III. Clinical and Administrative Information	1

## Supplies You May Need at an Immunization Clinic<sup>1</sup>

Vaccines you may need <sup>2</sup> Select the ones you need for the age of the patient you expect at your clinic.  Refrigerated (MMR may also be frozen)  Diphtheria, tetanus, and pertussis (DTaP)  DTaP-HepB-IPV (Pediarix)  DTaP-IPV/Hib (Pentacel)  DTaP-IPV (Kinrix, Quadracel)	<ul> <li>□ Current immunization schedules for children, adolescents, and adults</li> <li>□ Laptop computer, tablet, or smartphone</li> <li>□ Immunization record cards for patients (pediatric and adult)<sup>5</sup></li> <li>□ Release of information forms</li> <li>□ Vaccine Adverse Events Reporting System (VAERS) information</li> <li>□ Schedules, including dates and times,</li> </ul>	Miscellaneous Supplies <sup>2</sup> □ Appropriate storage units and monitoring equipment to maintain vaccine cold chain (see www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit. pdf)  □ Needle disposal "sharps" containers □ 3 cc syringes □ 22 and 25g needles
<ul> <li>☐ Haemophilus influenzae type b (Hib)</li> <li>☐ Hepatitis A (HepA)</li> <li>☐ Hepatitis B (HepB)</li> <li>☐ HepA-HepB (Twinrix)</li> <li>☐ Human papillomavirus (HPV)</li> </ul>	of future immunization clinics  Medical Emergency Supplies <sup>2</sup> "Medical Management of Vaccine Reactions in Children and Teens" <sup>4</sup>	<ul> <li>□ 5%";</li> <li>□ 1";</li> <li>□ 1½";</li> <li>□ 1 box of medical gloves (appropriate size range for staff)</li> <li>□ Sterile alcohol wipes</li> <li>□ Spot bandaids</li> <li>□ Rectangular bandaids</li> </ul>
☐ Influenza, injectable (IIV) (in season) ☐ Influenza, live attenuated intranasal (LAIV) (in season) ☐ Manadas graphs and all (MAMP)	□ "Medical Management of Vaccine Reactions in Adults"  First-line medication	<ul> <li>□ 1" sterile gauze pads or cotton balls</li> <li>□ Thermometers along with probe covers</li> <li>□ Emergency transport containers</li> </ul>
<ul> <li>☐ Measles, mumps, rubella (MMR)</li> <li>☐ Meningococcal ACWY</li> <li>☐ Meningococcal B</li> <li>☐ Pneumococcal conjugate (PCV13)</li> </ul>	☐ Epinephrine, aqueous 1:1000 dilution, in ampules, vials of solution, prepackaged or prefilled syringes, including autoinjectors.	☐ Paper towels ☐ Sanitizing products for surface
<ul><li>□ Pneumococcal polysaccharide (PPSV23)</li><li>□ Polio, inactivated (IPV)</li><li>□ Rotavirus (RV)</li></ul>	Injectors.  If autoinjectors are stocked, at least 3 should be available (pediatric and adult formulations as needed).  Other medications: H <sub>1</sub> antihistamines are for	Vaccine Information Statements (VISs)²  ☐ Most current version associated with each vaccine used in the clinic (available in English
<ul> <li>□ Tetanus-diphtheria, adult (Td)</li> <li>□ Tetanus, diphtheria, and pertussis (Tdap)</li> <li>□ Zoster, recombinant (RZV; Shingrix)</li> <li>□ Diluent<sup>3</sup> for ActHIB, Hiberix, MMR, Menveo, Pentacel, Rotarix, and Shingrix</li> </ul>	itching and hives only and not for managing anaphylaxis.  □ Diphenhydramine (e.g., Benadryl) oral (12.5 mg/5 mL liquid, 25 or 50 mg	and over 30 languages at www.immunize.org/vis)  Office Supplies  □ Calendar □ Stapler/staples
Frozen (Never pack frozen vaccine with dry ice)	capsules/tablets) or injectable (50 mg/mL solution)	□ Pens □ Tape
<ul><li>☐ Measles, mumps, rubella, varicella (MMRV)</li><li>☐ Varicella</li></ul>	☐ Hydroxyzine (e.g., Atarax, Vistaril) oral (10 mg/5 mL or 25 mg/5 mL liquid, 10 mg or 25 mg tablets, or 25 mg capsules)	<ul><li>☐ File folders</li><li>☐ Paper clips</li><li>☐ Scissors</li><li>☐ Post-its</li><li>☐ Pad of paper</li></ul>
☐ Zoster, live (ZVL; Zostavax)	Other supplies for emergencies:	
☐ Diluent³ for MMRV, Varivax, and Zostavax  For instructions on how to pack and transport vaccines, go to www.cdc.gov/vaccines/hcp/admin/storage/toolkit/ storage-handling-toolkit.pdf, pages 35–37.	<ul> <li>□ Syringes (1 and 3 cc) and needles (22 and 25g, 1", 11/4", 11/2", and 2") for epinephrine or diphenhydramine</li> <li>□ Alcohol wipes</li> </ul>	<ol> <li>See also "Tools to Assist Satellite, Temporary, and Off-Site Vaccination Clinics" at www.izsummitpartners.org/naiis-workgroups/</li> <li>Always check the expiration dates of all vaccines, medications, and medical supplies before using! In addition, be sure to check that you have the</li> </ol>
Immunization Clinic Documentation	☐ Tourniquet ☐ Stethoscope	most current versions of the VISs. To learn more about VISs, visit www.immunize.org/vis.
<ul> <li>□ Vaccine standing orders and protocols<sup>4</sup></li> <li>□ Vaccination administration record sheets<sup>4</sup></li> <li>(i.e., medical records, if needed)</li> <li>□ Billing forms, if needed</li> </ul>	<ul> <li>□ Blood pressure measuring device (with a variety of cuff sizes as needed)</li> <li>□ Tongue depressors</li> <li>□ Light source (e.g., flashlight for examina-</li> </ul>	<ol> <li>Diluent should not be frozen.</li> <li>These materials are available at www.immunize.org/handouts.</li> <li>These materials may be purchased at www.immunize.org/shop.</li> </ol>
<ul> <li>□ "Screening Checklist for Contraindications to Vaccines for Children and Teens"<sup>4</sup></li> <li>□ "Screening Checklist for Contraindications</li> </ul>	tion of mouth and throat)  Wristwatch or other timing device for measuring pulse	
to Vaccines for Adults" <sup>4</sup> "Summary of Recommendations for	☐ Telephone to call 911	
Child/Teen Immunization" <sup>4</sup> ☐ "Summary of Recommendations for Adult Immunization" <sup>4</sup>	For remote locations:  ☐ Pediatric and adult size pocket masks with one-way valve	
☐ Temperature log if needed	□ Oxygen (if available)	

 $\hfill\square$  Temperature log, if needed

# PEDIATRICS<sup>®</sup>

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#### Standards for Child and Adolescent Immunization Practices

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#### SPECIAL ARTICLE

#### Standards for Child and Adolescent Immunization Practices

National Vaccine Advisory Committee

ABBREVIATIONS. NVAC, National Vaccine Advisory Committee; ACIP, Advisory Committee on Immunization Practices; AAP, American Academy of Pediatrics; AAFP, American Academy of Family Physicians; VFC, Vaccines for Children Program; CDC, Centers for Disease Control and Prevention; VIS, Vaccine Information Statement; VAERS, Vaccine Adverse Events Reporting System; VICP, Vaccine Injury Compensation Program.

