

MARYLAND HEALTHCARE
PERSONNEL
immunization
INITIATIVE



2011-2012
TOOLKIT

Maryland Healthcare Personnel Immunization Initiative

Dear Partner in Prevention:

Welcome! We are delighted to have you as a partner in this important effort to increase immunization rates among healthcare personnel. Since the inception seven years ago, the *Maryland Healthcare Personnel (HCP) Immunization Initiative* has enlisted dozens of healthcare facilities and providers in our fight against the spread of vaccine-preventable diseases in healthcare settings.

A collaboration between the Maryland Department of Health and Mental Hygiene, Maryland Partnership for Prevention, and professional associations across the state, the Initiative has raised awareness locally and nationally about the importance of vaccination among healthcare professionals.

As the program evolves, we continue to strive to provide the most relevant, useful resources to support your vaccination efforts. This year's toolkit features new information and updated versions of important resources to support your campaign. We hope it will facilitate continued success.

Features of the 2011-12 Maryland Healthcare Personnel Immunization Initiative Toolkit:

- Listing of Maryland hospitals with the highest healthcare personnel vaccination rates (p. 39)
- Examples of successful strategies for increasing vaccination among healthcare personnel (p. 30)
- Specific information and tools arranged by disease, including:
 - Facts and Frequently Asked Questions
 - Vaccine Information Statements (VIS)
 - Standing Orders
 - Sample Vaccination Declination Forms

We appreciate your commitment to raising immunization rates among Maryland's healthcare personnel and look forward to working with you. Should you require additional information about this initiative, call Robin Decker at 410-767-6679 or Tiffany Tate at 410-902-4677.

Sincerely,

*2011-12 Maryland Healthcare Personnel Immunization
Initiative Planning Committee*

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- Initiative Supporting Partners
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Background

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 a one-time dose of Tdap as soon as feasible to all HCP who have not received Tdap previously. Give Td boosters every 10 years thereafter. 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 HCPs who have not or are unsure if they have previously received a dose of Tdap should receive a one-time dose of Tdap as soon as feasible, without regard to the interval since the previous dose of Td. Then, they should receive Td boosters every 10 years thereafter.

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

First do no harm

Protect patients by making sure all staff receive yearly influenza vaccine!

Healthcare employers are not only strongly encouraged to increase their employees' influenza immunization rates, in some instances, their organization's accreditation depends on it! In 2006, the Centers for Disease Control and Prevention (CDC) published vaccination influenza recommendations for healthcare settings, and in 2007, The Joint Commission established influenza infection control standards.

Big changes have taken place in influenza vaccination of healthcare personnel (HCP): The responsibility for increasing the rates of HCP influenza vaccination is rapidly shifting from the employee to the employer.

What's happened?

At CDC: In February 2006, CDC published "Influenza Vaccination of Health-Care Personnel." These recommendations "apply to HCP in acute care hospitals, nursing homes, skilled nursing facilities, physician offices, urgent care centers, and outpatient clinics, and to persons who provide home healthcare and emergency medical services." They were issued jointly by HICPAC (the Healthcare Infection Control Practices Advisory Committee) and ACIP (the Advisory Committee on Immunization Practices). The summary box in the right column presents an overview, including the recommendation that employers vaccinate employees at the work site at no cost. To obtain a copy of the complete recommendations, go to: www.cdc.gov/mmwr/PDF/tr/rr5502.pdf.

At The Joint Commission: In January 2007, a new infection control standard of The Joint Com-

mission went into effect. It requires accredited organizations to offer influenza vaccinations to staff, volunteers, and licensed independent practitioners who have close patient contact. The standard is an accreditation requirement for the Critical Access Hospital, Hospital, and Long Term Care accreditation programs.

Why is it happening?

The short answer is because HCP influenza vaccination rates remain appallingly low, and unvaccinated HCP are infecting vulnerable patients with influenza. Only half of HCP were vaccinated against influenza in the 2008–09 season, even though ACIP has urged annual influenza vaccination for HCP since 1981. Further, influenza transmission has been documented among patients in a variety of clinical settings, and infections have been linked to unvaccinated HCP. Clearly, we are doing our patients harm.

What should your healthcare facility do to comply?

In the box below are practical online resources healthcare organizations will find valuable in creating influenza vaccination programs for employees.

Summary of CDC's HICPAC / ACIP Recommendations

The committees that developed and endorsed these recommendations included persons with expertise in infectious diseases, infection control, pediatrics, vaccinology, internal medicine, and public health. The recommendations are as follows:

- **Educate HCP regarding the benefits of influenza vaccination** and the potential health consequences of influenza illness for themselves and their patients, the epidemiology and modes of transmission, diagnosis, treatment, and nonvaccine infection control strategies, in accordance with their level of responsibility in preventing health-care-associated influenza.
- **Offer influenza vaccine annually to all eligible HCP** to protect staff, patients, and family members and to decrease HCP absenteeism. Use of either available vaccine (i.e., inactivated [TIV] or live attenuated influenza vaccine [LAIV]) is recommended for eligible persons.
- **Provide influenza vaccination to HCP at the work site and at no cost** as one component of employee health programs. Use strategies that have been demonstrated to increase influenza vaccine acceptance, including vaccination clinics, mobile carts, vaccination access during all work shifts, and modeling and support by institutional leaders.
- **Obtain a signed declination from HCP who decline vaccination** for reasons other than medical contraindications.
- **Monitor HCP vaccination coverage and declination** at regular intervals during influenza season and provide feedback of ward-, unit-, and specialty-specific rates to staff and administration.
- **Use the level of HCP influenza vaccination coverage as one measure of a patient-safety quality program.**

Practical resources for vaccinating HCP against influenza

Centers for Disease Control and Prevention
Read "Influenza Vaccination of Health-Care Personnel" at www.cdc.gov/mmwr/PDF/tr/rr5502.pdf. Access CDC's Influenza web page: www.cdc.gov/flu

National Influenza Vaccine Summit (NIVS)
(Co-sponsored by the American Medical Association and CDC). See the NIVS Healthcare Workers home page: www.preventinfluenza.org/professionals.asp

The Joint Commission
Visit "Strategies for Implementing Successful Influenza Immunization Programs for Health Care Personnel Project": www.jointcommission.org/PatientSafety/InfectionControl/flu_monograph.htm

U.S. Dept. of Health & Human Services (HHS)
See the HHS "Health Care Personnel Initiative to Improve Influenza Vaccination Toolkit": www.hhs.gov/ophis/initiatives/vac toolkit

Immunization Action Coalition (IAC)
Get these IAC print materials online:

- ♦ "Standing Orders for Administering Influenza Vaccine to Adults" www.immunize.org/catg.d/p3074.pdf
- ♦ "Screening Questionnaire for Injectable Influenza Vaccination" www.immunize.org/catg.d/p4066.pdf
- ♦ "Screening Questionnaire for Intranasal Influenza Vaccination" www.immunize.org/catg.d/p4067.pdf
- ♦ "Declination of Influenza Vaccination" form www.immunize.org/catg.d/p4068.pdf

Visit IAC's
"Honor Roll for Patient Safety"
to view stellar examples of
influenza vaccination mandates
in healthcare settings at
www.immunize.org/honor-roll

General Recommendations on Immunization

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. The nonsimultaneous administration of yellow fever (YF) vaccine and inactivated vaccines.
2. Simultaneous administration of an inactivated and live vaccine (e.g., pneumococcal polysaccharide vaccine [PPSV] and zoster [Zos] vaccine).
3. Interchangeability of combination vaccines and single-component vaccines (e.g., using single-component *Haemophilus influenzae* type b [Hib], diphtheria and tetanus toxoids and acellular pertussis (DTaP), and inactivated poliovirus [IPV] for later doses in series, after a series has begun with DTaP-IPV/Hib).
4. Interchangeability of brands of combination vaccines and single-component vaccines (e.g., using DTaP-IPV/Hib and single-component hepatitis B [Hep B] vaccine for later doses in series that might have previously included DTaP-IPV-HepB and Hib).
5. Rotarix and RotaTeq need not be repeated if an infant spits up or regurgitates a dose.
6. Contact allergy to latex is neither a contraindication nor a precaution to the use of quadrivalent meningococcal conjugate vaccine (MCV4) in the absence of an anaphylactic allergy.
7. No need to repeat a dose of MCV4 vaccine given subcutaneously.
8. Revaccination with MCV4.
9. Appropriate storage and handling for the following vaccines at 35°F–46°F:
 - DTaP
 - Hib
 - Hepatitis A
 - Hepatitis B
 - Human papillomavirus (HPV)
 - PPSV
 - Measles, mumps, and rubella (MMR)
 - Pneumococcal conjugate vaccine (PCV)
 - Rotavirus (RV)
 - Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine
 - Trivalent inactivated influenza vaccine (TIV)
10. Initiation of live Zos vaccine in immunocompetent patients 3 months after remission from chemotherapy.
11. Avoiding conception for 1 month after vaccination with MMR or varicella (Var) vaccine.
12. A minimum age of 12 months for the fourth dose of DTaP.
13. Use of pneumococcal conjugate vaccine and *Haemophilus influenzae* b vaccine in persons receiving hematopoietic cell transplant or who are infected with human immunodeficiency virus, regardless of age.

There is no commercial support for this activity.

Credit: Constant Joseph Desbordes (1761–1827), *Baron Jean Louis Alibert (1768–1837) performing the vaccination against smallpox in the Château of Liancourt* (detail), c. 1820, French. Oil on canvas. Courtesy: Musée de l'Assistance Publique — Hôpitaux de Paris, Paris, France / Archives Charmet / The Bridgeman Art Library.

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General Recommendations on Immunization

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

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Summary

This report is a revision of the General Recommendations on Immunization and updates the 2006 statement by the Advisory Committee on Immunization Practices (ACIP) (CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2006;55[No. RR-15]). The report also includes revised content from previous ACIP recommendations on the following topics: adult vaccination (CDC. Update on adult immunization recommendations of the immunization practices Advisory Committee [ACIP]. MMWR 1991;40[No. RR-12]); the assessment and feedback strategy to increase vaccination rates (CDC. Recommendations of the Advisory Committee on Immunization Practices: programmatic strategies to increase vaccination rates—assessment and feedback of provider-based vaccination coverage information. MMWR 1996;45:219–20); linkage of vaccination services and those of the Supplemental Nutrition Program for Women, Infants, and Children (WIC program) (CDC. Recommendations of the Advisory Committee on Immunization Practices: programmatic strategies to increase vaccination coverage by age 2 years—linkage of vaccination and WIC services. MMWR 1996;45:217–8); adolescent immunization (CDC. Immunization of adolescents: recommendations of the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Medical Association. MMWR 1996;45[No. RR-13]); and combination vaccines (CDC. Combination vaccines for childhood immunization: recommendations of the Advisory Committee on Immunization Practices [ACIP], the American Academy of Pediatrics [AAP], and the American Academy of Family Physicians [AAFP]. MMWR 1999;48[No. RR-5]).

Notable revisions to the 2006 recommendations include 1) revisions to the tables of contraindications and precautions to vaccination, as well as a separate table of conditions that are commonly misperceived as contraindications and precautions; 2) reordering of the report content, with vaccine risk-benefit screening, managing adverse reactions, reporting of adverse events, and the vaccine injury compensation program presented immediately after the discussion of contraindications and precautions; 3) stricter criteria for selecting an appropriate storage unit for vaccines; 4) additional guidance for maintaining the cold chain in the event of unavoidable temperature deviations; and 5) updated revisions for vaccination of patients who have received a hematopoietic cell transplant. The most recent ACIP recommendations for each specific vaccine should be consulted for comprehensive details. This report, ACIP recommendations for each vaccine, and additional information about vaccinations are available from CDC at <http://www.cdc.gov/vaccines>.

Introduction

CDC recommends routine vaccination to prevent 17 vaccine-preventable diseases that occur in infants, children, adolescents, or adults. This report provides information for

clinicians and other health-care providers about concerns that commonly arise when vaccinating persons of various ages. Providers and patients encounter numerous issues, such as the timing of each dose, screening for contraindications and precautions, the number of vaccines to be administered, the educational needs of patients and parents, and interpreting and responding to adverse events. Vaccination providers help patients understand the substantial, occasionally conflicting, information about vaccination. These vaccination recommendations are intended for clinicians and other health-care providers who vaccinate patients.

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

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Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC)

Summary

This report summarizes recommendations of the Advisory Committee on Immunization Practices (ACIP) concerning the use of certain immunizing agents in health-care workers (HCWs) in the United States. It was prepared in consultation with the Hospital Infection Control Practices Advisory Committee (HICPAC) and is consistent with current HICPAC guidelines for infection control in health-care personnel. These recommendations can assist hospital administrators, infection control practitioners, employee health physicians, and HCWs in optimizing infection prevention and control programs. Background information for each vaccine-preventable disease and specific recommendations for use of each vaccine are presented. The diseases are grouped into three categories: a) those for which active immunization is strongly recommended because of special risks for HCWs; b) those for which immunoprophylaxis is or may be indicated in certain circumstances; and c) those for which protection of all adults is recommended. This report reflects current ACIP recommendations at the time of publication. ACIP statements on individual vaccines and disease updates in MMWR should be consulted for more details regarding the epidemiology of the diseases, immunization schedules, vaccine doses, and the safety and efficacy of the vaccines.

INTRODUCTION

Because of their contact with patients or infective material from patients, many health-care workers (HCWs) (e.g., physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative staff) are at risk for exposure to and possible transmission of vaccine-preventable diseases. Maintenance of immunity is therefore an essential part of prevention and infection control programs for HCWs. Optimal use of immunizing agents safeguards the health of workers and protects patients from becoming infected through exposure to infected workers ([Table 1](#)) (1-15). Consistent immunization programs could substantially reduce both the number of susceptible HCWs in hospitals and health departments and the attendant risks for transmission of vaccine-preventable diseases to other workers and patients (16). In addition to HCWs in hospitals and health departments, these recommendations apply to those in private physicians' offices, nursing homes, schools, and laboratories, and to first responders.

Any medical facility or health department that provides direct patient care is encouraged to formulate a comprehensive immunization policy for all HCWs. The American Hospital Association has endorsed the concept of immunization programs for both hospital personnel and patients (17). The following recommendations concerning vaccines of importance to HCWs should be considered during policy development ([Table 2](#)).

BACKGROUND

Diseases for Which Immunization Is Strongly Recommended

On the basis of documented nosocomial transmission, HCWs are considered to be at significant risk for acquiring or transmitting hepatitis B, influenza, measles, mumps, rubella, and varicella. All of these diseases are vaccine-preventable.

Hepatitis B

Hepatitis B virus (HBV) infection is the major infectious hazard for health-care personnel. During 1993, an estimated 1,450 workers became infected through exposure to blood and serum-derived body fluids, a 90% decrease from the number estimated to have been thus infected during 1985 (18-20). Data indicate that 5%-10% of HBV-infected workers become chronically infected. Persons with chronic HBV infection are at risk for chronic liver disease (i.e., chronic active hepatitis, cirrhosis, and primary hepatocellular

Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011

On August 18, 2011, this report was posted as an MMWR Early Release on the MMWR website (<http://www.cdc.gov/mmwr>).

This document provides updated guidance for the use of influenza vaccines in the United States for the 2011–12 influenza season. In 2010, the Advisory Committee on Immunization Practices (ACIP) first recommended annual influenza vaccination for all persons aged ≥ 6 months in the United States (1,2). Vaccination of all persons aged ≥ 6 months continues to be recommended. Information is presented in this report regarding vaccine strains for the 2011–12 influenza season, the vaccination schedule for children aged 6 months through 8 years, and considerations regarding vaccination of persons with egg allergy. Availability of a new Food and Drug Administration (FDA)–approved intradermally administered influenza vaccine formulation for adults aged 18 through 64 years is reported. For issues related to influenza vaccination that are not addressed in this update, refer to the 2010 ACIP statement on prevention and control of influenza with vaccines and associated updates (1,2).

Methodology for the formulation of the ACIP annual influenza statement has been described previously (1). The ACIP Influenza Work Group meets every 2–4 weeks throughout the year. Work Group membership includes several voting members of the ACIP, as well as representatives from ACIP Liaison Organizations. Meetings are held by teleconference and include discussion of influenza-related issues, such as vaccine effectiveness and safety, coverage in groups recommended for vaccination, feasibility, cost-effectiveness, and anticipated vaccine supply. Presentations are requested from invited experts, and published and unpublished data are discussed. CDC's Influenza Division provides influenza surveillance and antiviral resistance data, and the Immunization Safety Office and Immunization Services Division provide information on vaccine safety and distribution and coverage, respectively.

Vaccine Strains for the 2011–12 Influenza Season

The 2011–12 U.S. seasonal influenza vaccine virus strains are identical to those contained in the 2010–11 vaccine. These include A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens. The influenza A (H1N1) vaccine virus strain is derived from a 2009 pandemic influenza A (H1N1) virus (3).

Recommendations for Vaccination

Routine annual influenza vaccination is recommended for all persons aged ≥ 6 months (1). To permit time for production of

protective antibody levels (4,5), vaccination should optimally occur before onset of influenza activity in the community, and providers should offer vaccination as soon as vaccine is available. Vaccination also should continue to be offered throughout the influenza season.

Although influenza vaccine strains for the 2011–12 season are unchanged from those of 2010–11, annual vaccination is recommended even for those who received the vaccine for the previous season. Although in one study of children vaccinated against A/Hong Kong/68 (H3N2) virus, vaccine efficacy remained high against this strain 3 years later, the estimated efficacy of vaccine decreased over the seasons studied (6). Moreover, several studies have demonstrated that postvaccination antibody titers decline over the course of a year (7–10). Thus, annual vaccination is recommended for optimal protection against influenza.

Vaccine Doses for Children Aged 6 Months Through 8 Years

Children aged 6 months through 8 years require 2 doses of influenza vaccine (administered a minimum of 4 weeks apart) during their first season of vaccination to optimize immune response. In a study of children aged 5 through 8 years who received trivalent inactivated vaccine (TIV) for the first time, the proportion of children with protective antibody responses was significantly higher after 2 doses than after 1 dose (11).

The importance of vaccine priming might depend more on the similarity of the antigenic composition between the priming and second dose than the temporal interval between doses. From the 2003–04 to 2004–05 influenza seasons, the A(H1N1) virus antigen remained unchanged; however, the A(H3N2) virus antigen changed to a drifted strain, and the B virus antigen changed more substantially to a different lineage. In a study conducted over those two seasons, influenza-vaccine naïve children aged 6 through 23 months who received 1 dose of TIV in the spring of their first year of vaccination followed by a second dose in the fall were less likely to have protective antibody responses to the A(H3N2) and B virus antigens when compared with children who received 2 doses of identical vaccine in the fall (12). Response to the unchanged A(H1N1) virus antigen was comparable between the groups. In another study conducted over the same two seasons, unprimed children aged 10 through 24 months who received 1 dose of TIV during the fall of each season had similar responses to the unchanged A(H1N1) virus antigen as well as to the drifted A(H3N2) virus antigen when compared with children aged 6 through 24

Hepatitis B and the healthcare worker

CDC answers frequently asked questions about how to protect healthcare workers

The Immunization Action Coalition thanks Eric E. Mast, MD, MPH, chief, Prevention Branch, Division of Viral Hepatitis, National Center for HIV/AIDS, Hepatitis, STD, and TB Prevention; William L. Atkinson, MD, MPH, medical epidemiologist, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention; and Linda A. Moyer, RN, consultant to the Immunization Action Coalition, for reviewing and updating the following questions and answers.

Healthcare workers need more vaccinations than just hepatitis B!

For information about additional vaccines you may need, see the references at the bottom of page 3.

Which workers in the healthcare setting need hepatitis B vaccine?

The Occupational Safety and Health Administration (OSHA) requires that hepatitis B vaccine be offered to healthcare workers (HCWs) who have a reasonable expectation of being exposed to blood on the job. This requirement does not include HCWs who would not be expected to have occupational risk, such as receptionists, billing staff, and general office workers.

At what anatomic site should hepatitis B vaccine be administered to adults? What needle size should be used?

The deltoid muscle is recommended for routine intramuscular (IM) vaccination among adults. The gluteus muscle should not be used as a site for administering hepatitis B vaccine. The suggested needle size is 1”–2” depending on the recipient’s gender and weight (1” for females weighing less than 70 kg; 1½” for females weighing 70–100 kg; 1”–1½” for males weighing less than 120 kg; and 2” for males weighing 120 kg or more and females more than 100 kg). A 22- to 25-gauge needle should be used. For optimal protection, it is crucial that the vaccine be administered IM, not subcutaneously.

If a HCW had one dose only of hepatitis B vaccine 4 months ago, should the series be restarted?

No. The hepatitis B vaccine series should not be restarted when doses are delayed; rather, the series should be continued from where it stopped. The HCW should receive the second dose of vaccine now and the third dose at least 8 weeks later. There needs to be at least 16 weeks between the first and the third doses and at least 8 weeks between the second and third doses of vaccine.

Is it safe for HCWs to be vaccinated during pregnancy?

Yes. Limited data indicate no apparent risk for adverse events to developing fetuses. Current hepatitis B vaccines contain noninfectious hepatitis B surface antigen (HBsAg) and should pose no risk to the fetus. If the mother is being vaccinated be-

cause she is at risk for hepatitis B virus (HBV) infection (e.g., a HCW, a person with a sexually transmitted disease, an injection drug user, multiple sex partners), vaccination should be initiated as soon as her risk factor is identified during the pregnancy. If not vaccinated, a pregnant woman may contract an HBV infection, which might result in severe disease for the mother and chronic infection for the newborn. In addition, giving hepatitis B vaccine to the mother is not a contraindication to breastfeeding.

Which HCWs need serologic testing after receiving 3 doses of hepatitis B vaccine?

All HCWs who have a reasonable risk of exposure to blood or body fluids containing blood (e.g., HCWs with direct patient contact, HCWs who have the risk of needlestick or sharps injury, laboratory workers who draw or test blood) should have postvaccination testing for antibody to hepatitis B surface antigen (anti-HBs). Postvaccination testing should be done 1–2 months after the last dose of vaccine.

What should be done if a HCW’s postvaccination anti-HBs test is negative 1–2 months after the last dose of vaccine?

Repeat the 3-dose series and test for anti-HBs 1–2 months after the last dose of vaccine. If the HCW is still negative after a second vaccine series, the HCW is considered a non-responder to hepatitis B vaccination. HCWs who do not respond to vaccination should be tested for HBsAg to determine if they have chronic HBV infection. If the HBsAg test is positive, the person should receive appropriate counseling and medical management. Persons who test negative for HBsAg 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) prophylaxis for any known or likely exposure to HBsAg-positive blood.

How often should I test HCWs after they’ve received the hepatitis B vaccine series to make sure they’re protected?

For immune competent HCWs, periodic testing or

periodic boosting is not needed. Postvaccination testing (anti-HBs) should be done 1–2 months after the last dose of hepatitis B vaccine. If adequate anti-HBs (at least 10 mIU/mL) is present, nothing more needs to be done. If postvaccination testing is less than 10 mIU/mL, the vaccine series should be repeated and anti-HBs testing done, 1–2 months after the last dose of the second series. This information should be recorded in the HCW’s employee health record.

Should a HCW who performs invasive procedures and who once had a positive anti-HBs result be revaccinated if the anti-HBs titer is rechecked and is less than 10 mIU/mL?

No. Immune competent persons known to have responded to hepatitis B vaccination do not require additional passive or active immunization. Postvaccination testing should be done 1–2 months after the original vaccine series is completed. In this scenario, the initial postvaccination testing showed that the HCW was protected. Substantial evidence suggests that adults who respond to hepatitis B vaccination (anti-HBs of at least 10 mIU/mL) are protected from chronic HBV infection for as long as 23 years, even if there is no detectable anti-HBs currently. Only immunocompromised persons (e.g., hemodialysis patients, some HIV-positive persons) need to have anti-HBs testing and booster doses of vaccine to maintain their protective anti-HBs concentrations of at least 10 mIU/mL.

