded from any aspect of patient care, including the performance of Category III procedures, so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine (or an appropriate public health official), who tests the provider twice annually to demonstrate the maintenance of a viral burden of less than 5×10^2 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HIV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below).

General Recommendations

The rationale for these recommendations is presented below (in the section Background and Rationale). SHEA argues for comprehensive education concerning bloodborne pathogens for all healthcare providers and trainees. SHEA recommends managing infected providers in the context of a comprehensive approach to the management of all impaired providers. SHEA emphasizes the importance of patient safety as well as provider privacy and medical confidentiality. The Society also emphasizes the importance of offering employees who have disabilities reasonable accommodation for their disabilities. The guideline discusses exposure management in detail and, in general, recommends adherence to existing guidelines for managing exposures to these viruses. SHEA underscores that practitioners who are institutionally based and who develop one of these bloodborne pathogen infections are ethically bound to report their infections to their institutions' occupational medicine providers and to engage in the processes outlined below. Further, practitioners who are not institutionally based and who develop one of these bloodborne pathogen infections are ethically bound to engage their public health departments (consonant with state and local laws), as

described below. Finally, the society encourages routine voluntary, confidential testing of providers, emphasizing that providers who conduct Category III procedures should know their immune or infection status with respect to each of these 3 bloodborne pathogens. Specific details and the rationale for these recommendations are included in the body of the guideline.

INTRODUCTION

In 1990, in response to public and professional concern that arose in the wake of a highly publicized cluster of cases of provider-to-patient transmission of the human immunodeficiency virus (HIV) in a Florida dentist's practice,³⁻⁸ SHEA, in collaboration with the Association for Practitioners in Infection Control, published a position paper concerning the administrative management of healthcare providers who are infected with certain bloodborne pathogens.⁹ As additional information became available, in 1997 SHEA issued an updated position paper discussing the management of healthcare workers infected with hepatitis B virus (HBV), hepatitis C virus (HCV), HIV, or other bloodborne pathogens.¹⁰ The purpose of the present guideline is to provide updated guidance from SHEA regarding the administrative management of providers infected with these bloodborne pathogens, given the progress in the field since 1997.

Despite the widespread use of the hepatitis B vaccine, HBV remains the most commonly transmitted bloodborne pathogen in the healthcare setting. Although continued widespread administration of the vaccine should eventually mitigate this risk, any guideline for the years 2009 and beyond must include recommendations for HBV-infected providers. Similarly, the past 12 years' experience has provided insight in the factors influencing the risk for provider-to-patient transmission of HCV. Because we do not have a hepatitis C vaccine yet, and, with the prevalence of HCV infection rising around the world, this flavivirus is likely to become the most frequently transmitted bloodborne pathogen in health care in the years ahead. Provider-to-patient transmission of HIV has been extremely rare, with no cases reported worldwide since 2003. Nonetheless, the first instance of transmission of HIV from an infected provider to a patient was the driving force for the creation of guidelines and recommendations about providers infected with bloodborne pathogens.

This document provides updated information about each virus and the healthcare risks associated with infected practitioners and then addresses a series of questions relevant to the management of providers infected with each of these viruses. We then make recommendations about the management of providers infected with these bloodborne pathogens, citing the available evidence supporting the recommendations. The evidence base for these recommendations is limited at best. By the very nature of the topics being discussed, direct hypothesis-driven experimentation is virtually impossible, and may be complicated further by a low rate of voluntary

TABLE 2. Categorization of Healthcare-Associated Procedures According to Level of Risk for Bloodborne Pathogen Transmission

Category I: Procedures with de minimis risk of bloodborne virus transmission

- Regular history-taking and/or physical or dental examinations, including gloved oral examination with a mirror and/or tongue depressor and/or dental explorer and periodontal probe
- Routine dental preventive procedures (eg, application of sealants or topical fluoride or administration of prophylaxis^a), diagnostic procedures, orthodontic procedures, prosthetic procedures (eg, denture fabrication), cosmetic procedures (eg, bleaching) not requiring local anesthesia
- Routine rectal or vaginal examination
- Minor surface suturing
- Elective peripheral phlebotomy^b
- Lower gastrointestinal tract endoscopic examinations and procedures, such as sigmoidoscopy and colonoscopy
- Hands-off supervision during surgical procedures and computer-aided remote or robotic surgical procedures
- Psychiatric evaluations^c

Category II: Procedures for which bloodborne virus transmission is theoretically possible but unlikely

- Locally anesthetized ophthalmologic surgery
- Locally anesthetized operative, prosthetic, and endodontic dental procedures
- Periodontal scaling and root planing^d
- Minor oral surgical procedures (eg, simple tooth extraction [ie, not requiring excess force], soft tissue flap or sectioning, minor soft tissue biopsy, or incision and drainage of an accessible abscess)
- Minor local procedures (eg, skin excision, abscess drainage, biopsy, and use of laser) under local anesthesia (often under bloodless conditions)
- Percutaneous cardiac procedures (eg, angiography and catheterization)
- Percutaneous and other minor orthopedic procedures
- Subcutaneous pacemaker implantation
- Bronchoscopy
- Insertion and maintenance of epidural and spinal anesthesia lines
- Minor gynecological procedures (eg, dilatation and curettage, suction abortion, colposcopy, insertion and removal of contraceptive devices and implants, and collection of ova)
- Male urological procedures (excluding transabdominal intrapelvic procedures)
- Upper gastrointestinal tract endoscopic procedures
- Minor vascular procedures (eg, embolectomy and vein stripping)
- Amputations, including major limbs (eg, hemipelvectomy and amputation of legs or arms) and minor amputations (eg, amputations of fingers, toes, hands, or feet)
- Breast augmentation or reduction
- Minimum-exposure plastic surgical procedures (eg, liposuction, minor skin resection for reshaping, face lift, brow lift, blepharoplasty, and otoplasty)
- Total and subtotal thyroidectomy and/or biopsy
- Endoscopic ear, nose, and throat surgery and simple ear and nasal procedures (eg, stapedectomy or stapedotomy, and insertion of tympanostomy tubes)
- Ophthalmic surgery
- Assistance with an uncomplicated vaginal delivery^e
- Laparoscopic procedures
- Thoracoscopic procedures^f
- Nasal endoscopic procedures^g
- Routine arthroscopic procedures^h
- Plastic surgeryⁱ
- Insertion of, maintenance of, and drug administration into arterial and central venous lines
- Endotracheal intubation and use of laryngeal mask
- Obtainment and use of venous and arterial access devices that occur under complete antiseptic technique, using universal precautions, “no-sharp” technique, and newly gloved hands

Category III: Procedures for which there is definite risk of bloodborne virus transmission or that have been classified previously as “exposure-prone”

- General surgery, including nephrectomy, small bowel resection, cholecystectomy, subtotal thyroidectomy other elective open abdominal surgery
 - General oral surgery, including surgical extractions,^j hard and soft tissue biopsy (if more extensive and/or having difficult access for suturing), apicoectomy, root amputation, gingivectomy, periodontal curettage, mucogingival and osseous surgery, alveoplasty or alveoectomy, and endosseous implant surgery
-

TABLE 2. (Continued)

- Cardiothoracic surgery, including valve replacement, coronary artery bypass grafting, other bypass surgery, heart transplantation, repair of congenital heart defects, thymectomy, and open-lung biopsy
- Open extensive head and neck surgery involving bones, including oncological procedures
- Neurosurgery, including craniotomy, other intracranial procedures, and open-spine surgery
- Nonelective procedures performed in the emergency department, including open resuscitation efforts, deep suturing to arrest hemorrhage, and internal cardiac massage
- Obstetrical/gynecological surgery, including cesarean delivery, hysterectomy, forceps delivery, episiotomy, cone biopsy, and ovarian cyst removal, and other transvaginal obstetrical and gynecological procedures involving hand-guided sharps
- Orthopedic procedures, including total knee arthroplasty, total hip arthroplasty, major joint replacement surgery, open spine surgery, and open pelvic surgery
- Extensive plastic surgery, including extensive cosmetic procedures (eg, abdominoplasty and thoracoplasty)
- Transplantation surgery (except skin and corneal transplantation)
- Trauma surgery, including open head injuries, facial and jaw fracture reductions, extensive soft-tissue trauma, and ophthalmic trauma
- Interactions with patients in situations during which the risk of the patient biting the physician is significant; for example, interactions with violent patients or patients experiencing an epileptic seizure
- Any open surgical procedure with a duration of more than 3 hours, probably necessitating glove change

NOTE. Modified from Reitsma et al.¹

^a Does not include subgingival scaling with hand instrumentation.

^b If done emergently (eg, during acute trauma or resuscitation efforts), peripheral phlebotomy is classified as Category III.

^c If there is no risk present of biting or of otherwise violent patients.

^d Use of an ultrasonic device for scaling and root planing would greatly reduce or eliminate the risk for percutaneous injury to the provider. If significant physical force with hand instrumentation is anticipated to be necessary, scaling and root planing and other Class II procedures could be reasonably classified as Category III.

^e Making and suturing an episiotomy is classified as Category III.

^f If unexpected circumstances require moving to an open procedure (eg, laparotomy or thoracotomy), some of these procedures will be classified as Category III.

^g If moving to an open procedure is required, these procedures will be classified as Category III.

^h If opening a joint is indicated and/or use of power instruments (eg, drills) is necessary, this procedure is classified as Category III.

ⁱ A procedure involving bones, major vasculature, and/or deep body cavities will be classified as Category III.

^j Removal of an erupted or nonerupted tooth requiring elevation of a mucoperiosteal flap, removal of bone, or sectioning of tooth and suturing if needed.²

reporting of both infection status and high-risk provider-to-patient transmission events. Most data that we have about this subject come from documented instances of transmission. Many if not most of the conclusions from these studies are inferential. Some evidence comes from experimental laboratory studies or models. Thus, this guideline cannot have the scientific evidence-base found in many other guidelines. Nonetheless, we do have a broad experience working with these pathogens in the healthcare setting and the science base is much more robust than it was at the time the last guidance was published by SHEA in 1997.

EPIDEMIOLOGY

Provider-to-Patient Transmission of HBV

With respect to HBV transmission, through 1994, investigators at the Centers for Disease Control and Prevention (CDC) had identified 42 instances of provider-to-patient transmission of HBV (375 patients).¹¹ Subsequently, 2 additional clusters of provider-to-patient transmission of HBV infection were reported that involved surgeons who tested positive for HBeAg.^{12,13}

In one of these more recent clusters, 4 patients acquired

clinical hepatitis B infection from an orthopedic surgeon following surgeries conducted by the infected provider.¹³ In a second, more recent cluster, 19 of the 144 susceptible patients whose surgical team included an HBV-infected thoracic surgery resident became infected.¹² No specific events or breaks in technique were identified in either cluster that could explain the transmissions, although the thoracic surgery resident did not wear double gloves. Since 1996, there have been an additional 10 reports of hepatitis B transmission from providers to patients. These cases have generally been associated with HBV-infected surgeons; one case was associated with an infected dentist^{14,15} (I. Williams, CDC, personal communication). An important report from the United Kingdom underscored the potential for transmission from providers who are infected with so-called “pre-core” mutants of HBV.¹⁴ Such providers are HBeAg negative but have a high circulating viral burden. This report¹⁴ underscores the importance of directly measuring viral burden, as opposed to assaying for surrogate markers of viral burden (such as HBeAg). Only one relatively recent report is from North America: in this large outbreak, 75 patients were infected from procedures involving placement of subdermal electroencephalogram electrodes by

an HBeAg-positive technician.¹⁶ Although infection control procedures in this electroencephalography clinic were deemed inadequate, no specific mechanism for transmission was identified.

Although such clusters continue to occur (acknowledging that the United States does not have systemic surveillance measures to detect such cases), they appear to be occurring less frequently than in the past. In contrast, the problem of patient-to-patient transmission of HBV and HCV arising from inadequate infection control precautions, such as reuse of multidose vials of medication, has become increasingly important as a cause of iatrogenic bloodborne pathogen infection.¹⁷

Provider-to-Patient Transmission of HCV

Provider-to-patient transmission of HCV has been extremely uncommon in the United States and has had a reasonably unique epidemiology in this country. Conversely, transmission of HCV from infected providers has been somewhat more frequently detected in Europe (Table 3). As noted above, for all of these pathogens, provider-to-patient transmission of HCV is extremely unlikely in the course of routine (ie, non-invasive) patient care. The risk for provider-to-patient transmission of HCV appears to be even smaller than the risk for HBV transmission in the course of noninvasive patient care,

presumably because most individuals chronically infected with HCV have circulating viral loads that are orders of magnitude lower than those of the hepatitis B carriers who have been identified as transmitting infection to their patients.

Several instances of provider-to-patient transmission of HCV have been reported in the literature.^{18–32} The first documented instance of provider-to-patient transmission of HCV was reported from England in 1995 (Table 3).²³ A patient who had undergone cardiac surgery developed acute HCV infection and had no risk factors for infection. The first assistant surgeon on the operative team was found to be infected with HCV. A “look-back” study of the patients for whom the surgeon had provided care revealed that only one of the surgeon’s 278 patients developed HCV infection with a strain identical to the surgeon’s.²¹ During the time the UK investigation was in process, an additional instance of provider-to-patient transmission of HCV was reported from Spain.²² The detection of 2 unexpected cases of HCV infection among cardiac surgery patients participating in a study of transfusion-transmitted infections prompted a look-back study of the patients of a chronically HCV-infected surgeon. The Spanish look-back study identified an additional 4 HCV infections (ie, totaling 6 [2.7%] of the 222 patients who had been operated on by the surgeon).²² Five of the 6 HCV strains isolated from these patients were closely related to the strain

TABLE 3. Summary of Reports of Provider-to-Patient Hepatitis C Virus Transmission from the United Kingdom

Year	Provider’s occupation	Procedure	No. of patients tested	No. of probable cases	Transmission rate, % (95% CI)
1995	Cardiovascular surgery	Coronary artery bypass	270 ^a	1	0.37 (0.00–1.44)
1999	Gynecology	Gynecological procedure	3,628 ^b	7	0.19 (0.08–0.36)
2000	General surgery	Bowel surgery	627 ^c	2	0.32 (0.03–0.91)
2000	General surgery	Bowel surgery	1,145 ^d	4	0.35 (0.09–0.77)
2001	Obstetrics	Cesarean delivery	198 ^e	1	0.51 (0.00–1.97)
2002	Obstetrics and gynecology	Cesarean delivery	Investigation ongoing	Investigation ongoing	Investigation ongoing
2004	Obstetrics and gynecology	Cesarean delivery	Investigation ongoing	Investigation ongoing	Investigation ongoing
Overall	5,868	15	0.26 (0.13–0.38)

NOTE. Data provided by Fortune Ncube, MD, Health Protection Agency Centre for Infections, United Kingdom (personal communication). CI, confidence interval.

^a More than 97% of the procedures (ie, procedures in 270 of 278 patients) that the provider had participated in were classified by the incident team as “high-risk exposure-prone procedures.”