In 1992, the National Vaccine Advisory Committee (NVAC), in collaboration with the Ad Hoc Working Group for the Development of Standards for Pediatric Immunization Practices, a working group representing public and private agencies with input from state and local health departments, physician and nursing organizations, and public and private providers, developed a set of standards as to what constitutes the most essential and desirable immunization policies and practices. These standards were endorsed by a variety of medical and public health organizations and represented an important element in our national strategy to protect America's children against vaccine-preventable diseases.

Since that time, vaccine delivery in the United States has changed in several important ways. First, vaccination coverage rates among preschool children have increased substantially and are now monitored by the National Immunization Survey.<sup>1,2</sup> Second, vaccination of children has shifted markedly from the public to the private sector,<sup>3–5</sup> with an emphasis on vaccination in the context of primary care and the medical home.<sup>6</sup> The Vaccines for Children Program has provided critical support to this shift by covering the cost of vaccines for the most economically disadvantaged children and adolescents. Third, the development and introduction of performance measures, such as the National Committee for Quality Assurance's Health Plan Employer Data and Information Set, have focused national attention on the quality of preventive care, including vaccination. Finally, highquality research in health services has helped to refine strategies for raising and sustaining vaccination coverage levels among children, adolescents, and adults.8

Health care professionals who vaccinate children and adolescents continue to face important chal-

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lenges. These challenges include a diminishing level of experience—among patients, parents, and physicians—with the diseases that vaccines prevent, the ready availability of vaccine-related information that may be inaccurate or misleading, the increasing complexity of the vaccination schedule, and the failure of many health plans to pay for the costs associated with vaccination. In addition, recommendations from the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American Medical Association in 1996 underscored the need to focus on adolescent vaccination.<sup>9</sup>

In this context, NVAC, along with partners representing the federal agencies, state and local health departments, and professional organizations, revised and updated the standards during 2001–2002 to reflect these changes and challenges in vaccine delivery. The revision was approved by NVAC on February 8, 2002 (Table 1), and distributed widely among a variety of medical and public health organizations for review and endorsement. Table 2 lists those organizations that have formally endorsed the Standards for Child and Adolescent Immunization Practices.

The standards are directed toward "health care professionals," an inclusive term for the many people in clinical settings who share in the responsibility for vaccination of children and adolescents: physicians, nurses, midlevel practitioners (eg, nurse practitioners, physician assistants), medical assistants, and clerical staff. In addition to this primary audience, the standards are intended to be useful to public health professionals, policy makers, health plan administrators, employers who purchase health care coverage, and others whose efforts shape and support the delivery of vaccination services.

Of note, the use of the term "standards" should not be confused with a minimum standard of care. Rather, these standards represent the most desirable immunization practices, which health care professionals should strive to achieve. Given current resource limitations, some health care professionals may find it difficult to implement all of the standards, because of circumstances over which they have little control. The expectation is that, by summarizing best immunization practices in a clear and concise format, the standards will assist these providers in securing the resources necessary to implement this set of recommendations.

Availability of vaccines

- 1. Vaccination services are readily available.
- 2. Vaccinations are coordinated with other health care services and provided in a medical home<sup>6</sup> when possible.
- 3. Barriers to vaccination are identified and minimized.
- Patient costs are minimized.

Assessment of vaccination status

- 5. Health care professionals review the vaccination and health status of patients at every encounter to determine which vaccines are indicated.
- 6. Health care professionals assess for and follow only medically accepted contraindications. Effective communication about vaccine benefits and risks
  - Parents/guardians and patients are educated about the benefits and risks of vaccination in a culturally appropriate manner and in easy-to-understand language.

Proper storage and administration of vaccines and documentation of vaccinations

- 8. Health care professionals follow appropriate procedures for vaccine storage and handling.
- Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.
- People who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive ongoing education.
- 11. Health care professionals simultaneously administer as many indicated vaccine doses as possible.
- 12. Vaccination records for patients are accurate, complete, and easily accessible.
- 13. Health care professionals report adverse events after vaccination promptly and accurately to the Vaccine Adverse Events Reporting System (VAERS) and are aware of a separate program, the Vaccine Injury Compensation Program (VICP).
- 14. All personnel who have contact with patients are appropriately vaccinated.

Implementation of strategies to improve vaccination coverage

- 15. Systems are used to remind parents/guardians, patients, and health care professionals when vaccinations are due and to recall those who are overdue.
- Office- or clinic-based patient record reviews and vaccination coverage assessments are performed annually.
- 17. Health care professionals practice community-based approaches.

By adopting these standards, health care professionals can enhance their own policies and practices, making achievement of vaccination objectives for children and adolescents as outlined in *Healthy People 2010*, a nationwide health promotion and disease prevention agenda from the US Department of Health and Human Services, <sup>10</sup> both feasible and likely. Achieving these objectives will improve the health and welfare of all children and adolescents as well as the communities in which they live.

#### THE STANDARDS

#### Availability of Vaccines

1. Vaccination Services Are Readily Available

All health care professionals who provide primary care to children and adolescents should always include routinely recommended vaccines as a part of the care that they deliver in the medical home.<sup>6</sup> For some children and adolescents, the main contact with the health care system is not in a primary care provider's office; therefore, opportunities for vaccination may be missed. Thus, specialists and health care professionals in settings such as schools and school health clinics, sports physical clinics, family planning clinics, sexually transmitted disease clinics, and substance abuse treatment centers should assess each patient's vaccination status and either offer indicated vaccines or refer for vaccination if necessary. Information on vaccines administered outside the primary care setting should be communicated to the primary care provider.

2. Vaccinations Are Coordinated With Other Health Care Services and Provided in a Medical Home When Possible

Ideally, vaccines should be given as part of comprehensive health care. In primary care settings, vaccination services should be coordinated with routine well-care visits and other visits.<sup>6</sup> Patients who are vaccinated in other settings should be encouraged to receive subsequent vaccines in their primary care setting. Patients without a primary care provider should be assisted with identifying one.

#### 3. Barriers to Vaccination Are Identified and Minimized

Barriers to receiving vaccines include delays in scheduling appointments, requiring a well-care visit, long waiting periods in the office, and lack of culturally and age-appropriate educational materials. A physical examination, although an important part of well care, should not be required before administering vaccines: simply observing the patient and questioning about the patient's health status, immunization history, and vaccine contraindications are sufficient. In addition, vaccination-only visits should be available. Health care professionals should seek advice from parents/guardians and patients to identify ways to make vaccination services easier to use.