Before reading the recommendations of CDC’s Advisory Committee on Immunization Practices (ACIP) that say not to do this, we tested our employees for anti-HBs several years after they were vaccinated and some people had inadequate results, even though they had all completed a 3-dose series. What should we do now?

ACIP does not recommend periodic testing of vaccinated HCWs because anti-HBs concentrations decline over time, and HCWs remain protected even if their anti-HBs concentration declines to below

(page 1 of 3)

10 mIU/mL. For HCWs who have been vaccinated in the past and who do not have a documented response to vaccination of at least 10 mIU/mL, ACIP recommends testing for anti-HBs at the time of an exposure and providing appropriate management based on the results of testing. (See postexposure guidelines in Table 1.) If cost is not a great concern or if an employee or employer wants documented assurance of immunity, a revaccination series can be undertaken followed by testing 1–2 months after the 3rd dose of hepatitis B vaccine.

How often should anti-HBs testing be done on HCWs who perform invasive procedures?

For persons whose immune status is normal, periodic serologic testing to assess anti-HBs concentrations is not necessary. Persons who perform invasive procedures should be treated no differently from other HCWs with respect to anti-HBs testing. If a HCW has an exposure (e.g., needlestick), s/he should be evaluated for their need for immunoprophylaxis according to postexposure guidelines in Table 1.

If HCWs received hepatitis B vaccination in the past and were not tested for immunity, should

they be tested now?

No. In this scenario, a HCW does not need to be tested unless s/he has an exposure. If an exposure occurs, refer to the postexposure guidelines in Table 1.

How should a vaccinated HCW with an unknown anti-HBs response be managed if they have a percutaneous or mucosal exposure to blood or body fluids from an HBsAg-positive source?

This person should be tested for anti-HBs as soon as possible after exposure. If the anti-HBs concentration is at least 10 mIU/mL, no further treatment is needed. If the anti-HBs concentration is less than 10 mIU/mL, HBIG and one dose of hepatitis B vaccine should be administered. Prior to administering the HBIG and vaccine, blood should be drawn for a baseline HBsAg test. Subsequently, in 3–6 months, an additional anti-HBs and an HBsAg test should be performed. If the HBsAg is positive, the person is infected and should be referred for medical evaluation. If the anti-HBs result is at least 10 mIU/mL, the person is seroprotected. It is necessary to do postvaccination testing later than the usual recommended time frame because anti-HBs from HBIG

might be detected if testing is done any earlier. The postvaccination test result should be recorded in the person’s health record.

For a pre-employment physical, a HCW states she received all three hepatitis B vaccine doses as an adolescent. Would you test for anti-HBs?

If the HCW has written documentation of a full hepatitis B vaccine series, testing for anti-HBs at this point is not necessary. If the HCW has a subsequent exposure to HBV, hepatitis B immunoprophylaxis should be administered following guidelines for a person who has been vaccinated, but the immune response is not known (Table 1). This information should be documented in the HCW’s employee health record. This approach should be sufficient to meet the needs of the employer and the requirements of OSHA. If there is no written documentation of hepatitis B vaccination, see the next question.

(continued on next page)

Table 1: Recommendations for postexposure prophylaxis after percutaneous or mucosal exposure to HBV in an occupational setting

Vaccination and antibody response status of exposed persons ¹	Treatment			
	Source is HBsAg positive	Source is HBsAg negative	Source is unknown or not tested	
			High risk	Low risk
Unvaccinated	HBIG ² (1 dose) and begin a hepatitis B vaccine series	Begin a hepatitis B vaccine series	Begin a hepatitis B vaccine series	Begin a hepatitis B vaccine series
Known responder ³	No treatment	No treatment	No treatment	No treatment
Nonresponder ³				
Not revaccinated ⁴	HBIG (1 dose) and begin a revaccination series	Begin a revaccination series	HBIG (1 dose) and begin a revaccination series	Begin a revaccination series
After revaccination ⁴	HBIG (2 doses) ⁵	No treatment	HBIG (2 doses) ⁵	No treatment
Antibody response unknown	Test for anti-HBs ⁶ If adequate ³ , no treatment If inadequate, HBIG x 1 and vaccine booster	No treatment	Test for anti-HBs ⁶ If adequate, ³ no treatment If inadequate, give vaccine booster and check anti-HBs in 1–2 months	

1. Persons known to have had HBV infection in the past or who are chronically infected do not require HBIG or vaccine.
 2. Hepatitis B immune globulin (0.06 mL/kg) administered IM.
 3. Adequate response is anti-HBs of at least 10 mIU/mL after vaccination.
 4. Revaccination = additional 3-dose series of hepatitis B vaccine administered after the primary series.
 5. First dose as soon as possible after exposure and the second dose 1 month later.
 6. Testing should be done as soon as possible after exposure.

Source: This table was adapted from “Updated U.S. PHS Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis,” MMWR, 6/29/01, Vol. 50 (RR-11)

Several physicians in our group have no documentation showing they received hepatitis B vaccine. They are relatively sure, however, that they received the doses many years ago. What do we do now?

Because there is no documentation of vaccination, the 3-dose vaccination series should be administered and postvaccination testing should be performed 1–2 months after the third dose of vaccine. There is no harm in receiving extra doses of vaccine. Care should always be taken to document vaccine lot, date, manufacturer, route, and vaccine dosages. Postvaccination testing results should also be documented, including the date testing was performed. All organizations (e.g., hospitals, clinics) should develop policies or guidelines to assure valid hepatitis B immunization.

A healthcare worker (HCW) thinks she had 3 doses of hepatitis B vaccine in the past but has no documentation of receiving those doses. Before reading the recommendations to revaccinate her, we obtained an anti-HBs titer and the result was greater than 10 mIU/mL. With this lab result, can't we assume she is immune?

A positive anti-HBs indicates that the vaccinated person is immune at the time the HCW was tested, but does not necessarily assure that the HCW has long-term immunity. Long-term immunity has been shown only for persons attaining an adequate anti-HBs result of at least 10 mIU/mL after a 3-dose vaccination series. The most direct way to deal with this is to vaccinate the HCW with the 3-dose series of hepatitis B vaccine; test for anti-HBs in 1–2 months and document the result in the HCW's employee health record. An adequate anti-HBs result from a documented 3-dose vaccine series would assure not only seroprotection, but long-term protection, as well.

Of course, it is possible that the HCW has an anti-HBs result of greater than 10 mIU/mL because of an HBV infection in the past. If this is of concern, a total anti-HBc test could be performed to discern this (a positive result indicates a history of HBV infection at some undefined period in time).

I'm a nurse who received the hepatitis B vaccine series more than 10 years ago and had a positive follow-up titer (at least 10 mIU/mL). At present, my titer is negative (less than 10 mIU/mL). What should I do now?

Nothing. Data show that vaccine-induced anti-HBs levels might decline over time; however, immune memory (anamnestic anti-HBs response) remains

intact indefinitely following immunization. Persons with anti-HBs concentrations that decline to less than 10 mIU/mL are still protected against HBV infection. For HCWs with normal immune status who have demonstrated adequate anti-HBs (at least 10 mIU/mL) following vaccination, booster doses of vaccine or periodic anti-HBs testing is not recommended.

A person who is a known non-responder to hepatitis B vaccine has a percutaneous exposure to HBsAg-positive blood. According to older ACIP recommendations, I have the option to give HBIG x 2 or HBIG x 1 and initiate revaccination. How do I decide which to do?

Current recommendations have been revised. The recommended postexposure prophylaxis for persons who are non-responders to hepatitis B vaccine (i.e., have not responded to an initial 3-dose series and revaccination with a 3-dose series) is to give HBIG as soon as possible after exposure and a second dose of HBIG one month later (see Table 1). Exposed persons, who are known not to have responded to a primary vaccine series, but have not been revaccinated with a second 3-dose series, should receive a single dose of HBIG and reinstate the hepatitis B vaccine series with the first dose of hepatitis B vaccine as soon as possible after exposure.

If an employee does not respond to hepatitis B vaccination (employee has had two full series of hepatitis B vaccine), does s/he need to be removed from activities that expose her/him to bloodborne pathogens? Does the employer have a responsibility in this area beyond providing the vaccine?

There are no regulations that require removal from job situations where exposure to bloodborne pathogens could occur; this is an individual policy decision within the organization. OSHA regulations require that employees in jobs where there is a reasonable risk of exposure to blood be offered hepatitis B vaccine. In addition, the regulation states that adequate personal protective equipment be provided and that standard precautions be followed. Check your state OSHA regulations regarding additional requirements. If there are no state OSHA regulations, federal OSHA regulations should be followed. Adequate documentation should be placed in the employee record regarding non-response to vaccination. HCWs who do not respond to vaccination should be tested for HBsAg to determine if they have chronic HBV infection.

If the HBsAg test is positive, the person should receive appropriate counseling and medical management. Persons who test negative for HBsAg should be considered susceptible to HBV infection and should be counseled about precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known or likely exposure to HBsAg-positive blood (see Table 1).

Can a person with chronic HBV infection become a HCW?

Yes. All HCWs should practice standard precautions, which are designed to prevent HBV transmission, both from patients to HCW and from HCW to patient. There is, however, one caveat concerning HBV-infected HCWs. Those who are HBsAg positive and HBeAg (hepatitis B e antigen) positive should not perform exposure-prone procedures (e.g., gynecologic, cardiothoracic surgery) 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 might include notifying prospective patients of the HCW's seropositivity before they undergo exposure-prone invasive procedures. For more information on this issue, see the *Mortality and Morbidity Weekly Report*, "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures," *MMWR*, 7/12/91, Vol. 40(RR-8);1–9. This document is available at www.cdc.gov/mmwr/preview/mmwrhtml/00014845.htm.

Keep your own vaccination history!

Record the dates you received hepatitis B vaccine, as well as the results of your postvaccination serologic testing (anti-HBs).

Remember to save records of any vaccinations you receive so you don't have to repeat them.

To order adult immunization record cards, visit www.immunize.org/adultizcards.

For more information on vaccination recommendations for healthcare workers, see the following:

1. "Immunization of Health-Care Workers," *MMWR*, 12/26/97, Vol. 46 (RR-18), www.cdc.gov/mmwr/PDF/rr/rr4618.pdf
2. "Influenza Vaccination of Health-Care Personnel," *MMWR*, 2/24/06, Vol. 55 (RR-2), www.cdc.gov/mmwr/PDF/rr/rr5502.pdf
3. "Healthcare Personnel Vaccination Recommendations," Immunization Action Coalition, www.immunize.org/catg.d/p2017.pdf

Notes from the Field

Measles Outbreak — Hennepin County, Minnesota, February–March 2011

On March 2, 2011, the Minnesota Department of Health (MDH) confirmed measles in a Hennepin County resident aged 9 months. As of April 1, investigation of contacts and heightened surveillance had revealed a total of 13 epidemiologically linked cases in Hennepin County residents. Of those cases, 11 were laboratory confirmed, and two were in household contacts of confirmed cases and met the clinical case definition for measles.

The patients included children aged 4 months–4 years and one adult aged 51 years; seven of the 13 were of Somali descent. Eight patients were hospitalized. Vaccination status was known for 11 patients: five were too young to have been vaccinated, and six (all of Somali descent) had not been vaccinated because of parental concerns about the safety of the measles, mumps, and rubella (MMR) vaccine. The most recent rash onset was March 28. An additional, unrelated case of measles was confirmed in a Hennepin County resident aged 34 years who was exposed in Orlando, Florida, sometime during March 1–10.

The investigation determined that the index patient was a U.S.-born child of Somali descent, aged 30 months, who developed a rash February 15, 14 days after returning from a trip to Kenya. The patient attended a drop-in child care center 1 day before rash onset; measles developed in three contacts at the center and in one household contact. Secondary and tertiary exposures occurred in two congregate living facilities for homeless persons (four patients), an emergency department (two patients), and households (two patients). A virus isolate from the index patient was genotyped at CDC as B3, which is endemic in sub-Saharan Africa.

Outbreak control efforts have included following up with potentially exposed persons, providing immune globulin to persons without evidence of immunity, and recommending that persons without evidence of immunity who have been exposed to measles not leave their residence while potentially infectious (21 days). Multiple vaccination clinics have been held or scheduled at community venues and in the congregate living facilities.

In the United States, MMR vaccine normally is given as a 2-dose series, with the first dose at age 12–15 months and a second dose at age 4–6 years.* However, this series may be accelerated during outbreaks. In response to the current outbreak, MDH has recommended that children aged 6–11 months living in selected congregate living facilities receive a dose of MMR vaccine,† and that older children and adults in these facilities receive vaccine if they are susceptible and have had less than 2 doses of MMR vaccine. MDH also has recommended an accelerated vaccination schedule (a total of 2 doses of MMR vaccine separated by at least 28 days) for all children aged ≥12 months living in Hennepin County and all children of Somali descent living in the wider Minneapolis-St. Paul metropolitan area.

Measles was declared eliminated from the United States in 2000. However, importations of measles from other countries still occur, and low vaccination coverage associated with parental concerns regarding the MMR vaccine puts persons and communities at risk for measles. Public health and health-care providers should work with parents and community leaders to address concerns about the MMR vaccine to ensure high vaccination coverage and prevent measles.

* Additional information available at <http://www.cdc.gov/vaccines/recs/schedules/downloads/child/mmwr-child-schedule.pdf>.

† Because serologic response to the measles vaccine is variable among infants aged 6–11 months, infants vaccinated before age 12 months should be revaccinated on or after the first birthday with 1 dose of MMR vaccine followed by a second at least 28 days later.

Reported by

Hennepin County Public Health, Hopkins and Minneapolis; Minneapolis Dept of Health; Minnesota Dept of Health, St. Paul, Minnesota. Div of Viral Diseases, National Center for Immunization and Respiratory Diseases, CDC. Corresponding contributor: Ruth Lynfield, MD, Minnesota Dept of Health, 651-201-5414, ruth.lynfield@state.mn.us.



Vaccines and Preventable Diseases:

Healthcare Worker Vaccination

Prevention & Control of Mumps in Healthcare Settings

Prevention and control strategies should be applied in all healthcare settings where patient care occurs, including outpatient and long-term care facilities. An effective vaccination program is the best approach to prevent healthcare-associated mumps transmission. Healthcare facilities are encouraged to review employee immunization status for mumps and other vaccine preventable infections.

Persons born during or after 1957:

Adequate mumps vaccination for healthcare workers born during or after 1957 consists of 2 doses of a live mumps virus vaccine. Healthcare workers with no history of mumps vaccination and no other evidence of immunity should receive 2 doses (at a minimum interval of 28 days between doses). Healthcare workers who have received only 1 dose previously should receive a second dose.

Persons born before 1957:

Because birth before 1957 is only presumptive evidence of immunity, healthcare facilities should consider recommending at least 1 dose of a live mumps virus vaccine for unvaccinated workers born before 1957 who do not have physician-diagnosed mumps or laboratory evidence of mumps immunity. In addition, during a mumps outbreak, healthcare facilities should strongly consider recommending 2 doses of a live mumps virus vaccine to unvaccinated healthcare personnel born before 1957 who do not have evidence of mumps immunity. Facilities should plan in advance the logistics required to implement this 2-dose recommendation and may choose to proceed with appropriate assessment and vaccination before an outbreak occurs.

Receipt of MMR or MMRV vaccine is not a reason to exclude personnel from work.

See also: **Why might some people born before 1957 need to be vaccinated with MMR?** ([vac-faqs-tech.htm#012](http://www.cdc.gov/vaccines/imz/downloads/p/faq-why-might-some-people-born-before-1957-need-to-be-vaccinated-with-mmr.pdf))

NOTE: The combination MMRV vaccine is not licensed for those over 12 years old.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES
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ACIP Provisional Recommendations for Measles-Mumps-Rubella (MMR) 'Evidence of Immunity' Requirements for Healthcare Personnel

Date of ACIP vote: June 24, 2009

Date of posting of provisional recommendations: August 28, 2009

On June 24, 2009 the ACIP voted on revised recommendations for measles-mumps-rubella (MMR) 'evidence of immunity' requirements for healthcare personnel*. The Healthcare Infection Control Practices Advisory Committee (HICPAC) has endorsed these changes.

Summary of new recommendations:

Adequate presumptive evidence of immunity to measles, rubella, and mumps for persons who work in health care facilities:

Measles:

- a. Documented administration of two doses of live measles virus vaccine¹ *or*
- b. Laboratory evidence of immunity or laboratory confirmation of disease *or*
- c. Born before 1957²³⁴

Rubella

- a. Documented administration of one dose of live rubella virus vaccine¹ *or*
- b. Laboratory evidence of immunity or laboratory confirmation of disease *or*
- c. Born before 1957 (except women of childbearing age who could become pregnant)²³⁴

Mumps

- a. Documented administration of two doses of live mumps virus vaccine¹ *or*
- b. Laboratory evidence of immunity or laboratory confirmation of disease *or*
- c. Born before 1957²³⁴

¹ The first dose should be administered on or after the first birthday; the second dose of measles and mumps-containing vaccine should be administered no earlier than one month (i.e., a minimum of 28 days) after the first dose. Combined MMR vaccine generally should be used whenever any of its component vaccines is indicated.

² May vary depending on current state or local requirements.

³ For unvaccinated personnel born before 1957 who lack laboratory evidence of measles, mumps and/or rubella immunity or laboratory confirmation of disease, healthcare facilities should consider vaccinating personnel with two doses of MMR vaccine at the appropriate interval (for measles and mumps) and one dose of MMR vaccine (for rubella), respectively.

⁴ For unvaccinated personnel born before 1957 who lack laboratory evidence of measles, mumps and/or rubella immunity or laboratory confirmation of disease, healthcare facilities should recommend two doses of MMR vaccine during an outbreak of measles or mumps and one dose during an outbreak of rubella.

* These recommendations update two previous ACIP documents:

1. Immunization of Health Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/00050577.htm>
2. Measles, Mumps, and Rubella---Vaccine Use and Strategies for Elimination of Measles, Rubella, and Congenital Rubella Syndrome and the Control of Mumps: Recommendations of the Advisory Committee on Immunization Practices. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/00053391.htm>.

Update: Mumps Outbreak — New York and New Jersey, June 2009–January 2010

State and local health departments, in collaboration with CDC, continue to investigate a mumps outbreak that began in New York in June 2009 (1). The index case occurred in a boy aged 11 years who had returned on June 17 from a trip to the United Kingdom, where approximately 7,400 reports of laboratory-confirmed mumps were received by the Health Protection Agency in 2009.* He then attended a New York summer camp for tradition-observant Jewish boys, where he became symptomatic on June 28. Subsequently, other camp attendees and a staff member were reported to have mumps, and transmission continued in multiple locations when the camp attendees returned home. As of January 29, 2010, a total of 1,521 cases had been reported, with onset dates from June 28, 2009, through January 29, 2010, a substantial increase from the 179 cases reported as of October 30, 2009 (1). The outbreak has remained confined primarily to the tradition-observant Jewish community, with <3% of cases occurring among persons outside the community. The largest percentage of cases (61%) has occurred among persons aged 7–18 years, and 76% of the patients are male. Among the patients for whom vaccination status was reported, 88% had received at least 1 dose of mumps-containing vaccine, and 75% had received 2 doses. This is the largest mumps outbreak that has occurred in the United States since 2006 (2). Although mumps vaccination alone was not sufficient to prevent this outbreak, maintaining high measles, mumps, and rubella (MMR) vaccination coverage remains the most effective way to prevent outbreaks and limit their size when they occur.

Mumps cases included in this report were reported by January 29, 2010. Cases were classified according to the

2008 case definition of the Council of State and Territorial Epidemiologists[†]; only cases of probable and confirmed mumps are included in this report. In the United States, the Advisory Committee on Immunization Practices (ACIP) recommends that children receive 2 doses of measles, mumps, and rubella (MMR) vaccine, with the first dose administered at 12–15 months and the second dose near the time of school entry (at 4–6 years).[§] Methods used to obtain the vaccination status of patients have included parental report, review of vaccination cards, and verification from health-care providers.

The 1,521 outbreak-related mumps cases have been reported from several counties in New York and New Jersey; local transmission is continuing (Figure). The majority (675 [44%]) of cases have been reported from New York City (primarily Brooklyn), followed by Orange County, New York (364 [24%]);

[†] An illness with acute onset of unilateral or bilateral tender, self-limited swelling of the parotid or other salivary glands, lasting at least 2 days, and without other apparent cause. Probable case: a case that meets the clinical case definition without laboratory confirmation and is epidemiologically linked to a clinically compatible case. Confirmed case: a case that 1) meets the clinical case definition or occurs in a patient with a clinically compatible illness and 2) is either laboratory confirmed or is epidemiologically linked to a confirmed case. Available at http://www.cdc.gov/ncphi/diss/nndss/casedef/mumps_2008.htm.

[§] ACIP recommends 2 doses of mumps-containing vaccine for all school-aged children (i.e., grades K–12) and for adults at high risk for disease (i.e., persons who work in health-care facilities, international travelers, and students at post-high school educational institutions). Health-care workers born in or after 1957 without laboratory evidence of immunity should receive 2 doses of mumps-containing vaccine, and those born before 1957 without laboratory evidence of immunity should consider receiving 1 dose. During outbreaks, ACIP recommends offering a second dose of vaccine to children aged 1–4 years (8).

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* Available at <http://www.hpa.org.uk/hpr/archives/2010/news0210.htm#mmps>.



Rockland County, New York (298 [20%]); and four counties in New Jersey (159 [10%]). Twenty-five (2%) cases (reported during June 28–September 8) were associated with the summer camp in Sullivan County, New York; however, no additional cases occurred in the county after the camp ended in late August. Of the 1,521 patients, 1,477 (97%) are members of the tradition-observant Jewish community. Of the 44 cases not associated with this religious community, 33 have been reported from New York City; seven from New Jersey; two from Orange County, New York; and two from Rockland County, New York. Many of these outside cases have occurred among persons who have reported regular contact with members of the affected community.

Diagnostic laboratory testing for mumps (i.e., detection of mumps immunoglobulin M antibodies by various methods, detection of mumps RNA by real-time reverse transcription–polymerase chain reaction, or isolation of mumps virus in cell culture) has been performed for 761 (50%) cases. Of these, 385 (51%) cases are laboratory confirmed.

Of the 1,518 patients whose age is known, 1,385 (91%) are aged >6 years (Figure). The median age of patients is 15 years (range 3 months–90 years) and is similar in all areas with ongoing transmission except New Jersey, where the median age is 17 years. Of the 1,489 patients whose sex is known, 1,136 (76%) are male. Sixty-five reports of complications from mumps have been received: orchitis (55 cases), pancreatitis (five cases), aseptic meningitis (two cases), transient deafness (one case), Bell's palsy (one case), and oophoritis (one case). Nineteen hospitalizations from mumps have been reported; no deaths have occurred.

Vaccination status is known for 1,115 patients: 966 (91%) of 1,062 patients aged ≤18 years and 149 (33%) of 456 patients aged ≥19 years (Table). Of these patients, 976 (88%) had received at least 1 dose of mumps-containing vaccine before the outbreak, and 839 (75%) had received 2 doses. Among patients aged 7–18 years, the age group with the majority of cases and for whom 2 doses of MMR vaccine is recommended, 93% had received at least 1 dose, and 85% had received 2 doses. The vaccination status of the

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Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccine from the Advisory Committee on Immunization Practices, 2010

Despite sustained high coverage for childhood pertussis vaccination, pertussis remains poorly controlled in the United States. A total of 16,858 pertussis cases and 12 infant deaths were reported in 2009 (1; CDC, unpublished data, 2009). Although 2005 recommendations by the Advisory Committee on Immunization Practices (ACIP) called for vaccination with tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) for adolescents and adults to improve immunity against pertussis, Tdap coverage is 56% among adolescents and <6% among adults (2,3). In October 2010, ACIP recommended expanded use of Tdap. This report provides the updated recommendations, summarizes the safety and effectiveness data considered by ACIP, and provides guidance for implementing the recommendations.