^b Patient notification was performed in 2 stages: the identification of 4 transmissions triggered an extension of the look-back exercise, resulting in the identification of 3 additional infections.

^c All the patients included in the analysis had procedures that met investigators’ definition of “high risk exposure-prone procedures,” and 84% (627 of 750) of the infected provider’s exposure-prone procedures were characterized as “high risk exposure-prone procedures.”

^d All these patients had undergone exposure-prone procedures. Investigators assumed that this general surgeon’s workload was similar to that of the other general surgeon (ie, 84% of exposure prone procedures were “high-risk exposure prone procedures”).

^e All the patients tested and included in the table (ie, accounting for 198 of 228 of the provider’s procedures) were patients who had high “high risk exposure-prone procedures.”

isolated from the surgeon, and each of these patients had undergone valve replacement surgery.²²

An HCV-infected gynecologist in the UK transmitted infection to several patients. After a single patient became infected after a gynecological procedure,^{24,33} a detailed look-back study tested more than 4,500 patients, of whom 3,628 had undergone “high risk, exposure-prone procedures” that were performed by the surgeon in the previous 20 years. Seven additional patients were found to have HCV infection caused by strains of HCV closely related to the strain recovered from the surgeon (Table 3).²⁶

Ross and coworkers²⁸ from Germany reported the results of a look-back study of 207 of the 229 patients operated on by an HCV-infected orthopedic surgeon. Three of the 207 were found to be HCV infected, but only 1 (a patient who had undergone a total hip arthroplasty with trochanteric osteotomy) was infected with a strain that was similar to the strain recovered from the HCV-infected orthopedist.²⁸ Subsequently, these same investigators also conducted a look-back study of the patients of an HCV-infected obstetrician/gynecologist. The look-back study was prompted by the detection of an unanticipated instance of HCV infection in a patient who had undergone a cesarean delivery. This patient was found to be infected with an HCV strain that was virtually identical to the strain infecting the obstetrician/gynecologist who had performed the procedure.²⁹ The investigators screened 2,286 of the obstetrician/gynecologist’s 2,907 patients and found no further evidence of transmission.²⁹

Three additional patient-to-provider look-back studies involving the potential for transmission of HCV from health-care worker to patient have been reported from the United Kingdom (Table 3).^{27,34,35} In the first of these studies, 3 infections (among 1,900 patients) were attributed to an HCV-infected provider. In the second, 1 infection was found among 749 patients of an HCV-infected provider.³⁵ In the third, a look-back study has been reported as being initiated in the United Kingdom, although no results from the study have been published;²⁷ letters were sent to 228 patients of an HCV-infected practitioner offering follow-up testing, after an index case was identified as linked to the practitioner following an “exposure-prone” procedure.

Several reports involve HCV-infected anesthesiologists. In the United Kingdom,³¹ an HCV-infected anesthesiologist infected a patient during a procedure in which the anesthesiologist endotracheally intubated the patient, inserted a peripheral venous catheter, and provided general anesthesia. He did not participate in any procedure considered to be “exposure-prone.” The anesthesiologist vehemently denied injection drug use³¹; however, in several similar cases described below, drug diversion was implicated as the cause of blood-borne pathogen transmission.

Ross and colleagues³⁶ reported a cluster of 5 cases of HCV infection from an anesthesia assistant. The anesthesia assistant purportedly acquired acute HCV infection as a result of an occupational exposure to an HCV-infected patient in the op-

erating room (presumably, by contaminating an open wound on a finger of his right hand). This assistant may have presented an increased risk for transmission, since he was working while developing acute HCV infection and before having a detectable immunologic response at a time when his viral burden was likely high. In the course of 3 weeks (during which his finger was purportedly still weeping) he infected 5 patients. He vehemently denied drug abuse, but the similarity of this case to the case described by Sehulster and colleagues³⁷ (discussed below) is striking. An important feature of this cluster is the fact that the anesthesia assistant did not follow universal/standard precautions. He did not wear gloves (even when he had the open lesion on his right hand). Ross and colleagues³⁶ suggest that if the anesthesia assistant had followed universal/standard precautions, these infections would have likely been prevented.

In another highly unusual case, a child acquired HCV infection from his mother, who was functioning as his health-care provider.³⁸ The child was a hemophiliac whose mother administered his frequently required clotting-factor concentrate infusions. The mother (who had chronic HCV infection) did not wear gloves and recalled several instances in which she stuck her own finger with the needle (often with her own blood visible). Sequence analysis demonstrated that the HCV isolates from the mother and the child were identical.³⁸

For reasons that are not certain, look-back studies from the United Kingdom have found substantially more cases of transmission. Grouping the various studies from the United Kingdom yields a transmission rate of 0.19% (15 patients infected of 7,656 patients tested) without inclusion of index cases, and 0.26% with the inclusion of index cases. In contrast, studies from Germany have found no additional cases of transmission among more than 3,000 people tested, beyond the index cases that prompted the look-back studies. However, if one includes the index cases, the transmission rate for these studies is 0.13% (similar to the rate for the studies from the United Kingdom).

The experience in the United States is quite different. Injection drug use on the part of the infected provider appears to play a more central role in provider-to-patient HCV transmission. Williams and colleagues³⁹ recently reviewed the US experience, noting that 4 episodes of transmission have been detected. The first involved an HCV-infected surgical technician who infected approximately 40 of 346 patients during a 3-month period.^{37,39} This healthcare provider admitted self-injecting anesthesia medications and then using the same syringe to administer drugs to patients. The second involved an anesthesiologist who acquired HCV infection from one patient and subsequently, during the anesthesiologist’s acute phase of infection, transmitted the same strain of HCV to a patient; no further transmissions were identified. This anesthesiologist was also suspected to be abusing narcotics.^{20,39} The third case of HCV transmission is more similar to those seen in the United Kingdom. An HCV-infected cardiac surgeon was found to have infected as many as 14 of the 937

patients who could be evaluated from over a decade of surgical practice.³⁹ Narcotics abuse was not suspected. Interestingly, following an expert review of the surgeon's practice, the surgeon was treated for his HCV infection and was allowed to continue to practice; he continued to perform cardiovascular procedures that would by any measure be considered exposure-prone. He made modifications to his technique, including the use of double gloves and other safety devices, and in addition, his patients were prospectively tested for HCV infection; to date no additional instances of transmission have been detected. The fourth report describes a certified registered nurse anesthetist who transmitted HCV to at least 15 of 164 patients during a 4-month period coinciding with the acute phase of his own HCV infection. The certified registered nurse anesthetist did not perform exposure-prone procedures and a specific mechanism of transmission was not identified; however, similar to the first 2 cases, the nurse anesthetist was suspected of abusing patient medications.³⁹ A fifth instance of provider-to-patient transmission of HCV in the United States is currently under investigation, but the details are not yet available (J. Perz, CDC, personal communication).

Although the precise mode of transmission for HCV for the majority of these cases remains unknown, the circumstances surrounding several of the cases suggest that transmission was associated with percutaneous exposures. Clearly, at least in the United States, a number of the instances of provider-to-patient HCV transmission have been associated with diversion of patients' drugs to healthcare providers who were abusing injectable narcotics. Although the contribution of injection drug use to provider-to-patient transmission of HCV has been most noticeable in the United States, 2 additional cases, one from Spain, the other from Israel, underscore its potential importance. In the cluster of cases from Spain, an anesthesiologist who was addicted to opiates was diverting some of patients' narcotics for personal use and then injecting the patients with the same syringe that he had used, thereby infecting more than 200 patients.^{18,40} In the report from Israel, an injection drug-using anesthesiologist infected 33 patients by diverting some patients' drugs to himself and then using the same apparatus for injecting the drugs into the patient.³² Detection of underlying injection drug use in these circumstances is difficult, at best, so one cannot say for certain the extent to which this behavior may have influenced the other cases reported in the literature.

Summarizing the world literature and excluding those reports in which injection drug use was considered to be a contributing factor for transmission, there were 2 gynecologists, 3 cardiac or thoracic surgeons, 1 anesthesiologist, and 1 orthopedic surgeon involved in the instances of transmission. These data lend credence to the hypothesis that "exposure-prone, invasive procedures" are likely to pose the largest risk for provider-to-patient transmission of HCV.

Provider-to-Patient Transmission of HIV

In the 25 years since HIV was first isolated, only 4 instances of HIV transmission from infected health care workers to 1 or more patients have been reported.^{3-8,41-45} One cluster of infections occurred in the United States in 1990,³⁻⁸ 2 cases occurred in France,^{41,42,44,45} and 1 instance of transmission occurred in Spain.⁴³

The US cluster involved a dentist who had acquired immune deficiency syndrome (AIDS); 6 of his patients became HIV infected. Their HIV isolates were linked to his, both epidemiologically and by DNA sequencing.³⁻⁸ A thorough investigation by the CDC and viral phylogeny findings suggested practitioner-to-patient spread, though the precise mechanism or mechanisms of transmission were not determined. Although the dentist was a patient in his own practice, no infection control deficiencies were identified that would readily explain HIV transmission to the 6 patients. Additionally, the dentist did not recall occupational injuries that could have created an opportunity for cross-contamination. Despite substantial speculation, no data were uncovered suggesting intentional transmission.

The second instance of provider-to-patient HIV transmission involved an orthopedic surgeon in France who transmitted HIV to 1 patient. Transmission was confirmed through DNA sequence analysis of viral isolates obtained from the surgeon and the patient.^{42,45} The surgeon was not aware of his infection until surveillance case definition AIDS was diagnosed. French investigators initiated a look-back study of the surgeon's 3004 patients since 1983. Investigators successfully contacted 2458 patients and performed HIV serologic tests on 983. One patient was found to have acquired HIV infection. This patient had 3 procedures performed by the surgeon, had a negative HIV serology before undergoing the first of the 3 procedures, and was found to be infected with HIV when she underwent testing before the third procedure.^{42,45} The authors of the manuscript speculated that both the extended length of the initial procedure (10 hours) and the high likelihood that the surgeon had a high viral burden (since he had far advanced, untreated disease) contributed to the transmission. No breaches in recommended infection-control practices were identified in retrospect.

The third episode of provider-to-patient HIV transmission also was detected in France. In this unusual case, transmission of HIV is suggested to have occurred from an infected nurse to a patient, although no clear mechanism for transmission could be identified.⁴⁴ The investigators conducted a look-back study focusing on 7,580 patients for whom the infected nurse had provided care. They were able to locate 5,308 patients, and they serologically tested 2,293.⁴¹ No additional infections were identified. The nurse was coinfecting with HCV and had both a high HIV viral burden and advanced HCV-induced hepatic disease, including clotting abnormalities. HCV was apparently not transmitted to the patient, but the HIV isolates from patient and provider were closely related. The nurse was

unaware of either viral infection, though she became symptomatic enough to require hospitalization within 2 weeks of the date on which transmission was thought to have occurred. She denied injection drug use.

The fourth case occurred in Spain; a woman was infected with HIV by her obstetrician/gynecologist during cesarean delivery. Spanish officials conducted a look-back evaluation of the physician's patients. Of 275 patients on whom the practitioner had performed procedures, 250 could be tested, and none were found to be infected.⁴³

More than 4 dozen look-back studies have been conducted evaluating the HIV antibody status of patients retrospectively identified as having received medical or dental care from an HIV-infected practitioner^{5,46-57} (Lisa Panlilio, CDC, personal communication). None of these studies identified transmission of HIV infection. To our knowledge, only the report from France described above, in which an orthopedic surgeon infected one of his patients, identified iatrogenic transmission of HIV in a look-back study.^{42,45} In the United Kingdom, no cases of HIV transmission from a healthcare worker to a patient have been detected, despite 28 patient notification exercises and testing of more than 11,000 patients between 1988 and 2006 (F. Ncube, MD, Health Protection Agency Centre for Infections, United Kingdom, personal communication). One unusual cluster of patient-to-patient HIV transmission in a surgical practice in Australia has been described in the literature;⁵⁸ however, the practitioner providing the care was not infected.

PATHOGENESIS AND TRANSMISSION RISK

HBV, HCV, and HIV are most readily transmitted either parenterally or across mucous membranes. Therefore, experts uniformly agree that the risk for transmission of these viruses from an infected provider to a patient during the provision of routine healthcare that does not involve invasive procedures is negligible. In instances in which invasive procedures, and even exposure-prone invasive procedures, are being conducted, these risks are still quite small, but are clearly elevated when compared with other routine patient-care activities. For this reason, a precise assessment of the magnitude of risk for transmission of each of the viruses—in the context of procedures associated with risks for exposing patients to the infected provider's blood or virus-containing body fluids—becomes critical to the overall risk assessment. At least in part because these transmission events occur uncommonly for each of these 3 pathogens, such information is difficult to accumulate.

Several studies have attempted to measure the risk that is associated with single discrete exposures (eg, the "needlestick" transmission rate) for transmission of these 3 pathogens. Only a few manuscripts have addressed the risk to patients who are cared for by an HBV-infected practitioner,^{11,14,59-63} an HCV-infected practitioner,^{22,23,64-66} or an HIV-infected prac-

itioner.^{5,46-51,54,57,67} Several variables are likely to influence the transmission rate.

The first factor to influence risk is the intrinsic transmissibility of a specific pathogen. With respect to HBV, studies from the 1970s and 1980s demonstrated a risk for transmission associated with a percutaneous (ie, needlestick) exposure to blood from an HBV-infected individual that ranged from 6% to 37% (19%–37%, if the donor blood is HBeAg-positive).^{68,69} The risk for transmission of HCV associated with such exposures has been estimated at 1%–2% (summarized in Henderson⁶⁵). The risk for transmission of HIV associated with needlestick or percutaneous exposures has been estimated at 0.3% (summarized in Henderson⁷⁰). With the exception of the HBV studies (which do make the distinction between HBeAg-positive and HBeAg-negative source patients), none of the HCV or HIV transmission studies considers the circulating viral burden of the source patient in the risk calculation.

With respect to HIV transmission from provider to patient, since the previous version of this guideline¹⁰ was published in 1997, only 3 instances of transmission have been detected,⁴¹⁻⁴⁵ and in each instance only 1 patient was found to be infected, despite exhaustive look-back investigations.

A second important issue for consideration in assessing the risk for provider-to-patient transmission of bloodborne pathogens is the frequency with which providers sustain injuries that might present a risk for transmission to their patients.⁷¹⁻⁷⁹ Since the previous version of this guideline¹⁰ was published, numerous strategies and interventions designed to reduce the risk for occupational exposures for providers have been implemented (discussed in more detail in the later part of this section). Many of these interventions have been shown to be efficacious in reducing risks for occupational exposures;⁸⁰⁻⁸⁶ however, in many instances, the use of such interventions has been suboptimal.⁸⁷⁻⁸⁹ Another set of factors that relates directly to the frequency with which exposures occur includes both the experience of the practitioner and the expertise of the practitioner. With respect to experience, clearly, students and trainees are more likely to sustain such exposures. A special problem arises when a training institution becomes aware that a trainee is chronically infected with a bloodborne pathogen. Such instances should be handled on a case-by-case basis, in consultation with the institution's legal counsel, the house staff training director, infection control professionals, the dean of the school, and others who are involved stakeholders. To date, these cases have been handled unevenly across the country, with some institutions focusing on the disability-law aspects and others focusing on liability.⁹⁰ The institution should assist the trainee in selecting a career path best suited to her or his specific situation and should provide reasonable accommodation to students and trainees who have disabling conditions. The expertise of the practitioner is more complex to measure, but may be indirectly assessed by evaluating postprocedure infection rates, bleeding and other pro-

cedure-related complications, and other adverse events associated with the performance of the practitioner.