#### 4. Patient Costs Are Minimized

Out-of-pocket costs—including vaccine, administration, and office visit fees—should be as low as possible for all patients, and no child or adolescent should be denied vaccination because of inability to pay. Resources should be identified to keep patient vaccination costs as low as possible. Free vaccine is

**TABLE 2.** Organizations That Provide Endorsement for the Revised Standards for Child and Adolescent Immunization Practices

Advisory Committee on Immunization Practices Albert B. Sabin Vaccine Institute Ambulatory Pediatric Association American Academy of Family Physicians American Academy of Pediatrics American Academy of Physician Assistants American College of Emergency Physicians American College of Osteopathic Pediatricians American College of Preventive Medicine

American Medical Association American Nurses Association American Osteopathic Association American Public Health Association

Association of Immunization Program Managers Association of Maternal and Child Health Programs Association of State and Territorial Health Officials

Center for Pediatric Research

Centers for Medicare and Medicaid Services Council of State and Territorial Epidemiologists

Every Child by Two

Health Resources and Services Administration

Immunization Action Coalition Infectious Diseases Society of America

National Alliance for Hispanic Health

National Asian Women's Health Organization

National Assembly on School-Based Health Care

National Association for City and County Health Officials

National Association for Pediatric Nurse Practitioners

National Association of School Nurses

National Coalition for Adult Immunization

National Foundation for Infectious Diseases

National Institute of Allergy and Infectious Diseases

National Medical Association

National Network of Immunization Nurses and Associates

National Partnership for Immunization

National Perinatal Association

Partnership for Prevention

Pediatric Infectious Disease Society

Project Immunize Virginia

Rotary International

Society for Adolescent Medicine

Society for Teachers of Family Medicine

Vaccine Education Center at the Children's Hospital of Philadelphia

available through some public programs, although health care professionals who offer these vaccines may charge a reasonable administration fee. Sources of publicly funded vaccines include the Vaccines for Children Program (VFC), Public Health Service Section 317 grants to states, and state or local programs. Children and adolescents should be screened for their eligibility to receive vaccines through these programs. Vaccinations provided through VFC or Section 317 grants may not be denied because of an inability to pay the administration fee, and health care professionals should ensure that parents/ guardians and patients are aware of this requirement (applies to all vaccines purchased using Centers for Disease Control and Prevention [CDC] contracts, regardless of the setting—private or public—in which the vaccines are administered).

To minimize costs for patients, health plans and insurance plans should include the provision and administration of all routinely recommended vaccines as a covered benefit for all children and adolescents. Furthermore, to minimize costs for health care professionals, purchasers and health plans

should reimburse health care professionals adequately for delivering vaccines, including the time required for vaccine administration and for communication about vaccine benefits and risks. The CDC maintains a web page about VFC at http://www.cdc.gov/nip/vfc.

#### Assessment of Vaccination Status

5. Health Care Professionals Review the Vaccination and Health Status of Patients at Every Encounter to Determine Which Vaccines Are Indicated

Health care professionals should review the vaccination status of all patients at all health care visits to minimize the number of missed opportunities to vaccinate. This review should determine whether the patient has received any vaccinations elsewhere or is at high risk for disease or undervaccination. This information should be documented in the patient's chart and preventive health summary. Health care professionals who do not offer vaccinations should refer patients to a primary care provider for needed vaccinations.

6. Health Care Professionals Assess for and Follow Only Medically Accepted Contraindications

Withholding vaccinations because of medical concerns that are not contraindications results in missed opportunities for prevention. Health care professionals should ask about any condition or circumstance that might indicate that a vaccination should be withheld or delayed and about previous adverse events temporally associated with any vaccination. Health care professionals should support their decisions about what constitutes a contraindication or deferral for each vaccine by consulting the Guide to Contraindications to Vaccinations published by the CDC (available at: http://www.cdc.gov/nip/ recs/contraindications.pdf); the harmonized recommendations of the ACIP, the AAP, and the AAFP (available at: http://www.cdc.gov/nip/recs/childschedule.htm#Printable); the AAP's Red Book and other relevant recommendations; Vaccine Information Statements; and manufacturers' package inserts. Contraindications and deferrals should be documented in the medical record.

### Effective Communication About Vaccine Benefits and Risks

7. Parents/Guardians and Patients Are Educated About the Benefits and Risks of Vaccination in a Culturally Appropriate Manner and in Easy-to-Understand Language

Health care professionals should allow sufficient time with parents/guardians and adolescent patients to discuss the benefits of vaccines, the diseases that they prevent, any known risks from vaccines, the immunization schedule and the need to receive vaccines at the recommended ages, and the importance of bringing the patient's hand-held vaccination record to each health care visit. Health care professionals should encourage parents/guardians and adolescent patients to take responsibility for ensuring that the patient is fully vaccinated.

For all commonly used childhood vaccines, all

health care professionals are required by federal law to give a Vaccine Information Statement (VIS) to vaccine recipients or their parents/guardians at each visit. A VIS is a vaccine-specific, 2-page information sheet, produced by the CDC, that describes the benefits and risks of a vaccine. If necessary, health care professionals should supplement the VIS with oral explanations or other written materials that are culturally and linguistically appropriate. Health care professionals should review written materials with patients and their parents/guardians and address questions and concerns.

Health care professionals should encourage parents/guardians and adolescent patients to inform the health care professional of adverse events after the vaccine to be administered and explain how to obtain medical care, if necessary. (See Standard 13 for a description of the Vaccine Adverse Events Reporting System [VAERS]).

General vaccination information for health care professionals, parents, and members of the public may be obtained by calling the CDC National Immunization Information Hotline at 1-800-232-2522 (English) or 1-800-232-0233 (Spanish). Information about vaccine risk communication for health care professionals can be found at http://www.cdc.gov/nip/ vacsafe/research/peds.htm and in the latest edition of the Red Book. VISs are available in English and numerous other languages from state health departments and at http://www.cdc.gov/nip/publications/ VIS/default.htm and http://www.immunize.org. Recommendations for national standards for culturally and linguistically appropriate services in health care may be found at http://www.omhrc.gov/omh/ programs/2pgprograms/finalreport.pdf.

## Proper Storage and Administration of Vaccines and Documentation of Vaccinations

8. Health Care Professionals Follow Appropriate Procedures for Vaccine Storage and Handling

Vaccines should be handled and stored as recommended in the manufacturers' package inserts; the expiration date for each vaccine should be noted. Temperatures at which vaccines are stored and transported should be monitored and recorded twice daily. Summary information about vaccine storage and handling procedures are also available from state and local health departments and the CDC. Health care professionals should monitor vaccine inventory and undertake efforts to reduce wastage and loss. CDC-recommended storage and handling procedures are available from the CDC by calling 404-639-8222.

9. Up-to-Date, Written Vaccination Protocols Are Accessible at All Locations Where Vaccines Are Administered

To promote the safe and effective use of vaccines, health care professionals should maintain written protocols that detail the following: vaccine storage and handling; the recommended vaccination schedule, vaccine contraindications, and administration techniques; treatment and reporting of adverse events; vaccine benefit and risk communication; and

vaccination record maintenance and accessibility. These protocols should be consistent with established guidelines, reviewed frequently, and revised as needed to ensure that they remain up-to-date.