ACIP recommends a single Tdap dose for persons aged 11 through 18 years who have completed the recommended childhood diphtheria and tetanus toxoids and pertussis/diphtheria and tetanus toxoids and acellular pertussis (DTP/DTaP) vaccination series and for adults aged 19 through 64 years (4,5). Two Tdap vaccines are available in the United States. Boostrix (GlaxoSmithKline Biologicals, Rixensart, Belgium) is licensed for use in persons aged 10 through 64 years, and Adacel (Sanofi Pasteur, Toronto, Canada) is licensed for use in persons aged 11 through 64 years. Both Tdap products are licensed for use at an interval of at least 5 years between the tetanus and diphtheria toxoids (Td) and Tdap dose. On October 27, 2010, ACIP approved the following additional recommendations: 1) use of Tdap regardless of interval since the last tetanus- or diphtheria-toxoid containing vaccine, 2) use of Tdap in certain adults aged 65 years and older, and 3) use of Tdap in undervaccinated children aged 7 through 10 years.

The Pertussis Vaccines Working Group of ACIP reviewed published and unpublished Tdap immunogenicity and safety data from clinical trials and observational studies on use of Tdap. The Working Group also considered the epidemiology of pertussis, provider and program feedback, and data on the barriers to receipt of Tdap. The Working Group then presented policy options for consideration to the full ACIP. These additional recommendations are intended to remove identified barriers and programmatic gaps that contribute to suboptimal vaccination coverage. An important barrier that limited vaccination of persons with Tdap was unknown history of Td booster. Programmatic gaps included lack of a licensed Tdap vaccine for children aged 7 through 10 years and adults aged 65 years and older. In light of the recent increase of pertussis in

the United States, the additional recommendations are made to facilitate use of Tdap to reduce the burden of disease and risk for transmission to infants (Box).

Timing of Tdap Following Td

Safety. When Tdap was licensed in 2005, the safety of administering a booster dose of Tdap at intervals <5 years after Td or pediatric DTP/DTaP had not been studied in adults. However, evaluations in children and adolescents suggested that the safety of intervals as short as 18 months was acceptable (6). Rates of local and systemic reactions after Tdap vaccination in adults were lower than or comparable to rates in adolescents during U.S. prelicensure trials; therefore, the safety of using intervals as short as 2 years between Td and Tdap in adults was inferred (4).

Additional data on the safety of administering Tdap <5 years after Td are now available. Two studies were conducted with 387 persons aged 18 through 76 years who received a Tdap or combined Tdap-inactivated polio vaccine (Tdap-IPV) vaccination either within 21 days, or <2 years following a previous Td-containing vaccine (7,8). Tdap-IPV vaccine is not licensed in the United States. In both studies, immediate or short-term adverse events (e.g., 30 minutes to 2 weeks) after receipt of Tdap or Tdap-IPV were examined. The majority of these events were limited to local reactions, including pain (68%–83%), erythema (20%–25%), and swelling (19%–38%) (7,8). Serious adverse events related to the receipt of Tdap or Tdap-IPV shortly after Td or Td-IPV vaccinations did not occur. However, the number of subjects in these studies was small and does not exclude the potential for rare, but serious, adverse events.

Guidance for use. ACIP recommends that pertussis vaccination, when indicated, should not be delayed and that Tdap should be administered regardless of interval since the last tetanus or diphtheria toxoid-containing vaccine. ACIP concluded that while longer intervals between Td and Tdap vaccination could decrease the occurrence of local reactions, the benefits of protection against pertussis outweigh the potential risk for adverse events.

Adults Aged 65 Years and Older

Unpublished data from trials for Adacel (N = 1,170) and Boostrix (N = 1,104) on the safety and immunogenicity of Tdap in adults aged 65 years and older who received vaccine were provided to ACIP by Sanofi Pasteur and GlaxoSmithKline.

Notes from the Field

Pertussis — California, January–June 2010

The number of pertussis cases reported to the California Department of Public Health (CDPH) has increased substantially during 2010. The increase in cases was first noted in late March among patients admitted to a children's hospital. During January 1–June 30, 2010, a total of 1,337 cases were reported, a 418% increase from the 258 cases reported during the same period in 2009. All cases either met the Council of State and Territorial Epidemiologists definitions for confirmed or probable pertussis or had an acute cough illness and *Bordetella pertussis*-specific nucleic acid detected by polymerase chain reaction from nasopharyngeal specimens (1).

During January–June in California, the incidence of pertussis was 3.4 cases per 100,000 population. County rates ranged from zero to 76.9 cases per 100,000 (median: 2.0 cases). By age group, incidence was highest (38.5 cases per 100,000) among infants aged <1 year; 89% of cases were among infants aged <6 months, who are too young to be fully immunized. Incidence among children aged 7–9 years and 10–18 years was 10.1 cases and 9.3 cases per 100,000, respectively.

Of 634 case reports with available data, 105 (16.6%) patients were hospitalized, of whom 66 (62.9%) were aged <3 months. Incidence among Hispanic infants (49.8 cases per 100,000) was higher than among other racial/ethnic populations. Five deaths were reported, all in previously healthy Hispanic infants aged <2 months at disease onset; none had received any pertussis-containing vaccines.

The incidence of pertussis is cyclical, with peaks occurring every 3–5 years in the United States (2). The last peak was in 2005, when approximately 25,000 cases were reported nationally and approximately 3,000 cases in California, including eight deaths in infants aged <3 months. If the rates from the first half of the year persist throughout 2010, California would have its highest annual rate of pertussis reported since 1963 and the most cases reported since 1958.

CDPH is attempting to prevent transmission of pertussis to vulnerable infants (3) by disseminating educational materials and clinical guidance, raising community awareness, and offering free tetanus, diphtheria, and acellular pertussis (Tdap) vaccine to

birthing hospitals and local health departments to support postpartum vaccination of mothers and close contacts of newborns.

Reported by

K Winter, MPH, K Harriman, PhD, R Schechter, MD, E Yamada, MD, J Talarico, DO, G Chavez, MD, California Dept of Public Health.

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Salmonella Newport Infections Associated with Consumption of Unpasteurized Milk — Utah, April–June 2010

On April 29, 2010, the Utah Department of Health (UDOH) was notified of three cases of *Salmonella enterica* serotype Newport infection. The three patients recently had consumed unpasteurized milk purchased from a store in northern Utah (store A). In Utah, unpasteurized milk can be sold legally at licensed dairies or by licensed dairies at dairy-owned retail stores meeting specific requirements (1). A central Utah dairy licensed to sell unpasteurized milk (dairy A) owns and sells unpasteurized milk at store A and a second northern Utah store (store B). By May 3, 2010, three additional patients with *S. Newport* infections had been reported; all recently had consumed unpasteurized milk purchased from store A. UDOH notified the Utah Department of Agriculture and Food (UDAF) of the suspected association between illness and unpasteurized milk consumption, and UDAF suspended sales of unpasteurized milk at the two stores on May 3, 2010.

During April 29–June 3, 2010, a total of 10 *S. Newport* cases were reported to UDOH; all 10 patients had consumed unpasteurized milk from store A (seven patients) or store B (three patients). The patients ranged in age from 2 to 56 years (median: 21 years); six were female. One patient was



Vaccines and Preventable Diseases:

Varicella Vaccine - Q&As about Health Care Providers

Clinical Questions and Answers



Does ACIP recommend varicella vaccination of health care providers (HCPs)?

ACIP, with support by the Hospital Infection Control Practices Advisory Committee (HICPAC), recommends that health care institutions ensure that all health care providers have evidence of immunity to varicella. For health care providers, evidence of immunity includes any of the following:

- Documentation of two doses of varicella vaccine;
- Blood tests showing immunity to varicella or laboratory confirmation of prior disease; or
- Receipt from a health care provider of a) a diagnosis of chickenpox or herpes zoster (shingles); or b) verification of a history of chickenpox or herpes zoster (shingles).

Birth before 1980 is not considered evidence of immunity for HCPs because of the potential for nosocomial transmission of varicella to high-risk patients.

Health care institutions should establish protocols and recommendations for screening and vaccinating HCPs and for management of HCPs after exposure in the workplace.

Should HCPs be tested for varicella zoster virus (VZV) immunity prior to vaccination?

Serologic screening before vaccination of personnel who have negative or uncertain history of varicella disease is likely to be cost effective. Most adults (70-90%) who do not remember having chickenpox actually have protection in their blood when tested. Institutions may elect to test all HCPs regardless of disease history because a small proportion of persons with a positive history of disease might be susceptible. The tests most widely used to detect varicella IgG antibody after natural varicella infection among HCPs are latex agglutination (LA) and ELISA. Although the LA test is generally more sensitive than commercial ELISAs, a recent report indicated that the LA test can produce false-positive results, particularly when only a single concentration of serum is evaluated. Therefore, for the purpose of screening HCPs for varicella susceptibility, a less sensitive and more specific commercial ELISA should be considered.

Should HCPs be tested after vaccination to ensure that they are immune?

The ACIP and HICPAC do not recommend routine testing of HCPs for varicella immunity after two doses of vaccine. Available commercial assays are not sensitive enough to detect antibody after vaccination in all

instances. Sensitive tests have indicated that 99% of adults develop antibodies after the second dose. However, seroconversion does not always result in full protection against disease, and no data regarding correlates of protection are available for adults. See also **How should vaccinated HCPs be managed after exposure to natural varicella?** ([#natural](#)).

 [TOP](#) ([#top](#))

Are recently vaccinated HCPs at risk for transmitting vaccine virus to susceptible persons?

The risk of transmission of vaccine virus from persons who develop a varicella-like rash after vaccination is low, and has been documented only after exposures in households and long term care facilities. No cases have been documented after vaccination of HCPs. Moreover, the benefits of vaccinating HCPs who do not have evidence of immunity outweigh this extremely low potential risk. As a safeguard, precautions should be taken for personnel who develop rash after vaccination. These individuals should avoid contact with persons without evidence of immunity who are at risk for severe disease and complications until all lesions resolve (i.e., crusted over or fade away) or no new lesions appear within a period of 24 hours.

How should vaccinated HCPs be managed after exposure to natural varicella?

Exposed HCPs who have received 2 doses of vaccine should be monitored daily during days 8-21 after exposure through the employee health program or by an infection control nurse to determine clinical status (i.e., daily screening for fever, skin lesions, and systemic symptoms). They should also be instructed to report any symptoms as they occur without delay. If symptomatic, HCPs should be placed on sick leave immediately. Exposed HCPs who have received 1 dose of vaccine and who are exposed to VZV should receive the second dose of vaccine within 3-5 days post exposure to rash (provided 4 weeks have elapsed after the first dose). After vaccination, management is similar to that of 2-dose vaccine recipients described above.

What is recommended for unvaccinated HCPs without evidence of immunity who are exposed to natural varicella?

Unvaccinated HCPs who have no evidence of immunity and are exposed to natural varicella are potentially infective from days 8-21 after exposure and should be furloughed during this period. Postexposure vaccination is recommended within 3-5 days of exposure to rash, since it may attenuate the disease substantially if infection occurred. If the exposure did not cause infection, vaccination more than 5 days after exposure is still indicated as it induces protection against subsequent infection.

See also **Vaccines & Immunizations: Healthcare Workers** ([../..spec-grps/hcw.htm](#))

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Return to main Varicella Vaccination page ([default.htm](#))

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Successful Campaigns for Vaccinating Healthcare Personnel

Successful Campaigns for Vaccinating Healthcare Personnel

- ✦ Prior to the start of influenza season, remind healthcare personnel of the importance of vaccination and when the vaccine will be available.
- ✦ Sponsor a kick-off event.
- ✦ Offer vaccine free of charge to all staff and volunteers.
- ✦ Educate employees via fact sheets, newsletters or bulletin board posting. Advise employees about the benefits of vaccination for themselves, patients, and co-workers.
- ✦ Administer vaccine under a standing orders protocol. Request that staff who decline vaccination sign a declination form that includes their reason for not getting vaccinated.
- ✦ Make vaccines available to all employees on all shifts.
- ✦ Use mobile carts to offer vaccine in all different clinic areas, service meetings, grand rounds, and or near cafeteria entrances.
- ✦ In late November, identify employees not yet vaccinated and remind them by email or telephone that the flu vaccine is available.
- ✦ Work closely with the pharmacy department to get an ample supply of vaccine for employees.
- ✦ Encourage the facility director, service chiefs, and other managers to set an example by getting vaccinated and encouraging their staff to get immunized.
- ✦ Hold contests or drawings for those who have been vaccinated. Offer winning individuals or departments lunch, days offs, electronics, or other incentives.

Adapted from VA Influenza Vaccination Toolkit. United States Department of Veterans Affairs, September 2005.

Mandatory Influenza Vaccination of Health Care Workers: Translating Policy to Practice

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(See the editorial commentary by Pavia, on pages 465–7.)

Background. Influenza vaccination of health care workers has been recommended since 1984. Multiple strategies to enhance vaccination rates have been suggested, but national rates have remained low.

Methods. BJC HealthCare is a large Midwestern health care organization with ~26,000 employees. Because organizational vaccination rates remained below target levels, influenza vaccination was made a condition of employment for all employees in 2008. Medical or religious exemptions could be requested. Predetermined medical contraindications include hypersensitivity to eggs, prior hypersensitivity reaction to influenza vaccine, and history of Guillan-Barré syndrome. Medical exemption requests were reviewed by occupational health nurses and their medical directors. Employees who were neither vaccinated nor exempted by 15 December 2008 were not scheduled for work. Employees still not vaccinated or exempt by 15 January 2009 were terminated.

Results. Overall, 25,561 (98.4%) of 25,980 active employees were vaccinated. Ninety employees (0.3%) received religious exemptions, and 321 (1.2%) received medical exemptions. Eight employees (0.03%) were not vaccinated or exempted. Reasons for medical exemption included allergy to eggs (107 [33%]), prior allergic reaction or allergy to other vaccine component (83 [26%]), history of Guillan-Barré syndrome (15 [5%]), and other (116 [36%]), including 14 because of pregnancy. Many requests reflected misinformation about the vaccine.

Conclusions. A mandatory influenza vaccination campaign successfully increased vaccination rates. Fewer employees sought medical or religious exemptions than had signed declination statements during the previous year. A standardized medical exemption request form would simplify the request and review process for employees, their physicians, and occupational health and will be used next year.

Influenza infection is associated with 36,000 excess deaths and >200,000 hospitalizations in the United States annually [1, 2]. It is the leading cause of vaccine-preventable death in the United States every year [3]. The risk of complications associated with influenza is higher among older persons, young children, and patients with underlying medical conditions [2, 4]. Infected people may shed virus before symptoms develop [5–8], and health care workers often work while sick. Outbreaks of influenza in hospitals have been well described [3, 4, 9–12].

Influenza vaccination of health care workers reduces

employee illness and absenteeism [4, 13–15]. In nursing home settings, vaccination of health care workers has been shown to decrease morbidity and mortality among nursing home residents [16–18]. The impact of vaccination of workers in acute care settings is more difficult to study because of the short duration of most hospitalizations. Other evidence for the importance of herd immunity on influenza rates comes from a Japanese study in which the vaccination of school children against influenza resulted in decreased mortality associated with pneumonia or influenza in the general population [19].

Annual influenza vaccination was first recommended for health care workers by the Advisory Committee on Immunization Practices in 1984 [3, 20, 21]. The Society for Healthcare Epidemiology [22], the Association for Professionals in Infection Control [11], and the Infectious Disease Society of America [23] also strongly endorse health care worker vaccination. The US National Health objectives for 2010 include a health care worker influenza vaccination rate of 60%. Recommended prac-

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tices to improve vaccination rates include making the vaccine available without charge to employees at multiple convenient sites and times, using incentives and rewards, and having visible leadership support [21, 24–27]. More recently, declination statements have been suggested as a way to increase vaccination rates. The impact of these statements is still being studied [28–30]. Despite these efforts, vaccination rates among health care workers remain low across the United States; the influenza vaccination rate among US health care workers during 2006–2007 was 44.4% [3].

Mandatory vaccination is a controversial strategy that pits health care worker autonomy against patient safety [31–36]. Other vaccines, such as measles, mumps, and rubella vaccine and varicella vaccine, are already required by many health care facilities, as is annual tuberculin skin testing. Virginia Mason Hospital (Seattle, WA) implemented a mandatory influenza vaccination program in 2004, and there have been media reports of other individual hospitals instituting similar programs. There are no reports in the literature of large multihospital systems implementing a mandatory influenza vaccination policy.

Annual influenza campaigns at BJC HealthCare include free vaccine available at multiple sites and times, extensive publicity, incentives and educational programs, and more recently, declination statements. In 2007, influenza vaccination rates were added to the BJC patient safety and quality scorecard used at all hospitals in the organization. Hospital leaders receive incentives based on their hospital's performance on scorecard measures. Despite significant efforts by occupational health and infection prevention specialists, the vaccination rate among BJC employees remained below the BJC goal of 80%. In 2008, BJC HealthCare implemented a mandatory influenza vaccination policy for all employees.

METHODS

Setting. BJC HealthCare is a large Midwestern health care organization with ~26,000 employees. Facilities include 11 acute care hospitals and 3 extended care facilities, as well as day care centers, employed physician groups, occupational medicine, home care, and behavioral health services. Hospitals are located in urban, suburban, and rural settings and range from 40 to 1250 beds. Of the acute care hospitals, 1 adult and 1 pediatric facility are teaching hospitals.

BJC Occupational Health Services coordinates and standardizes occupational health programs through the Council of Occupational Health Professionals, which includes a representative from each facility. Bimonthly council meetings are designed for education, policy, and procedure standardization, coordination of occupational health and safety surveillance, and development of interventions throughout BJC. Each facility uses the centralized BJC occupational health database for tracking employee vaccinations, immune status, and occupational

injuries and exposures. The database includes demographic and job information on all BJC employees.

2008 Influenza policy. In 2008, as a patient safety initiative, influenza vaccination was made a condition of employment for all BJC employees, regardless of job function, including clinical and nonclinical staff, contracted clinical personnel, and volunteers. Hospital-employed physicians, including hospitalists, residents, and fellows, were included in the policy. Most attending physicians affiliated with BJC HealthCare are in private practice or are employed by Washington University School of Medicine (St. Louis, MO) and are not covered by the policy. The policy was communicated to employees through their managers, with standardized educational materials and fact sheets provided; an Intranet site; letters mailed to employees' homes; articles in *BJC Today*, an in-house newspaper distributed at all facilities; and "Town Hall Meetings" scheduled throughout the vaccination campaign with infectious diseases physicians, infection prevention specialists, and occupational health nurses available for questions or concerns. The CEO of BJC published a letter in the BJC newspaper explaining the rationale for the policy. The multidisciplinary implementation team met regularly before and during the vaccination campaign to ensure timely, consistent, and coordinated communication and responses to any issues that arose.

Free vaccine, including thimerosal-free and intranasal preparations, was available at multiple locations at all facilities starting 15 October 2008. Vaccinations were tracked at each facility in real time. Multiple methods of tracking vaccination were available to each facility, including badge scanners, consent forms with carbon copies, a database into which managers could directly enter their vaccinated employees, and preprinted labels with bar codes. All data were entered in real time or were downloaded regularly into the BJC occupational health database. Feedback was provided not less than weekly to managers at the facilities. Managers interacted with their staff to ascertain reasons for noncompliance and to provide coaching about influenza, the vaccine, and the consequences of noncompliance.

Employees who were neither vaccinated nor exempted by 15 December 2008 were suspended without pay. Those who were vaccinated before 15 January 2009 could return to work. Employees still not vaccinated or exempt by 15 January 2009 were terminated for failure to meet their conditions of employment.

Exemptions. Medical or religious exemptions could be requested. Religious accommodations required a letter from the employee to Human Resources that stated a religious conviction opposed to vaccination. Employees were notified within 5 days whether their request had been granted.

Medical exemptions required a letter from a licensed physician (MD or DO) that stated a medical contraindication to influenza vaccination. Predetermined accepted medical contraindications were based on the Advisory Committee on Im-

munization Practices recommendations [3]. These included hypersensitivity to eggs, prior hypersensitivity reaction to influenza vaccine, and history of Guillan-Barré syndrome. Pregnancy was accepted as a medical exemption if requested by the employee's physician, despite the vaccine being recommended during pregnancy, because the vaccine is listed as a category C agent. Occupational health nurses reviewed other reasons on a case-by-case basis with assistance from their medical director as needed. Employees received a form within 5 days that stated whether their request had been granted. Denials included an explanation of the reason for denial on the form. Second requests with clarifications could be submitted for review. Some physicians who had written exemption request letters were contacted directly by the facility occupational health medical director for clarification or at the request of the employee. Granted medical exemptions could be permanent or temporary (1 year only). Concerned employees not meeting criteria for exemption could discuss their concerns with the occupational health nurses or medical directors. Employees who were granted an exemption were encouraged to wear an isolation mask while providing patient care during the influenza season to avoid contracting or transmitting influenza. No specific enforcement was put in place, and no data on compliance were collected.

RESULTS

Of 25,980 active employees, 25,561 (98.4%) were vaccinated (Table 1). Medical exemptions were granted to 321 employees (1.24%). Religious accommodations were granted to 90 employees (0.35%). Overall, 25,974 employees (99.96%) were compliant with the policy (vaccinated or exempt). Only 8 employees (0.03%) were terminated for noncompliance with the policy. At the 2 teaching hospitals, there were 907 residents and fellows in >27 graduate medical education programs. All of these trainees complied with the new policy: 902 (99.45%) were vaccinated, and 5 received exemptions (3 medical and 2 religious). Vaccination rates in 2008 increased by 43.4%, compared with rates in 2006, and by 26.5%, compared with rates in 2007 (Figure 1).

Of 372 requested medical exemptions, 321 (86.3%) were granted (188 permanent and 133 temporary). Reasons for medical exemption included allergy to eggs (107 [33% of exemptions; 0.4% of all employees]), prior allergic reaction or allergy to other vaccine component (83 [26% of exemptions; 0.31% of employees]), history of Guillan-Barré syndrome (15 [5% of exemptions; 0.05% of employees]), and other (116 [36%]). The majority (89 [77%]) of employees with other indications for a medical exemption received a temporary exemption: 50 for a prior vaccine reaction that was not further specified, 25 for medical reasons not further specified by their physician, and 14 for pregnancy. The remaining 27 (23%) of 116 employees

Table 1. Summary of Employee Vaccination Status

Vaccination status	No. (%) of employees
Vaccinated	25,561 (98.4)
Religious exemption granted	90 (0.35)
Medical exemption granted	321 (1.24)
Egg allergy	107
Prior reaction and/or allergy to other component	83
History of Guillan-Barré syndrome	15
Other	116
Policy compliant (vaccinated or exempt)	25,972 (99.96)
Noncompliant (neither vaccinated or exempt)	8 (0.03)
Total employees	25,980

with other indications were granted permanent exemptions: 15 for a prior severe reaction to an influenza vaccine, 5 for a neurologic condition, 3 for concerns of triggering a flare of an autoimmune disease, 2 for being vegan, 1 for multiple food sensitivities, and 1 for concern for increased risk of rejection of a transplanted organ.