The third issue that warrants consideration is how frequently such an exposure occurs and is then followed by exposure to a patient (ie, the so-called “recontact” or “bleed-back” risk). For example, intraoperative injuries sustained by surgical care providers offer an opportunity for “recontact” to occur. In 2 studies of intraoperative provider injuries, 11.4%–29% of the sharp objects that caused injury to the provider “recontacted” the patient.^{73,79} These exposures can be prevented by immediately replacing the contaminated suture needle or other sharp object before reuse. Recontacts can also occur when the provider is injured by bone spicules or materials permanently embedded in the patient’s body.^{73,79} These sources of potential patient exposure might be prevented by the use of safety devices or other interventions. For example, such exposures might be prevented by the use of reinforced gloves,^{91,92} double-gloving, glove-liners, or other devices or materials to protect the provider’s hands.^{89,91,93–96} Gloves constructed of monofilament polymers or other materials resistant to tears have become available for use when manipulation of bone fragments or suture wires is needed, but their use has been associated with a decrease in tactile sensation. In addition, the use of blunted suture needles has been shown to decrease the risk of percutaneous injuries to the surgeon.^{86,97–99}

A fourth factor to consider in the risk assessment is the effect of the infected provider’s circulating viral burden. However, with the exception of the HBV studies (which do make the distinction between HBeAg-positive and HBeAg-negative source patients), none of the HCV or HIV transmission studies considers the circulating viral burden of the source patient in the risk calculation, although the likelihood of HIV transmission is increased if a source case patient has advanced AIDS and, presumably, an elevated HIV viral load. For HBV, 5 studies have attempted to measure the viral burden of the provider associated with transmission of infection. In these studies, source case surgeons were found to have circulating HBV DNA levels between 6.4×10^4 and 5.0×10^9 GE/mL. In a modeling study designed to assess the inoculum associated with the most common types of exposures, viral burdens equivalent to 10^4 GE/mL or less were associated with exposures to fewer than 1 virion.¹⁰⁰ An analysis of the technique used by one HBeAg-positive cardiovascular-thoracic surgeon implicated as the source of a cluster of HBV infections may shed some light on the risk for transmission associated with very high viral burdens.^{12,101} In this study, when the surgeon repeatedly tied knots, snugging them against his index finger, shear injuries occurred through his gloves, and both the saline irrigant used to rinse the inside of his gloves and the outer surface of the gloves tested positive for hepatitis B surface antigen (HBsAg).^{12,101} Despite evidence suggesting a decreased risk for contamination with blood and/or body fluids associated with the practice of double-gloving,⁷¹ this surgeon did not wear 2 pairs of gloves—neither during clin-

ical care nor for the experiments described above. Nonetheless, because of the extremely high viral burden associated with HBeAg positivity (100 million to 10 billion HBV particles per milliliter of blood),¹⁰² barriers may be relatively ineffective in preventing transmission, so the establishment of some cutoff value makes implicit sense.

A fifth issue to consider is the magnitude of risk of transmission of bloodborne pathogens following various types of exposures (summarized in Henderson⁷⁰). For HIV, this risk has been studied extensively. The average risk of transmission associated with percutaneous exposures to blood-contaminated sharp objects that have been used on HIV-infected individuals is 0.32% (21 infections associated with 6,498 exposures; 95% confidence interval, 0.18%–0.46%) (summarized in Henderson⁷⁰). The risk for transmission of HBV from an HBeAg-positive source subject is approximately $2 \log_{10}$ higher; the likelihood of transmission of HCV from an HCV-infected source subject is intermediate, and is estimated to be approximately 10-fold less than that for HBV (ie, approximately 1%–2% per exposure).⁶⁵ The estimated risk for transmission of HIV associated with mucocutaneous exposure is 0.03% (1 infection associated with 2,885 exposures), but this estimate is biased, because the single transmission occurred before prospective data were collected from the involved institution.¹⁰³ The risk of infection associated with intact skin exposure to blood from an HIV-infected individual is below detection in the few studies that have attempted to measure it.¹⁰⁴ Data estimating these latter risks are not available for either HBV or HCV, though one might reasonably assume that the risks might be higher for HCV and higher yet for HBV, given the numbers of cases infection detected for the hepatitis viruses, as well as the higher average circulating viral burdens in chronically infected individuals.

Because the risks for provider-to-patient transmission of these 3 bloodborne pathogens are apparently quite different (albeit there is a small risk for each of the 3 viruses), SHEA decided in the previous version of this guideline in 1997 to consider them individually.¹⁰ This updated version also follows that approach.

In 1991, the US Public Health Service published guidelines designed to prevent provider-to-patient transmission of HBV and HIV.¹⁰⁵ Since that document was published, we have gained substantial insight into the factors that contribute to the risks for healthcare-associated transmission of these pathogens; we have witnessed substantial progress in the management of HBV, HCV, and HIV infection; we have seen the development of sensitive molecular tests designed to measure circulating viral burdens for these infections; and we have implemented a variety of interventional strategies designed to reduce these risks.

More than 20 infectious diseases have been transmitted by needlestick injuries.¹⁰⁶ However, HBV, HCV, and HIV infections remain overwhelmingly the most important diseases to consider in provider-to-patient transmission. Other blood-

borne diseases remain of hypothetical concern only. For this reason, this guideline will focus only on HBV, HCV, and HIV.

CLINICAL PROGRESS SINCE PUBLICATION OF THE 1997 SHEA GUIDELINE

HBV

The previous version of this SHEA guideline¹⁰ relied on the presence of HBeAg as a surrogate marker of infectivity and did not consider direct measurement of the HBV DNA viral burden in making recommendations about practice restrictions. One major advance since the publication of the previous guideline is the recognition that presence of HBeAg is not a sensitive marker for HBV infectivity. Indeed, several instances of provider-to-patient transmission of HBV have involved providers who were infected with strains of HBV that did not produce HBeAg (so-called “pre-core” mutants).^{14,107} The use of HBeAg as a surrogate marker for infectivity has been effectively replaced by molecular tests that measure a patient’s circulating viral burdens with precision. A third major advance is the availability of antiviral medications and other approaches to treat HBV infection. The past decade has seen the development of treatment strategies that, for the first time, offer some hope of reducing patients’ viral burdens, and also of producing durable remissions, if not cures. The US Food and Drug Administration has approved 7 antiviral agents (interferon- α , peg interferon, lamivudine, telbivudine, adefovir, tenofovir, and entecavir) for the treatment of chronic hepatitis B in the United States; others (eg, emtricitabine and clevudine) are currently under evaluation. Of patients who received monotherapy with one of the approved agents for 1 year, 14%–30% became negative for HBeAg, and 21%–67% developed undetectable HBV DNA levels.¹⁰⁸ The role of combination therapies is at too preliminary a stage to judge their efficacy; however, some studies have suggested that therapy with combinations of some of the newer nucleoside and nucleotide analogues (eg, truvada) are superior, or preferable, to monotherapy for patients who have HBeAg or high circulating levels of HBV DNA.¹⁰⁸ Although the evidence base for the use of antiviral and/or immunological therapy for hepatitis B is not yet fully adequate (ie, current therapy for chronic hepatitis B infection most often does not eradicate HBV and most studies demonstrate limited long-term efficacy), the role of therapy, the impact on the potential transmission risk, and the impact on practice restrictions have not yet been fully investigated.

HCV

As is the case with HBV, in the past decade we have gained more sophistication and precision in our ability to measure the circulating viral burdens of patients infected with HCV. In addition, new antiviral agents and combinations of agents have been employed with increasing success to treat individuals who have acute and chronic HCV infection. A National

Institutes of Health Consensus Development Conference and 2 academic professional societies have published congruent treatment guidelines for individuals who are chronically infected with HCV.^{109–112} These guidelines emphasize that individuals who have chronic hepatitis C infection who are 18 years of age or older, have detectable HCV RNA in serum, and evidence of chronic hepatitis (either elevated serum alanine aminotransferase levels or active hepatitis and/or fibrosis) should be treated, assuming they are willing to participate in the therapy and that there are no contraindications to the use of the indicated antiviral agents. Also of importance are the several published studies that suggest that acute HCV infection can be treated with nearly 100% success.^{113–116} Whether these recommendations might apply to HCV-infected practitioners who want to be able to perform exposure-prone invasive procedures (whether or not they have evidence of chronic hepatitis) is not addressed in this guideline.

HIV

Substantial progress also has been made for HIV. Tests to monitor HIV RNA viral load are now routine, and highly active antiretroviral therapy has been routinely given for more than a decade. None of the existing guidelines have incorporated treatment of the infected practitioner into the decision about practice restriction for HIV-infected providers who wish to continue performing exposure-prone invasive procedures.

CURRENT PUBLISHED GUIDELINES

In the United States, in the aftermath of the national and international publicity surrounding the instances of iatrogenic HIV infection linked to the Florida dentist,^{3–8} the CDC issued guidelines for HIV-infected and HBV-infected providers¹⁰⁵ in July of 1991. From an implementation perspective, 3 aspects of these guidelines were problematic: (1) the need to classify a subset of invasive procedures as “exposure-prone,” (2) the requirement that an infected practitioner notify prospective patients of her or his infection status, and (3) the legal and administrative implementation strategies concerning the establishment and workings of the Expert Review Panel, an administrative requirement of the guidelines. Although we have witnessed substantial clinical progress and much has been written about these issues, these problems remain largely unresolved 18 years after publication of the original CDC guideline.¹⁰⁵

The anxiety associated with the publicity surrounding the Florida dentist case-cluster prompted Congressional scrutiny of the 1991 CDC guideline,¹⁰⁵ and, ultimately, resulted in the US Congress passing Federal legislation (PL. 102–141) requiring states to certify that they have implemented the July 1991 CDC guideline¹⁰⁵ or “equivalent” guidelines. Interestingly, since the 1991 CDC guideline¹⁰⁵ was published, the United States has identified no additional instances of provider-to-patient HIV transmission and only rare instances of

either HCV or HBV transmission. The fact that only a small number of cases have been detected is attributable to a variety of factors, including less aggressive case-finding by the CDC and other local and state public health officials (ie, no active ongoing surveillance), the use of primary strategies to prevent exposure, and the efficacy of highly active antiretroviral therapy, which has lowered the viral burden in HIV-infected "source patients," has reduced the likelihood of hospitalization, and has decreased the need for and the numbers of invasive procedures that place healthcare workers at risk for exposure. To date, the management of infected practitioners therefore appears to have been effectively managed at the individual, the institutional or at the state level.

Although no new US Public Health Service guidelines regarding infected providers have been published since 1991, guidelines have been published outside the United States, and several articles have been published that argue differing points of view about this complex issue. The issue remains controversial for several complicated reasons. First, at least in part because of the manner in which HIV infection first presented in society, American public opinion has consistently reflected a "zero-risk" stance. Second, although most guidelines have focused on practice restrictions for infected providers who conduct exposure-prone procedures, a panel of experts convened by the CDC was unable to come to consensus about which invasive procedures are "exposure-prone," at least in part because of the substantial variability from provider to provider. The United Kingdom guidelines detail their definition of "exposure-prone" procedures.¹¹⁷ Also, recently, a group convened at the University of Virginia created a table of procedures, divided into 3 categories: (1) procedures with de minimis risk of viral transmission, (2) procedures for which viral transmission is theoretically possible but unlikely, and (3) procedures that are associated with a definite risk of viral transmission or that are directly characterized as exposure prone procedures.¹ We have included a similar table in this guideline (Table 2), modified slightly from the table created by the University of Virginia group; the committee that drafted this guideline also expressed the strong opinion that some procedures listed under Category III might well be moved to Category II if the practitioner follows recommended work practice controls and uses appropriate safety devices. Third, this topic offers a unique confluence for the disciplines of epidemiology, medicine, ethics and law, and experts in these disciplines express widely divergent views about the optimal approach. Each of these issues deserves additional discussion.

Despite the fact that experts uniformly agree that infected providers who are not conducting invasive procedures present virtually no risk to their patients, as recently as 2005, a study found that 89% of respondents acknowledged that they would want to know whether their doctor or dentist is infected with HIV; 82% agreed that disclosure of HBV or HCV infection in a provider should be mandatory; and only 38% thought that infected providers should be allowed to provide patient

care of any kind.¹¹⁸ Some have argued that by not completely restricting providers infected with bloodborne pathogens, the discipline of medicine has betrayed its responsibility to patients.¹¹⁹ Because public opinion is far from aligned with the existing science base, a major issue becomes "What level of risk will society tolerate?"

ETHICAL ISSUES

A useful perspective is to consider the accommodations society has made for medical or psychiatric conditions in the healthcare worker, or a history of substance use, which also could put patients at risk. In certain cases, these conditions may necessitate restriction of the healthcare worker from certain aspects of healthcare practice. Restriction is not viewed as justified, however, when these conditions are well treated and the healthcare provider is able to practice in a safe and competent way.

Similarly, we feel that infection with a bloodborne pathogen does not itself justify restriction on the practice of an otherwise competent healthcare provider. As with providers who have medical, psychiatric, or substance-use problems, healthcare providers infected with bloodborne pathogens should seek ongoing care and treatment. SHEA recommends the additional protection of restricting health care providers from performing Category III procedures if the healthcare provider is infected with a bloodborne pathogen and meets other criteria, as delineated in this document.

The ethics of this issue are also complex. Healthcare providers have an ethical, professional and fiduciary responsibility to act in the best interests of their patients. Healthcare providers have a duty to ensure patient safety. The fact that healthcare providers are bound by the principle of nonmaleficence, which requires them to do no harm to patients and to do what is possible to prevent harm, is widely accepted. Nonetheless, this simple formulation of the principle of nonmaleficence provides limited guidance, because many beneficial interventions also present risks to patients. Consistent with the principle of nonmaleficence or "do not harm," healthcare providers are expected to act in accordance with the standards of their profession to prevent harm in the practice of patient care. Accordingly, healthcare providers have an obligation to follow the accepted standards of practice to prevent the transmission of bloodborne pathogens to patients. These standards include knowledge about and diligent utilization of infection control procedures, as well as careful attention to individual factors that can be controlled to reduce any risk of transmission.

Over the last 2 decades, considerable progress has been made in our understanding of HIV, HCV, and HBV infections. Sensitive tests to measure levels of circulating virus have been developed, as well as an impressive armamentarium of interventions to control the infections, including effective antiviral therapies for each disease. We know that when individuals are treated so that their viral load becomes and re-

mains low or undetectable, the risk of transmission to others is greatly decreased. Technological and other advances in equipment and infection control procedures, as well as work-practice controls that have reduced the risk of occupational injuries to healthcare providers and, therefore, indirectly improved patient safety, have further reduced the risk of transmission in healthcare settings.