10. People Who Administer Vaccines and Staff Who Manage or Support Vaccine Administration Are Knowledgeable and Receive Ongoing Education

Health care professionals or others who administer vaccinations should be knowledgeable and receive continuing education in vaccine storage and handling; the recommended vaccine schedule, contraindications, and administration techniques; treatment and reporting of adverse events; vaccine benefit and risk communication; and vaccination record maintenance and accessibility. With appropriate training and in accordance with state law/regulation/policy, people other than physicians and nurses may administer vaccines. In addition, other staff should receive training and continuing education related to their specific roles and responsibilities that affect vaccination services.

The CDC sponsors distance-based training opportunities (eg, satellite broadcasts, web-based training, videotapes, self-administered print materials) for health care professionals. Information about training is available at http://www.cdc.gov/nip/ed.

11. Health Care Professionals Simultaneously Administer as Many Indicated Vaccine Doses as Possible

Administering vaccines simultaneously (at the same visit), in accordance with recommendations from the ACIP, the AAP, and the AAFP, is safe, effective and indicated. Although the immunization schedule provides age flexibility for administering certain vaccine doses, simultaneous administration decreases the number of visits needed and the potential for missed doses and enables earlier protection. When indicated vaccines are not simultaneously administered, arrangements should be made for the patient's earliest return to receive the needed vaccination(s). Additional information on the safety of simultaneous vaccination may be found at http://www.cdc.gov/nip/vacsafe/research/simultaneous.htm.

12. Vaccination Records for Patients Are Accurate, Complete, and Easily Accessible

Vaccination records for patients should be recorded on a standard form in an easily accessible location in the medical record to facilitate rapid review of vaccination status. Accurate record keeping helps to ensure that only needed vaccinations are given. As required by federal law (42 US Code 300aa-25), health care professionals should ensure that records contain the following information for each vaccination: the date of administration, the vaccine manufacturer and lot number, the signature and title of the person administering the vaccine, and the address where the vaccine was given. Vaccine refusal should also be documented.

The medical record maintained by the primary care provider should document all vaccines received, including those received at a specialist's office or in another health care setting. When a health care pro-

fessional who does not routinely care for a patient vaccinates that patient, the patient's primary care provider should be informed.

All vaccinations administered should be reported to state or local immunization registries, where available, to ensure that each patient's vaccination history remains accurate and complete. Registries also may be useful for verifying the vaccination status of new patients, determining which vaccines are needed at a visit, printing official records, and providing reminders and recalls to parents, guardians, and patients.

Health care professionals should ensure that each patient has a hand-held vaccination record that documents each vaccine received, including the date and the name of the health care professional who administered the vaccine. Health care professionals should encourage parents/guardians and adolescent patients to bring the patient's hand-held record to each health care visit so that it can be updated.

The CDC maintains an Immunization Registry Clearinghouse. Information about this clearinghouse is available at http://www.cdc.gov/nip/registry/.

13. Health Care Professionals Report Adverse Events After Vaccination Promptly and Accurately to the Vaccine Adverse Events Reporting System (VAERS) and Are Aware of a Separate Program, the National Vaccine Injury Compensation Program (VICP)

Health care professionals should promptly report all clinically significant adverse events after vaccination to the VAERS even if the health care professional is not certain that the vaccine caused the event. Health care professionals should document in detail the adverse event in the patient's medical record as soon as possible. Providers should be aware that parents/guardians and patients may report to VAERS and that if they choose to do so, they are encouraged to seek the help of their health care provider.

The National Vaccine Injury Compensation Program (VICP) is a no-fault system that compensates people of any age for injuries or conditions that may have been caused by a vaccine recommended by the CDC for routine use in children. Health care professionals should be aware of the VICP to address questions raised by parents/guardians and patients.

Because VAERS and VICP are separate programs, a report of an event to VAERS does not result in the submission of a compensation claim to VICP. A brief description and contact information for both programs is provided on each VIS for those vaccines covered by the National Childhood Vaccine Injury Act

Information about VAERS, as well as guidance about how to obtain and complete a VAERS form, can be found at http://www.vaers.org or by calling 1-800-822-7967. Information about the VICP is available at http://www.hrsa.gov/osp/vicp or by calling 1-800-338-2382.

## 14. All Personnel Who Have Contact With Patients Are Appropriately Vaccinated

Health care professionals and other personnel who have contact with patients should be appropriately

vaccinated. Offices and clinics should have policies to review and maintain the vaccination status of staff and trainees. ACIP recommendations for vaccinating health care workers are available at ftp://ftp.cdc.gov/pub/publications/mmwr/rr/rr4618.pdf.

## Implementation of Strategies to Improve Vaccination Coverage

15. Systems Are Used to Remind Parents/Guardians, Patients, and Health Care Professionals When Vaccinations Are Due and to Recall Those Who Are Overdue

Evidence demonstrates that reminder/recall systems improve vaccination coverage. 11 Patient reminder/recall interventions inform individuals that they are due (reminder) or overdue (recall) for specific vaccinations. Patient reminders/recalls can be mailed or communicated by telephone; an autodialer system can be used to expedite telephone reminders. Patients who might be at high risk for not complying with medical recommendations, for example, those who have missed previous appointments, should receive more intensive follow-up. Similarly, provider reminder/recall systems alert health care professionals when vaccines are due or overdue. Notices should be placed in patient charts or communicated to health care professionals by computer or other means. Immunization registries can facilitate automatic generation of reminder/recall notices.

## 16. Office- or Clinic-Based Patient Record Reviews and Vaccination Coverage Assessments Are Performed Annually

Evidence shows that assessments are most effective in improving vaccination coverage in a practice when they combine chart reviews to determine coverage with the provision of results to health care professionals and staff. Effective interventions also may incorporate incentives or compare performance with a goal or a standard. Coverage should be assessed regularly so that reasons for low coverage in the practice or in a subgroup of patients are identified and addressed. For assistance in conducting vaccination coverage assessments, health care professionals should contact their state or local immunization program.

## 17. Health Care Professionals Practice Community-Based Approaches

All health care professionals share in the responsibility to achieve the highest possible degree of community protection against vaccine-preventable diseases. Immunization protects the entire community as well as the individual. No community is optimally protected against vaccine-preventable diseases without high vaccination coverage. Therefore, health care professionals should consider the needs of the community (especially underserved populations) as well as those of their patients. Community-based approaches may involve working with partners in the community, including public health departments, managed care organizations, other service providers such as the US Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), advocacy groups, schools, and service organizations to determine community needs and develop vaccination services that address these needs.

## NATIONAL VACCINE ADVISORY COMMITTEE (NVAC)

The NVAC was chartered in 1988 to advise and make recommendations to the director of the National Vaccine Program and the assistant secretary for health, Department of Health and Human Services, on matters related to the prevention of infectious diseases through immunization and the prevention of adverse reactions to vaccines. The NVAC is composed of 15 members from public and private organizations representing vaccine manufacturers, physicians, parents, and state and local health agencies. In addition, representatives from governmental agencies involved in health care or allied services serve as ex-officio members of the NVAC.