Eight employees (0.03%) were not vaccinated or granted an exemption, and their employment was terminated. Two employees worked with information systems in the corporate offices of BJC HealthCare. The other 6 noncompliant employees were from 4 acute care hospitals: 1 laboratory technician, 1 patient care technician, 1 paramedic, 1 nurse, 1 sitter, and 1 physical therapist. The remaining hospitals and service organizations had no noncompliant employees. Two employees were per diem employees, 3 were part-time, and 3 were full-time employees. The median duration of employment before termination was 37.5 months (range, 23–134 months). Of these employees, most did not submit an exemption request. One employee submitted a request for a religious exemption 2 days before termination, after being unable to obtain a doctor's note stating a medical contraindication; the request was denied.

Adverse events reported by employees were tracked in the occupational health database. Twenty-one employees (0.08%) reported a possible adverse reaction. Eleven reported a sore arm. Five reported a possible allergic reaction, and 1 reported a possible vagal response with fainting. Four events of uncertain relation to the vaccine were also reported by employees, including 2 cases of fever and myalgias, 1 with upper respiratory symptoms, and 1 case of a new neurologic syndrome diagnosed as chronic inflammatory demyelinating polyneuropathy, which could not be objectively linked to the influenza vaccine because of several other potential antecedent triggers.

DISCUSSION

The mandatory vaccination program successfully increased vaccination rates at a large multihospital health care organization. Efforts during previous years included most recommended

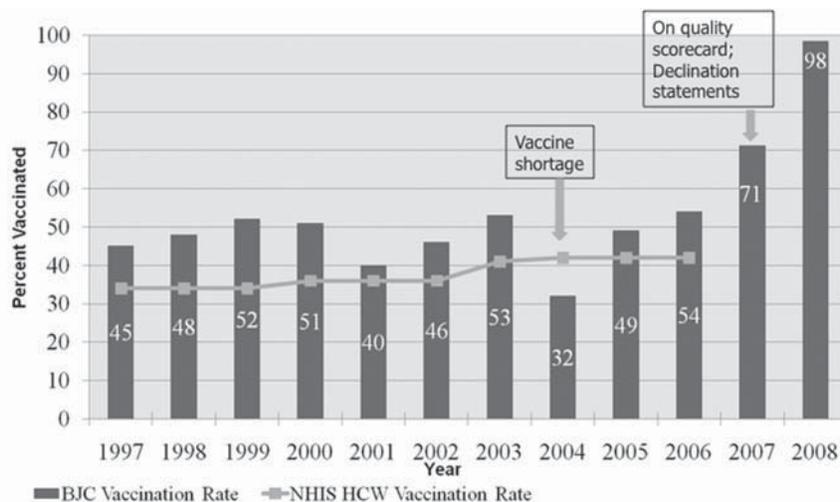


Figure 1. BJC HealthCare annual influenza vaccination rates (percentage of total employees). The National Health Interview Survey rates of influenza vaccination among health care workers during 1997–2006 are shown with the trend line.

practices to maximize vaccination rates, including free, easily available vaccine, incentives, and leadership support. Despite these efforts, rates were still suboptimal (Figure 1). The mandatory program markedly increased vaccination rates across all facilities. Key factors that supported the success of the program included consistent communication emphasizing patient safety and quality of care, coordinated campaigns, leadership support, and medical director support to talk with any employee with concerns about the vaccine, on request. The program was established as a patient safety initiative; thus, no prospective attempts were made to link to absenteeism. Because of the way that employees are reimbursed for time off work, we were unable to distinguish between sick time and vacation time and, thus, could not assess the impact of the program on absenteeism. In addition, the year that the program was implemented had a mild influenza season; therefore, finding reduced absenteeism would be difficult to link to the vaccination program.

Few other organizations have established mandatory influenza vaccination programs. Virginia Mason Hospital implemented a mandatory program in 2004, with resulting vaccination rates of >98%. Several smaller hospitals were mentioned in the media for attempting mandatory campaigns, but no details have been published. To our knowledge, this is the first report of a large multihospital health care organization implementing a mandatory influenza vaccination program.

Some programs allow health care workers to sign declination forms stating that they understand the risks of not receiving the influenza vaccine to themselves, their patients, and their families. Declination statements have recently been publicized as a potentially valuable strategy for increasing vaccination rates [11, 21, 22], but data on their efficacy are mixed [28–30]. We found that many fewer employees sought medical or religious

exemptions than had signed declination statements in previous years. Requests for religious exemptions were reviewed by Human Resources at each facility. The letter from the employee had to state a sincere religious conviction opposed to vaccination. Some requests were only submitted after medical exemption requests had been denied, and some requests stated opposition to a mandatory policy, not to vaccination itself. These requests were denied.

Severe egg allergy is a contraindication to receipt of the influenza vaccine [3]. Virginia Mason Hospital provides free, on-site egg allergy testing for employees seeking an exemption on the basis of egg allergy. Our organization did not attempt to verify reports of significant egg allergy or allergy to other vaccine components. Egg allergy rates decrease with age, and reported rates in the medical literature range from 0% to 0.35% [37–39]. Overall, 107 (0.4%) of all employees reported a significant egg allergy.

Exemption requests often reflected misinformation about the vaccine and about influenza among employees and among their physicians. Several requests cited chemotherapy or an immunosuppressed state as reasons not to get the vaccine, even though these groups are at high risk for complications from influenza and are specifically recommended to be vaccinated. Several requests cited pregnancy, although the vaccine is recommended during pregnancy [3, 40]. Other requests did not include enough information to make a determination of the validity of the request. Some health care workers whose initial request for exemption was denied returned to their personal physician for a more detailed note or requested that occupational health contact their physician to discuss their request. Some community physicians felt beleaguered by these multiple contacts. A standardized form listing accepted contraindications and their definitions, with

checkboxes and space for additional information and contact information, would simplify the request and review process for health care workers, their physicians, and occupational health staff.

BJC HealthCare benefitted from strong leadership support for this initiative and a solid infrastructure for timely and consistent communication. The experience at our organization may not be completely generalizable. Economic factors at the time of the study may have limited the number of employees willing to lose their jobs. Influenza vaccination rates increased in 2007 (Figure 1) and may have continued to increase even without a mandatory vaccination policy, although we believe that such a dramatic increase would have been unlikely. Not all physicians affiliated with BJC HealthCare are employees of the organization and, thus, were not covered by the policy. All physicians employed by the organization, however, including ~900 residents and fellows, complied with the policy. In conclusion, a mandatory influenza vaccination policy was successful in increasing vaccination rates at a large multihospital health care organization with ~26,000 employees.

Acknowledgments

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Potential conflicts of interest. All authors: no conflicts.

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Basic Surgical Masks Protect Healthcare Workers Against Novel H1N1 Infection

Megan Brooks

March 30, 2010 — Ordinary surgical masks are just as effective as high-filtration N95 respirators in protecting hospital staff from the novel pandemic influenza A strain H1N1, according to an observational study published in the April 1 issue of *Clinical Infectious Diseases*.

There is "ongoing debate" about the efficacy of surgical masks versus N95 respirators for influenza A (H1N1) protection, Brenda Sze Peng Ang, MD, from the Department of Infectious Diseases, Tan Tock Seng Hospital (TTSH), Singapore, and colleagues note in their report. Optimal respiratory protection against the virus "remains controversial, and randomized, controlled trials have yet to be done."

To learn more about the comparative efficacy of surgical masks and N95 respirators in protecting healthcare workers from H1N1, Dr. Ang and colleagues analyzed the incidence of H1N1 among healthcare workers from April 25 through August 31, 2009, at TTSH. The hospital is designated by the Ministry of Health to manage outbreaks of emerging infection and has "robust surveillance systems to detect infection in staff," the investigators note in their report.

The first case of pandemic H1N1 in Singapore was identified on May 26, 2009, and from April 25 to June 18, when there was no local transmission of H1N1, 2154 patients with acute respiratory infection (ARI) and 58 with confirmed pandemic H1N1 were treated at TTSH. A total of 573 healthcare workers reported having ARI, but none had pandemic H1N1.

From June 19 to July 21, local transmission of H1N1 had occurred and healthcare workers at TTSH were using N95 respirators in the emergency room and an H1N1 isolation area. During this time, 5301 patients with ARI and 689 with confirmed H1N1 were treated at the hospital, and 1065 healthcare workers reported having ARI.

From July 22 to August 31, when there was continued local transmission of H1N1, surgical masks were worn by healthcare personnel in the emergency department and the isolation facility. During this period, 2694 patients with ARI and 424 patients with H1N1 were treated at TTSH. There were 955 healthcare workers with ARI and 15 confirmed cases of H1N1 during this time.

Dr. Ang and colleagues observed that the incidence of H1N1 remained low when healthcare workers were using N95 masks and when they were using ordinary surgical masks, suggesting, they say, that surgical masks and respirators did not differ in their effectiveness in preventing hospital staff from acquiring H1N1.

Actually, however, there were fewer ARI and H1N1 cases among staff when surgical masks were being worn than when N95 respirators were being worn at the hospital, Dr. Ang and colleagues point out.

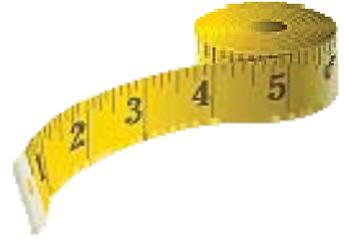
"What is more important than using high-filtration or respirator masks for known or suspected cases is to have a uniform policy, such as using surgical masks, when in close contact with all patients," Dr. Ang noted in a written statement. "This way, health care workers are protected from getting infected by patients not initially thought to have H1N1."

According to the researchers, none of the healthcare workers who cared for patients with known H1N1 infection acquired infection from them. Those healthcare workers who did acquire pandemic H1N1 "appeared to have been infected from community exposure or in social settings with colleagues," they note.

The authors have disclosed no relevant financial relationships.

Clin Infect Dis. 2010;50:1011-1014. [Abstract](#)

HOW DO YOU MEASURE UP?



The Maryland Health Care Commission has published the results of a survey assessing the 2010-11 healthcare personnel influenza vaccination rates of Maryland hospitals.

Congratulations to the Five Hospitals With the Highest HCP Vaccination Rates:

Holy Cross Hospital - 100%

Civista Medical Center - 100%

St. Mary's Hospital - 100%

Fort Washington Hospital - 99.8%

James Lawrence Kernan Hospital - 98.8%

To access the results—

1. Go to: <http://mhcc.maryland.gov/consumerinfo/hospitalguide/index.htm>
2. Click on “Healthcare-Associated Infections” on the vertical menu on the left side.
3. Click on “Health Care Worker (HCW) Seasonal Influenza Vaccinations”

Policies and Procedures

Annotated Code of Maryland
Article – Health – General § 18-404 (2011)
Immunization against influenza virus and pneumococcal disease

(a) Definitions. --

- (1) In this section the following words have the meanings indicated.
- (2) "Employee" means an individual employed full-time or part-time directly, through contract with another entity, or as an independent contractor, by a related institution.
- (3) "Related institution" has the meaning provided under § 19-301 of this article.
- (4) "Medically contraindicated" means that a medical treatment is potentially detrimental to the health of the individual intended to be treated.

(b) Immunizations generally; consent. --

- (1) Subject to subsection (e) of this section, each related institution in the State shall immunize residents against the influenza virus and pneumococcal disease.
- (2) Subject to subsection (e) of this section, each related institution in the State shall immunize employees against the influenza virus.
- (3) Before an immunization under this section is administered, the related institution shall obtain written consent to administer the immunization from:
 - (i) The resident or employee receiving the immunization; or
 - (ii) The legal guardian of the resident receiving the immunization.

(c) Protocol. -- Each related institution shall conduct the immunizations required under subsection (b) of this section:

- (1) In accordance with the recommendations established by the Advisory Committee on Immunization Process of the United States Centers for Disease Control and Prevention that are in effect at the time the related institution conducts the immunizations; and
- (2) By December 1 of each year that the immunization is required.

(d) New residents or employees. -- A related institution that accepts an individual as a new

resident or accepts an individual as a new employee after December 1 but before April 1 shall:

(1) Determine the individual's status for immunization as required under subsection (b) of this section; and

(2) If necessary, provide or arrange for an immunization as required under subsection (b) of this section.

(e) Circumstances under which vaccine not required. -- A resident or employee is not required to receive a vaccine under this section if:

(1) The vaccine is medically contraindicated for the resident or employee;

(2) The vaccine is against the resident's or employee's religious beliefs; or

(3) After being fully informed by the related institution of the health risks associated with not receiving a vaccine, the resident or employee refuses the vaccine.

(f) Documentation. --

(1) (i) Each related institution shall document the annual immunization against influenza virus and immunization against pneumococcal disease received by each resident in the resident's medical record.

(ii) Each related institution shall document the annual immunization against influenza virus received by each employee in the employee's personnel file.

(2) If a resident or employee refuses to be immunized as required under subsection (b) of this section, the related institution shall document the refusal and the reason for the refusal.

(g) Notification; educational and informational materials. -- Each related institution shall:

(1) Notify each prospective resident and each prospective employee of the immunization requirements of this section and request that the resident or employee agree to be immunized in accordance with subsection (b)(3) of this section; and

(2) Make available to all residents and employees of the related institution educational and informational materials relating to immunization against influenza virus and immunization against pneumococcal disease.

Source: www.lexisnexis.com/hottopics/mdcode/

TEMPLATE POLICY STATEMENT

Protect Your Patients.
Protect Yourself.



Influenza Immunization
Among Health Care Workers

An APIC Member Initiative

[YOUR INSTITUTION'S NAME] Policy for Influenza Immunization of Health Care Workers

Influenza is a serious infection that causes an average of 36,000 deaths and 114,000 hospitalizations in the United States each year.¹ Health care workers* are at high risk for acquiring influenza infection because of their exposure to ill patients, as well as their exposure in the community. Health care workers infected with influenza can spread the virus to patients in their care.²⁻⁴ In fact, research suggests that health care workers can be a key source of institutional outbreaks, contributing to increased morbidity and mortality among vulnerable patients.¹ Health care workers encounter patients throughout the influenza season in a variety of settings, including medical practices, general hospitals, specialty hospitals, pediatric hospitals,^{5,6} long-term care facilities,⁷ emergency departments,⁸ ambulatory care settings, rehabilitation facilities and home-care sites.

Vaccination is the primary means of reducing transmission and preventing influenza infection, yet immunization rates among health care workers remain low. Only 36 percent of workers who have direct contact with patients are immunized annually, despite long-standing recommendations issued by the Centers for Disease Control and Prevention (CDC) and the Association for Professionals in Infection Control and Epidemiology (APIC) and other national health care organizations.^{1,9,10}

Greater emphasis needs to be placed on improving influenza immunization rates among health care workers to help ensure patient safety and protection—especially for patients at increased risk of influenza-related complications.⁷ Immunization also provides personal protection for health care workers and minimizes workforce absenteeism during the influenza season.¹¹

TRANSMISSION

Influenza is transmitted by direct and indirect contact and by droplet contact. There may be an airborne component to transmission as well. Therefore, the virus is easily spread from person to person via coughing, sneezing, and contact with contaminated items and surfaces. The virus can spread rapidly, especially in classrooms, households, offices, and medical settings.

Individuals are generally infectious 1-4 days before the onset of symptoms; however, only around 50% of infected persons will develop classical symptoms of influenza, making exclusion of infected health care workers difficult.^{1,12} Moreover, individuals remain infectious five or more days after symptoms appear. Studies show health care personnel are more likely than staff in other areas to work through or return to work sooner during illness, thus increasing the likelihood of transmitting the virus to patients.¹³

INSTITUTIONAL INFLUENZA OUTBREAKS

Institutional influenza outbreaks can have serious implications for both the patient and health care provider. These events can put patients at risk, result in or exacerbate existing staff shortages, curtail admissions, and increase health care costs. An outbreak in a tertiary neonatal intensive care unit (NICU) in the year 2000 included 19 infants, one of whom died. Only 15 percent of staff in the facility had been immunized against influenza. Although investigators could not pinpoint the source of the outbreak, a health care worker was the suspected source; since influenza-like-illness was not found in the mothers of these infants.¹⁴

A 2001 report documented an outbreak that included four influenza cases among patients in a 12-bed, single-room transplant unit. Three of the four affected patients had no visitors between admission and influenza infection to account for the spread. Investigators concluded that health care workers were the likely source of transmission.¹⁵

A very large outbreak in the early 1990s occurred in a nursing home in New York. Nineteen percent of residents developed influenza. A total of 34 individuals developed pneumonia; 19 were hospitalized, and two died. In this facility, only 10 percent of health care workers were immunized.¹⁶

While index cases are not always identifiable, health care workers can easily propagate an outbreak as they move from patient to patient. It is also clear that unvaccinated health care workers can be the index case for influenza in a facility, potentially posing a threat to high-risk patients and other workers.

ECONOMIC IMPACT OF OUTBREAKS

Influenza outbreaks are associated with substantial direct and indirect costs. An outbreak in an internal medicine ward of a French hospital in 1999, in which 41 percent of patients and 23 percent of staff were infected, resulted in 14 days of staff sick leave and suspension of all admissions to the ward, including eight that were previously scheduled. The total cost of the outbreak in this small ward was estimated at \$34,000 (U.S. dollars).¹⁷ Amantadine resistance was documented in a small pediatric NICU outbreak. Oseltamivir, an expensive alternative therapy, was used to halt the outbreak instead. In a bone marrow transplant unit, Oseltamivir was also used in place of prophylactic amantadine during an outbreak because concomitant use of immuno-suppressant therapy and amantadine has been shown to increase the incidence of patient falls, which could have had dire consequences in these patients.¹⁸

Ensuring the health and safety of health care workers has additional implications for patient safety and health care cost containment. Hiring replacement workers often means assuming additional costs beyond those associated with salary. Studies show that using pool staff in place of experienced unit staff increases the incidence of medical errors. On occasions when staff members work a double shift, it has been shown that attention decreases after 12 hours of work.¹⁹

ROLE OF HEALTH CARE FACILITIES

Health care facilities have an important role to play in maximizing influenza vaccination rates among health care workers. Every facility should develop and implement comprehensive influenza vaccination programs for employees.^{8,9}

RECOMMENDATIONS

[NAME OF INSTITUTION] recommends the following measures be implemented to increase influenza immunization rates among its health care workers and improve patient safety and personal health.

- Health care workers should receive an annual influenza immunization to prevent spread of the virus to vulnerable patients.
- Develop an influenza immunization program that is implemented annually, to
 - Educate health care workers about the importance of influenza immunization in health care settings and the low risk of adverse events associated with immunization;²⁰
 - Increase vaccine demand among health care workers;
 - Reduce barriers to immunization of health care workers by developing programs that increase access to immunization and reduce the cost of the vaccine;²¹ and
 - Facilitate the influenza vaccination process, for example, through the use of standing orders issued by the Occupational Health Program for influenza vaccination of health care workers.
- Monitor annual immunization rates of employees and provide feedback through the infection control and patient safety programs.
- Monitor and track influenza rates among health care workers and compare those figures to this group's immunization rates. Providing this information may stimulate health care workers to seek vaccination.
- Work with public health officials to track community incidence of influenza, using data from emergency rooms, physicians' offices, and clinics. As the incidence increases, infection control and hospital administration should work together to identify pending admissions of potential influenza cases and to establish parameters for visitor restrictions.

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Source:

www.apic.org/AM/Template.cfm?Section=Search§ion=Protect_Your_Patient_Protect_Yourself&template=/CM/ContentDisplay.cfm&ContentFileID=12144

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

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), IN (intranasal), or .
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)

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	Td	8/01/02	P	LA	U0376AA	AVP	6/10/94	8/1/2002	JTA
	Td	9/1/2002	P	LA	U0376AA	AVP	6/10/94	9/1/2002	PWS
	Td	3/1/2003	P	LA	U0376AA	AVP	6/10/94	3/1/2003	TAA
	Tdap	6/14/2010	P	LA	AC52B030AA	GSK	11/18/2008	6/14/2010	JTA
Hepatitis A ⁷ (e.g., HepA, HepA-HepB) Give IM. ⁶	HepA-HepB	8/1/2002	P	RA	HAB239A4	GSK	8/25/1998	8/1/2002	JTA
	HepA-HepB	9/1/2002	P	RA	HAB239A4	GSK	8/25/1998	9/1/2002	PWS
	HepA-HepB	3/1/2003	P	RA	HAB239A4	GSK	8/25/1998	3/1/2003	TAA
Hepatitis B ⁷ (e.g., HepB, HepA-HepB) Give IM. ⁶	HepA-HepB	8/1/2002	P	RA	HAB239A4	GSK	7/11/2001	8/1/2002	JTA
	HepA-HepB	9/1/2002	P	RA	HAB239A4	GSK	7/11/2001	9/1/2002	PWS
	HepA-HepB	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	MMR	8/1/2002	P	RA	0025L	MRK	6/13/2002	8/1/2002	JTA
	MMR	11/1/2002	P	RA	0025L	MRK	6/13/2002	11/1/2002	TAA
Varicella (VAR) Give SC. ⁶	VAR	8/1/2002	P	LA	0799M	MRK	12/16/1998	8/1/2002	JTA
	VAR	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	Menveo	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.

Influenza

Facts About Seasonal Influenza for Adults

What is influenza?

Seasonal influenza (flu) is a contagious viral infection of the nose, throat and lungs that usually occurs in the fall and winter months and can cause severe illness. In the Northern Hemisphere, influenza activity generally occurs during December – March, but activity can occur as early as October and as late as May occasionally, but usually in limited areas. Influenza is thought to be spread from person to person, primarily when an infected person coughs or sneezes. Influenza may lead to hospitalization or even death, especially among the elderly. On average, each year between 5 percent and 20 percent of the population contract influenza, more than 200,000 are hospitalized, and 36,000 die from seasonal influenza-related complications annually.

This flu season could be worse. There is a new and very different flu virus spreading worldwide among people called [novel H1N1 flu](#). This virus may cause more illness or more severe illness than usual. Vaccines are the best tool we have to prevent influenza; however, the seasonal flu vaccine is unlikely to provide protection against novel H1N1 influenza. However **a novel H1N1 vaccine is currently in production and may be ready for the public in the fall**. The novel H1N1 vaccine is not intended to replace the seasonal flu vaccine – it is intended to be used along-side seasonal flu vaccine.

Symptoms

Typical seasonal influenza illness is characterized by the abrupt onset of fever, chills, cough, headache, runny nose, sore throat, and muscle and joint pain. Unlike other common respiratory infections that are often called “the flu,” influenza can cause more severe illness that can result in complications leading to hospitalization and death. However, persons with mild symptoms such as cough and mild fever can also have an infection with influenza virus, and symptoms can be similar to those caused by other respiratory viruses. Persons with mild symptoms can still transmit influenza virus to others, including to persons at risk for more severe influenza virus infections.

Prevention

Getting a seasonal flu vaccine is the best way to prevent influenza. The time to vaccinate is as soon as vaccine is available and throughout the influenza season. Because the flu vaccine is updated every year to keep up with changes in circulating flu viruses and because immunity to influenza viruses declines within a year after vaccination, it is important to get vaccinated against influenza every year.

Who should get seasonal influenza vaccine?

Summary of seasonal influenza vaccination recommendations for adults

Annual vaccination against seasonal influenza is recommended for any adult who wants to reduce the risk for becoming ill with influenza or of transmitting it to others. Vaccination also is recommended for all adults in the following groups, because these persons are either at high risk for influenza complications, or are close contacts of persons at high risk:

- Persons 50 years of age or older;
- Women who will be pregnant during the influenza season;
- Persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus);
- Persons who have immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus);
- Persons who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration;
- Residents of nursing homes and other chronic-care facilities;
- Health care personnel;
- Household contacts and caregivers of children younger than 5 years of age and adults 50 years of age and older, with particular emphasis on vaccinating contacts of children younger than 6 months of age; and,
- Household contacts and caregivers of persons with medical conditions that put them at high risk for severe complications from influenza.