The accumulated experience and data provide reassuring evidence that the magnitude of risk for provider-to-patient transmission of HIV, HCV and HBV, although not zero, is exceedingly small. At the same time, the burdens of certain restrictions that have been placed on healthcare providers out of concern for patient safety have been disproportionately high. Qualified and experienced healthcare providers have suffered from discrimination, loss of privacy, liability, and loss of their jobs and their livelihoods. These burdens, associated with highly personal and stigmatizing diagnoses, seem unjustified in the face of an extremely low risk that can be further reduced by reasonable accommodations in the workplace and the diligence of healthcare providers and institutions.

All healthcare providers should comply with institutional policies and procedures designed to protect patients. Healthcare providers have an ethical responsibility to promote their own health and well being, and a responsibility to remove themselves from care situations if it is clear that there is a significant risk to patients despite appropriate preventive measures.

Infection with a bloodborne pathogen does not itself justify restriction on the practice of an otherwise competent healthcare provider. Healthcare providers infected with bloodborne pathogens should seek ongoing care and treatment. Restrictions may be justifiably imposed when a healthcare provider has a physical or mental impairment that affects his or her judgment and/or jeopardizes patient safety. Examples might include exudative lesions or weeping dermatitis; a history of poor infection-control technique or adherence to proper technique; mental confusion; or a prior incident of transmitting a bloodborne pathogen to a patient.

LEGAL ISSUES

From the legal perspective, the courts have been relatively unsupportive of infected healthcare providers. Although some authorities have argued that proscriptive state regulations are responding “to a problem that does not exist,”¹²⁰ many legal actions were filed against infected healthcare providers and their institutions, based either on the CDC guidelines of July 1991,¹⁰ professional societies’ adoption of these guidelines, or both. In many, if not most of these actions, a practitioner was sued, not for infecting patients, but rather for inflicting mental anguish, for causing “pain and suffering,” for assault, for the practitioner’s failure to comply with the “duty to warn” the patient of risk, or for various other legal issues. Virtually all of these suits were filed because of the possibility

that patients may have been unnecessarily exposed to the risk for infection, not because the patients were infected with bloodborne pathogens. Outcomes for these cases have been highly variable, and have not, to our knowledge, established a definitive precedent.

HBV

Existing US guidelines, published in 1991 and not, to date, ever revised,¹⁰⁵ recommend that “healthcare providers who perform exposure-prone procedures and who do not have serologic evidence of immunity to HBV from vaccination or from previous infection should know their HBsAg status and, if that is positive, should also know their HBeAg status. If infected with HBV (and HBeAg positive) providers should not perform exposure-prone procedures unless they have sought counsel from an Expert Review Panel and been advised under what circumstances, if any, they may continue to perform these procedures. Such circumstances would include notifying prospective patients of the healthcare worker’s seropositivity before they undergo exposure-prone invasive procedures.”¹⁰⁵

Several countries have issued modified guidelines for the management of HBV-infected providers based on the infected provider’s circulating viral burdens. Unfortunately, the evidence base for these recommendations is minuscule, and the existing recommendations are quite disparate.

In the United Kingdom, HBV-infected providers who are HBeAg positive may not conduct exposure-prone invasive procedures; HBV-infected providers who are HBeAg negative but have HBV DNA levels of greater than 10^3 GE/mL may not conduct exposure-prone invasive procedures; and HBV-infected providers who are HBeAg negative and have HBV DNA levels of less than 10^3 GE/mL may conduct exposure-prone invasive procedures but must be retested at least every 12 months to ensure that the level of viremia remains below 10^3 GE/mL.¹²¹ More recently, authorities in the United Kingdom have also recommended¹²² that HBV-infected healthcare providers who are HBeAg negative and who have pretreatment HBV DNA levels of 10^3 – 10^5 GE/mL could be allowed to perform exposure prone procedures if they are receiving suppressive oral antiviral therapy and if their viral loads have decreased to below 10^3 GE/mL. The major challenge associated with this latter recommendation is the development of an effective monitoring strategy to make certain that the circulating viral burden remains less than 10^3 GE/mL.¹²² The availability of various testing systems further complicates monitoring.

A European consortium was convened to create recommendations for HBV-infected providers and reached slightly different conclusions.¹²³ In their recommendations, HBV-infected providers who are HBeAg positive are instructed that they may not perform exposure-prone procedures.¹²³ HBV-infected providers who are HBeAg negative but have HBV DNA levels of less than 10^4 GE/mL may conduct exposure-

prone invasive procedures but must be retested at least annually to make certain that the circulating viral burden remains below 10^4 GE/mL.¹²³ These guidelines also emphasize that providers who are detected as having transmitted HBV should not perform exposure-prone procedures, and HBV-infected providers who have been treated and whose post-treatment DNA levels have fallen to less than 10^4 GE/mL may conduct exposure-prone procedures but must be retested every 3 months to ensure that the viral burden remains below 10^4 GE/mL.¹²³

Scientists from the Netherlands published a third set of recommendations suggesting that HBV-infected providers who have HBV DNA levels of less than 10^5 GE/mL may conduct exposure-prone invasive procedures, but must be retested at least annually.¹²⁴

In a thoughtful analysis, van der Eijk et al¹²⁵ listed the challenges to standardizing recommendations for practice restrictions for HBV-infected providers, emphasizing that guidelines have to strike a balance between excluding providers unnecessarily and patient safety. More recently, the Viral Hepatitis Prevention Board, a European consortium whose mission is to contribute to the control and prevention of viral hepatitis, convened a meeting of international experts from the public and private sectors to try to harmonize these recommendations.¹²⁶ This meeting identified a number of issues that the contributors felt needed to be addressed before development of standardized recommendations, and consensus could not be achieved.¹²⁶ Included in this list of issues are the following: (1) the variability of HBV DNA levels among chronically infected individuals; (2) the paucity of data linking levels of viremia to risk for transmission; (3) the variable reliability and reproducibility of the molecular tests used to measure HBV DNA, as well as the variability between the differing test systems; (4) the lack of standardization among the different tests used to detect HBV DNA; and (5) the variability and durability of therapeutic antiviral effects and, specifically, the length of time viremia can be effectively suppressed before “escape” mutant viruses emerge.

HCV

No US Public Health Service guidelines address the management of providers infected with HCV, including the 1991 CDC recommendations.¹⁰⁵ The UK guidelines¹⁰⁹ are quite prescriptive regarding hepatitis C, stating that HCV-infected providers who have circulating HCV RNA may not conduct exposure-prone invasive procedures. Further, trainees found to have circulating HCV RNA should be restricted from starting training in exposure-prone invasive procedures.¹²⁷ The UK guidelines also address treatment, noting that HCV-infected providers who have circulating HCV RNA who receive antiviral treatment and become HCV RNA negative for a period of 6 months can be permitted to return to performing exposure-prone invasive procedures but must be retested in 6 months to confirm the durability of the response.¹⁰⁹

The European Consortium could not reach consensus about the management of HCV-infected providers, concluding that “on balance it is not recommended that exposure-prone procedures be forbidden for HCV-infected healthcare workers.”¹²³ Similarly, the scientists from the Netherlands addressed only HBV infection, and did not discuss HCV-infected providers.¹²⁴ Furthermore, the findings of the Viral Hepatitis Prevention Board with respect to HBV (eg, variable HBV DNA levels, paucity of data linking levels of viremia to risk for transmission, variable rates of reliability and reproducibility of molecular tests used to measure HBV DNA, variability and lack of standardization of the differing test systems, variability and durability of therapeutic antiviral effects, and length of time viremia can be effectively suppressed before “escape” mutant viruses emerge) also apply to individuals chronically infected with HCV.

HIV

The UK guidelines¹¹⁷ recommend restriction of the practice of HIV-infected providers.¹⁰⁵ The US guidelines recommend that HIV-infected practitioners, “not perform exposure-prone procedures unless they have sought counsel from an Expert Review Panel and been advised under what circumstances, if any, they may continue to perform these procedures. Such circumstances would include notifying prospective patients of the HCW’s seropositivity before they undergo exposure-prone invasive procedures.”¹⁰⁵ Neither guideline bases recommendations on the clinical status of the infected provider or on the viral burden of the HIV-infected provider.

CURRENT ASSESSMENT

SHEA emphasizes that, more than 20 years after the publication of the “Universal Precautions” guidelines,¹²⁸ blood and potentially contaminated body fluids (eg, cerebrospinal fluid, peritoneal fluid, amniotic fluid, pleural fluid, synovial fluid, pericardial fluid, semen, vaginal secretion, and any blood-contaminated fluid) from any patient must be considered to have the potential to transmit bloodborne pathogens, irrespective of the patient’s primary or secondary diagnosis. Although this principle was initially intended to apply to patients, we find it equally relevant to healthcare providers who may be infected with HIV, HBV, HCV, and/or another bloodborne pathogen. The magnitude of risk for provider-to-patient transmission of bloodborne pathogens may never be known with precision; however, the additional experience gained over the past 20 years provides reassuring evidence that these risks are extremely small.

In the previous version of this guideline, SHEA expressed the opinion that most of the issues applicable to HBV-infected providers would generally apply to providers who are infected with HIV and might also hold for providers infected with HCV. In this revised version, SHEA decided to deal with each of the pathogens individually—at least with respect to setting policies for infected providers. This decision was made for a

TABLE 4. Definitions of the Strength of Recommendations and the Quality of the Evidence Supporting Them

Category and grade	Definition
Strength of recommendation	
A	Good evidence to support a recommendation for use
B	Moderate evidence to support a recommendation for use
C	Poor evidence to support a recommendation for or against use
D	Moderate evidence to support a recommendation against use
E	Good evidence to support a recommendation against use
Quality of evidence	
I	Evidence exists from at least one properly randomized, controlled trial
II	Evidence comes from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than one center), from multiple time-series studies, or from dramatic results in uncontrolled experiments
III	Evidence comes from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

NOTE. The classification scheme is that developed by the Infectious Diseases Society of America,¹³⁴ which are adapted from the Canadian Task Force on the Periodic Health Examination.¹³⁵

variety of reasons. First, the “average” risk for transmission following a single parenteral exposure is at least 10-fold and probably 100-fold higher for HBV than for HIV. The risk for HCV transmission appears to be intermediate between those for HIV and HBV.⁶⁵ Second, chronic carriers of these 3 viral pathogens typically exhibit substantial differences in viral burden (ie, the number of intact virions per milliliter of blood); thus, circumstances that might involve a measurable risk for transmission of HBV may not necessarily be associated with a measurable risk for transmission of HIV. Third, postexposure management strategies, including treatment, have evolved considerably, and treatment for each of these diseases since the previous version of this guideline was published. Pre-exposure receipt of hepatitis B vaccine has led to a dramatic decrease in the incidence of HBV infection in healthcare personnel. Further, postexposure prophylaxis for HBV infection using hepatitis B immune globulin and/or hepatitis B vaccine is both safe and highly effective. Although its efficacy has not been proven in a clinical trial, postexposure prophylaxis for HIV infection using 2-drug or 3-drug combinations has likely contributed to the dramatic decrease in occupationally acquired HIV infection in healthcare workers in the United States. The last such case documented by the CDC occurred in 1999.^{70,129} Unfortunately, neither pre-exposure nor postexposure prophylaxis exist for HCV.

For these reasons, the version of this guideline will continue to consider each pathogen individually. The following recommendations are based on the following information: (1) available scientific information about the magnitude of risk for provider-to-patient transmission of the bloodborne pathogens; (2) clinical hospital epidemiology and infection control experience and management of HBV, HCV and HIV related problems in the healthcare setting since 1981; and (3) experience with the implementation and interpretation of prior recommendations and guidelines, including those issued pre-

viously by the US Public Health Service.^{102,130-133} The recommendations are classified according to the scheme developed by the Infectious Diseases Society of America¹³⁴ (Table 4).

GUIDELINE RECOMMENDATIONS

BACKGROUND AND RATIONALE

These recommendations are based on the thorough consideration of the risks for provider-to-patient transmission of these pathogens, from the information provided by (1) the past 50 years’ experience with these pathogens in the health-care setting; (2) the reported experience with HBV-infected providers and their patients^{11-16,61-63,136} (I. Williams, CDC, Personal Communication), HCV-infected providers and their patients,^{18-32,35,37,39,40,64} and HIV-infected providers and their patients^{3-8,41-57}; (3) studies of the frequency of various types of occupational exposures^{65,71-79,137,138}; (4) studies of the magnitude of risk of transmission of bloodborne pathogens following various types of exposures^{70,104,139,140}; (5) the substantial progress biomedical science has made in accurately measuring viral burden as an indicator of disease activity, and, possibly, infectivity, for all 3 viral infections; (6) the availability of an effective vaccine for HBV; (7) the development of effective postexposure management strategies, as well as therapy that can substantially suppress HIV and HBV infection and can suppress and even cure HCV infection; (8) progress made in modifying procedures and devices to create a safer healthcare environment; and (9) the resources required to develop a unique administrative approach for the management of providers infected with these 3 bloodborne pathogens.

The major changes in the risk calculus since the publication of our prior set of recommendations are, first, that effective antiviral therapeutic interventions have been developed for

all 3 pathogens, and, second, that a number of engineering and work-practice controls have been introduced into the healthcare environment that have contributed substantially to decreasing the risk for occupational injuries to healthcare providers and, therefore, indirectly, to improving patient safety.

I. PRACTICE ISSUES

1. Should healthcare providers who are infected with HBV be allowed to practice? If so, under what clinical, serological, or viral burden parameters?

Recommendation

All blood and potentially blood-containing fluids (ie, cerebrospinal fluid, peritoneal fluid, amniotic fluid, pleural fluid, synovial fluid, pericardial fluid, semen, vaginal secretion, and any blood-contaminated fluid) from patients and providers must be regarded as potentially infectious for HBV (A-III). All providers should follow the tenets of Standard Precautions (A-III). Only the following body fluids have been implicated in the transmission of bloodborne viruses: blood, blood products, semen, cervical secretions, cerebrospinal fluid, peritoneal fluid, pleural fluid, synovial fluid, pericardial fluid, and amniotic fluid. Transfers of blood or other potentially infectious materials from providers to patients must be avoided (A-III). Tears, saliva, vomitus, sputum, urine and stool are not considered to be capable of transmitting bloodborne viruses unless contaminated with blood. Nonetheless, healthcare providers should practice Standard Precautions and avoid contact with these fluids, as they are potentially infectious for additional pathogens (eg, saliva for herpes simplex virus, stool for hepatitis A virus).

HBV-infected healthcare providers should not be prohibited from participating in patient-care activities solely on the basis of their HBV infection (A-III). HBV-infected providers should not be restricted from participating in Category I or Category II Procedures (Table 2) (A-III). Providers infected with HBV who are either HBeAg positive or who have circulating viral burdens greater than or equal to 10^4 GE/mL should refrain from performing Category III procedures (A-III). Healthcare providers who have circulating HBV burdens of less than 10^4 GE/mL should be allowed to perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogens, so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine staff (or an appropriate public health official), who tests the provider twice per year to demonstrate the maintenance of a viral burden of less than 10^4 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HBV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including

the routine use of double-gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below) (A-III).