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#### **Standards for Child and Adolescent Immunization Practices**

National Vaccine Advisory Committee Pediatrics 2003:112:958-963

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#### **ERRATA**

Numerical errors occurred in the article by Holt et al, titled "Response to Intravenous Immunoglobulin Predicts Splenectomy Response in Children With Immune Thrombocytopenic Purpura," that was published in the January 2003 issue of Pediatrics (2003;111:87-90). On page 88, right column (fourth paragraph of the "Response to IVIG" section), the second sentence currently reads: "Response to IVIG was a sensitive predictor of response to splenectomy in 91% of patients, with a specificity of 66%, a positive predictive value of 87%, and a negative predictive value of 75%." It should read: "Response to IVIG was a sensitive predictor of response to splenectomy in 88% of patients, with a specificity of 75%, a positive predictive value of 91%, and a negative predictive value of 67%."

Two errors occurred in the article by the National Vaccine Advisory Committee, titled "Standards for Child and Adolescent Immunization Practices," that was published in the October 2003 issue of *Pediatrics* (2003;112:958–963). On page 958, left column (first footnote), the National Vaccine Advisory Committee is based in Washington, DC. On page 963, left column (second paragraph of the "National Vaccine Advisory Committee (NVAC)" section), the correct affiliation for Peter R. Paradiso, PhD, is Wyeth Vaccines.

Decimal errors occurred in the article by Verstraeten et al, titled "Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases," that was published in the November 2003 issue of Pediatrics (2003;112:1039-1048). On page 1039, right column (first paragraph), the fifth sentence currently reads: "... may have exceeded the 1995 EPA guidelines for exposure to organic Hg (1  $\mu$ g/kg/d vs 3  $\mu$ g/kg/d)..." It should read: "... may have exceeded the 1995 EPA guidelines for exposure to organic Hg  $(0.1 \,\mu g/kg/d \, vs \, 0.3 \,\mu g/kg/d)...$ "

Also in this article, as indicated, Thomas Verstraeten, MD, was an employee of the Centers for Disease Control and Prevention when he worked on the study. He is currently employed by GlaxoSmithKline.

# Recommendations from the National Vaccine Advisory Committee: Standards for Adult Immunization Practice

NATIONAL VACCINE ADVISORY COMMITTEE The Advisory Committee on Immunization Practices (ACIP) makes recommendations for routine vaccination of adults in the United States. Standards for implementing the ACIP recommendations for adults were published by the National Vaccine Advisory Committee (NVAC) in 2003<sup>2</sup> and by the Infectious Diseases Society of America in 2009.3 In addition, NVAC published a report in 2012 outlining a pathway for improving adult immunization rates. 4 While most of these documents included guidelines for immunization practice, recent changes in the practice climate for adult immunization necessitated an update of existing adult immunization standards. Some of these changes include expansion of vaccination services offered by pharmacists and other community immunization providers both during and since the 2009 H1N1 influenza pandemic; vaccination at the workplace; increased vaccination by providers who care for pregnant women; and changes in the health-care system, including the Affordable Care Act (ACA), which requires first-dollar coverage of ACIP-recommended vaccines for people with certain private insurance plans, or those who are beneficiaries of expanded Medicaid plans.<sup>5</sup> The ACA first-dollar provision is expected to increase the number of adults who will be insured for vaccines. Other changes include expanding the inclusion of adults in state immunization information systems (IISs) (i.e., registries) and the Centers for Medicare & Medicaid Services Meaningful Use Stage 2 requirements, which mandate provider reporting of immunizations to registries, including reporting of adult vaccination in states where such reporting is allowed.<sup>6</sup> For the purposes of this report, provider refers to any individual who provides health-care services to adult patients, including physicians, physician assistants, nurse practitioners, nurses, pharmacists, and other health-care professionals.

While previous versions of the adult immunization standards have been published, recommendations for adult vaccination are published annually, and many health-care organizations have endorsed routine assessment and vaccination of adults, vaccination among adults continues to be low.<sup>7–15</sup> Several barriers to adult vaccination include:

- Lack of health-care provider and patient knowledge about the need for vaccinating both healthy and high-risk adults.
- Medical management of acute and chronic illnesses, which usually receives priority over preventive services.
- Some providers not offering vaccines or offering only a subset of vaccines recommended for adults, and many adult patients unaware of their recommended vaccines.

- Private and public payer payment for vaccines complicated for providers, and not all those who vaccinate adults are recognized as providers by third-party payers.
- Medicare setting limits on coverage for vaccines based on the type of plan. For example:
  - o Fully reimbursed vaccines through Medicare Part B are limited to vaccines against influenza, pneumococcal, tetanus-diphtheria (Td) (as part of wound management but not routine booster doses), and hepatitis B (for certain intermediate and high-risk groups such as patients with end-stage renal failure or diabetes).<sup>16</sup>
  - Medicare Part D provides limited coverage for the remainder of vaccines recommended for adults, often requiring significant out-ofpocket costs to patients (e.g., zoster vaccine; tetanus, diphtheria, and pertussis vaccine; and routine booster doses of Td vaccines).<sup>16</sup>
  - Vaccines included in Medicare Part D plans are pharmacy or drug benefits rather than medical benefits. Because most medical providers are not enrolled as pharmacy providers, receiving reimbursement for these vaccines is a challenge. Many providers, both medical and nonmedical, experience complexities in dealing with billing processes and the level of payment for Part D claims. Pharmacist vaccinators are established providers for Part D vaccines but are still challenged by coverage variability in insurance plans.
- Medicaid vaccination coverage and authorized vaccines vary by state, with some states covering only a subset of vaccines recommended for adults by ACIP. Medicaid coverage of ACIPrecommended vaccines is further complicated by the Supreme Court decision allowing states to opt out of increased Medicaid coverage.<sup>17</sup>
- Out-of-pocket costs to patients are a known barrier. For example:
  - While the ACA removed out-of-pocket costs for many privately insured people, not all providers and patients are likely to be aware of this provision.
  - Some providers may not be eligible for reimbursement under some health insurance plans because they are not authorized as in-network providers for vaccination services.
  - o Many adults remain uninsured.

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 Patients may see many different providers, including specialists who may not be vaccine providers. The presence of multiple providers of health services may complicate coordination of care and reduce the likelihood that patients' vaccination needs are routinely assessed and needed vaccines are offered.

Despite these barriers, a number of strategies have been shown to improve receipt of adult immunizations. One of the most important predictors of vaccination receipt among adults is a health-care provider's recommendation and offer of vaccine during the same visit. The importance of a provider recommendation for vaccination has been demonstrated repeatedly. 18-22 Other approaches shown to increase vaccination coverage include patient and provider reminder/recall systems; provider assessment and feedback about vaccination

practices; use of standing orders or protocols; reducing patient out-of-pocket costs; worksite interventions with on-site, actively promoted vaccination services; and other community-based and health-care system-based interventions implemented in combination.<sup>21</sup>

The need to review and revise earlier standards is based on several factors:

- Emphasis on the role of all providers, even nonvaccinating providers, to assess immunization status and recommend needed vaccines was not included in earlier adult immunization standards documents and is generally not included in clinical training programs.
- Community vaccinators and pharmacists are increasingly recognized as integral to achieving higher adult vaccination rates.
- Reliance on electronic health records (EHRs) is increasing and there are meaningful use incentives for eligible medical providers to enter patient immunization information into IISs for Medicare and Medicaid EHR incentive payments.
- A change in communication strategies for educating and contacting patients, with the availability of the Internet and social media, is underway.
- New opportunities are afforded by the ACA to provide vaccination within the shifting landscape of vaccine financing. There is also a shift in payment models away from fee-for-service toward payment for better outcomes of care.
- Federal funds for immunization programs that had been used for underinsured children may become available for purchasing vaccines for uninsured adults as the number of children insured for vaccines increases due to implementation of the ACA.