Facts About Seasonal Influenza for Adults

Summary of seasonal influenza vaccination recommendations for children and adolescents aged 6 months – 18 years

Vaccination of all children aged 6 months – 18 years is recommended for the 2009-10 influenza season. Children and adolescents at high risk for influenza complications should continue to be a focus of vaccination efforts as providers and programs transition to routinely vaccinating all children and adolescents.

Children and adolescents at higher risk for influenza complications are those:

- Aged 6 months up to their 5th birthday
- Who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus);
- Who are immunosuppressed (including immunosuppression caused by medications or by human immunodeficiency virus)
- Who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration;
- Who are receiving long-term aspirin therapy, who therefore, might be at risk for experiencing Reye syndrome after influenza virus infection;
- Who are residents of chronic-care facilities; and,
- Who will be pregnant during the influenza season.

Children and adolescents who are household contacts of any of the high risk groups above are also recommended for annual vaccination.

Note: Children younger than 6 months of age are the pediatric group at highest risk of seasonal influenza complications, yet they are too young to receive the influenza vaccine. The best way to protect these children is to vaccinate their close contacts, including siblings and out of home care givers, against seasonal influenza.

Vaccine Safety

Two different types of seasonal influenza vaccine are available.

Injected vaccine

The injected influenza vaccine can be given to persons 6 months of age and older. It is usually given as a shot in the upper arm or in the thigh. There may be some mild soreness, redness or swelling at the injection site which may last 1 to 2 days. Other possible mild side effects include a headache and low-grade fever for a day after vaccination.

Intranasal vaccine

The intranasal vaccine can be given to healthy persons 2 to 49 years of age, but should not be given to persons with chronic medical conditions. In addition, it should not be given to pregnant women or to persons who are in close contact with severely immune-suppressed persons. There may be a runny nose, headache, low-grade fever, sore throat, fatigue or cough after vaccination

Facts About Seasonal Influenza for Adults

Two different types of seasonal influenza vaccine are available: injectable inactivated influenza vaccine (TIV) and live attenuated influenza vaccine (LAIV) administered as a nasal spray. TIV is recommended for use by people 6 months of age and older with or without chronic medical conditions. LAIV is recommended for healthy people 2 to 49 years of age. Recommendations for the use of both vaccines are posted on the Web site of the Centers for Disease Control and Prevention, <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>.

- FACT:** Influenza can be prevented with safe, effective vaccines.
- FACT:** To protect infants younger than 6 months of age from influenza and its complications, adults, other household members, and out-of-home caregivers of these children should be vaccinated.
- FACT:** Each year, on average, 36,000 people in the United States die from seasonal influenza complications, including an average of about 100 deaths each year in children younger than 5 years of age. Greater than 90% of deaths occur in persons 65 years of age and older.
- FACT:** During the 1990's, an average of more than 200,000 people were hospitalized each year for influenza-related complications.
- FACT:** Total direct hospitalization costs of a severe influenza epidemic are estimated to be over \$3 billion.
- FACT:** Inactivated seasonal influenza vaccine is paid for by Medicare Part B.
- FACT:** Because influenza viruses can change from year to year and because protection from the vaccine does not last more than one year, annual influenza vaccination is necessary.
- FACT:** Influenza vaccine does not protect against respiratory infections caused by viruses other than influenza. Many respiratory illnesses are often called "the flu", but only some of these illnesses are actually caused by the influenza virus.
- FACT:** Influenza can worsen chronic heart disease, lung disease and diabetes, and can lead to bacterial or viral pneumonia.
- FACT:** In most influenza seasons, 5-20% of the U.S. population will be infected with seasonal influenza virus. These infections typically cause the infected person to miss work or school, or be ill while on vacation.
- FACT:** Anyone who wants to avoid becoming ill with influenza or transmitting it to others should get vaccinated.
- FACT:** Most persons who are recommended for vaccination do not get vaccinated.

Fluzone[®] Intradermal (Influenza Virus Vaccine) **Facts at a Glance**

About Fluzone Intradermal Vaccine

Fluzone Intradermal vaccine is the first influenza vaccine licensed in the United States that uses a new microinjection system for intradermal delivery of vaccine.¹

Fluzone Intradermal vaccine is indicated for active immunization of persons 18 through 64 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.¹

The microinjection system uses an ultra-thin needle of 0.06 inches (1.5 mm) in length, or less than one-tenth the length of the standard needles used for the traditional intramuscular route of administration.¹

Fluzone Intradermal vaccine is supplied as a single-dose, preservative-free, prefilled syringe.¹

Sanofi Pasteur already has licensed a microinjection system influenza vaccine marketed as Intanza or ID flu[®] in more than 40 countries including Australia, Canada, and countries in Europe.¹

About Intradermal Microinjection

Intradermal vaccination delivers the vaccine into the dermal layer of the skin. The dermal layer contains a high concentration of specialized cells, known as dendritic cells, which play a key role in generating an immune response.¹

Fluzone vaccine contains 15 mcg of hemagglutinin per strain of influenza in a 0.5 mL dose. Fluzone Intradermal vaccine contains 9 mcg of hemagglutinin per strain of influenza in a 0.1 mL dose.

Fluzone Intradermal Vaccine Availability

Fluzone Intradermal vaccine will be available to health-care providers this fall for immunizations administered during the upcoming 2011-2012 influenza season.¹

Visit VaccineShopper.com[®] for more information on ordering Fluzone Intradermal vaccine.¹

About Fluzone Intradermal Vaccine Clinical Trials

The safety and immunogenicity of Fluzone Intradermal vaccine in comparison to Fluzone vaccine has been evaluated in clinical trials featuring 4,276 adults 18 years through 64 years of age (2,855 participants received Fluzone Intradermal vaccine and 1,421 participants received Fluzone vaccine via intramuscular administration).¹

Fluzone Intradermal vaccine was shown in adults 18 through 64 years of age to provide an immune response similar (non inferior) to Fluzone vaccine administered via the intramuscular route. Hemagglutination inhibition antibody geometric mean titers (GMTs) were non-inferior to those following Fluzone for all three strains. Seroconversion rates following Fluzone Intradermal were non-inferior to those following Fluzone for both A strains but not for strain B.

Fluzone Intradermal vaccine is safe, with a comparable systemic reaction profile to the intramuscular vaccine. Intradermal microinjection deposits influenza vaccine near the surface of the skin; therefore, local reactions are more easily visible. In clinical trials, the most common solicited injection-site reactions reported in participants given the intradermal vaccine were erythema (redness) (>75%), swelling (>50%), induration (hardness) (>50%), pain (>50%), and pruritus (itching) (>40%). Injection-site and systemic

reactions with intradermal administration were transient, resolving in three to seven days without sequelae. The injection-site reactions were more frequent with participants given the intradermal vaccine compared to the intramuscular vaccine, with the exception of pain, which was similar.¹

Important Safety Information

The most common local and systemic adverse reactions to Fluzone Intradermal vaccine include erythema (redness), induration (hardness), swelling, pain, and pruritus (itching) at the vaccination site; headache, myalgia (muscle ache), and malaise. Other adverse reactions may occur. Fluzone Intradermal vaccine should not be administered to anyone with a severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine, including egg protein, or to a previous dose of any influenza vaccine. The decision to give Fluzone Intradermal vaccine should be based on the potential benefits and risks, especially if Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine. Vaccination with Fluzone Intradermal vaccine may not protect all individuals.

Before administering Fluzone Intradermal vaccine or Fluzone vaccine, please see full Prescribing Information available at www.sanofipasteur.us or www.vaccineshoppe.com.

About Influenza

Influenza is a serious respiratory illness that is easily spread and can lead to severe complications, even death.^{3,4}

Each year in the U.S., 5 to 20 percent of the population gets the flu and an average of 226,000 people are hospitalized from flu-related complications.⁵

Depending on virus severity during the influenza season, deaths can range from 3,000 to a high of about 49,000 people.⁵

— Combined with pneumonia, influenza is the nation's eighth leading cause of death.⁶

References

1. Fluzone Intradermal vaccine [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc.; 2011.
2. Nestle FO, Nickoloff BJ. Deepening our understanding of immune sentinels in the skin. *The Journal of Clinical Investigation*. 2007;117:2382-2385.
3. Centers for Disease Control and Prevention (CDC). Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. *MMWR*. 2009;58(RR-8):1-52.
4. CDC. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2008. *MMWR*. 2008;57(RR-7):1-64.
5. CDC. Estimates of deaths associated with seasonal influenza – United States, 1976-2007. *MMWR*. 2010;59(33):1057-1062.
6. CDC. Deaths: Final data for 2006. National vital statistic reports. 2009. http://www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_14.pdf. Accessed March 30, 2010.

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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**.

VAERS does not provide medical advice.

8 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.

9 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



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?

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 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.

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8 How can I learn more?

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



Vaccine Information Statement (Interim)
Inactivated Influenza Vaccine (7/26/11) 42 U.S.C. §300aa-26

INFLUENZA VACCINE ADMINISTRATION RECORD:

“I have read or have had explained to me the information in the Vaccine Information Statement about the influenza vaccine. I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of the vaccine(s) listed below and ask that the vaccine(s) be given to me or to the person named below for whom I am authorized to make this consent.”

Information about the person to receive vaccine – PLEASE PRINT				
Name:				
_____	_____	_____	____/____/____	____
Last	First	Middle Initial	Birthdate	Age
Address:				
_____	_____	_____	_____	_____
Street	City	County	State	Zip
Signature of person to receive vaccine or person authorized to make the request:				
X _____			Date: _____	

Clinic/Office Address:	
VIS(s) given to patient? (Please initial)	Date of VIS: <input type="checkbox"/> 7/26/11 (Inactivated) <input type="checkbox"/> 7/26/11 (LAIV)
Vaccine Given:	<input type="checkbox"/> Inactivated _____ <input type="checkbox"/> Live (LAIV)
Date Vaccine Administered:	
Vaccine Manufacturer:	<input type="checkbox"/> Inactivated _____ <input type="checkbox"/> MedImmune (LAIV)
Vaccine Lot Number:	
Administration Site:	<input type="checkbox"/> Injection Site _____ <input type="checkbox"/> Intranasal
Signature and Title of Vaccine Administrator:	

Standing Orders for Administering Influenza Vaccine to Adults

Purpose: To reduce morbidity and mortality from influenza by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate patients who meet any of the criteria below.

Procedure:

1. Identify adults with no history of influenza vaccination for the current influenza season.
2. Screen all patients for contraindications and precautions to influenza vaccine:
 - a. **Contraindications:** a serious systemic or anaphylactic reaction after ingesting eggs, after receiving a previous dose of influenza vaccine, or to an influenza vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. Do not give live attenuated influenza vaccine (LAIV; nasal spray) to an adult with a history of hypersensitivity to eggs, either anaphylactic or non-anaphylactic; who is pregnant, is age 50 years or older, or who has chronic pulmonary (including asthma), cardiovascular (excluding hypertension), renal, hepatic, neurologic/neuromuscular, hematologic, or metabolic (including diabetes) disorders; immunosuppression, including that caused by medications or HIV.
 - b. **Precautions:** moderate or severe acute illness with or without fever; history of Guillain Barré syndrome within 6 weeks of a previous influenza vaccination; for TIV only, allergic reaction to eggs consisting of hives only (observe patient for at least 30 minutes following vaccination); for LAIV only, close contact with an immunosuppressed person when the person requires 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
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
4. Administer influenza vaccine as follows: a) For adults of all ages, give 0.5 mL of injectable trivalent inactivated influenza vaccine (TIV-IM) intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle. (Note: A ⅝" 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; or b) For healthy adults younger than age 50 years, give 0.2 mL of intranasal LAIV; 0.1 mL is sprayed into each nostril while the patient is in an upright position; or c) For adults ages 18 through 64 years, give 0.1 ml TIV-ID intradermally by inserting the needle of the microinjection system at a 90 degree angle in the deltoid muscle; or d) For adults ages 65 years and older, give 0.5 mL of high-dose TIV-IM intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle.
5. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reasons(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date). (name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Sample Declination Form

Declination: I understand that, because I work in a health care environment, I may place patients and co-workers at risk if I work while infected with influenza. Although I have been informed of the risks and benefits of the vaccine, I choose not to be vaccinated and am declining the vaccine at this time. I understand that by declining this vaccine, I will be at risk of acquiring influenza and spreading it to others.

Reason(s) I do not wish to take the vaccine. Check all that apply.

- I never catch the flu
- Do not feel I am at risk for the flu
- I will catch the flu from the flu vaccine
- I had side effects after I had the vaccine in the past
- I will stay home if I catch the flu so I will not spread it to patients or colleagues
- I am allergic to eggs
- I have had Guillain-Barre Syndrome
- Other _____

I understand that this declination will be void if I later decide to be vaccinated.

Print Name

Date

Signature

Additional Resources: Vaccinating HCP Against Influenza

ARTICLES & PAPERS

Influenza, Hepatitis B, and Tetanus Vaccination Coverage among Health Care Personnel in the United States

Peng-jun Lu & Gary L. Euler. (2011, February 3). Influenza, Hepatitis B, and Tetanus Vaccination Coverage among Health Care Personnel in the United States [Abstract]. *American Journal of Infection Control*. Retrieved from www.ajicjournal.org/article/S0196-6553%2810%2900944-2/abstract

Novel Influenza A (H1N1) Virus Infections Among Health-Care Personnel --- United States, April--May 2009

Novel Influenza A (H1N1) Virus Infections Among Health-Care Personnel --- United States, April--May 2009. (2009, June 19). *MMWR*, 58(23), 641-645. Retrieved from www.cdc.gov/mmwr/preview/mmwrhtml/mm5823a2.htm

Pandemic (H1N1) 2009 Risk for Frontline Health Care Workers

Marshall, C., Kelso, A., McBryde, E., Barr, I.G., Eisen, D.P., Sasadeusz, J., et al. (2011, June). Pandemic (H1N1) 2009 risk for frontline health care workers. *Emerging Infectious Diseases*, 17(6). Retrieved from www.cdc.gov/EID/content/17/6/1000.htm

Healthcare Workers Choose Flu Shots over Masks

Kling, J., (2011, May 20). Healthcare Workers Choose Flu Shots over Masks. *Medscape Medical News*. Retrieved from www.medscape.com/viewarticle/743136

Working while sick may have led to healthcare-associated H1N1 cases

Working while sick may have led to healthcare-associated H1N1 cases. (2011, May 4). *CIDRAP Flu News Scan*. Retrieved from www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/may0411flunewsscan.html

Vaccinating Health Care Workers against Influenza: The Ethical and Legal Rationale for a Mandate

Abigale L. Ottenberg, Joel T. Wu, Gregory A. Poland, Robert M. Jacobson, Barbara A. Koenig, & Jon C. Tilburt. (2011, February). Vaccinating Health Care Workers Against Influenza: The Ethical and Legal Rationale for a Mandate [Abstract]. *American Journal of Public Health*, 101(2), 212-216. Retrieved from <http://ajph.aphapublications.org/cgi/content/abstract/101/2/212>

APIC Position Paper: Influenza Vaccination Should Be a Condition of Employment for Healthcare Personnel, Unless Medically Contraindicated

Linda R. Greene, Tracy Cox, Susan Dolan, Patricia Gray, Raed Khoury, Patricia Kulich, Frank E. Myers, Charlene Ludlow, & Stephen Streed. (2011, January 27). APIC Position Paper: Influenza Vaccination Should Be a Condition of Employment for Healthcare Personnel, Unless Medically Contraindicated. Advisory Committee on Immunization Practices (ACIP). Retrieved from www.apic.org/Content/NavigationMenu/GovernmentAdvocacy/PublicPolicyLibrary/APIC_Influenza_Immunization_of_HCP_12711.PDF

Health Care Worker Knowledge, Attitudes, and Beliefs Regarding Mandatory Influenza Vaccination

Lauren E. Douville, Angela Myers, Mary Anne Jackson, & John D. Lantos. (2010, January). Health Care Worker Knowledge, Attitudes, and Beliefs Regarding Mandatory Influenza Vaccination. *Archives of Pediatrics & Adolescent Medicine* 164(1). Retrieved from <http://archpedi.ama-assn.org/cgi/reprint/164/1/33.pdf>

APHA and AMDA issue position statements in support of mandating influenza vaccination for healthcare workers, joining seven other professional associations on IAC's Honor Roll for Patient Safety

To access the APHA position paper, go to www.apha.org/advocacy/policy/policysearch/default.htm?id=1410

To access the AMDA position statement, go to www.amda.com/governance/resolutions/J11.cfm

APHA and AMDA issue position statements in support of mandating influenza vaccination for healthcare workers, joining seven other professional associations on IAC's Honor Roll for Patient Safety. (2011, April 11). *IAC Express*, 923. Retrieved from www.immunize.org/express/issue923.asp#n2

American Pharmacists Association adopts a policy mandating influenza vaccination for pharmacy personnel; four more organizations join IAC's Honor Roll for Patient Safety

To read the APhA policy statement, go to www.pharmacist.com/AM/Template.cfm?Section=House_of_Delegates&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=25910

American Pharmacists Association adopts a policy mandating influenza vaccination for pharmacy personnel; four more organizations join IAC's Honor Roll for Patient Safety. (2011, May 31). *IAC Express*, 933. Retrieved from www.immunize.org/express/issue933.asp#n4

Workplace efforts to promote influenza vaccination among healthcare personnel and their association with uptake during the 2009 pandemic influenza A (H1N1)

Katherine Harris, Jurgen Maurer, Carla Black, Gary Euler, & Srikanth Kadiyala. (2011, April 5). Workplace efforts to promote influenza vaccination among healthcare personnel and their association with uptake during the 2009 pandemic influenza A (H1N1) [Abstract]. *Vaccine*, 29(16), 2978-2985. Retrieved from www.sciencedirect.com/science/article/pii/S0264410X11001848

Prompting employees to commit to flu vaccination time raises uptake

Prompting employees to commit to flu vaccination time raises uptake. (2011, June 14). *CIDRAP News Scan*. Retrieved from www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/jun1411newsscan.html

Modified flu vaccination policy showed good results in health workers

Modified flu vaccination policy showed good results in health workers. (2011, June 13). *CIDRAP Flu News Scan*. Retrieved from www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/jun1311flunewsscan.html

WEB PAGES

Vaccines & Immunizations: For Specific Groups of People: Healthcare Workers

CDC. (Updated February 16, 2011). Vaccines & Immunizations: For Specific Groups of People: Healthcare Workers. Retrieved June 17, 2011, from www.cdc.gov/vaccines/spec-grps/hcw.htm

Ask the Experts: Influenza Vaccination Issues for Healthcare Workers

Immunization Action Coalition. Ask the Experts: Influenza Vaccination Issues for Healthcare Workers. Retrieved June 17, 2011, from www.immunize.org/askexperts/experts_inf.asp#workers

Seasonal Influenza (Flu): Guidelines and Recommendations: Prevention Strategies for Seasonal Influenza in Healthcare Settings

CDC. (Updated September 20, 2010). Seasonal Influenza (Flu): Guidelines and Recommendations: Prevention Strategies for Seasonal Influenza in Healthcare Settings. Retrieved June 17, 2011, from www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm

Information for Healthcare Professionals: Influenza - *prevent a bad disease with a good vaccine!*

Prevent Influenza. (Reviewed May 2010). Information for Healthcare Professionals: Influenza - *prevent a bad disease with a good vaccine!* Retrieved June 17, 2011, from www.preventinfluenza.org/profs_workers.asp

APIC's *Protect Your Patients, Protect Yourself* Toolkit

APIC. Protect Your Patients. Protect Yourself. Retrieved June 17, 2011, from www.apic.org/Content/NavigationMenu/PracticeGuidance/Topics/Influenza/toolkit_welcome.htm

OTHER RESOURCES

HHS Action Plan to Prevent Healthcare-Associated Infections

www.hhs.gov/ash/initiatives/hai/index.html

HHS Action Plan to Prevent Healthcare-Associated Infections: Influenza Vaccination of Healthcare Personnel

www.hhs.gov/ash/initiatives/hai/tier2_flu.html

HHS Unveils New Interactive Video to Prevent Healthcare-Associated Infections

www.hhs.gov/ash/initiatives/hai/training/index.html

Providing a Safer Environment for Health Care Personnel and Patients through Influenza Vaccination

Providing a Safer Environment for Health Care Personnel and Patients through Influenza Vaccination. (2009, June 25). The Joint Commission. Retrieved from www.jointcommission.org/assets/1/18/Flu_Monograph.pdf

Immunization of Healthcare Workers: Recommendations and Challenges

Immunization of Healthcare Workers: Recommendations and Challenges [webcast archive]. (2011, March 16). The MidAtlantic Public Health Training Center. Retrieved from www.jhsph.edu/maphtc/training_events/archives/031611_Immunization_of_Health_Care

Hepatitis B

Facts About Hepatitis B for Adults

What is hepatitis B?

Hepatitis B is a serious liver disease caused by the hepatitis B virus (HBV). The virus can affect people of all ages. Once infected, some people are never able to rid themselves of the virus. This long-term or “chronic” HBV infection can lead to liver cirrhosis, liver cancer and death. The virus is found in the blood and body fluids of infected people and is most often spread among adults through sexual contact or by sharing needles and other drug paraphernalia with an infected person. HBV can also be spread through normal household contact with HBV-infected persons, or by passage of the virus from an HBV-infected mother to her infant during birth.

Symptoms

Hepatitis B can often be a “silent disease” that affects people without making them feel sick; this is more common among children. People who do get sick from hepatitis B might experience loss of appetite, tiredness, stomachache, nausea and vomiting. They might also experience yellowing of the whites of the eyes (jaundice) and/or joint pain. People with chronic HBV infection usually do not feel sick for many years, but will have symptoms if they develop the most serious complications from hepatitis B, like cirrhosis or liver cancer.

Treatment

There is no specific treatment for newly acquired HBV infection. Medicines are available to treat people with chronic hepatitis B. These medicines work for some people, but not for all.

Prevention

Safe, effective hepatitis B vaccines are available. The vaccines are used to protect everyone from newborn babies to older adults. The vaccination series is usually given as three doses over a six-month period. However, more flexible schedules can be used. Hepatitis B vaccine is recognized as the first anti-cancer vaccine because it can prevent liver cancer caused by chronic HBV infection.

Who should get hepatitis B vaccine?