Discussion. We have chosen a cut-off of 10^4 GE/mL to separate providers who can and cannot perform Category III procedures. This level was chosen in the absence of data that definitively associate a given level with either a clear risk for transmission or, more importantly, an absence of risk. As noted above, one modeling experiment suggested that the most common types of exposure to a provider who had a viral burden of 10^4 GE/mL would be associated with an exposure to less than 1 virion.¹⁰⁰ In addition to that modeling experiment, another important piece of evidence that supports this threshold is the fact that, in all of the instances of transmission from an HBeAg-negative provider to a patient in which the source provider's viral burden has been measured, the implicated provider had a circulating viral burden in excess of 10^4 GE/mL,¹²³ except in one case,¹⁴¹ and the validity of that one case has been questioned, because the sample was taken from the provider more than 3 months after the transmission occurred.¹²⁴ Setting the cutoff for the circulating HBV viral burden at 10^3 GE/mL would have resulted in restricting the practices of 58% of the HBV-infected providers in the United Kingdom and nearly 95% of such providers in the Netherlands.¹²⁶

These guidelines suggest a cutoff of 10^4 GE/mL and allow an individual who has a circulating viral load of less than 10^4 GE/mL to continue to conduct Category III procedures as long as the individual (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine staff (or an appropriate public health official), who tests the provider twice per year to demonstrate the maintenance of a viral burden of less than 10^4 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HBV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an infection control expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving for Category II and Category III procedures, use of puncture-resistant gloves, use of blunted surgical needles,^{86,97-99} use of "hands-free" technique,¹⁴² and other work practice controls, among many others); and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below). If a provider is receiving treatment for this infection, the efficacy of the treatment should be considered in the

context of the specific infection being treated. In general, because of their very high viral burdens, providers who have acute HBV infection and those who have HBV infection in the absence of immunological responses should not perform Category III procedures. Providers whose infections have resolved and who have no evidence of circulating virus should not be restricted in any way.

Individuals relying on these guidelines must keep in mind that each such case must be evaluated on its own merit and that the molecular testing strategies discussed in the document are subject to several limitations. These include (1) the fact that infected individuals' HBV DNA levels may vary over time, (2) there are limited scientific data linking levels of viremia to risk for transmission, (3) the fact that the different currently marketed test for measuring HBV viral burden may produce variable results (4) the varying level of reproducibility of these molecular tests, (5) the fact that antiviral therapy may produce transient or limited responses (particularly with respect to monotherapy for HBV), and (6) the variety of virological and patient-related factors (eg, adherence to the recommended antiviral regimen) that may contribute to the development of "escape" mutants. SHEA underscores that these guidelines are, of necessity, malleable and modifiable as more information becomes available.

Antiviral therapy clearly reduces the circulating HBV viral burden to levels below acceptable cutoff values.¹⁴³ Since, to date, therapies have been suppressive and not curative, this approach is associated with the clear possibility of antiviral agent-related toxicity, as well as the theoretical possibility of fostering resistance among viruses from the infected provider. The effect of therapy should be considered carefully by the Occupational Medicine physician and the Expert Review Panel, as well as by the provider's personal physician who has expertise in the management of HBV infection.

2. Should healthcare providers who are infected with HCV be allowed to practice? If so, under what clinical, serological or viral burden parameters?

Recommendation

HCV-infected providers should not be prohibited from participating in patient-care activities solely on the basis of their HCV infection (A-III).

HCV-infected providers should not be restricted from participating in Category I or Category II Procedures (A-III); providers infected with HCV who have circulating viral burdens of greater than or equal to 10^4 GE/mL should refrain from performing Category III procedures (B-III).

Healthcare providers who have circulating HCV burdens of less than 10^4 GE/mL should be allowed to perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogens, so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up rou-

tinely by Occupational Medicine staff (or an appropriate public health official), who tests the provider twice per year to demonstrate the maintenance of a viral burden of less than 10^4 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HCV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below) (B-III).

Discussion. These guidelines recommend that HCV-infected healthcare providers who have circulating viral burdens of less than 10^4 GE/mL not be restricted from any aspect of health care so long as the infected provider follows the detail of the recommendation. Specifically, the provider must be willing to consult with, and follow the recommendations of, an infection control expert. The infected provider must strictly adhere to the recommended procedures (eg, routine use of double-gloving for Category II and III procedures, frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires], use of puncture-resistant gloves, blunted surgical needles,^{86,97-99} "hands-free" technique^{142,144} and other work practice controls, among many others). Finally, the infected provider must agree to the information in, and sign, a contract or letter from the Expert Review Panel that characterizes her or his responsibilities. One might have easily argued for no restrictions whatsoever for HCV-infected providers, on the basis of the experience in the United States alone.

The selection of a practice-restriction-threshold of 10^4 GE/mL is arbitrary, but, as noted above (in the section Legal Issues), some European guidelines have taken a far more restrictive tack. Because there have been virtually no such cases in the United States, we have, nonetheless, chosen a conservative cutoff for restricting practitioners. We have recommended practice restrictions for providers who perform Category III procedures whose viral burdens are 10^4 GE/mL or greater. We have based this decision on the *in vitro* HBV data cited above (in the section Pathogenesis and Transmission Risk), as well as the clinical experience with patient-to-provider transmission of HCV in the United Kingdom. In addition, we note that therapy for HCV is becoming increasingly effective, so that many providers who are identified as infected with HCV can have their infections eradicated. Studies of the efficacy of the treatment of acute HCV infection often demonstrate cure rates in excess of 95%, with studies of the treatment of chronically infected individuals demon-

strating cure rates of up to 70% or 80%, particularly for individuals infected with a treatment-favorable genotype.¹⁴⁵⁻¹⁴⁷

Individuals relying on these guidelines must keep in mind that each such case must be evaluated on its own merit and that the molecular testing strategies discussed in the document are subject to several limitations. These include (1) the fact that infected individuals' HCV RNA levels may vary over time, (2) the paucity of scientific data linking levels of viremia to risk for transmission, (3) the fact that the different currently marketed test for measuring HCV viral burden may produce variable results, (4) the varying level of reproducibility of these molecular tests, (5) the fact that antiviral therapy may produce transient or limited responses, and (6) the variety of virological and patient-related factors (eg, adherence to the recommended antiviral regimen) that may contribute to the development of "escape" mutants. SHEA underscores that these guidelines are, of necessity, malleable and modifiable as more information becomes available.

3. Should healthcare providers who are infected with HIV be allowed to practice? If so, under what clinical, serological or viral burden parameters?

Recommendation

HIV-infected healthcare providers should not be prohibited from participating in patient-care activities solely on the basis of their HIV infection (A-III). HIV-infected providers should not be restricted from participating in Category I or Category II procedures; providers infected with HIV who have circulating viral burdens equal to or in excess of 5×10^2 GE/mL should refrain from performing Category III procedures (A-III). Healthcare providers who have circulating HIV burdens of less than 5×10^2 GE/mL should be allowed to perform those Category III activities identified as associated with a risk for provider-to-patient transmission of bloodborne pathogens, so long as the infected provider (1) is not detected as having transmitted infection to patients; (2) obtains advice from an Expert Review Panel about continued practice; (3) undergoes follow-up routinely by Occupational Medicine staff, who test the provider twice per year to demonstrate the maintenance of a viral burden of less than 5×10^2 GE/mL; (4) also receives follow-up by a personal physician who has expertise in the management of HIV infection and who is allowed by the provider to communicate with the Expert Review Panel about the provider's clinical status; (5) consults with an expert about optimal infection control procedures (and strictly adheres to the recommended procedures, including the routine use of double-gloving for Category II and Category III procedures and frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]); and (6) agrees to the information in and signs a contract or letter from the Expert Review Panel that characterizes her or his responsibilities (discussed in more detail in Recommendation 8, below) (B-III).

Discussion. These guidelines recommend that HIV-infected

healthcare providers who have circulating viral burdens of less than 5×10^2 GE/mL not be restricted from any aspect of health care, so long as the infected provider follows the detail of the recommendation. Specifically, the provider must be willing to consult with, and follow the recommendations of, an infection control expert. The infected provider must strictly adhere to the recommended procedures, (eg, routine use of double-gloving for Category II and III procedures; frequent glove changes during procedures, particularly if performing technical tasks known to compromise glove integrity [eg, placing sternal wires]; use of puncture-resistant gloves blunted surgical needles,^{86,97-99} and "hands-free" technique,^{142,144} and other work practice controls, among many others). Finally, the infected provider must agree to the information in, and sign, a contract or letter from the Expert Review Panel that characterizes her or his responsibilities.

As is the case for our recommendations for HBV-infected practitioners and HCV-infected practitioners, we acknowledge that the selection of a practice-restriction-threshold of 5×10^2 GE/mL is arbitrary; however, as noted above (in the section on Legal Issues), European guidelines have taken a far more restrictive tack. Because no provider-to-patient transmissions of HIV infection have been detected in the United States since the initial cases involving the Florida dentist (discussed in more detail in the sections Epidemiology and Current Published Guidelines, above), we have chosen to recommend permitting an HIV-infected practitioner to conduct Category III procedures if his or her viral burden is suppressed below 5×10^2 GE/mL. We chose 5×10^2 GE/mL as the threshold, in part, because individuals who typically have their viral burdens suppressed to the "undetectable" range (generally <50 copies/mL) occasionally have levels that spike to 5×10^2 GE/mL, despite ongoing effective antiretroviral therapy. We have recommended practice restrictions for a provider who performs Category III procedures and has a viral burden of 5×10^2 GE/mL or greater. Because this recommendation represents a substantial departure from other similar guidelines, we have recommended a relatively low threshold for restriction. Since data do not exist to provide evidence for the most appropriate threshold, this lower threshold was selected solely on the basis of opinions of the committee that drafted this guideline. This threshold should be revisited on a regular basis and modified on the basis of additional accumulating experience. Our committee also noted that highly active antiretroviral therapy is continuing to improve to the point that most HIV-infected providers can have their infections suppressed to this level or below. SHEA underscores that these guidelines are, of necessity, malleable and can be modified as more information becomes available.

Individuals relying on these guidelines must keep in mind that each such case must be evaluated on its own merit and that the molecular testing strategies discussed in the document are subject to several limitations. These include (1) the fact that infected individuals' circulating HIV levels may vary over time, (2) the paucity of scientific data linking levels of

viremia to risk for transmission, (3) the fact that the different currently marketed test for measuring viral burden may produce variable results, (4) the current variability in the level of reproducibility of these molecular tests, (5) the fact that antiviral therapy may produce transient or limited responses, and (6) the variety of virological and patient-related factors (eg, adherence to the recommended antiviral regimen) that may contribute to the development of “escape” mutants. In general, because of their very high viral burdens, providers who are experiencing the HIV seroconversion illness should not perform Category III procedures.

4. For providers who are infected with HBV, HCV, and/or HIV and who have circulating viral burdens greater than the recommended cutoff values, which procedures should they be precluded from performing?

Recommendation

HBV, HCV, and HIV infected providers should not be restricted from participating in Category I or Category II Procedures solely on the basis of their bloodborne pathogen infection (A-III). HBV-infected providers who are either HBeAg positive or who have circulating HBV burdens greater than or equal to 10^4 GE/mL should refrain from conducting procedures listed in Category III (A-III). HCV-infected providers who have circulating viral burdens greater than or equal to 10^4 GE/mL should refrain from conducting procedures listed in Category III (B-III). HIV-infected providers who have circulating viral burdens greater than or equal to 5×10^2 GE/mL should refrain from conducting procedures listed in Category III (A-III).

Discussion. Historically, the concept of “exposure-prone” procedures has been a point of controversy, though several more recent guidelines and manuscripts have suggested that “exposure-prone” procedures can be defined.^{1,109,117,121} In the previous version of this guideline, SHEA suggested that “exposure-prone” procedures might be defined as those that have been “epidemiologically implicated” in patient-to-provider transmission. This approach has proved to be flawed; for example, one recent case-cluster of provider-to-patient transmission of HBV suggested that the implantation of electroencephalography electrodes was implicated in the transmission of HBV.¹⁶ No guideline would include implantation of electroencephalography electrodes as an “exposure-prone” procedure. Some authorities have suggested that providers, rather than procedures, might be exposure-prone, suggesting that technical expertise and experience may play a more substantive role in the risk for provider-to-patient exposure, rather than the procedures themselves. We favor a modification of the approach taken by Reitsma et al¹; namely, 3 tiers of procedural risk (Table 2). Most guidelines do not consider the impact of the introduction of safer devices and safer work practice controls to the risk calculus for infections with these 3 pathogens. As noted above in the section Path-

ogenesis and Transmission Risk, the use of reinforced gloves,^{91,92} double gloves, glove-liners, or other devices or materials to protect the provider’s hands,^{89,91,93-96} and use of blunted suture needles,^{86,97-99} as well as a variety of other safer devices and work practices, have been shown to decrease the risks for percutaneous injuries. The members of the committee drafting this guideline emphasized that the consistent use of safety devices by a practitioner should be one factor considered by the Expert Review Panel when deciding about practice restrictions. Some members of the committee felt that consistent use of these procedures and techniques might move some procedures from Category III to Category II for individual practitioners.

5. If restricted from performing certain types of procedures, should providers who are infected with HBV, HCV, and/or HIV be restricted on the basis of (A) clinical status, (B) laboratory parameters of disease activity and/or progression (and, if so, at what specific “set-points” for each infection), and/or (C) clinical performance (eg, technical skill or lack of adherence to important infection control procedures); and if so, who measures and who decides, and what are the criteria for restriction?

Recommendation

Healthcare practice restrictions should be based on several factors, including (1) evidence of transmission of infection to patients; (2) advice from the Expert Review Panel about continued practice; (3) advice from the Occupational Medicine specialist who is following up the provider; (4) advice from the provider’s physician who has expertise in the bloodborne pathogen infection; (5) viral burden measurements of greater than or equal to 10^4 GE/mL (for HBV or HCV infection) or greater than or equal to 5×10^2 GE/mL (for HIV infection); (6) lack of adherence to recommended infection control procedures; and (7) inability to safely provide patient care (eg, development of another contagious disease such as tuberculosis or development of a bloodborne pathogen-associated disorder, such as HIV-associated neurological disease) (A-III).

Discussion. SHEA recommends that restrictions should be based on various combinations of these data. Anyone clearly implicated in the transmission of one of these organisms should become the subject of scrutiny. The factors listed above (ie, clinical status, laboratory parameters, and clinical performance) all contribute to the assessment of the individual’s ability to practice safely. This ongoing assessment is one of the important roles that should be assumed by the Expert Review Panel (discussed in detail in Recommendation 8, below). The expert review panel and the occupational medicine physician should also consider the possibility of narcotics diversion in the transmission of these infections. Providers identified as acutely infected with any of these pathogens should be carefully evaluated for viral burdens and

should engage the expert review panel through their occupational medicine and/or public health practitioners.