As such, the NVAC recommends that the Assistant Secretary for Health promote the use of the 2013 updated NVAC Standards for Adult Immunization Practice by all health-care professionals and payers in the public and private sectors who provide care for adults.

#### STANDARDS FOR ADULT IMMUNIZATION PRACTICE

Every health-care provider, in all settings, has a fundamental responsibility to ensure that all patients are upto-date with respect to recommended immunizations. The purpose of the Standards for Adult Immunization Practice, which are summarized in the Figure, is to provide guidance to adult health-care providers across the spectrum of health care. This section addresses the

Figure. Summary of 2013 National Vaccine Advisory Committee's standards for adult immunization practices

Audience	Summary of standards
All providers	Incorporate immunization needs assessment into every clinical encounter.
	• Strongly recommend needed vaccine(s) and either administer vaccine(s) or refer patient to a provider who can immunize.
	Stay up-to-date on, and educate patients about, vaccine recommendations.
	• Implement systems to incorporate vaccine assessment into routine clinical care.
	• Understand how to access immunization information systems (i.e., immunization registries).
Non-immunizing providers	• Routinely assess the immunization status of patients, recommend needed vaccine(s), and refer patient to an immunizing provider.
	Establish referral relationships with immunizing providers.
	Follow up to confirm patient receipt of recommended vaccine(s).
Immunizing providers	Ensure professional competencies in immunizations.
3 1	<ul> <li>Assess immunization status in every patient care and counseling encounter and strongly recommend needed vaccine(s).</li> </ul>
	• Ensure that receipt of vaccination is documented in patient medical record and immunization registry.
Professional health-care-	Provide immunization education and training of members, including trainees.
related organizations/ associations/health-care	<ul> <li>Provide resources and assistance to implement protocols and other systems to incorporate vaccine needs assessment and vaccination or referral into routine practice.</li> </ul>
systems	Encourage members to be up-to-date on their own immunizations.
	Assist members in staying up-to-date on immunization information and recommendations.
	Partner with other immunization stakeholders to educate the public.
	Seek out collaboration opportunities with other immunization stakeholders.
	Collect and share best practices for immunization.
	Advocate policies that support adult immunization standards.
	• Insurers/payers/entities that cover adult immunization services should assure their network is adequate to provide timely immunization access and augment with additional vaccine providers if necessary.
Public health departments	Determine community needs, vaccination capacity, and barriers to adult immunization.
'	<ul> <li>Provide access to all ACIP-recommended vaccinations for insured and uninsured adults and work toward becoming an in-network provider for immunization services for insured adults.</li> </ul>
	<ul> <li>Partner with immunization stakeholders and support activities and policies to improve awareness of adult vaccine recommendations, increase vaccination rates, and reduce barriers.</li> </ul>
	Ensure professional competencies in immunizations.
	Collect, analyze, and disseminate immunization data.
	<ul> <li>Provide outreach and education to providers and the public.</li> </ul>
	<ul> <li>Work to decrease disparities in immunization coverage and access.</li> </ul>
	• Increase immunization registry access and use by vaccine providers for adult patients.
	<ul> <li>Develop capacity to bill for immunization of injured people.</li> </ul>
	• Ensure preparedness for identifying and responding to outbreaks of vaccine-preventable diseases.
	<ul> <li>Promote adherence to applicable laws, regulations, and standards among adult immunization stakeholders.</li> </ul>

ACIP = Advisory Committee on Immunization Practices

roles of all providers with regard to immunizations, including the role of all providers to conduct routine assessment of vaccination needs for their patients, recommend needed vaccines, and either administer

needed vaccines or, for providers who currently do not stock all recommended vaccines, refer patients to places where they can get recommended vaccines.

#### 1. Standards for all providers, including those who do and do not provide immunization services

Part of routine clinical care for all providers should include an assessment of their patients' immunization status and a recommendation to the patient and/or the patient's caregiver for needed vaccines. Assessment and recommendation can be accomplished through the following practices:

- a. Emphasize the importance of immunizations during patient encounters, incorporate patient assessment of vaccine needs into routine clinical practice, and document vaccination status in patient medical records. IISs and EHRs should be referenced as sources of data about a patient's vaccine history.
- b. Strongly recommend all immunizations that patients need.
- c. Provide all recommended vaccines to patients who need them at the time of the visit. If the vaccines are not given or, if the provider does not have the vaccines in stock, refer the patient to a vaccine provider known to be able to provide the recommended vaccinations. Because vaccine uptake is much higher among patients when the vaccine is recommended and offered at the same visit, providers who are able to stock vaccines for their patients are strongly encouraged to do so.<sup>18</sup>
- d. Ensure that they, and their practice staff, are up-to-date on their own vaccinations per ACIP health-care personnel vaccine recommendations<sup>23</sup> and consistent with professional guidelines. Examples of current professional association guidelines include the following:
  - i. The American Nurses Association (ANA) has a longstanding policy supporting immunizations for nurses and all people across the life span. ANA believes that nurses have a professional and ethical obligation to be immunized because it protects both the health of the nurse and the health of his/ her patients and community.8
  - ii. The National Association of County and City Health Officials (NACCHO) urges health-care employers and local health departments to require influenza vaccination for all staff members as a condition of employment.9
  - iii. The American Pharmacists Association recommends that its members be up-to-date on immunizations as a professional standard.<sup>10</sup>

- The American Medical Association's policy supports the vaccination of health-care professionals against communicable diseases to prevent transmission to their patients.<sup>11</sup>
- The Infectious Diseases Society of America recommends that all health-care workers be fully immunized according to ACIP recommendations.<sup>12</sup>
- The American Academy of Physicians Assistants recommends that physician assistants (PAs) should be immunized against vaccine-preventable diseases for which health providers are at high risk. Doing so not only protects PAs, but also protects patients by preventing provider-to-patient transmission.<sup>13</sup>
- vii. The American College of Physicians recommends that all health-care providers be immunized against influenza; diphtheria; hepatitis B; measles, mumps, and rubella; pertussis (whooping cough); and varicella (chickenpox) according to ACIP recommendations.14
- The American College of Obstetricians and Gynecologists (ACOG) recommends that College Fellows have an ethical obligation to follow recommendations for vaccination themselves and other safety policies put into place by their local or national public health authorities, such as the Centers for Disease Control and Prevention (CDC) and ACOG.15

#### e. Implement systems to:

- i. Incorporate vaccination assessment into routine care for outpatients.
- ii. Identify patients for needed vaccines based on age, risk factor indications for vaccination, and prior vaccination history.
- iii. Incorporate vaccination assessment and appropriate vaccination of hospitalized patients and those in long-term care facilities with recommended vaccines, especially influenza and pneumococcal vaccines.
- Ensure follow-up for needed vaccinations after hospital discharge.
- f. Educate patients about vaccines they need using understandable language, including the vaccine information statements for those vaccines covered by the Vaccine Injury Compensation Program.

g. For providers in states that include adult immunization records in their state IIS or registry, understand how to access the IIS as a source to check for vaccines that a patient has already received or should have received. Checking the IIS at each patient encounter reduces the likelihood of unnecessary vaccinations and provides information about receipt of other vaccines and whether the patient has appropriately completed the vaccination series as recommended.