- ◆ **All children and adolescents from birth through 18 years of age.**
- ◆ **Persons at risk of sexual HBV transmission:** men and women who have had more than one sex partner during the previous six months or who have had a recently acquired sexually transmitted disease (STD); men who have sex with men; and persons receiving treatment for STDs, and persons with HIV infection.
- ◆ **Persons at risk of HBV transmission by percutaneous or mucosal exposure to blood:** people whose jobs potentially expose them to human blood or blood-contaminated body fluids, including most healthcare workers and some public safety workers; injection drug users; and persons with end-stage kidney disease.
- ◆ **People living with or having sexual contact with a person who has chronic HBV infection.**
- ◆ **Travelers who live or work for at least six months in areas where HBV infection is of high or intermediate endemicity, or who stay for shorter periods and will likely have contact with blood (e.g., in a medical setting) or sexual contact with local persons.**
- ◆ **Inmates of correctional facilities, including all inmates who receive a medical evaluation in federal and state prisons, jails, and juvenile correction facilities.**
- ◆ **Residents and staff of institutions and nonresidential daycare facilities for developmentally disabled persons.**
- ◆ **People with chronic liver disease including hepatitis C.**
- ◆ **All adults requesting protection from HBV infection.**

Settings where hepatitis B vaccination is recommended for all adults

- STD treatment facilities
- HIV testing and treatment facilities
- Facilities providing drug-abuse treatment and prevention services
- Healthcare 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
- Institutions and residential daycare facilities for persons with developmental disabilities

National Foundation for Infectious Diseases
4733 Bethesda Avenue, Suite 750, Bethesda, MD 20814
(301) 656-0003. Web site: www.nfid.org August 2009

Facts About Hepatitis B for Adults

- FACT:** Hepatitis B virus (HBV) infection can be prevented with a safe and effective vaccine.
- FACT:** You cannot get hepatitis B from the hepatitis B vaccine.
- FACT:** During the 1970s and 1980s, 200,000 to 300,000 persons were infected with HBV each year in the United States.
- FACT:** Hepatitis B incidence has declined substantially since 1991 when a strategy to eliminate HBV transmission through immunization began to be implemented. The decline in incidence has been greatest among children and adolescents, who are recommended to be routinely vaccinated against hepatitis B.
- FACT:** In 2007, rates of new cases of acute hepatitis B were highest among adults aged 30 – 44 years of age.
- FACT:** More than 50% of new hepatitis B cases could be prevented if hepatitis B vaccination were routinely offered to all persons attending sexually transmitted disease clinics and to all correctional facility inmates.
- FACT:** About 42% of adults who become infected with HBV have a risk factor for infection in 2007.
- FACT:** Even if a person infected with HBV does not feel sick, he or she can still infect others.
- FACT:** HBV infection can result in chronic (life-long) infection that increases a person's risk of developing chronic liver disease, including cirrhosis and liver cancer.
- FACT:** An estimated 800,000- 1.4 million people in the United States have chronic HBV infection.
- FACT:** HBV infection kills about 2,000 to 4,000 people in the United States each year, usually as the result of complications from chronic liver disease.
- FACT:** HBV is found in blood and other body fluids such as semen and vaginal secretions. The hepatitis B virus is 100 times more infectious than HIV, the virus that causes AIDS.
- FACT:** Hepatitis B is a sexually-transmitted disease but can also be transmitted during normal household contact with an infected person.
- FACT:** The hepatitis B vaccine is the first vaccine that prevents a form of cancer — liver cancer.
- FACT:** Infants born to HBV-infected women have a very high chance of getting HBV infection from their mothers unless they receive their first hepatitis B vaccination at birth.

Vaccine Safety

Hepatitis B vaccine is safe and effective. You cannot get hepatitis B from the vaccine. The most common side effect of the vaccine is soreness at the injection site. As with any medicine, there are very small risks that serious problems could occur after getting the vaccine. However, the potential risks associated with hepatitis B disease are much greater than the potential risks associated with the hepatitis B vaccine.

HEPATITIS B 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 hepatitis B?

Hepatitis B is a serious disease that affects the liver. It is caused by the hepatitis B virus (HBV). HBV 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 is more common among adults.

Children who become infected usually do not have acute illness.

Chronic (long-term) infection. Some people go on to develop chronic HBV infection. This can be very serious, and often leads to:

- liver damage (cirrhosis)
- liver cancer
- death

Chronic infection is more common among infants and children than among adults. People who are infected can spread HBV to others, even if they don't appear sick.

- In 2005, about 51,000 people became infected with hepatitis B.
- About 1.25 million people in the United States have chronic HBV infection.
- Each year about 3,000 to 5,000 people die from cirrhosis or liver cancer caused by HBV.

Hepatitis B virus is spread through contact with the blood or other body fluids of an infected person. A person can become infected by:

- contact with a mother's blood and body fluids at the time of birth;
- contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores;
- contact with objects that could have blood or body fluids on them such as toothbrushes or razors;
- having unprotected sex with an infected person;
- sharing needles when injecting drugs;
- being stuck with a used needle on the job.

2 Hepatitis B vaccine: Why get vaccinated?

Hepatitis B vaccine can prevent hepatitis B, and the serious consequences of HBV infection, including liver cancer and cirrhosis.

Routine hepatitis B vaccination of U.S. children began in 1991. Since then, the reported incidence of acute hepatitis B among children and adolescents has dropped by more than 95% – and by 75% in all age groups.

Hepatitis B vaccine is made from a part of the hepatitis B virus. It cannot cause HBV infection.

Hepatitis B vaccine is usually given as **a series of 3 or 4 shots**. This vaccine series gives long-term protection from HBV infection, possibly lifelong.

3 Who should get hepatitis B vaccine and when?

Children and Adolescents

- All children should get their first dose of hepatitis B vaccine **at birth** and should have completed the vaccine series by 6-18 months of age.
- Children and adolescents through 18 years of age who did not get the vaccine when they were younger should also be vaccinated.

Adults

- All unvaccinated adults **at risk for HBV infection** should be vaccinated. This includes:
 - sex partners of people infected with HBV,
 - 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 with jobs that expose them to human blood,
 - household contacts of people infected with HBV,
 - 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.

- Anyone else who wants to be protected from HBV infection may be vaccinated.

4 Who should NOT get hepatitis B vaccine?

- Anyone with a life-threatening allergy to **baker's yeast**, or to **any other component of the vaccine**, should not get hepatitis B vaccine. Tell your provider 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 provider can give you more information about these precautions.

Pregnant women who need protection from HBV infection may be vaccinated.

5 Hepatitis B vaccine risks

Hepatitis B is a very safe vaccine. Most people do not have any problems with it.

The following **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 have gotten hepatitis B vaccine in the United States.

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 The National Vaccine Injury Compensation Program

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

8 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):
 - Call **1-800-232-4636 (1-800-CDC-INFO)**
 - Visit CDC websites at:
 - www.cdc.gov/ncidod/diseases/hepatitis
 - www.cdc.gov/vaccines
 - www.cdc.gov/travel



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

Vaccine Information Statement (Interim)
Hepatitis B (7/18/07) 42 U.S.C. § 300aa-26

Standing Orders for Administering Hepatitis B Vaccine to Adults

Purpose: To reduce morbidity and mortality from hepatitis B virus (HBV) infection by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate adults who meet any of the criteria below.

Procedure:

1. Identify adults in need of hepatitis B vaccination based on the following criteria:
 - a. Age younger than 19 years with no or unknown history of prior receipt of a complete series of hepatitis B vaccine
 - b. Age 19 years or older meeting any of the following criteria:
 - patient with end-stage renal disease, including patients receiving hemodialysis
 - patient with HIV infection
 - patient with chronic liver disease
 - sexually active and not in a long-term, mutually monogamous relation (i.e., more than 1 sex partner during the previous 6 months)
 - under evaluation or treatment for a sexually transmitted disease (STD)
 - a male who has sex with males
 - current or recent injection-drug user
 - at occupational risk of infection through exposure to blood or blood-contaminated body fluids (e.g., healthcare worker, public safety worker, trainee in a health professional or allied health school)
 - client or staff of an institution for persons with developmental disabilities
 - sex partner or household member of a person who is chronically infected with HBV (including an HBsAg-positive adopted child)
 - planned travel to a country with high or intermediate prevalence of chronic HBV infection (a list of countries is available at www.cdc.gov/travel/diseases.htm)
 - housed in or seen for care in a setting in which a high proportion of persons have risk factors for HBV infection (e.g., STD treatment facilities, correctional facilities, institutions for developmentally disabled persons)
 - c. Any person who wishes to be vaccinated against HBV infection
2. Screen all patients for contraindications and precautions to hepatitis B vaccine:
 - a. **Contraindication:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of hepatitis B vaccine or to a hepatitis B vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - b. **Precaution:** moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient’s medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speakers with the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. 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.
5. Provide subsequent doses of hepatitis B vaccine to complete each patient’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.
6. Document each patient’s vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to hepatitis B vaccine 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.

*For persons born in Asia, the Pacific Islands, Africa, or other countries identified as having high rates of HBV infection (see MMWR 2005;54 [No. RR-16]:25), ensure that they have also been tested for hepatitis B surface antigen (HBsAg) to find out if they are chronically infected. If test is performed on same visit, give hepatitis B vaccine after the blood draw. Do not delay initiating hepatitis B vaccination while waiting for test results. If patient is found to be HBsAg-positive, appropriate medical follow-up should be provided.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date). (name of practice or clinic)

Medical Director’s signature: _____ Effective date: _____

Sample Declination Form

Declination: I understand that, because I work in a health care environment, I may place patients and co-workers at risk if I work while infected with hepatitis B. Although I have been informed of the risks and benefits of the vaccine, I choose not to be vaccinated and am declining the vaccine at this time. I understand that by declining this vaccine, I will be at risk of acquiring hepatitis B and spreading it to others.

Reason(s) I do not wish to take the vaccine. Check all that apply.

- Do not feel I am at risk for hepatitis B
- I will stay home if I get hepatitis B so I will not spread it to patients or colleagues
- Other _____

I understand that this declination will be void if I later decide to be vaccinated.

Print Name

Date

Signature

MMR

Facts About Measles for Adults

What is measles?

Measles is a highly contagious virus found throughout the world. People get measles disease by breathing in the measles virus which is spread when an infected person coughs, sneezes or talks. You can get measles just by being in the same room with an infected person.

Prevention

There is a vaccine to protect against measles. The vaccine is frequently given as part of a combination vaccine, called the MMR vaccine, which protects against measles, mumps and rubella. There is also a vaccine that protects only against measles.

Symptoms

Symptoms of measles include high fever, rash, runny nose, watery eyes, coughing, diarrhea, and earache.

The average time between exposure to the measles virus and the development of symptoms is usually from 10 to 14 days.

Who should get MMR vaccine?

- ◆ Adults born in 1957 or later who do not have a medical contraindication should receive at least one dose of the MMR vaccine, unless they have documentation of vaccination with at least one dose of measles-, rubella-, and mumps-containing vaccine or other acceptable evidence of immunity to these three diseases.
- ◆ College and university students, health care personnel, child care workers such as teachers and day care personnel and international travelers are at increased risk for measles, and should receive two doses of the MMR vaccine to ensure adequate protection.

Vaccine Safety

The measles vaccine and the combined MMR vaccine are very safe and effective and generally have few side effects. Mild reactions such as fever, redness or swelling at the injection site have been reported. As with any medicine, there are very small risks that serious problems could occur after getting the vaccine. However, the potential risks associated with measles disease are much greater than the potential risks associated with the measles vaccine. MMR vaccine should not be given to persons who are pregnant or severely immunosuppressed.

Facts About Measles for Adults

- FACT:** Measles can be prevented with a safe and effective vaccine.
- FACT:** The risk of death from measles is higher for infants and adults than for children.
- FACT:** Of the 140 confirmed cases of measles reported in 2008, approximately 25% occurred among adults.
- FACT:** Pregnant women who get measles disease have an increased risk for early labor, miscarriage, and low birth weight infants.
- FACT:** Measles is contagious from 4 days before until 4 days after the rash appears.
- FACT:** Measles can cause life-threatening pneumonia and brain inflammation, middle-ear infection, severe diarrhea and sometimes death.
- FACT:** Outbreaks of measles in 2008, primarily affected those who has not been vaccinated with MMR vaccine.
- FACT:** Most cases of measles in the United States now result from infections acquired in other countries or are linked to such imported cases.
- FACT:** Globally, an estimated 10 million cases of measles occur annually, resulting in an estimated 197,000 deaths, nearly all of these among children less than five years old.

Facts About Mumps for Adults

What is mumps?

Mumps is an acute viral disease that is spread from person to person by coughing or sneezing. People who have mumps may spread the infection to others, even when they do not have any symptoms or their illness is mild.

Prevention

There is a vaccine to protect against mumps. The vaccine is given to adults as part of a combination vaccine, called the MMR vaccine, which protects against measles, mumps and rubella. There is also a vaccine that protects only against mumps.

Symptoms

The symptoms of mumps include a low grade fever and swelling or tenderness of one or more of the salivary glands in the cheeks and under the jaw. In postpubertal males, up to 30% may also experience testicular pain and swelling.

Symptoms usually appear between 12 and 25 days after a person has been exposed to the virus. However, as many as 30-40% of the cases may be asymptomatic and nearly 50% are associated with non-specific or primarily respiratory symptoms, with or without parotitis

Who should get MMR vaccine?

- ◆ Adults born in 1957 or later including non-pregnant women of childbearing age who do not have a medical contraindication should receive at least one dose of the MMR vaccine, unless they have documentation of vaccination with at least one dose of MMR vaccine or other acceptable evidence of immunity to these three diseases.
- ◆ College and university students, health care personnel, child care workers such as teachers and day care personnel, and international travelers are at increased risk for mumps. These persons should receive two doses of the MMR vaccine or have other acceptable evidence of immunity, in order to ensure adequate protection.

Vaccine Safety

The mumps vaccine and the combined MMR vaccine are safe and highly effective in preventing mumps. Occasionally, adults who get the mumps vaccine will develop a low-grade fever or swelling of the salivary glands in the cheeks and neck. Other adverse events that are associated with the measles and/or rubella component of MMR, including fever, rash and joint symptoms in adult women, may also infrequently occur. As with any medicine, there are very small risks that serious problems could occur after getting the vaccine. However, the potential risks associated with mumps disease are much greater than the potential risks associated with the mumps vaccine.

National Foundation for Infectious Diseases
4733 Bethesda Avenue, Suite 750, Bethesda, MD 20814
(301) 656-0003. Web site: www.nfid.org August 2009

Facts About Mumps for Adults

- FACT:** Mumps can be prevented with a safe and effective vaccine.
- FACT:** Mumps is the most contagious from 3 days before to 5 days after the onset of parotitis.
- FACT:** Approximately two-fifth of infected people do not have symptoms of mumps.
- FACT:** Serious complications of mumps are more common among adults than among children.
- FACT:** About 2-3 out of every 10 adolescent or adult men who have mumps may experience painful swelling of the testicles. Sterility rarely occurs.
- FACT:** Rare complications caused by mumps include infection of the brain (encephalitis) and inflammation of the covering of the brain and spinal cord (meningitis). Other rare complications include arthritis, kidney and pancreas problems, deafness, and inflammation of the ovaries.
- FACT:** In 2006, a multistate outbreak of mumps occurred in the United States that affected more than 6,000 people. The majority of the cases occurred among collage age persons, but adolescents and adults were also affected.
- FACT:** In 2008, of the 386 reported cases of mumps, 54% were between 15 and 59 years old.

Facts About Rubella for Adults

What is rubella?

Rubella, also called German measles, is caused by a virus that is spread from person to person when an infected person coughs or sneezes. Rubella is also spread by direct contact with the nasal or throat secretions of an infected person. If a pregnant woman gets rubella during pregnancy, particularly during the first 3 months, her baby is at risk of having serious birth defects.

Prevention

There is a safe and effective vaccine to protect against rubella. The vaccine is usually given to adults as part of a combination vaccine, called the MMR vaccine, that protects against measles, mumps and rubella. There is also a vaccine that protects against rubella only.

Symptoms

Symptoms of rubella may include a rash, slight fever, aching joints, and reddened eyes. The rash first appears on the face and spreads from head to toe. The lymph nodes just behind the ears and at the back of the neck may swell, causing soreness and pain. Many people with rubella have few or no symptoms, and up to half of the people who have the disease may not get a rash. In most cases of rubella, symptoms appear within 16 to 18 days after exposure.

Who should get MMR vaccine?

- ◆ Adults born in 1957 or later including non-pregnant women of childbearing age who do not have a medical contraindication should receive at least one dose of the MMR vaccine, unless they have documentation of vaccination with at least one dose of measles-, rubella-, and mumps-containing vaccine or other acceptable evidence of immunity to these three diseases.
- ◆ College and university students, health care personnel, child care workers such as teachers and day care personnel, and international travelers are at increased risk for rubella and these persons should receive two doses of the MMR vaccine or have other acceptable evidence of immunity, regardless of age, in order to ensure adequate protection.

Vaccine Safety

The rubella vaccine and the combined MMR vaccine are very safe. The most common side effect is burning or stinging at the injection site. Other common side effects include fever, rash, headache and general weakness. Another adverse event that are associated with the rubella component of MM R vaccine is joint symptoms in adult women. As with any medicine, there are very small risks that serious problems could occur after getting the vaccine. However, the potential risks associated with rubella are much greater than the potential risks associated with the rubella vaccine.

Facts About Rubella for Adults

- FACT:** Rubella can be prevented with a safe, effective vaccine.
- FACT:** Rubella is contagious from 7 days before until 5 to 7 days after the rash appears.
- FACT:** In most cases of rubella, symptoms appear within 12 to 23 days, and 20% to 50% of cases may not exhibit symptoms.
- FACT:** If a pregnant woman gets rubella during the first 3 months of pregnancy, her baby has a good chance of having serious birth defects such as deafness, cataracts, heart defects, liver and spleen damage, and mental retardation
- FACT:** During 2001-2008, 79% of all reported cases of rubella occurred among people 15 years of age and older.
- FACT:** As many as 7 million women of childbearing age are susceptible to rubella.
- FACT:** Up to 7 % of young adults are susceptible to the rubella virus.

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



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

Vaccine Information Statement (Interim)
MMR Vaccine (3/13/08) 42 U.S.C. §300aa-26

Standing Orders for Administering Measles, Mumps & Rubella Vaccine to Adults

Purpose: To reduce morbidity and mortality from measles, mumps, and rubella by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate adults who meet any of the criteria below.

Procedure

1. Identify adults in need of initial vaccination against measles, mumps, or rubella who (a) were born in 1957 or later with no history of receipt of live, measles-, mumps-, and/or rubella-containing vaccine given at age 12 months or older or other acceptable evidence of immunity (e.g., laboratory evidence); (b) are women of any age planning to become pregnant and who do not have evidence of immunity; or (c) are healthcare workers born before 1957 without evidence of immunity. Measles, mumps, and rubella (MMR) vaccine (rather than single-antigen vaccine) is recommended if one or more antigens is indicated.
2. Identify adults in need of a second dose of MMR vaccine who (a) were born in 1957 or later and are either planning to travel internationally, a student in a college, university, technical, or vocational school, or (b) are healthcare workers born before 1957 at potential risk of infection from a current mumps outbreak.
3. Screen all patients for contraindications and precautions to measles, mumps, and rubella (MMR) vaccine:
 - a. **Contraindications:**
 - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of MMR vaccine or to an MMR vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - pregnant now or may become pregnant within 1 month
 - known severe immunodeficiency, hematologic and solid tumors; congenital immunodeficiency; receiving long-term immunosuppressive therapy, severely immunocompromised from HIV infection, including CD4+ T-lymphocyte count of less than 200 cells per μL
 - b. **Precautions:**
 - recent (within the past 11 months) receipt of antibody-containing blood product (specific interval depends on product)
 - history of thrombocytopenia or thrombocytopenic purpura
 - moderate or severe acute illness with or without fever
4. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
5. Administer 0.5 mL MMR vaccine subcutaneously (23–25g, $\frac{5}{8}$ " needle) in the posterolateral fat of the upper arm.
6. For adults in need of a second dose of MMR, observe a minimum interval of 4 weeks between the first and second doses.
7. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
8. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
9. Report all adverse reactions to MMR vaccine 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.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Sample Declination Form

I have read, or have had read to me, information concerning the MMR vaccine, and I have had an opportunity to ask questions about it. I understand the benefits and risks of MMR vaccination as described. However, I do not want the vaccine given to me.

I also understand that, because I work in a health care environment, I may place patients and co-workers at risk if I work while infected with measles, mumps, and/or rubella (German measles). By declining this vaccine, I acknowledge that I will be at risk of acquiring measles, mumps, and/or rubella and spreading it to others.

Reason(s) I do not wish to take the vaccine. Check all that apply.

- I do not think I will not contract measles, mumps, and/or rubella
- I do not think these are serious illnesses
- I had side effects after I received the vaccine in the past
- I will stay home if I get any of these illnesses so I will not spread it to patients or colleagues
- Other _____

I understand that this declination will be void if I later choose to be vaccinated.

Print Name

Date

Signature

Varicella

Facts About Chickenpox and Shingles for Adults

What is chickenpox?

Chickenpox, also known as varicella, is a very contagious disease caused by the varicella-zoster virus. It is spread easily through the air by infected people when they sneeze or cough. The disease also spreads through contact with an infected person's chickenpox blisters. Because chickenpox is very contagious, it is possible for people who have never had chickenpox nor been vaccinated against it to become infected just by being in a room with someone who has the disease. However, transient exposure is not likely to result in infection.

Symptoms of chickenpox

Early symptoms may include body aches, fever, fatigue, and irritability. A rash then appears and develops into as many as 250-500 itchy blisters over the entire body, that usually last for 5-7 days and heal with scabs. The rash may even spread into the mouth or other internal parts of the body. The illness is usually not severe, but the risk of hospitalization and death is increased among adolescents and adults. Symptoms appear between 10 and 21 days after exposure to the varicella-zoster virus. Persons who were vaccinated against chickenpox may sometimes develop chickenpox disease but the presentation is usually mild, with approximately 50 or fewer red bumps that rarely evolve to blisters.

What is shingles?

Shingles, or herpes zoster, is a common illness that strikes about 1 million Americans each year, about half of whom are 60 years of age and older. Shingles is caused by the varicella-zoster virus, the same virus that causes chickenpox. When people are first infected with the varicella-zoster virus, usually as children, they get chickenpox. Years or decades later, the virus can reactivate and cause shingles. Anyone who has had chickenpox is at risk of shingles. Shingles is associated with normal aging and with anything that weakens the immune system such as certain medications, cancers, or infections, but it can also occur in healthy children and younger persons.

Symptoms of shingles

A painful, blistering rash tends to occur on one side of the body, usually on the trunk or face. There may be pain, numbness or tingling of the area 2 to 4 days before the rash appears. Pain or numbness usually resolves within weeks, but it can sometimes persist for much longer. Damage can occur to the eyes or other organs if they are involved. One of the most serious long-term consequences of shingles is post-herpetic neuralgia (PHN), a condition where pain persists after the rash has resolved. PHN pain can be very difficult to treat and it can diminish quality of life and functioning to a degree comparable to congestive heart failure, heart attack, type II diabetes and major depression.

Prevention

Chickenpox can be prevented by vaccination. Children who have never had chickenpox should get two doses of chickenpox vaccine, with the 1st dose administered at 12 – 15 months of age and the 2nd at 4-6 years of age. Two doses, administered 4-8 weeks apart, are also recommended for people 13 years of age or older. There is a safe and effective vaccine to prevent shingles. It prevents shingles in 50 percent of those vaccinated and reduces the incidence of PHN by 66 percent. Although people who are vaccinated may still get shingles, they are likely to experience a milder case than un-vaccinated persons.

National Foundation for Infectious Diseases
4733 Bethesda Avenue, Suite 750, Bethesda, MD 20814
(301) 656-0003. Web site: www.nfid.org August 2009

Who should get chickenpox vaccine?

The chickenpox vaccine is recommended for *all* susceptible children and adults who do not have contraindications for vaccination. A second dose catch-up varicella vaccination is recommended for children, adolescents, and adults who previously had received only one dose. Persons belonging to the following groups who have not received the vaccine and have not already had chickenpox should receive special consideration because they are at a higher risk for exposure/transmission:

- ◆ Healthcare workers.
 - ◆ College students.
 - ◆ Household contacts of immunocompromised persons.
 - ◆ Residents and staff in institutional settings.
 - ◆ Inmates and staff of correctional institutions
 - ◆ Military personnel.
 - ◆ Nonpregnant women of childbearing age.
 - ◆ Teachers and day care workers.
 - ◆ Non-immune persons who have been international travelers
- exposed to chickenpox should receive varicella vaccine to prevent or diminish the severity of illness. The vaccine is most effective if given within 3 days (72 hours) to 5 days (120 hours) of the exposure. Vaccine is still recommended after 5 days of the exposure to prevent future disease if this current exposure does not result in disease.

Who should get shingles vaccine?

The shingles vaccine is recommended for anyone 60 years of age and older to keep the varicella-zoster virus from re-activating and causing shingles.