6. Should students, residents, fellows, and other trainees who are infected with HBV, HCV, and/or HIV be discouraged from entering certain specialties and/or subspecialties? How and by whom should these decisions be made?

Recommendation

Healthcare institutions should make certain that students and trainees are fully educated about the risks associated with testing of themselves for, and management of patients with, bloodborne pathogen infections (A-III). All providers who are at risk for occupational exposure to blood should be immunized with the hepatitis B vaccine, unless it is contraindicated (A-I). All healthcare providers should know their serological status with respect to antibody to HBsAg, which should be measured 1–6 months after the completion of their HBV immunization series (A-III). Institutions should assist students and trainees who are determined to be infected with bloodborne pathogens in identifying and selecting career choices that will be the least influenced by their infection(s) (A-III). Healthcare institutions should maintain the privacy and medical confidentiality of students and trainees identified as infected with bloodborne pathogens (A-III). HBV-infected students and trainees who are either HBeAg positive or who have circulating HBV burdens greater than or equal to 10^4 GE/mL should refrain from training in or conducting procedures listed in Category III (A-III); HCV-infected students and trainees who have circulating viral burdens in excess of 10^4 GE/mL should refrain from training in or conducting procedures listed in Category III (B-III); HIV-infected students and trainees who have circulating viral burdens greater than or equal to 5×10^2 GE/mL should refrain from conducting procedures listed in Category III (B-III). Students and trainees who are not receiving optimal therapy for their bloodborne pathogen infection(s) should seek such treatment (A-I).

Discussion. A special problem arises when a training institution becomes aware that a trainee is chronically infected with a bloodborne pathogen. Each of these instances should be handled on a case-by-case basis, in consultation with the institution's legal counsel, the house staff training director, infection control professionals, the Dean of the school, and others who are involved stakeholders. To date, these cases have been handled unevenly across the United States, with some institutions focusing on the disability-law aspects and others focusing on liability.⁹⁰ The law concerning these issues is changing rapidly and is relatively untested in the higher courts. The institution, however, does have responsibility to make certain that the trainee is fully informed about the risks—both to the trainee and to his or her patients—associated with clinical practice. The institution should under-

score the importance of appropriate treatment and the importance of adherence to infection control recommendations. The institution should assist the trainee in selecting a career path best suited to her or his specific situation and should provide reasonable accommodation to students and trainees who have disabling conditions. By adopting the modification of the position initially proffered by Reitsma et al¹ (ie, the 3-tiered risk schema), SHEA advocates encouraging trainees who are infected with HBV, HCV, and/or HIV and whose infection(s) cannot be effectively cleared or whose infections cannot be suppressed below the thresholds identified in Recommendations 1, 2, and 3 (above), to select career paths that do not involve the highest-risk procedures. In instances in which the decision is made to continue training, SHEA advocates having the student be closely supervised by an attending provider who is aware of the student's status when the student is learning or performing Category II procedures.

7. Should providers infected with HBV, HCV, and/or HIV be subject to specific monitoring programs, and, if so, how and by whom and to whom should the data be reported?

Recommendation

Providers infected with HBV, HCV, and/or HIV who perform Category III procedures should have their circulating viral burdens measured at least every 6 months by an engaged occupational medicine practitioner and should undergo periodic evaluations (at a minimum, twice per year) by a physician selected by the provider who has demonstrated expertise in the management of the provider's infection. Results of the viral burden tests should be reviewed by the Occupational Medicine physician, should be reviewed with the provider's personal physician, and should be evaluated by the provider's Expert Review Panel (A-III).

Discussion. Because the guidelines recommend viral burden cutoffs for practice restrictions, SHEA believes that an ongoing monitoring program is essential. Most molecular assay results are reproducible only within about half an order of magnitude. A fraction of infected individuals have fluctuating viral burdens. SHEA recommends a major role for the Occupational Medicine practitioner in supervising the monitoring program. This role would include, but not be limited to, measuring the provider's circulating viral burden at least twice annually and providing advice to the Expert Review Panel about the provider's progress and ongoing clinical status. For independent practitioners working only from an office, these functions should be fulfilled by the city, county or state health department (consonant with state and local laws). Elements of follow-up are summarized in Table 5.

TABLE 5. Functions of the Expert Review Panel

1. Evaluation of the infected provider's clinical status
2. Assessment of the provider's viral burden data
3. Assessment of the provider's experience and expertise
4. Assessment of the procedures performed by the provider and the specific techniques used to perform these procedures
5. Determination of the extent to which the provider adheres to accepted infection control precautions
6. Provision of recommendations about the use of specific barriers, work practice controls, and infection prevention strategies for the conduct of specific procedures and assess the provider's willingness to adhere to these recommendations
7. Provision of counseling to the provider about her or his ethical obligation to report a patient exposure, should one occur, and about the appropriate procedures to follow, should an exposure occur
8. Develop and execute a contract between the infected provider and the Expert Review Panel and/or institution (see Table 5)
9. In instances in which transmission is suspected, consider the potential for narcotics diversion
10. Notify Risk Management should a breach in procedure or a patient exposure occur
11. Notification of the appropriate licensure board for breaches of the signed contract with the Expert Review Panel (if required by state regulations)

NOTE. In instances in which an infected provider is not institutionally based, this responsibility should fall to the local or state health department (consonant with existing state laws).

8. Prior recommendations have suggested the creation of an Expert Review Panel for assisting institutions in managing providers infected with bloodborne pathogens. Is there a role for such a panel in 2009 and beyond? If so, what is that role, and at what level should the committee be convened (eg, at the institutional, city, or state level), who should comprise such a committee, what should be the committee's charge, and how and by whom should the committee be managed? Do committee members accept liability for participation?

Recommendation

Healthcare providers infected with HBV, HCV, and/or HIV should have their clinical status and laboratory data reviewed by an Expert Review Panel (A-III). Such a panel could exist at a state, regional, county, city, or institutional level, consonant with the individual provider's circumstance and with state and local laws. The review panel should include, but not necessarily be limited to, individuals who have expertise in the infected provider's specialty or subspecialty, Healthcare Epidemiology, Infectious Diseases or Hepatology (specifically with expertise in the bloodborne pathogen[s] being discussed), Occupational Medicine, and/or hospital administration; the infected provider's physician; a public health official (in states in which this issue is managed at the state level); a human resources professional; and, perhaps, an individual with legal and/or ethics expertise. The review panel will advise

the healthcare provider, the Occupational Medicine physician, and/or the patient's primary physician about the provider's practice and about the advisability of her or his performing Category III procedures, as well as about the use of infection control interventions (A-III). The panel will create a contract or letter detailing the provider's responsibilities and those of the panel (Figure 1). Before the provider returns to practice, this document must be agreed to and signed by the provider and the panel chair (A-III). The panel should reconsider the provider's performance in the event any of the following occurs: the provider's viral load increases to above the recommended level for consideration of restrictions from performing Category III procedures; the provider develops another contagious disease (eg, tuberculosis); the provider develops another condition that might adversely effect patient safety (eg, HIV-associated neurological impairment or hepatic encephalopathy); the provider fails to strictly adhere to recommended infection control practices; a patient is exposed to a potentially contaminated body fluid of the provider; and/or if there is evidence of provider-to-patient transmission (A-III). The entity chartering the panel should indemnify the panel members against any legal risks and/or costs (A-III).

Discussion. SHEA believes that the creation of an Expert Review Panel to assist in the management of these providers is an important aspect of a patient safety program. Such a program could exist at a state, county, city or institutional level. We believe that the fact that no such cases have received publicity in the United States since the early part of this decade is an indirect reflection of the efficacy of this approach. The basic functions of the Expert Review Panel are described in Table 5. The panel, at a minimum, should include representation from Hospital Epidemiology, Infectious Diseases, the provider's specialty or subspecialty, Occupational Medicine (ie, the individual involved in monitoring the provider), hospital administration, and, perhaps, legal representation. Each case will be slightly different from the next, and each should be considered independently in context. These subtle differences underscore the importance of the Expert Review Panel. The panel should develop a formal letter or contract delineating its specific recommendations regarding the provider's performance, training in infection control, conduct of specific procedures, follow-up, and management, among other issues (Figure 1). Table 6 provides a list of issues for the infection control professional and the Expert Review Panel to consider when providing advice to infected providers regarding the performance of various procedures. Table 7 provides detail concerning the elements of this letter or contract. The requirement for a twice-annual meeting of the panel may be met by a confidential conference call or secure electronic communication. The Occupational Medicine physician, the infection control professional, and/or the state epidemiologist can serve as gatekeepers for the twice-annual review. So long as the contract is being fulfilled and no guideline violations are identified, additional face-to-face meetings

Date

Dear Dr. [Name]:

[Hospital or Health Department name]'s Expert Advisory Panel on Infected Healthcare Workers met on [date], to discuss your case. The Panel reviewed the medical literature relevant to healthcare workers infected with [HBV, HCV, HIV]. In addition, we reviewed guidelines, including the 1991 CDC Guideline pertaining to healthcare workers infected with bloodborne pathogens and the position statements of selected medical professional societies pertaining to the guideline. The Panel concluded the following:

You are permitted to continue your [specialty/subspecialty] training or practice at [hospital name]. If you agree to the Panel requirements below, it is mutually understood that you will comply with the following guidelines:

- You must double-glove for all [discipline] procedures, whether those procedures are carried out in the operating room, in an imaging suite, at the bedside, or in a treatment room.
- You must change gloves approximately every 2-3 hours, or in the event that glove damage occurs during a procedure. Glove damage has been shown to occur more frequently during longer procedures, and has been specifically associated with certain activities, (e.g., tying sternal wires). You are encouraged to increase your frequency of glove changes under such circumstances.
- You should avoid digital palpation of needle tips and blind probing in poorly visualized or highly confined anatomic sites.
- If you suffer an injury which penetrates your gloves and skin, but during which you do not observe contact of your blood with the surgical field, you should check your hands to be certain you are not bleeding. If you are not bleeding, you may rejoin the case after changing gloves. If you are bleeding, you should withdraw from the case. If the device that injured you recontacted the patient, you must notify [your representative to the expert review panel] who must assure that the patient is made aware of the potential exposure and is treated appropriately.
- If you suffer an injury that causes you to bleed during a procedure and your blood contacts the surgical field, you must withdraw from the case and contact [your representative to the expert review panel], immediately. She/he will assure that the patient will be informed that a possible [HBV/HCV/HIV] exposure has taken place and the patient will be offered appropriate postexposure management, including immuno-/chemoprophylaxis and follow-up, as appropriate. To the extent possible, your identity will be protected.
- The Panel requests that you continue under the care of a physician with expertise in [HBV/HCV/HIV] medicine in order to appropriately monitor and manage your illness.

If you agree to the outlined restrictions on your practice, please sign below.

Signature: _____ Date: _____

Witness: _____ Date: _____

[Name, Expert Advisory Panel Representative]

FIGURE 1. Sample contract letter between an Expert Review Panel and a healthcare provider infected with a bloodborne pathogen. The letter delineates the specific recommendations of the panel and the responsibilities of the panel and of the infected provider. Table 7 provides more detail on the elements of such a letter or contract.

TABLE 6. Issues for the Hospital Epidemiologist and the Expert Review Panel to Consider When Providing Advice to Infected Healthcare Providers Regarding the Performance of Various Procedures

1. The precise procedures for which permission is sought, the historical risks for provider-to-patient bloodborne pathogen transmission associated with these procedures, the provider's experience with such procedures, and the likelihood of patient exposure to provider blood during these procedures
2. Gather evidence of the infected provider's skills, practices, and adherence to the institutional infection control plan (particularly with respect to standard precautions)
3. Investigate and discuss with the provider the availability of safer devices that will reduce the risk for patient exposures (eg, spring-loaded retractable needles, guards that shield dangerous tips, and blunted surgical needles)
4. Investigate and discuss the availability of barriers that will reduce the risks for exposures (eg, reinforced gloves,^{91,92} double gloves, gloves constructed of monofilament polymers or other materials resistant to tears, glove-liners, and other devices or materials to protect the provider's hands^{89,91,93-96})
5. Discuss work process controls, such as the "hands free" technique in the operating room¹⁴²
6. Emphasize the need and ethical obligation to notify the hospital epidemiologist, immediate supervisor, or other individual, as detailed (or identified) in the contract, should a breach and/or patient exposure occur
7. Emphasize a detailed description of the process to be used in the event of breach of infection control procedures or a patient exposure

of the Expert Review Panel may not be needed. In instances in which guideline violations are identified or in instances in which the provider's clinical status has changed significantly, the entire review panel should meet to consider the new information. The committee emphasizes that the Expert Review Panel should not advise the practitioner about his or her health and treatment options; this responsibility falls to the provider's personal physician.

II. DISCLOSURE ISSUES

9. Are there any medical settings in which a healthcare provider infected with HBV, HCV, and/or HIV should be routinely required to notify patients of his or her bloodborne pathogen status; and, if so, what are the specific types of circumstances requiring notification?

Recommendation

Providers infected with HBV, HCV, and/or HIV who are adhering to the guidelines above should not be required to disclose their infection status to any patient (unless the provider has been the source for an exposure for a patient, as discussed in Recommendation 11A, below) (A-III).

Discussion. Societal views of patients' rights are strong, and most patients feel that they have a right to know if their physician or other healthcare provider is infected with a potentially transmissible bloodborne pathogen (irrespective of the magnitude of risk).^{118,148,149} A national survey conducted in 2004 demonstrates little change in public views of this issue.¹¹⁸ Case law has generally concluded that informed consent includes disclosure of risks that may be perceived by patients as being important even if, by rational consideration, they are negligible. These positions aside, in both previous versions of this guideline, we concluded that a requirement for such disclosure would very likely require a provider to abandon or substantially modify his or her practice—an un-

warranted outcome in light of our current understanding of the risks for provider-to-patient transmission of these bloodborne pathogens. The existing 1991 US Public Health Service guidelines¹⁰⁵ require that patients who are to have "exposure-prone invasive procedures" performed by HIV-positive or HBeAg-positive, HBV-infected practitioners be notified of the practitioner's infection status prior to the procedure. On the basis of the substantial changes in the risk profile since the previous version of this guideline was published (eg, new safety devices, new infection control strategies, better techniques for monitoring diseases, effective postexposure management, and effective therapy), SHEA feels even more strongly that such a position is unwarranted. If practitioners adhere to the components of this guideline with respect to modifying their practices when an increased level of risk is present, in the absence of an adverse patient exposure to blood or blood-containing body fluids (discussed in Recommendation 11, below), the risk for provider-to-patient transmission is so small that it cannot be accurately measured. SHEA's position on these issues remains essentially unchanged. An earlier iteration of the American Hospital Association Patients' Bill of Rights argues for disclosure of relevant information to patients,^{150,151} although this "Bill of Rights" has subsequently been replaced by a plain-language document that does not directly address this issue. The American Medical Association Council on Judicial Affairs also includes a general statement in favor of patient disclosure.¹⁵²

10. Are there circumstances for which an infected healthcare provider should be required to obtain informed consent that includes disclosure of the provider's serostatus from a patient prior to a procedure?