#### 2. Standards for non-immunizing providers

Because data show that (1) patients are more likely to get vaccinated when vaccines are recommended by trusted health-care professionals and (2) vaccine uptake is higher when vaccine is provided at the same time, primary care providers are strongly urged to stock and provide all recommended adult vaccines. Providers whose facilities are unable to provide certain immunizations (e.g., medical specialists' offices, which do not routinely provide vaccines for adults) still have a significant role in ensuring that their patients receive needed vaccines. Non-vaccinating providers should:

- a. Routinely assess whether their patients are upto-date on recommended vaccinations, strongly recommend said vaccines, and refer patients to vaccine providers for needed vaccines.
- b. Establish patient referral relationships with vaccine providers in their area.
  - i. Ensure that referral location does not create other barriers for the patient.
    - 1. Ensure that the vaccine provider offers the recommended vaccines, and that the provider is eligible for payment by patient's insurer to minimize out-ofpocket costs for the patient and any delay in vaccination.
    - 2. Provide information to the patient during the visit about which vaccines are needed, including a prescription when necessary and the contact information for the vaccination referral location.
  - ii. Ensure appropriate follow-up of vaccine receipt by the patient at the patient's next visit, and encourage the vaccine provider to document vaccination (e.g., in the IIS and/or the patient's medical record) and with the patient's primary care provider, if known.

#### 3. Standards for immunizing providers

All providers who have a role as a primary source of health care for patients should stock all ACIP-recommended vaccines for adults. Standards for all providers who immunize adults include ensuring professional competencies in knowledge of vaccine recommendations, vaccine needs assessment, vaccine administration, vaccine storage and handling, documentation of vaccination, and communicating information about vaccination to the patient's medical home.

- a. Observe professional competencies regarding immunizations by ensuring that vaccine providers:
  - i. Are up-to-date on current ACIP vaccine recommendations, appropriate vaccine administration techniques, and vaccine storage and handling guidelines.
  - ii. Have up-to-date, culturally competent materials for patient counseling about the benefits and risks of vaccinations.
  - iii. Are knowledgeable regarding valid contraindications, adverse events, and reporting of adverse events.
  - iv. Use correct vaccine administration techniques.
  - v. Are knowledgeable about which vaccines may be administered at the same visit to reduce missed opportunities for vaccination.
  - vi. Have systems in place and training for appropriate response to adverse event(s) that may occur after vaccination, including severe allergic reactions.
  - vii. Have staff who are educated in appropriate vaccine storage and handling systems and vaccine monitoring in their practice.
- b. Assess and strongly recommend vaccinations during every patient care and counseling encounter.
  - i. Written vaccination assessment protocols are available and implemented after appropriate staff training.
  - ii. Protocols or standing orders are used (when appropriate for the setting and patient type) to administer routinely recommended vaccines, and protocols are kept up-to-date.
  - iii. Staff competencies in vaccine needs assessment, counseling, and vaccine administration as part of standing orders or protocols are periodically assessed.
  - iv. Reminder recall systems are in place to remind providers and patients about

needed vaccines and to ensure that vaccine series are completed to optimize vaccination benefits.

- c. Ensure receipt of vaccination is documented.
  - i. Record receipt of vaccination in the patient's EHR.
  - ii. Provide a record of vaccines administered to patients, either written or electronic.
  - iii. Use the IIS to record administered vaccines in states that allow adult vaccination information to be entered into the registry.
  - iv. If the vaccinator is not the patient's primary care provider, then communicate vaccine receipt with the patient's primary care provider, if known.

#### 4. Standards for professional health-care-related organizations, associations, and health-care systems Standards with respect to immunizations include:

- a. Integrate educational information on immunizations into professional training, including training of students in undergraduate and postgraduate training programs. This training includes support for incorporating modules on immunization into medical, nursing, and pharmacy schools, as well as allied health profession curricula.
- b. Provide resources and assistance for providers to implement protocols or standing orders, where feasible, and other systems changes to improve routine assessment of vaccine needs and vaccination.
- c. Encourage their members, trainees, and students to ensure that their own vaccinations are up-todate as a standard of the profession.
- d. Assist their members, employees, trainees, and students in remaining current regarding ACIP immunization recommendations by providing updates through routine communications and continuing education.
- e. Make educational materials for patients regarding vaccine recommendations available to their memberships.
- f. Partner with community organizations, such as immunization coalitions or vaccine advocacy groups, to improve public awareness of adult immunizations.
- g. Participate in collaboration opportunities with other members of the immunization community (including public health, public and private medical, nursing and pharmacy services provid-

- ers, patient advocacy, health systems, and other entities).
- h. Offer modules to help providers assess and improve adult vaccination coverage of their patients as a measure of quality improvement within clinical practices.
- i. Provide resources to assist providers in implementing and operationalizing immunization services within their practices, including helping providers understand the payment for vaccines based on insurance type and benefit design (e.g., private insurance, Medicare Part B, or Medicare Part D).
- j. Provide resources (i.e., forms and other tools) for collecting and sharing best practices among adult immunization stakeholders.
- k. Advocate public policies that support these adult immunization standards.
- 1. Insurers/payers/entities that cover adult immunization services should ensure that their networks are adequate to provide timely immunization access and augment with additional vaccine providers, if necessary (e.g., public health departments, pharmacists, and worksites).

#### 5. Standards for public health departments

Public health departments may provide vaccination services and, in that role, public health professionals should adhere to the standards of their profession. Additionally, the professional associations that represent public health professionals and public health departments (e.g., Association of State and Territorial Health Officials, NACCHO, Association of Immunization Managers, and the Council of State and Territorial Epidemiologists) should promote adherence to the standards of the public health profession, particularly as they relate to adult immunizations. Public health has additional roles in assessing immunization program needs and the impact of vaccination programs, including educating the public and providers about immunizations. These additional roles include the following:

- a. Determine community needs and capacity for adult immunization administration and barriers for patient access.
  - i. Work toward decreasing disparities in immunization access based on factors such as race/ethnicity, insurance status, poverty, and location (e.g., rural areas or medically underserved areas).
- b. Develop policies and/or regulations (legislation) that promote high vaccination rates and reduce