Facts About Chickenpox and Shingles for Adults

- FACT:** Chickenpox (varicella) can be prevented with a vaccine. Sometimes vaccinated persons come down with chickenpox after vaccination but the illness is usually mild with < 50 lesions.
- FACT:** Chickenpox is contagious from 1 to 2 days before the appearance of rash until all blisters have formed scabs or lesions fade away (if no blisters develop).
- FACT:** Following exposure to an infectious person, it usually takes 10 to 21 days before the symptoms of chickenpox begin to appear.
- FACT:** Adults are more likely than children to die from chickenpox and have serious complications resulting from varicella infection. Currently, less than 5% of adults are susceptible to infection with the chickenpox virus; younger adults are more likely to be susceptible.
- FACT:** Immunocompromised people are more likely to have serious illness with complications as a result of chickenpox. The best way to prevent infection in such people is by immunizing their susceptible family members and their other close contacts. However, some immunocompromised people are eligible for vaccination.
- FACT:** If a pregnant woman gets varicella during the first 20 weeks of pregnancy, her baby has a 1 in a 100 risk of having serious birth defects such as shortening and scarring of limbs, cataracts, small head size, abnormal development of the brain and mental retardation
- FACT:** There are about 1 million cases of shingles diagnosed annually in the U.S. About half of cases are in those 60 years of age and older.
- FACT:** Shingles, typically affects people over 50 years of age and those whose immune systems have been weakened by HIV infection, cancers, or treatment with immunosuppressive drugs.
- FACT:** There is a safe, effective vaccine to prevent shingles; it is recommended for everyone 60 years of age and older.
- FACT:** Shingles is caused by the varicella-zoster virus.
- FACT:** Initial infection with varicella-zoster cause chickenpox but the virus can then remain silent in the body for decades. Reactivation of the virus causes shingles.
- FACT:** Shingles causes a painful, blistering rash that usually appears on just one side of the body, most often on the torso or face.
- FACT:** Pain and numbness may occur in the location of the rash two to four days before the rash appears.
- FACT:** The chance of getting shingles increases with age.

- FACT:** Post-herpetic neuralgia (PHN), a long-lasting shingles pain syndrome, is the most common complication of shingles.
- FACT:** PHN diminishes quality of life to a degree similar to congestive heart failure, heart attack, type II diabetes and major depression.
- FACT:** Antiviral medications can be used to treat shingles in its acute stage; however, these medications do not have an effect on whether PHN will persist afterward.
- FACT:** Medications used to treat PHN pain are only modestly effective.
- FACT:** There is a vaccine available that reduces the risk of risk of shingles by 50% and the risk of post-herpetic neuralgia by 66%.
- FACT:** The vaccine is recommended for people even if they've had shingles before because shingles can recur. The vaccine should also be given to people in the recommended age groups even if they cannot recall if they have ever had chickenpox.

Vaccine Safety

Research has shown 1-dose chickenpox vaccine to be 70-90% effective in preventing disease and 95% effective in preventing severe disease. Two doses of vaccine were 99% effective in preventing disease in children in clinical trials. Varicella vaccine is also very safe. The most common side effects are mild and may include pain and redness at the injection site. A mild rash may develop. As with any medicine, there are very small risks that serious problems could occur after getting the vaccine. However, the potential risks associated with varicella disease are much greater than the potential risks associated with the varicella vaccine.

Research has shown shingles vaccine to be 51% effective in preventing shingles and 67% effective in preventing the painful condition of post-herpetic neuralgia, one of the most common complications of shingles. No specific safety concerns arose during the shingles vaccine trial. The most common side-effects following the shingles vaccine are redness, pain, tenderness, and swelling at the injection site and headache.

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.

Chickenpox

3/13/08

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.

4

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.

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



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

Vaccine Information Statement (Interim)
Varicella Vaccine (3/13/08) 42 U.S.C. §300aa-26

SHINGLES VACCINE

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See <http://www.immunize.org/vis>.

1 What is shingles?

Shingles is a painful skin rash, often with blisters. It is also called Herpes Zoster, or just Zoster.

A shingles rash usually appears on one side of the face or body and lasts from 2 to 4 weeks.

Its main symptom is pain, which can be quite severe. Other symptoms of shingles can include fever, headache, chills and upset stomach.

Very rarely, a shingles

infection can lead to pneumonia, hearing problems, blindness, brain inflammation (encephalitis) or death.

For about 1 person in 5, severe pain can continue even long after the rash clears up. This is called **post-herpetic neuralgia**.

Shingles is caused by the Varicella Zoster virus, the same virus that causes chickenpox.

Only someone who has had chickenpox – or, rarely, has gotten chickenpox vaccine – can get shingles. The virus stays in your body, and can cause shingles many years later.

You can't catch shingles from another person with shingles. However, a person who has never had chickenpox (or chickenpox vaccine) could get **chickenpox** from someone with shingles. This is not very common.

Shingles is far more common in people 50 years of age and older than in younger people. It is also more common in people whose immune systems are weakened because of a disease such as cancer, or drugs such as steroids or chemotherapy.

At least 1 million people a year in the United States get shingles.

2 Shingles vaccine

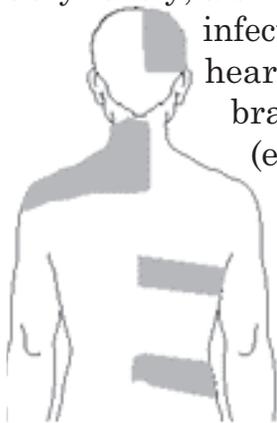
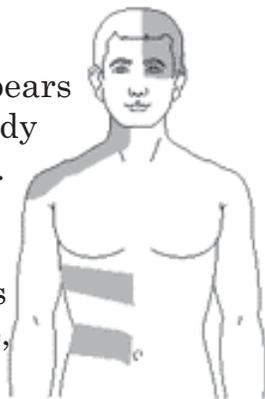
A vaccine for shingles was licensed in 2006. In clinical trials, the vaccine reduced the risk of shingles by 50%. It can also reduce pain in people who still get shingles after being vaccinated.

A single dose of shingles vaccine is recommended for adults 60 years of age and older.

3 Some people should not get shingles vaccine or should wait

A person should not get shingles vaccine who:

- has ever had a life-threatening allergic reaction to gelatin, the antibiotic neomycin, or any other component of shingles vaccine. Tell your doctor if you have any severe allergies.
- has a weakened immune system because of current:
 - AIDS or another disease that affects the immune system,
 - treatment with drugs that affect the immune system, such as prolonged use of high-dose steroids,
 - cancer treatment such as radiation or chemotherapy,



- cancer affecting the bone marrow or lymphatic system, such as leukemia or lymphoma.

- is pregnant, or might be pregnant. Women should not become pregnant until at least 4 weeks after getting shingles vaccine.

Someone with a minor acute illness, such as a cold, may be vaccinated. But anyone with a moderate or severe acute illness should usually wait until they recover before getting the vaccine. This includes anyone with a temperature of 101.3° F or higher.

4 What are the risks from shingles vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. However, the risk of a vaccine causing serious harm, or death, is extremely small.

No serious problems have been identified with shingles vaccine.

Mild Problems

- Redness, soreness, swelling, or itching at the site of the injection (about 1 person in 3).
- Headache (about 1 person in 70).

Like all vaccines, shingles vaccine is being closely monitored for unusual or severe problems.

5 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 <http://www.vaers.hhs.gov>, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

6 How can I learn more?

- Ask your doctor or other health care provider. They can give you the vaccine package insert or suggest other sources of information.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)**
 - Visit the CDC's website at <http://www.cdc.gov/vaccines>



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement

Shingles

10/6/2009

Standing Orders for Administering Varicella (Chickenpox) Vaccine to Adults

Purpose: To reduce morbidity and mortality from varicella (chickenpox) by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law), may vaccinate adults who meet any of the criteria below.

Procedure

1. Identify adults in need of varicella (chickenpox) vaccination who (a) were born in the U.S. in 1980 or later or (b) are a healthcare worker or non-U.S.-born person, and who also meet any of the following criteria:

- lack documentation of 2 doses of varicella vaccine
- lack a history of varicella based on diagnosis or verification of varicella by a healthcare provider
- lack a history of herpes zoster based on healthcare provider diagnosis
- lack laboratory evidence of immunity or laboratory confirmation of disease

Note: Because HIV-infected adults are at increased risk of severe disease from varicella, vaccination may be considered (2 doses, given 3 months apart) for HIV-infected adults and adolescents with CD4+ T-lymphocytes count ≥ 200 cells/ μ L.

2. Screen all patients for contraindications and precautions to varicella vaccine:

a. Contraindications:

- a history of a serious reaction (e.g., anaphylaxis) after a previous dose of varicella vaccine or to a varicella vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
- pregnant now or may become pregnant within 1 month (pregnant women should be vaccinated upon completion or termination of pregnancy)
- having any malignant condition, including blood dyscrasias, leukemia, lymphomas of any type, 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
- family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents, siblings) unless the immune competence of the potential vaccine recipient has been clinically substantiated or verified by a laboratory

b. Precautions:

- recent (within the past 11 months) receipt of antibody-containing blood product (specific interval depends on product)
- moderate or severe acute illness with or without fever

3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.

4. Administer 0.5 mL varicella vaccine subcutaneously (23–25g, $\frac{5}{8}$ " needle) in the posterolateral fat of the upper arm.

5. Administer a second dose 4–8 weeks after the first dose.

6. Document each patient's vaccine administration information and follow up in the following places:

a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).

b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.

7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.

8. Report all adverse reactions to varicella vaccine 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.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Sample Declination Form

I have read, or have had read to me, information concerning the varicella vaccine, and I have had an opportunity to ask questions about it. I understand the benefits and risks of varicella vaccination as described. However, I do not want the vaccine at this time.

I also understand that, because I work in a health care environment, I may put patients and co-workers at risk if I work while infected with varicella (chickenpox). By declining this vaccine, I acknowledge that I will be at risk of acquiring varicella and spreading it to others.

Reason(s) I do not wish to take the vaccine. Check all that apply.

- I already have had chickenpox
- I do not think I will contract chickenpox
- I do not think chickenpox is a serious disease
- I had side effects when I was vaccinated against chickenpox in the past
- I will stay home if I get chickenpox so I will not spread it to patients or colleagues
- Other _____

I understand that this declination will be void if I later decide to be vaccinated.

Print Name

Date

Signature

Tdap

Facts About Tetanus for Adults

What is tetanus?

Tetanus, commonly called lockjaw, is caused by a bacterial toxin, or poison, that affects the nervous system. It is contracted through a cut or wound that becomes contaminated with tetanus bacteria. The bacteria can get in through even a tiny pinprick or scratch, but deep puncture wounds or cuts like those made by nails or knives are especially susceptible to infection with tetanus. Tetanus bacteria are present worldwide and are commonly found in soil, dust and manure. Tetanus causes severe muscle spasms, including “locking” of the jaw so the patient cannot open his/her mouth or swallow, and may lead to death by suffocation. Tetanus is not transmitted from person to person.

Prevention

Vaccination is the only way to protect against tetanus. Due to widespread immunization, tetanus is now a rare disease in the U.S. A booster immunization against tetanus is recommended every 10 years. A new combination vaccine, called Tdap, protects against tetanus, diphtheria and pertussis, and should be used for persons 11-64 years instead of Td (tetanus-diphtheria vaccine). Td should be used for adults 65 years and older. Adolescents and adults who have never received immunization against tetanus should start with a 3-dose primary series given over 7 to 12 months.

Symptoms

Common first signs of tetanus include muscular stiffness in the jaw (lockjaw) followed by stiffness of the neck, difficulty in swallowing, rigidity of abdominal muscles, generalized spasms, sweating and fever.

Symptoms usually begin 7 days after bacteria enter the body through a wound, but this incubation period may range from 3 days to 3 weeks.

Who should get Tdap or Td vaccine?

- ◆ All adults aged 19-64 years who have not already received Tdap and have not had a Td booster immunization in the last 10 years should receive a single dose of Tdap (rather than Td). Adults ≥ 65 years who have not had a Td booster in the last 10 years should receive Td.
- ◆ Older adults and diabetics, who are at higher risk for tetanus, should carefully review of their history of tetanus immunization and receive Td or Tdap if they have not had a Td in the last 10 years.
- ◆ Adults who have never received immunization against tetanus should receive a three dose primary series.
- ◆ Adults who are health-care workers or who are in contact with infants <1 year of age should also receive Tdap vaccine if they have not had a Td in the past 2 years, in order to protect against pertussis (whooping cough).
- ◆ All adolescents and adults who deferred their regular booster during 2001-2002 because of shortages of the vaccine – the supply problems have been resolved.
- ◆ Adolescents aged 11-18 years who have not already received Tdap or Td should receive a single dose of Tdap (rather than Td) to add protection against pertussis (whooping cough).
- ◆ Any adult or adolescent who has recovered from tetanus (lockjaw) disease should receive Tdap or Td.

Vaccine Safety

Tetanus vaccine and the combination Td and Tdap vaccines are very safe and effective. Most people have no problems with either. When side effects do occur, they usually include soreness and redness or swelling at the injection site. As with any medicine, there are very small risks that serious problems could occur after getting the vaccine. However, the potential risks associated with tetanus disease are much greater than the potential risks associated with the tetanus vaccine. You cannot get tetanus from the vaccine.

Facts About Tetanus for Adults

- FACT:** Tetanus can be prevented with safe and effective vaccines.
- FACT:** You cannot get tetanus from the vaccine.
- FACT:** Tetanus is caused by a toxin produced by a type of bacteria found worldwide in soil, dust and manure.
- FACT:** Tetanus is not transmitted from one person to another; vaccination provides protection of the vaccinated individual only.
- FACT:** Almost all reported cases of tetanus occur in persons who either have never received the primary series of tetanus-preventing immunizations, or those who completed a primary series but have not had a booster vaccination in the past 10 years.
- FACT:** Approximately 10-20% of reported cases of tetanus are fatal.
- FACT:** In the U.S., where 50 or fewer cases of tetanus occur each year, deaths are more likely to occur in persons 60 years of age and older and in persons who are diabetic.
- FACT:** People with tetanus may have to spend several weeks in the hospital under intensive care and frequently require ventilator support.
- FACT:** For adults, a tetanus booster every 10 years ensures protection against tetanus. Tdap booster provides protection against tetanus, diphtheria and pertussis, and Td provides protection against tetanus and diphtheria.
- FACT:** Recovery from tetanus may not result in immunity. Patients recovering from tetanus should be immunized soon after their condition has stabilized.

Facts About Diphtheria for Adults

What is diphtheria?

Diphtheria is an acute bacterial disease that usually affects the tonsils, throat, nose and/or skin. It is usually spread from person to person by breathing in droplets that contain diphtheria bacteria. These droplets are produced after an infected person has coughed, sneezed or even laughed. The disease can also be spread by contact with items such as drinking glasses and soiled tissues which are contaminated by discharges from an infected person. Diphtheria bacteria can cause a “membrane” to form over the throat that can lead to breathing problems. Untreated diphtheria can occasionally result in heart failure, paralysis or death. Although no longer a common disease in the US, diphtheria remains a large problem in other countries and can pose a serious threat to those not fully immunized who travel to other countries or have contact with international travelers coming to the US.

Prevention

There is a vaccine to prevent diphtheria. Most people receive their first doses as children in the form of a combined vaccine called DTwP (diphtheria-tetanus-whole-cell pertussis) or DTaP (diphtheria and tetanus toxoids and acellular pertussis). At age 11 –12, children also receive a booster dose of a combined vaccine called Td (tetanus and diphtheria toxoids) or Tdap (tetanus and diphtheria toxoids and acellular pertussis for adolescents and adults)

For adults, a combination vaccine, called a Td booster, protects against both tetanus and diphtheria. It should be administered once every 10 years from the last dose of a diphtheria-containing vaccine to maintain immunity. Adults 19-64 years should receive a single dose of Tdap to replace one Td booster.

Symptoms

In its early stages, diphtheria may be mistaken for a severe sore throat. Other symptoms include a low grade fever and enlarged lymph nodes (swollen glands) located in the neck. Another presentation of diphtheria can be skin lesions that may be painful, red and swollen. Symptoms usually appear 2 to 4 days after infection, with a range of 1 to 6 days. Untreated diphtheria patients may continue to carry diphtheria bacteria and can be contagious for up to 4 weeks. Some persons may also carry the diphtheria bacteria and spread the disease even though they themselves do not develop symptoms.

Who should get Td/Tdap vaccine?

- ◆ All persons who did not receive a primary series of immunization against tetanus and diphtheria during childhood.
- ◆ Persons who have not received a booster dose within the past 10 years.
- ◆ All adolescents and adults who deferred their regular booster during 2001-2002 because of shortages of the vaccine – the supply problems have been resolved.
- ◆ Among adolescents aged 11-18 years and adults 19-64 years who have not already received Tdap (Td in combination with acellular pertussis antigens), a single dose of Tdap is preferred for the regular booster (rather than Td) to add protection against pertussis (whooping cough) .
- ◆ Adults who have recovered from diphtheria disease.

Vaccine Safety

The tetanus and diphtheria (Td) and tetanus, diphtheria and acellular pertussis (Tdap) vaccines are very safe, and very few people experience any side effects. When side effects do occur, they are usually soreness, redness or swelling at the injection site, and a slight fever. As with any medicine, there are very small risks that serious problems could occur after getting the vaccine. The potential risks associated with diphtheria are much greater than the potential risks associated with the diphtheria vaccine. You cannot get diphtheria from the vaccine.

National Foundation for Infectious Diseases
4733 Bethesda Avenue, Suite 750, Bethesda, MD 20814
(301) 656-0003. Web site: www.nfid.org August 2008

Facts About Diphtheria for Adults

- FACT:** Diphtheria can be prevented with safe and effective vaccines.
- FACT:** You cannot get diphtheria from the vaccine.
- FACT:** Diphtheria is transmitted to others through close contact with discharges from an infected person's nose, throat, eyes and/or skin lesions.
- FACT:** Nearly one out of every 10 people who get diphtheria will die from it.
- FACT:** Diphtheria can lead to breathing problems, and sometimes heart failure, paralysis or death if untreated.
- FACT:** Most cases of diphtheria occur among people who are unvaccinated or inadequately vaccinated.
- FACT:** Contracting diphtheria is not always followed by lasting immunity, so even those persons who have recently recovered from the disease need to be immunized.
- FACT:** A tetanus-diphtheria (Td) shot every 10 years gives protection against both tetanus and diphtheria. A tetanus-diphtheria-acellular pertussis (Tdap) shot gives protection against tetanus, diphtheria and pertussis.
- FACT:** Although no longer a common disease in the United States, diphtheria remains a large problem in other countries and can pose a serious threat to United States citizens who may not be fully immunized and who travel to other countries or have contact with immigrants or international travelers coming to the U.S.
- FACT:** An epidemic of diphtheria in Eastern Europe and the newly independent states of the former Soviet Union resulted in over 160, 000 cases and over 4,000 deaths between 1990 and 2001.

Facts About Pertussis for Adults

What is pertussis?

Pertussis, also known as whooping cough, is a serious infection that spreads easily from person to person. The infection causes coughing spells so severe that it can be hard to breathe, eat or sleep. Coughing can even lead to cracked ribs, and is also complicated by pneumonia or hospitalization.

Pertussis has been on the rise in the United States since an all-time low of just over 1,000 cases were reported in 1976. While 25,616 cases were reported to the U.S. Centers for Disease Control and Prevention (CDC) in 2005, the vast majority of cases go unreported and some estimates of true incidence range from one to three million cases annually.

Symptoms

Early symptoms of pertussis are similar to the common cold or bronchitis and may include runny nose, sneezing and low-grade fever. Spasms of coughing then become progressively worse, accompanied by vomiting or incontinence. Sometimes a “whoop” sound occurs while gasping for breath at the end of a coughing spell. Adults rarely have the classic “whoop”, but the spasms of cough can last for weeks, even months.

Prevention

Whooping cough is most contagious before the coughing starts, so the most effective way to prevent it is through immunization. The whooping cough booster vaccine for adults (and adolescents) is called Tdap (tetanus-diphtheria-acellular pertussis). Children get a different formulation, called DTaP. Both protect against tetanus, diphtheria and pertussis.

Two Tdap vaccines are currently licensed for use in the U.S. One preparation can be used for both adults and adolescents, and the other has been approved for use only in adolescents:

- ADACEL (sanofi pasteur) for use in persons 11 to 64 years of age
- Boostrix (GlaxoSmithKline) for use in persons 10 to 18 years of age

Who should get the Tdap vaccine?

The CDC recommends that adults 19 to 64 years of age (and adolescents 11 to 18 years of age) receive a single dose of Tdap in place of the next Td (tetanus-diphtheria) booster recommended for all adults and adolescents. In addition, the CDC has issued recommendations for specific adult populations to have the dose of Tdap before the usual 10 year interval after the last booster dose of Td :

- Adults who have or who anticipate having close contact with infants younger than 12 months of age. (e.g., parents, grandparents younger than 65 years of age, childcare providers, healthcare workers)
- Healthcare personnel in hospitals or ambulatory care settings who have direct patient contact. Priority is given to vaccination of workers in direct contact with infants younger than 12 months of age.
- Pregnant women after delivery, before discharge from the hospital or birthing center.

Vaccine Safety

The Tdap vaccine is safe. Reactions to the vaccine are usually mild. The most common reactions after vaccination are pain and redness at the injection site. Other adverse events are possible. Please consult with your doctor. A healthcare professional should be informed if you have developed Guillain-Barré syndrome within six weeks following a prior tetanus vaccination, if you are pregnant or nursing, or if you have experienced Arthus-type hypersensitivity reactions (i.e., rare but severe, exaggerated local reactions) following a prior tetanus vaccine.

Facts About Pertussis for Adults

- FACT:** Pertussis is a serious infectious disease that has been on the rise in the United States over the last decade, across all age groups.
- FACT:** Protection against pertussis from early childhood vaccines wears off, leaving adults and adolescents at risk for infection.
- FACT:** The Chinese refer to pertussis as the “cough of 100 days” due to the prolonged, dry cough that is experienced by infected individuals.
- FACT:** Pertussis can be difficult to diagnose because early symptoms may appear like the common cold or bronchitis.
- FACT:** Pertussis causes coughing spells that can affect breathing, eating and sleeping. It can even lead to cracked ribs and hospitalization.
- FACT:** Pertussis causes coughing that lasts for weeks, even months. Sometimes a “whoop” sound occurs while gasping for breath during a bad coughing spell. However, the “whoop” is not always present; adults rarely have the classic “whoop.”
- FACT:** The vast majority of cases are not reported. While 25,616 cases of pertussis were reported to the U.S. Centers for Disease Control and Prevention in 2005, experts estimate that the true number may actually be one to three million cases annually.
- FACT:** Adults and adolescents can spread pertussis to infants who have not yet had all of their vaccines, even before a cough develops. Infants have the highest rates of pertussis complications and deaths.
- FACT:** Parents, grandparents and older siblings are often the source of pertussis in infants.
- FACT:** A booster vaccine, known as Tdap (tetanus-diphtheria-acellular pertussis), is available to protect against pertussis. One formulation can be used for adults and adolescents. The other has been approved for adolescents only.
- FACT:** The pertussis booster vaccine protects against two other important diseases— tetanus and diphtheria.
- FACT:** The CDC recommends that adults 19 to 64 years of age (and adolescents 11 to 18 years of age) receive a single dose of Tdap in place of the Td (tetanus-diphtheria) booster previously recommended for all adults.
- FACT:** The CDC also recommends that adults in close contact with infants younger than 12 months of age, healthcare personnel with direct patient contact — especially with infants younger than 12 months of age — and pregnant women directly after delivery receive a single dose of Tdap.