Recommendation

Providers infected with HBV, HCV, and/or HIV who are adhering to the guidelines above should be required to obtain informed consent for a procedure but should not be required to disclose

TABLE 7. Elements of the Contract between an Infected Healthcare Provider and the Expert Review Panel

Responsibilities of the healthcare provider
1. Agrees to twice yearly follow-up by Occupational Medicine, including measurement of viral burden using tests specified by the panel
2. Agrees to twice yearly evaluations by a private physician who has expertise in the provider's specific blood-borne pathogen infection and agrees to have this physician discuss the results of these evaluations with the provider's Expert Review Panel
3. Agrees to formal training in infection control via a course identified by the infection control expert, or, alternatively agrees to counseling by the infection control professional concerning the use of appropriate infection control procedures, safety devices and work practice controls
4. Agrees to follow the recommended procedures and practices identified in the previous item (responsibility 3)
5. Agrees to notify the occupational medicine or the public health authority participating in the panel regarding any change in provider status that may increase risk to the patient (eg, new neurological findings, development of another contagious disease [eg, tuberculosis])
6. Acknowledges the ethical obligation to do so, and agrees to report instances immediately in which a patient exposure may have occurred to the hospital epidemiologist or to appropriate institutional/public health authorities identified in the contract, so that the potentially exposed patient may receive appropriate postexposure management and counseling
7. If receiving treatment, agrees to continue treatment as prescribed and agrees to notify occupational medicine if the treatment regimen is modified for any reason
8. Agrees to re-evaluation by expert panel and revision of contract should clinical status or viral burden change
Responsibilities of the institution and/or public health authorities
1. Agrees to convene Expert Review Panel at least twice annually (see text) to assess provider's clinical and virologic status as well as the provider's ongoing performance and her or his ability to continue to perform requested procedures
2. Agrees to maintain provider's medical privacy and confidentiality
3. Agrees to develop and follow institutional or provider-based follow-up procedure for potential patient exposure that makes every effort to ensure practitioner confidentiality
4. Panel participants should have no liability
5. Develops process for notifying hospital Risk Management

NOTE. Some aspects of this contract may be mandated by state laws, so the contract should carefully consider the legal requirements for the state in which the contract is being issued. A sample contract letter is shown in Figure 1.

their serostatus as part of the process of informed consent from patients on whom they are about to perform a procedure (A-III).

Discussion. If a practitioner adheres to the guidelines outlined in detail above, SHEA concludes that the risk for transmission would be so small that informed consent about the risk of transmission would not be required. In special circumstances associated with a known or anticipated increased level of risk (eg, a provider who has previously transmitted infection to a patient or a provider who has a viral burden in excess of those listed in these guidelines is performing a Category III procedure), obtaining informed consent is rational, prudent, and advised.

III. EXPOSURE MANAGEMENT

11. How should a provider-to-patient blood exposure or other hazardous body fluid exposure to HBV, HCV, and/or HCV be managed?

11A. Should a provider who is the source of a patient exposure be required to undergo testing for bloodborne pathogen infection?

Recommendation

A provider who is aware that he or she is the source of a significant patient exposure to his or her blood or hazardous body fluid should undergo testing for infection with bloodborne pathogens,

even if not known to be infected with HBV, HCV, and/or HIV (A-III). Healthcare institutions should develop specific policies to deal with such exposures and should establish sanctions for providers who refuse testing for bloodborne pathogens in these circumstances (A-III). Such policies should be formally drawn and approved by institutional attorneys and governing boards (A-III).

Recommendation

In the event of possible or documented patient exposure to blood or potentially hazardous body fluids from an infected provider, the involved provider is ethically obligated to notify immediately either the Occupational Medicine physician who is conducting follow-up for the provider or the chair of the provider's Expert Review Panel (A-III). Whoever is notified should immediately engage the infection control team, the hospital administration, and institutional risk management team to ensure there is appropriate follow-up and medical management for the potentially exposed patient (A-III). In the event of possible or documented patient exposure to blood or potentially hazardous body fluids from an infected provider who is not institutionally based, the provider is ethically bound to contact the official in the public health establishment who is providing Expert Review Panel oversight (A-III). This individual, in turn, should immediately ensure that there is appropriate follow-up and medical management for the potentially exposed patient (A-III).

Discussion. State laws and State policies and procedures vary substantially with respect to testing for bloodborne path-

ogens. Healthcare institutions electing to develop policies that compel testing of the source individual should make certain that such policies are legal in their jurisdictions and should apply such policies only to exposures for which scientific precedent establishes that HBV, HCV, or HIV transmission could occur.

11B. Should an inadvertently exposed patient be notified of the exposure?

Recommendation

A patient who has been exposed (ie, by way of percutaneous, mucous membrane, or nonintact-skin exposure) to the blood or potentially contaminated body fluid of any provider should be notified of the exposure promptly and given clear options for follow-up testing and management (A-III). An exposed patient (1) should be notified about the exposure promptly; (2) should subsequently be notified of the outcome of the source provider's HBV, HCV, and HIV test results; (3) should receive expert counseling regarding the implications of the event; and (4) should be offered effective postexposure treatment appropriate for the exposure in instances in which an exposure to a bloodborne pathogen is documented (consistent with current CDC guidelines^{153,154}) (A-III). Institutions should establish policies requiring self-reporting to the infection control program or occupational health program and to the exposed patient's primary physician of provider-to-patient blood or hazardous body fluid exposure (A-III). The exposed patient should not be notified of the source provider's name or of the exact circumstances of the exposure but should be provided with enough information to understand the implications of the exposure fully (A-III).

Discussion. For a variety of reasons, in instances in which a provider-to-patient blood exposure occurs, the patient has a right to know that the exposure has occurred, irrespective of whether the provider is known to be infected with a bloodborne pathogen. The patient must be notified about the exposure and presented with options for postexposure treatment (as appropriate), as well as appropriate follow-up.^{153,154} In addition, the patient must receive counseling about the risk for transmission and the strategies that are effective in preventing subsequent transmission of the bloodborne pathogen to which the patient was exposed. Since any exposure to blood may place patients at risk for acquiring a bloodborne infection, patients should always be notified of such occurrences. The identity of the source (ie, the infected provider) should not be disclosed. Needlestick transmissions (as well as mucous membrane and nonintact-skin transmissions) of HBV, HCV, and HIV infection have all been amply documented. Since negative serologic test results do not completely eliminate the possibility of transmission of bloodborne pathogens, any blood exposure creates a requirement for notification of the exposed patient. Notification also allows the exposed patient to have the option of receiving recommended postexposure management (eg, appropriate chemoprophylaxis or immunoprophylaxis). Institutions should designate

a responsible person for informing an exposed patient and ensuring patient follow-up. Ultimate responsibility for follow-up should be assigned to the patient's physician, even if the physician is the source of the exposure. The physician providing the follow-up should receive expert guidance from a member of the Infection Control and/or Occupational Health staff. SHEA would not recommend that the source of the exposure be involved in counseling, informed consent, or test explanation, in light of the potential for conflict of interest. The hospital epidemiologist, infection control practitioner, or other staff knowledgeable both about the risks and routes of transmission of bloodborne pathogens, as well as the counseling of individuals exposed to bloodborne pathogens, should be available for support and consultation.

11C. Should an inadvertently exposed patient be required to undergo baseline serologic testing?

Recommendation

The exposed patient and his or her physician should be asked for consent to perform baseline testing for bloodborne infections (when consonant with state and/or local laws) (A-III). If consent is obtained, the patient's serum should be tested for evidence of HBV, HCV, and HIV infection (A-III). If the patient refuses testing, the institution should seek the permission of the patient or the patient's representative to store available baseline serum from the patient (A-III). If neither testing nor storage can be accomplished, the patient or the patient's proxy should be asked to sign a formal declination emphasizing that these services were offered and declined (A-III).

Discussion. Although the exposed patient cannot be compelled to have and may clearly choose not to have such testing performed, such testing would help establish the basis (and some of the best evidence) for a claim against the institution and/or the practitioner. Exposed patients should be made aware of the potential value and detriment of negative and positive test results. For patients who refuse testing (and consonant with state and local laws regarding testing), institutions should attempt to obtain informed consent from the patient to allow the institution to preserve a carefully labeled and dated baseline serum sample from the exposed patient. Although such samples cannot be tested against the patient's will, these samples ultimately represent important evidence in such a case. Patients refusing to consent to serum storage should be asked to sign a form noting their declination for both serologic testing and serum storage.

11D. How (and by whom) should an inadvertently exposed patient be followed and, if appropriate, treated?

Recommendation

Exposed patients should be counseled regarding the risks for infection and the symptoms of acute HBV, HCV, and HIV infection (A-III), should be offered postexposure chemoprophylaxis and/or immunoprophylaxis as is characterized in current CDC guidelines for an exposed healthcare worker^{153,154} (A-II), and should be

followed in a manner analogous to the existing CDC guidelines for providers who sustain occupational exposures to HIV or other bloodborne pathogens.^{153,154} Institutions and/or providers involved in such exposures should provide testing at no cost to the patient and should provide the details of appropriate follow-up to the patient and her or his physician (A-I).

IV. TESTING ISSUES

12. Should any, or perhaps all, providers be routinely tested for HIV infection?

Recommendation

Mandatory HBV, HCV, or HIV screening of healthcare providers is not recommended (A-III). A provider who conducts Category III procedures is ethically obligated to know his or her infection status with respect to HBV, HCV, and HIV (A-III). Institutions should provide voluntary confidential testing for their employees (A-III). A provider who knows that he or she is the source of a patient exposure (ie, as defined by the CDC—a percutaneous, mucous membrane or nonintact-skin exposure) to his or her blood or hazardous blood or body fluid should report the exposure and should undergo testing for infection with bloodborne pathogens (A-III).

V. LOOK-BACK STUDIES

13. If an infected provider is identified, under what circumstances should a look-back study be conducted?

Recommendation

Look-back studies should be conducted only on a case-by-case basis in instances in which compelling evidence for increased risk for provider-to-patient transmission is identified (A-III). A decision to initiate a look-back study should be made in collaboration with the infected provider's Expert Review Panel, institutional leadership, and appropriate local and/or state public health authorities (A-III).

Discussion. Although look-back studies may occasionally provide useful information, most look-back studies have yielded no useful information, and all such investigations are extremely labor-intensive and resource-intensive.^{48,57} SHEA recommends that such studies be conducted only when factors are identified that suggest an increased risk for provider-to-patient transmission of one of these bloodborne pathogens.

A variety of circumstances may prompt initiation of a look-back study. These include (1) if an infected healthcare worker is identified during the investigation of a possible instance of healthcare-associated transmission of one of these viruses, (2) if provider-to-patient transmission infection is documented or presumed, (3) if there is disclosure of a bloodborne pathogen infection associated with a viral burden higher than the thresholds defined in Recommendations 1, 2, and 3 (above), by a healthcare worker who has been conducting Category

III procedures, or (4) if an ongoing screening program identifies an infected healthcare worker who has been conducting Category III procedures and who has a viral burden in excess of the thresholds noted in Recommendations 1, 2, and 3 (above). The goals for such an investigation include (1) the provision of information to patients regarding the nature and magnitude of risks to which they may have been exposed, (2) the identification of patients who may have become infected with one or more of these bloodborne pathogens as a result of healthcare interventions and who may benefit from treatment, (3) the prevention of additional instances of transmission, (4) the management of institutional risks, and (5) the reassurance of the public.

The decision about whether to conduct a look-back study should be made on a case-by-case basis. Factors that would suggest an increased risk for provider-to-patient transmission that would prompt such a study include (1) identification of an infected patient in the practice of an infected provider (and the demonstration of that the patient's and the provider's viral isolates are related), (2) the healthcare provider's clinical specialty and the types of procedures performed are among those associated with increased risk for transmission, (3) concern that a given provider fails to follow recommended infection control procedures, (4) evidence of substandard clinical practice (eg, high postoperative infection rates or frequent occupational exposures), and (5) comorbid medical diagnoses in the infected provider that might elevate risk (eg, conditions resulting in, for example, nonintact skin or early dementia).

The identification of a documented instance of provider-to-patient transmission of one of these 3 bloodborne pathogens should invariably result in a thorough look-back exercise. In the absence of a documented instance of provider-to-patient transmission, the Expert Review Panel should evaluate the risk for transmission on a case-by-case basis. If a look-back study is implemented, every effort should be made to preserve the privacy and medical confidentiality of the infected provider.

In instances in which the infected provider is institutionally based, the provider's institution should be responsible for the notification program, with appropriate collaboration with the local and state public health authorities. In instances in which the provider is not institutionally based, local or state public health authorities should decide about the need for such a study. If the decision is made to initiate such a study, the decision should be made, and the study conducted, by the appropriate public health authorities.

SUMMARY

SHEA favors a comprehensive approach to managing healthcare providers who have been identified as being infected with HBV, HCV, and/or HIV in the broader context of all institutional health and credentialing programs. Such an ap-

proach allows the assessment of the provider-to-patient transmission risks in appropriate perspective. Thus, reasons for broadly restricting practice should be consonant with existing impaired-provider and disability guidelines, and should be based on the following criteria: (1) the provider has a viral burden above the recommended threshold for the relevant virus, (2) the provider has a medical condition or conditions resulting in the provider's inability to perform assigned tasks, (3) the provider has documented untoward events (ie, the provider is known to have transmitted HBV, HCV, or HIV), (4) the provider refuses or is unable to follow recommended guidelines to prevent transmission of infectious diseases, and/or (5) the provider is unable to perform regular duties, assuming that "reasonable accommodation" has been offered for the disability.

AUTHORSHIP STATEMENT

A subcommittee of the Guidelines Committee of The Society for Healthcare Epidemiology of America drafted this guideline. The SHEA Board of Directors approved the final draft. This consensus statement represents SHEA's position on these controversial issues, and does not represent the opinions of the individual contributors to the document or of individual members of the organization.

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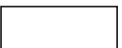
Recommended Adult Immunization Schedule—United States - 2012

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group¹

VACCINE ▼	AGE GROUP ►	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years
Influenza ²		1 dose annually					
Tetanus, diphtheria, pertussis (Td/Tdap) ^{3,*}		Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs					
Varicella ^{4,*}		2 Doses					
Human papillomavirus (HPV) Female ^{5,*}		3 doses					
Human papillomavirus (HPV) Male ^{5,*}		3 doses					
Zoster ⁶						1 dose	
Measles, mumps, rubella (MMR) ^{7,*}		1 or 2 doses			1 dose		
Pneumococcal (polysaccharide) ^{8,9}		1 or 2 doses					1 dose
Meningococcal ^{10,*}		1 or more doses					
Hepatitis A ^{11,*}		2 doses					
Hepatitis B ^{12,*}		3 doses					

*Covered by the Vaccine Injury Compensation Program

	For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection		Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)		Tdap recommended for ≥65 if contact with <12 month old child. Either Td or Tdap can be used if no infant contact		No recommendation
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Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

Figure 2. Vaccines that might be indicated for adults based on medical and other indications¹

VACCINE ▼	INDICATION ►	Pregnancy	Immunocompromising conditions (excluding human immunodeficiency virus [HIV]) ^{4,6,7,14}	HIV infection ^{4,7,13,14} CD4+ T lymphocyte count		Men who have sex with men (MSM)	Heart disease, chronic lung disease, chronic alcoholism	Asplenia ¹³ (including elective splenectomy and persistent complement component deficiencies)	Chronic liver disease	Diabetes, kidney failure, end-stage renal disease, receipt of hemodialysis	Health-care personnel	
				< 200 cells/ μL	≥ 200 cells/ μL							
Influenza ²			1 dose TIV annually			1 dose TIV or LAIV annually	1 dose TIV annually			1 dose TIV or LAIV annually		
Tetanus, diphtheria, pertussis (Td/Tdap) ^{3,*}		Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs										
Varicella ^{4,*}		Contraindicated		2 doses								
Human papillomavirus (HPV) Female ^{5,*}			3 doses through age 26 yrs			3 doses through age 26 yrs						
Human papillomavirus (HPV) Male ^{5,*}			3 doses through age 26 yrs				3 doses through age 21 yrs					
Zoster ⁶		Contraindicated			1 dose							
Measles, mumps, rubella (MMR) ^{7,*}		Contraindicated		1 or 2 doses								
Pneumococcal (polysaccharide) ^{8,9}			1 or 2 doses									
Meningococcal ^{10,*}		1 or more doses										
Hepatitis A ^{11,*}						2 doses						
Hepatitis B ^{12,*}				3 doses								

*Covered by the Vaccine Injury Compensation Program

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).



For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection



Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)



Contraindicated



No recommendation

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of January 1, 2012. For all vaccines being recommended on the Adult Immunization Schedule: a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/pubs/acip-list.htm). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Footnotes — Recommended Adult Immunization Schedule—United States - 2012

1. Additional information

- Advisory Committee on Immunization Practices (ACIP) vaccine recommendations and additional information are available at: <http://www.cdc.gov/vaccines/pubs/acip-list.htm>.
- Information on travel vaccine requirements and recommendations (e.g., for hepatitis A and B, meningococcal, and other vaccines) available at <http://wwwnc.cdc.gov/travel/page/vaccinations.htm>.

2. Influenza vaccination

- Annual vaccination against influenza is recommended for all persons 6 months of age and older.
- Persons 6 months of age and older, including pregnant women, can receive the trivalent inactivated vaccine (TIV).
- Healthy, nonpregnant adults younger than age 50 years without high-risk medical conditions can receive either intranasally administered live, attenuated influenza vaccine (LAIV) (FluMist), or TIV. Health-care personnel who care for severely immunocompromised persons (i.e., those who require care in a protected environment) should receive TIV rather than LAIV. Other persons should receive TIV.
- The intramuscular or intradermal administered TIV are options for adults aged 18–64 years.
- Adults aged 65 years and older can receive the standard dose TIV or the high-dose TIV (Fluzone High-Dose).

3. Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination

- Administer a one-time dose of Tdap to adults younger than age 65 years who have not received Tdap previously or for whom vaccine status is unknown to replace one of the 10-year Td boosters.
- Tdap is specifically recommended for the following persons:
 - pregnant women more than 20 weeks' gestation,
 - adults, regardless of age, who are close contacts of infants younger than age 12 months (e.g., parents, grandparents, or child care providers), and
 - health-care personnel.
- Tdap can be administered regardless of interval since the most recent tetanus or diphtheria-containing vaccine.
- Pregnant women not vaccinated during pregnancy should receive Tdap immediately postpartum.
- Adults 65 years and older may receive Tdap.
- Adults with unknown or incomplete history of completing a 3-dose primary vaccination series with Td-containing vaccines should begin or complete a primary vaccination series. Tdap should be substituted for a single dose of Td in the vaccination series with Tdap preferred as the first dose.
- For unvaccinated adults, administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second.
- If incompletely vaccinated (i.e., less than 3 doses), administer remaining doses.

Refer to the ACIP statement for recommendations for administering Td/Tdap as prophylaxis in wound management (See footnote 1).

4. Varicella vaccination

- All adults without evidence of immunity to varicella (as defined below) should receive 2 doses of single-antigen varicella vaccine or a second dose if they have received only 1 dose.
- Special consideration for vaccination should be given to those who
 - have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of persons with immunocompromising conditions) or
 - are at high risk for exposure or transmission (e.g., teachers; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).
- Pregnant women should be assessed for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.
- Evidence of immunity to varicella in adults includes any of the following:
 - documentation of 2 doses of varicella vaccine at least 4 weeks apart;
 - U.S.-born before 1980 (although for health-care personnel and pregnant women, birth before 1980 should not be considered evidence of immunity);
 - history of varicella based on diagnosis or verification of varicella by a health-care provider (for a patient reporting a history of or having an atypical case, a mild case, or both, health-care providers should seek either an epidemiologic link to a typical varicella case or to a

7. Measles, mumps, rubella (MMR) vaccination (cont'd)

Rubella component:

- For women of childbearing age, regardless of birth year, rubella immunity should be determined. If there is no evidence of immunity, women who are not pregnant should be vaccinated. Pregnant women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health-care facility.

Health-care personnel born before 1957:

- For unvaccinated health-care personnel born before 1957 who lack laboratory evidence of measles, mumps, and/or rubella immunity or laboratory confirmation of disease, health-care facilities should consider routinely vaccinating personnel with 2 doses of MMR vaccine at the appropriate interval for measles and mumps or 1 dose of MMR vaccine for rubella.

8. Pneumococcal polysaccharide (PPSV) vaccination

- Vaccinate all persons with the following indications:
 - age 65 years and older without a history of PPSV vaccination;
 - adults younger than 65 years with chronic lung disease (including chronic obstructive pulmonary disease, emphysema, and asthma); chronic cardiovascular diseases; diabetes mellitus; chronic liver disease (including cirrhosis); alcoholism; cochlear implants; cerebrospinal fluid leaks; immunocompromising conditions; and functional or anatomic asplenia (e.g., sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, splenic dysfunction, or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]);
 - residents of nursing homes or long-term care facilities; and
 - adults who smoke cigarettes.
- Persons with asymptomatic or symptomatic HIV infection should be vaccinated as soon as possible after their diagnosis.
- When cancer chemotherapy or other immunosuppressive therapy is being considered, the interval between vaccination and initiation of immunosuppressive therapy should be at least 2 weeks. Vaccination during chemotherapy or radiation therapy should be avoided.
- Routine use of PPSV is not recommended for American Indians/Alaska Natives or other persons younger than 65 years of age unless they have underlying medical conditions that are PPSV indications. However, public health authorities may consider recommending PPSV for American Indians/Alaska Natives who are living in areas where the risk for invasive pneumococcal disease is increased.

9. Revaccination with PPSV

- One-time revaccination 5 years after the first dose is recommended for persons 19 through 64 years of age with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); and for persons with immunocompromising conditions.
- Persons who received PPSV before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if at least 5 years have passed since their previous dose.
- No further doses are needed for persons vaccinated with PPSV at or after age 65 years.

10. Meningococcal vaccination

- Administer 2 doses of meningococcal conjugate vaccine quadrivalent (MCV4) at least 2 months apart to adults with functional asplenia or persistent complement component deficiencies.
- HIV-infected persons who are vaccinated should also receive 2 doses.
- Administer a single dose of meningococcal vaccine to microbiologists routinely exposed to isolates of *Neisseria meningitidis*, military recruits, and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic.
- First-year college students up through age 21 years who are living in residence halls should be vaccinated if they have not received a dose on or after their 16th birthday.
- MCV4 is preferred for adults with any of the preceding indications who are 55 years old and younger; meningococcal polysaccharide vaccine (MPSV4) is preferred for adults 56 years and older.
- Revaccination with MCV4 every 5 years is recommended for adults previously vaccinated with MCV4 or MPSV4 who remain at increased risk for infection (e.g., adults with anatomic or functional asplenia or persistent complement component deficiencies).

11. Hepatitis A vaccination

- Vaccinate any person seeking protection from hepatitis A virus (HAV) infection and persons with any of the following indications:
 - men who have sex with men and persons who use injection drugs;

- laboratory-confirmed case or evidence of laboratory confirmation, if it was performed at the time of acute disease);
- history of herpes zoster based on diagnosis or verification of herpes zoster by a health-care provider; or
- laboratory evidence of immunity or laboratory confirmation of disease.

5. Human papillomavirus (HPV) vaccination

- Two vaccines are licensed for use in females, bivalent HPV vaccine (HPV2) and quadrivalent HPV vaccine (HPV4), and one HPV vaccine for use in males (HPV4).
- For females, either HPV4 or HPV2 is recommended in a 3-dose series for routine vaccination at 11 or 12 years of age, and for those 13 through 26 years of age, if not previously vaccinated.
- For males, HPV4 is recommended in a 3-dose series for routine vaccination at 11 or 12 years of age, and for those 13 through 21 years of age, if not previously vaccinated. Males 22 through 26 years of age may be vaccinated.
- HPV vaccines are not live vaccines and can be administered to persons who are immunocompromised as a result of infection (including HIV infection), disease, or medications. Vaccine is recommended for immunocompromised persons through age 26 years who did not get any or all doses when they were younger. The immune response and vaccine efficacy might be less than that in immunocompetent persons.
- Men who have sex with men (MSM) might especially benefit from vaccination to prevent condyloma and anal cancer. HPV4 is recommended for MSM through age 26 years who did not get any or all doses when they were younger.
- Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, persons who are sexually active should still be vaccinated consistent with age-based recommendations. HPV vaccine can be administered to persons with a history of genital warts, abnormal Papanicolaou test, or positive HPV DNA test.
- A complete series for either HPV4 or HPV2 consists of 3 doses. The second dose should be administered 1–2 months after the first dose; the third dose should be administered 6 months after the first dose (at least 24 weeks after the first dose).
- Although HPV vaccination is not specifically recommended for health-care personnel (HCP) based on their occupation, HCP should receive the HPV vaccine if they are in the recommended age group.

6. Zoster vaccination

- A single dose of zoster vaccine is recommended for adults 60 years of age and older regardless of whether they report a prior episode of herpes zoster. Although the vaccine is licensed by the Food and Drug Administration (FDA) for use among and can be administered to persons 50 years and older, ACIP recommends that vaccination begins at 60 years of age.
- Persons with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication, such as pregnancy or severe immunodeficiency.
- Although zoster vaccination is not specifically recommended for health-care personnel (HCP), HCP should receive the vaccine if they are in the recommended age group.

7. Measles, mumps, rubella (MMR) vaccination

- Adults born before 1957 generally are considered immune to measles and mumps. All adults born in 1957 or later should have documentation of 1 or more doses of MMR vaccine unless they have a medical contraindication to the vaccine, laboratory evidence of immunity to each of the three diseases, or documentation of provider-diagnosed measles or mumps disease. For rubella, documentation of provider-diagnosed disease is not considered acceptable evidence of immunity.

Measles component:

- A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who
 - are students in postsecondary educational institutions;
 - work in a health-care facility; or
 - plan to travel internationally.
- Persons who received inactivated (killed) measles vaccine or measles vaccine of unknown type from 1963 to 1967 should be revaccinated with 2 doses of MMR vaccine.

Mumps component:

- A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who
 - are students in postsecondary educational institutions;
 - work in a health-care facility; or
 - plan to travel internationally.
- Persons vaccinated before 1979 with either killed mumps vaccine or mumps vaccine of unknown type who are at high risk for mumps infection (e.g., persons who are working in a health-care facility) should be considered for revaccination with 2 doses of MMR vaccine.

- persons working with HAV-infected primates or with HAV in a research laboratory setting;
- persons with chronic liver disease and persons who receive clotting factor concentrates;
- persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A; and
- unvaccinated persons who anticipate close personal contact (e.g., household or regular babysitting) with an international adoptee during the first 60 days after arrival in the United States from a country with high or intermediate endemicity. (See footnote 1 for more information on travel recommendations). The first dose of the 2-dose hepatitis A vaccine series should be administered as soon as adoption is planned, ideally 2 or more weeks before the arrival of the adoptee.
- Single-antigen vaccine formulations should be administered in a 2-dose schedule at either 0 and 6–12 months (Havrix), or 0 and 6–18 months (Vaqta). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule may be used, administered on days 0, 7, and 21–30 followed by a booster dose at month 12.

12. Hepatitis B vaccination

- Vaccinate persons with any of the following indications and any person seeking protection from hepatitis B virus (HBV) infection:
 - sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months); persons seeking evaluation or treatment for a sexually transmitted disease (STD); current or recent injection-drug users; and men who have sex with men;
 - health-care personnel and public-safety workers who are exposed to blood or other potentially infectious body fluids;
 - persons with diabetes younger than 60 years as soon as feasible after diagnosis; persons with diabetes who are 60 years or older at the discretion of the treating clinician based on increased need for assisted blood glucose monitoring in long-term care facilities, likelihood of acquiring hepatitis B infection, its complications or chronic sequelae, and likelihood of immune response to vaccination;
 - persons with end-stage renal disease, including patients receiving hemodialysis; persons with HIV infection; and persons with chronic liver disease;
 - household contacts and sex partners of persons with chronic HBV infection; clients and staff members of institutions for persons with developmental disabilities; and international travelers to countries with high or intermediate prevalence of chronic HBV infection; and
 - all adults in the following settings: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug-abuse treatment and prevention services; health-care settings targeting services to injection-drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients; and institutions and nonresidential daycare facilities for persons with developmental disabilities.
- Administer missing doses to complete a 3-dose series of hepatitis B vaccine to those persons not vaccinated or not completely vaccinated. The second dose should be administered 1 month after the first dose; the third dose should be given at least 2 months after the second dose (and at least 4 months after the first dose). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, give 3 doses at 0, 1, and 6 months; alternatively, a 4-dose Twinrix schedule, administered on days 0, 7, and 21–30 followed by a booster dose at month 12 may be used.
- Adult patients receiving hemodialysis or with other immunocompromising conditions should receive 1 dose of 40 µg/mL (Recombivax HB) administered on a 3-dose schedule or 2 doses of 20 µg/mL (Engerix-B) administered simultaneously on a 4-dose schedule at 0, 1, 2, and 6 months.

13. Selected conditions for which *Haemophilus influenzae* type b (Hib) vaccine may be used

- 1 dose of Hib vaccine should be considered for persons who have sickle cell disease, leukemia, or HIV infection, or who have anatomic or functional asplenia if they have not previously received Hib vaccine.

14. Immunocompromising conditions

- Inactivated vaccines generally are acceptable (e.g., pneumococcal, meningococcal, and influenza [inactivated influenza vaccine]), and live vaccines generally are avoided in persons with immune deficiencies or immunocompromising conditions. Information on specific conditions is available at <http://www.cdc.gov/vaccines/pubs/acip-list.htm>.