ACIP Provisional Recommendations for Health Care Personnel on use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) and use of Postexposure Antimicrobial Prophylaxis

Date of ACIP vote: February 23, 2011

Date of posting of provisional recommendations: April 4, 2011

Scheduled date of publication of recommendations in CDC Morbidity and Mortality Weekly Report: fall 2011 (Immunization of Healthcare Personnel) and 2012 (full pertussis-containing vaccines recommendations)

On February 23, 2011 the ACIP approved revised recommendations for healthcare personnel on use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) and use of postexposure antimicrobial prophylaxis. Revised recommendations on use of Tdap in healthcare personnel incorporate the changes made by ACIP at the October 2010 meeting and support direct language to remove barriers to facilitate the uptake of Tdap.

Use of Tdap in healthcare personnel:

- The ACIP recommends that all healthcare personnel (HCP), regardless of age, should receive a single dose of Tdap as soon as feasible if they have not previously received Tdap and regardless of the time since last Td dose.
- Tdap is not currently licensed for multiple administrations. After receipt of Tdap, HCP should receive routine booster immunization against tetanus and diphtheria according to previously published guidelines.
- 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).

Postexposure antimicrobial prophylaxis in healthcare personnel:

- Healthcare facilities should maximize efforts to prevent transmission of *Bordetella pertussis*. Respiratory precautions should be taken to prevent unprotected exposure to pertussis.
- Data on the need for postexposure antimicrobial prophylaxis in Tdap-vaccinated HCP are inconclusive. Some vaccinated HCP are still at risk for *B. pertussis*. Tdap may not preclude the need for postexposure antimicrobial prophylaxis.
- Postexposure antimicrobial prophylaxis is recommend 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.

^{¶¶} Hospitals, as defined by the Joint Commission on Accreditation of Healthcare Organizations, do not include long-term-care facilities such as nursing homes, skilled-nursing facilities, or rehabilitation and convalescent care facilities. Ambulatory-care settings include all outpatient and walk-in facilities.

This document available at: <http://www.cdc.gov/vaccines/recs/provisional/default.htm>

ACIP Provisional Recommendations for Pregnant Women on Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap)

Date of ACIP vote: June 22, 2011

Date of posting of provisional recommendations: August 5, 2011

On June 22, 2011, the ACIP approved recommendations for use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) for pregnant women, and updated Tdap recommendations for persons in contact with infants and special situations. These recommendations are in line with the overall CDC strategy to reduce the burden of pertussis disease in infants and are consistent with existing ACIP recommendations for use of Tdap.

Summary of new recommendations:

Use of Tdap in pregnant women

Women's health care providers should implement a Tdap vaccination program for pregnant women who previously have not received Tdap. Health care providers should administer Tdap during pregnancy, preferably during the third or late second trimester*. Alternatively, if not administered during pregnancy, Tdap should be administered immediately postpartum.

Vaccination of adolescents and adults in contact with infants

Adolescents and adults who have or who anticipate having close contact with an infant aged less than 12 months (e.g., parents, siblings, grandparents, child-care providers and healthcare providers) and who previously have not received Tdap should receive a single dose of Tdap to protect against pertussis. Ideally, these adolescents and adults should receive Tdap at least 2 weeks before beginning close contact with the infant.

Special situations

Pregnant women due for tetanus booster

If a tetanus and diphtheria booster vaccination is indicated during pregnancy for a woman who has previously not received Tdap (i.e., more than 10 years since previous Td), then health care providers should administer Tdap during pregnancy, preferably during the third or late second trimester*.

Wound management for pregnant women

As part of standard wound management care to prevent tetanus, a tetanus toxoid-containing vaccine might be recommended for wound management in a pregnant woman if 5 years or more have elapsed since the previous Td. If a Td booster is indicated for a pregnant woman who previously has not received Tdap, health care providers should administer Tdap.

Pregnant women with unknown or incomplete tetanus vaccination

To ensure protection against maternal and neonatal tetanus, pregnant women who never have been vaccinated against tetanus should receive three vaccinations containing tetanus and reduced diphtheria toxoids during pregnancy. The recommended schedule is 0, 4 weeks, and 6 to 12 months. Tdap should replace 1 dose of Td, preferably during the third or late second trimester* of pregnancy.

*After 20 weeks gestation

This document available at: <http://www.cdc.gov/vaccines/recs/provisional/default.htm>

Summary Basis for Regulatory Action

Date: July 8, 2011

From: CDR Edward W. Wolfgang, MSA, BSN, Chair of the Review Committee

LT Juan C. Lacayo, Ph.D., Regulatory Project Manager

BLA/ STN: 125106/680

Applicant Name: GlaxoSmithKline Biologicals (GSK)

Date of Submission: September 20, 2010

Proprietary Name/Established Name: Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed, (Tdap), Boostrix®

Proposed Indication: Active immunization against tetanus, diphtheria, and pertussis in individuals 65 years of age and older.

Recommended Action: Approval

Signatory Authorities Action: Approval

Offices Signatory Authority: Wellington Sun, M.D., Director, DVRPA

I concur with the summary review.

I concur with the summary review and include a separate review to add further analysis.

I do not concur with the summary review and include a separate review.

Specific Documentation used in Developing the SBRA	Reviewer Name – Document Date
Clinical Review	Ann Schwartz, M.D.
Pharmacovigilance Review	Patricia Rohan, M.D.
Statistical Review	Lihan Yan Ph.D.
CMC Review	Leslie Wagner
CMC Review	Drusilla Burns, Ph.D.
Biomonitoring Review	Lillian Ortega
Electronic Integrity Review	David Schwab
Labeling Reviews	Maryann Gallagher Juan C. Lacayo, Ph.D. Ann Schwartz, M.D.

TETANUS, DIPHTHERIA (Td) or TETANUS, DIPHTHERIA, PERTUSSIS (Tdap) **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?

Children 6 years of age and younger are routinely vaccinated against tetanus, diphtheria and pertussis. But older children, adolescents, and adults need protection from these diseases too. Td (Tetanus, Diphtheria) and Tdap (Tetanus, Diphtheria, Pertussis) vaccines provide that protection.

TETANUS (Lockjaw) causes painful muscle spasms, usually all over the body.

- It can lead to tightening of the jaw muscles so the victim cannot open his mouth or swallow. Tetanus kills about 1 out of 5 people who are infected.

DIPHTHERIA causes a thick covering in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and even death.

PERTUSSIS (Whooping Cough) causes severe coughing spells, 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.

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 averaged more than 1,300 cases of tetanus and 175,000 cases of diphtheria each year before vaccines. Since vaccines have been available, tetanus cases have fallen by over 96% and diphtheria cases by over 99.9%.

Before 2005, only children younger than 7 years of age could get pertussis vaccine. In 2004 there were more than 8,000 cases of pertussis in the U.S. among adolescents and more than 7,000 cases among adults.

2 Td and Tdap vaccines

- Td vaccine has been used for many years. It protects against tetanus and diphtheria.
- Tdap was licensed in 2005. It is the first vaccine for adolescents and adults that protects against all three diseases.

Note: At this time, Tdap is licensed for only one lifetime dose per person. Td is given every 10 years, and more often if needed.

These vaccines can be used in three ways: 1) as catch-up for people who did not get all their doses of DTaP or DTP when they were children, 2) as a booster dose every 10 years, and 3) for protection against tetanus infection after a wound.

3 Which vaccine, and when?

Routine: Adolescents 11 through 18

- A dose of Tdap is recommended for adolescents who got DTaP or DTP as children and have not yet gotten a booster dose of Td. The preferred age is 11-12.
- Adolescents who have already gotten a booster dose of Td are encouraged to get a dose of Tdap as well, for protection against pertussis. Waiting at least 5 years between Td and Tdap is encouraged, but not required.
- Adolescents who did not get all their scheduled doses of DTaP or DTP as children should complete the series using a combination of Td and Tdap.

Routine: Adults 19 and Older

- All adults should get a booster dose of Td every 10 years. Adults under 65 who have never gotten Tdap should substitute it for the next booster dose.
- Adults under 65 who expect to have close contact with an infant younger than 12 months of age (including women who may become pregnant) should get a dose of Tdap. Waiting at least 2 years since the last dose of Td is suggested, but not required.
- Healthcare workers under 65 who have direct patient contact in hospitals or clinics should get a dose of Tdap. A 2-year interval since the last Td is suggested, but not required.

New mothers who have never gotten Tdap should get a dose as soon as possible after delivery. If vaccination is needed *during* pregnancy, Td is usually preferred over 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 may be used for people who have never had a dose. But 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, or
- adults 65 and older.

Tdap and 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 DTP, DTaP, DT, or Td 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 provider 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 *can* get Td).
- Talk to your provider 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.

Getting tetanus, diphtheria or pertussis would be much more likely to lead to severe problems than getting either 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 (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 (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 (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)

Vaccine Information Statement (Interim)
Td & Tdap Vaccines (11/18/08) U.S.C. 42 §300aa-26

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

- Two adults had nervous system problems after getting the vaccine during clinical trials. These may or may not have been caused by the vaccine. These problems went away on their own and did not cause any permanent harm.

Tdap or Td

- Swelling, severe pain, 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 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 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

A federal program exists to help pay for the care of anyone who has a serious reaction to 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.

8 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) or
 - Visit CDC's website at www.cdc.gov/vaccines.



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

Standing Orders for Administering Tetanus-Diphtheria Toxoids & Pertussis Vaccine (Td/Tdap) to Adults

Purpose: To reduce morbidity and mortality from tetanus, diphtheria, and pertussis by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate adults who meet the criteria below.

Procedure

1. Identify adults in need of vaccination against tetanus, diphtheria, and pertussis based on the following criteria:
 - a. lack of documentation of at least 3 doses of tetanus- and diphtheria-containing toxoids
 - b. lack of documentation of pertussis-containing vaccine given since age 7 years in adults who
 - are younger than age 65 years, including pregnant women in the third or late second trimester (after 20 weeks gestation)
 - are age 65 years or older who have or anticipate having contact with an infant younger than age 12 months or are a healthcare worker
 - c. completion of a 3-dose primary series of tetanus- and diphtheria-containing toxoids with receipt of the last dose being 10 years ago or longer
 - d. recent deep and dirty wound (e.g., contaminated with dirt, feces, saliva) and lack of evidence of having received tetanus toxoid-containing vaccine in the previous 5 years
 - e. age 65 years or older and wanting to be protected against pertussis
2. Screen all patients for contraindications and precautions to tetanus and diphtheria toxoids (Td) and, if applicable, pertussis vaccine (Tdap):
 - a. **Contraindications:**
 - a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of Td or to a Td or Tdap component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - for Tdap only, a history of encephalopathy within 7 days following DTP/DTaP not attributable to another identifiable cause
 - b. **Precautions:**
 - history of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
 - history of an arthus-type reaction following a previous dose of tetanus-containing and/or diphtheria-containing vaccine, including meningococcal conjugate vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-containing vaccine
 - moderate or severe acute illness with or without fever
 - for Tdap only, progressive or unstable neurologic disorder, uncontrolled seizures or progressive encephalopathy
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL Td or Tdap vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle.
5. Provide subsequent doses of either Td or Tdap to adults as follows:
 - a. to complete the primary 3-dose schedule: observe a minimum interval of 4 weeks between the first and second doses, and 6 months between the second and third doses.
 - b. to boost with Tdap or Td after primary schedule is complete: **for Tdap**, there is no minimum interval following Td; **for Td booster**, boost routinely every 10 years.
 - c. In pregnancy, if a one-time dose of Tdap has never been administered, give Tdap in the third or late second trimester (after 20 weeks gestation). If not administered during pregnancy, give Tdap in immediate postpartum period.
6. Document each patient's vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to Td and Tdap vaccines to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date). (name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Sample Declination Form

I have read, or have had read to me, information concerning the Tdap vaccine, and I have had an opportunity to ask questions about it. I understand the benefits and risks of Tdap vaccination as described. However, I do not want the vaccine given to me.

I also understand that, because I work in a health care environment, I may place patients and co-workers at risk if I work while infected with tetanus, diphtheria, and/or pertussis. By declining this vaccine, I acknowledge that I will be at risk of acquiring tetanus, diphtheria, and/or pertussis and spreading it to others.

Reason(s) I do not wish to take the vaccine. Check all that apply.

- I do not believe I will contract tetanus, diphtheria, and/or pertussis
- I do not believe these are serious diseases
- I had side effects after I was vaccinated against these diseases in the past
- I will stay home if I catch these diseases so I will not spread it to patients or colleagues
- Other _____

I understand that this declination will be void if I later choose to be vaccinated.

Print Name

Date

Signature

Meningococcal

Facts About Meningococcal Disease for Adults

What is meningococcal disease?

Meningococcal (muh-nin-jo-cock-al) disease is a very serious bacterial infection that causes severe swelling of the protective lining around the brain and spinal cord (meningitis) or infection of the bloodstream (meningococcal bacteremia). Less often, it causes arthritis or pneumonia. The bacteria that cause meningococcal disease are spread by close, direct contact with a person who is carrying the bacteria in their nose or throat. Even with appropriate treatment, one in ten people who get meningococcal disease will die and two more will have serious permanent disabilities including brain damage, hearing loss and limb amputations.

Prevention

Meningococcal conjugate vaccine is effective at preventing meningococcal disease caused by four of the five types of bacteria that cause the majority of meningococcal disease worldwide. The vaccine can be given to anyone 2 to 55 years old. Another vaccine (the “polysaccharide vaccine”) protects against the same four types of meningococcal bacteria and is available for people over 55 years old.

The conjugate meningococcal vaccine is recommended for all adolescents 11-18 years of age, college freshmen living in dormitories and other persons 19-55 years of age who are at increased risk of meningococcal disease.

Symptoms

In its early stages, meningococcal disease symptoms can include fever, headache, body aches and a stiff neck. These symptoms may be mild and can easily be mistaken for less severe illnesses, like a cold or flu. But symptoms can progress quickly, killing an otherwise healthy young person in less than 48 hours. Other symptoms that may occur are nausea, vomiting, confusion, sleepiness, sensitivity to light and a rash (usually dark purple spots on the arms, legs or torso).

Who should get meningococcal conjugate vaccine?

- ◆ Adolescents 11-18 years of age
- ◆ College freshmen living in dormitories
- ◆ Other adults at increased risk of meningococcal disease, including : military recruits, international travelers going to certain areas where meningococcal disease is epidemic, microbiologists who may be working with *Neisseria meningitidis*, and people who have had their spleen removed (or who have non-functioning spleens) as well as other adults with certain medical conditions.

Vaccine Safety

The meningococcal conjugate vaccine is safe. Reactions to the vaccine are usually mild. The most common reactions are pain and redness at the injection site. The vaccine cannot cause meningococcal disease. Guillain-Barré Syndrome, a syndrome of muscle weakness, has been reported rarely among some people who were vaccinated with meningococcal conjugate vaccine. People for whom meningococcal vaccination is recommended but who have a history of Guillain-Barré Syndrome should talk to their doctors – the meningococcal polysaccharide vaccine may be a good alternative for them..

National Foundation for Infectious Diseases
4733 Bethesda Avenue, Suite 750, Bethesda, MD 20814
(301) 656-0003. Web site: www.nfid.org August 2008

Facts About Meningococcal Disease for Adults

- FACT:** **Meningococcal conjugate vaccine** is a safe and effective vaccine licensed to prevent meningococcal disease in persons 2-55 years old.
- FACT:** The vaccine protects against four of the five main types of meningococcal bacteria that cause meningococcal disease. These four types cause 75% of cases in adults and adolescents.
- FACT:** You cannot get meningococcal disease from the vaccine.
- FACT:** The vaccine is safe and side effects after vaccination are usually minor and can include pain and redness at the injection site. There have been rare reports of severe muscle weakness occurring in association with getting this vaccine.
- FACT:** Up to 2,800 Americans get meningococcal disease every year; one in every ten will die, even with treatment.
- FACT:** Two in ten of those who survive will have serious permanent disabilities like brain damage, hearing loss and limb amputations.
- FACT:** College-bound students, particularly those who will live in dormitories, are at higher risk for this disease.
- FACT:** The bacteria are spread through close, direct contact with a person carrying the bacteria.
- FACT:** The bacteria are not spread by casual contact such as breathing air where an infected person has been.
- FACT:** Early symptoms of meningococcal disease (fever, headache, body aches and stiff neck) may be mistaken for other less serious illnesses like the common cold or flu, but meningococcal disease symptoms can progress quickly killing an otherwise healthy young person in two days or less.
- FACT:** The meningococcal conjugate vaccine is recommended for all college freshmen living in dormitories (if they have not already received it). It is recommended for other adults who are at increased risk of meningococcal disease, including military recruits, persons traveling to areas where there is more meningococcal disease, or persons with certain medical conditions.

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MENINGOCOCCAL VACCINES

WHAT YOU NEED TO KNOW

Many Vaccine Information Statements are available in Spanish and other languages. See 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 fluid surrounding the brain and spinal cord.

Meningococcal disease also causes blood infections.

About 1,000 - 2,600 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 survive, another 11-19% lose their arms or legs, become deaf, have problems with their nervous systems, become 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 with certain medical conditions, such as lack of a spleen. College freshmen who live in dormitories, and teenagers 15-19 have an increased risk of getting meningococcal disease.

Meningococcal infections can be treated with drugs such as penicillin. Still, about 1 out of every ten people who get the disease dies 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)** was licensed in 2005. It is the preferred vaccine for people 2 through 55 years of age.
- **Meningococcal polysaccharide vaccine (MPSV4)** has been available since the 1970s. It may be used if MCV4 is not available, and 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. Meningococcal vaccines cannot prevent all types of the disease. But they do protect many people who might become sick if they didn't get the vaccine.

Both vaccines work well, and protect about 90% of people who get them. MCV4 is expected to give better, longer-lasting protection.

MCV4 should also be better at preventing the disease from spreading from person to person.

3 Who should get meningococcal vaccine and when?

A dose of MCV4 is recommended for children and adolescents 11 through 18 years of age.

This dose is normally given during the routine pre-adolescent immunization visit (at 11-12 years). But those who did not get the vaccine during this visit should get it at the earliest opportunity.

Meningococcal vaccine is also recommended for other people at increased risk for meningococcal disease:

- College freshmen living in dormitories.
- Microbiologists 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 terminal complement component deficiency (an immune system disorder).
- People who might have been exposed to meningitis during an outbreak.

MCV4 is the preferred vaccine for people 2 through 55 years of age in these risk groups. MPSV4 can be used if MCV4 is not available and for adults over 55.

How Many Doses?

People 2 years of age and older should get 1 dose. Sometimes a second dose is recommended for people who remain at high risk. Ask your provider.

MPSV4 may be recommended for children 3 months to 2 years of age under special circumstances. These children should get 2 doses, 3 months apart.

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 either meningococcal vaccine should not get another dose.
- Anyone who has a severe (life threatening) **allergy to any vaccine component** should not get the vaccine. Tell your provider 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 provider. People with a **mild illness** can usually get the vaccine.
- Anyone who has ever had **Guillain-Barré Syndrome** should talk with their provider before getting MCV4.
- Meningococcal vaccines may be given to pregnant women. However, MCV4 is a new vaccine and has not been studied in pregnant women as much as MPSV4 has. It should be used only if clearly needed.
- 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.

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 fever.

Severe problems

- Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare.
- A serious nervous system disorder called **Guillain-Barré Syndrome** (or GBS) has been reported among some people who received MCV4. This happens so rarely that it is currently not possible to tell if the vaccine might be a factor. Even if it is, the risk is very small.

6 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 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

A federal program exists to help pay for the care of anyone who has had a rare serious reaction to a vaccine.

For information about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit their website at www.hrsa.gov/vaccinecompensation.

8 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):
 - Call **1-800-232-4636 (1-800-CDC-INFO)**
 - Visit CDC's National Immunization Program website at www.cdc.gov/vaccines
 - Visit CDC's meningococcal disease website at www.cdc.gov/ncidod/dbmd/diseaseinfo/meningococcal_g.htm
 - Visit CDC's Travelers' Health website at wwwn.cdc.gov/travel



Standing Orders for Administering Meningococcal Vaccine to Adults

Purpose: To reduce morbidity and mortality from meningococcal disease by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate adults who meet any of the criteria below.

Procedure

1. Identify adults in need of vaccination against meningococcal disease based on any of the following criteria:
 - a. age 19 through 21 years, anticipate college enrollment, and lack documentation of receipt of quadrivalent meningococcal conjugate vaccine (MCV4) at age 16 years or older. Currently enrolled college students who meet these criteria *may* be vaccinated.
 - b. anticipated travel to a country in the “meningitis belt” of sub-Saharan Africa or other location of epidemic meningococcal disease, particularly if contact with the local population will be prolonged
 - c. diagnosis of a damaged spleen; splenectomy
 - d. diagnosis of persistent complement component deficiency (an immune system disorder)
 - e. employment as a microbiologist with routine exposure to isolates of *N. meningitidis*
 - f. anticipated travel to Mecca, Saudi Arabia, for the annual Hajj
 - g. military recruits
 - h. history of receiving either MCV4 or meningococcal polysaccharide vaccine (MPSV4: Menomune [sanofi]) at least 5 years earlier and having continued risk for infection (e.g., living in or recurrent travel to epidemic disease areas).
 - i. any other adult wishing to decrease their risk for meningococcal disease
2. Screen all patients for contraindications and precautions to meningococcal vaccine:
 - a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of meningococcal vaccine or to a meningococcal vaccine component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/appendices/B/excipient-table-2.pdf.
 - b. **Precautions:** moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient’s medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
4. For adults ages 55 years and younger, administer 0.5 mL MCV4 via the intramuscular route (22–25g, 1–1½" needle) in the deltoid muscle. (Note: a ⅝" needle may be used for patients weighing less than 130 lbs [<60kg] 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.) If the person has a permanent contraindication or precaution to MCV4, or if MCV4 is unavailable and immediate protection is needed, MPSV4 is an acceptable alternative, although it must be given subcutaneously. For these adults and adults older than age 55 years, administer 0.5 mL MPSV4 via the subcutaneous route (23–25g, ⅝" needle) in the posterolateral fat of the upper arm.
5. Schedule additional vaccination as follows:
 - a. For adults identified above in 1.c., 1.d., or who have HIV infection, give 2 doses, 2 months apart.
 - b. For adults who remain at high risk (e.g., categories 1.b. through 1.e.), give 1 dose every 5 years.
6. Document each patient’s vaccine administration information and follow up in the following places:
 - a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
 - b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to meningococcal vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date). (name of practice or clinic)

Medical Director’s signature: _____ Effective date: _____

Sample Declination Form

I have read, or have had read to me, information concerning the meningococcal vaccine, and I have had an opportunity to ask questions about it. I understand the benefits and risks of meningococcal vaccination as described. However, I do not want the vaccine given to me.

I also understand that, because I work in a health care environment, I may place patients and co-workers at risk if I work while infected with meningococcal meningitis. By declining this vaccine, I acknowledge that I will be at risk of acquiring meningococcal meningitis and spreading it to others.

Reason(s) I do not wish to take the vaccine. Check all that apply.

- I do not believe I will contract meningococcal meningitis
- I do not believe the disease is serious
- I had side effects when I received the vaccine previously
- I will stay home if I catch the disease so I will not spread it to patients or colleagues
- Other _____

I understand that this declination will be void if I later choose to be vaccinated.

Print Name

Date

Signature

Acknowledgements

A special thanks to our Supporting Partners:

Alcohol and Drug Abuse Administration
APIC Delmarva Long Term Care Chapter
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Greater Baltimore APIC Chapter
LifeSpan MidAtlantic
Maryland Ambulatory Surgical Association (MASA)
Maryland Board of Nursing
MedStar Institute for Innovation
Mental Hygiene Administration
Statewide Advisory Commission on Immunization
University of Maryland School of Nursing

If you would like to become a partner in the Maryland Healthcare Personnel Immunization Initiative, please email hcwinfo@immunizemaryland.org or call 410-902-4677.

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