- immunization barriers for adult patients and their providers.
- c. Immunization programs should collaborate with existing public health programs that provide clinical services, such as sexually transmitted disease control programs, substance abuse treatment services, and tuberculosis control programs to incorporate vaccine administration and recordkeeping.
- d. Ensure professional competency by providing or supporting education to adult health-care providers on routine adult immunizations.
- e. Maintain surveillance for vaccine-preventable diseases to recognize potential disease outbreaks or problems with vaccines and to assist in the control of vaccine-preventable diseases in the event of outbreaks.
- f. Collect, analyze, and disseminate available data on vaccine coverage to the public and health-care providers in their jurisdiction to identify and address gaps in coverage.
- g. Provide resources and assistance for vaccine providers to implement protocols or standing orders, where feasible, and other systems changes to improve routine assessment of vaccine needs and vaccination.
- h. Provide best practice examples to health-care providers and collaborate with providers in implementing these best practices.
- i. Provide subject-matter expertise to train and educate vaccine providers and their staff on vaccine recommendations, proper storage and handling, and proper vaccine administration.
- Collaborate with providers to assist in implementing and operationalizing immunization services within their practices.
- k. Partner with professional medical, pharmacy, nursing, and other provider organizations; healthcare networks; community organizations; and advocacy groups (e.g., mental health services, diabetes educators, asthma educators, correctional facilities, and substance abuse providers) to:
  - Increase awareness and knowledge of adult immunizations and methods to reach recommended target populations for immunization; and
  - Educate their members and trainees regarding immunizations.
- l. Provide outreach and education to the public and providers about vaccines.

- i. Collaborate with professional medical, pharmacy, nursing, and other provider organizations; health-care networks; community organizations; business and civic groups; and advocacy groups (e.g., mental health services, diabetes educators, asthma educators, correctional facilities, and substance abuse providers) to:
  - Increase public awareness and knowledge of adult immunizations and reach recommended target populations for immunization.
  - 2. Provide culturally competent public education through appropriate venues, including the use of social media and ethnic media.
- m. Work toward including adults in all state IISs, reduce barriers to including adult vaccination records in IISs, and ensure that IISs meet new standards of EHR interoperability to track and maintain adult vaccination records.
- n. Expand access to and provide training for IISs to all adult health-care providers.
- o. Provide access to all ACIP-recommended vaccinations.
  - i. Ensure capacity to provide all ACIP-recommended vaccines and immunization services for insured and uninsured adults.
  - Work toward becoming an in-network provider for immunization services for insured adults.
- p. Ensure preparedness for, and investigate and work to control, outbreaks of vaccine-preventable diseases when they occur. Managing these outbreaks should include activities such as creating, maintaining, and practicing emergency preparedness plans for vaccine responses to outbreaks such as pandemic influenza.
- q. Demonstrate accountability and good stewardship of public financing for vaccines.
- r. Communicate information about vaccine shortages, when they occur, to providers and the public.
- s. Communicate information on vaccine recalls and vaccine safety issues to providers and the public.
- t. Promote adherence to applicable laws, regulations, and standards among adult immunization stakeholders.

#### CONCLUSION

The environment surrounding adult immunizations has changed dramatically since the last Standards for Adult Immunization Practices were issued by NVAC in 2003.<sup>2</sup> These updated and revised Standards for Adult Immunization Practice represent a continued effort by NVAC to advance action to improve adult immunization coverage rates in the U.S. aligned with its 2011 report, "A Pathway to Leadership for Adult Immunization: Recommendations of the National Vaccine Advisory Committee." With these Standards, NVAC provides a concise description of desirable immunization practices that will improve the provision of adult immunizations in the U.S. As an evolution of the work from the National Adult and Influenza Immunization Summit established by CDC, the Immunization Action Coalition, and the National Vaccine Program Office, these revised standards have been widely reviewed by major professional organizations and other partners in adult immunization. NVAC recommends that the Assistant Secretary for Health promote the use of these updated Standards for Adult Immunization Practices by all health-care professionals and health-care systems in the public and private sectors who provide and pay for care for adults. NVAC firmly advocates that all providers follow these Standards and believes that these Standards will be useful to inform immunization practice and immunization policy development.

The National Vaccine Advisory Committee (NVAC) voted in favor of this report at the September 10, 2013, NVAC meeting. Initial drafts of this document were developed by a National Adult and Influenza Immunization Summit writing committee including Anu Bhatt, Carolyn Bridges, Karen Donoghue, Columba Fernandez, Rebecca Gehring, Laura Lee Hall, Donna Lazorik, Marie-Michele Leger, Trini Mathew, Debbye Rosen, Mitch Rothholz, Litjen Tan, and LaDora Woods.

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## **Skills Checklist** for Vaccine **Administration**

During the COVID-19 pandemic, the CDC recommends additional infection control measures for vaccination (see www.cdc.gov/vaccines/pandemicguidance/index.html).

The Skills Checklist is a self-assessment tool for healthcare staff who administer immunizations. To complete it, review the competency areas below and the clinical skills, techniques and procedures outlined for each area. Score yourself in the Self-Assessment column. If you check **Needs to Improve**, you indicate further study, practice, or change is needed. When you check Meets or Exceeds, you indicate you believe you are performing at the expected level of competence, or higher.

Supervisors: Use the Skills Checklist to clarify responsibilities and expectations for staff who administer vaccines. When you use it to assist with performance reviews, give staff the opportunity to score themselves in advance. Next, observe their performance as they

administer vaccines to several patients, and score in the Supervisor Review columns. If improvement is needed, meet with them to develop a Plan of Action (see bottom of page 3) to help them achieve the level of competence you expect; circle desired actions or write in others.

The video "Immunization Techniques: Best Practices with Infants, Children, and Adults" helps ensure that staff administer vaccines correctly. (View at www.youtube.com/watch?v=WsZ6NEijlfl or order online at www.immunize.org/dvd.) Another helpful resource is CDC's Vaccine Administration eLearn course, available at www.cdc. gov/vaccines/hcp/admin/resource-library.html.

•••••••••••••••••••••••••••••••••••••••			Self-Assessment		Supervisor Review		
COMPETENCY	CLINICAL SKILLS, TECHNIQUES, AND PROCEDURES	NEEDS TO IMPROVE	MEETS OR EXCEEDS	NEEDS TO IMPROVE	MEETS OR EXCEEDS	PLAN OF ACTION	
A	Welcomes patient/family and establishes rapport.						
Patient/Parent Education	Explains what vaccines will be given and which type(s) of injection(s) will be done.						
Laucanon	3. Answers questions and accommodates language or literacy barriers and special needs of patient/parents to help make them feel comfortable and informed about the procedure.						
	Verifies patient/parents received Vaccine Information Statements (VISs) for indicated vaccines and has had time to read them and ask questions.						
	5. Screens for contraindications (if within employee's scope of work).						
	Reviews comfort measures and aftercare instructions with patient/parents, and invites questions.						
B Medical and	Identifies the location of the medical protocols (e.g., immunization protocol, emergency protocol, reporting adverse events to the Vaccine Adverse Event Reporting system [VAERS], reference material).						
Office Protocols	Identifies the location of epinephrine, its administration technique, and clinical situations where its use would be indicated.						
	3. Maintains up-to-date CPR certification.						
	Understands the need to report any needlestick injury and to maintain a sharps injury log.						
	5. Demonstrates knowledge of proper vaccine handling (e.g., maintains and monitors vaccine at recommended temperature and protects from light).						

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Adapted from California Department of Public Health, Immunization Branch

	Self-Assessment			or Review		
COMPETENCY	CLINICAL SKILLS, TECHNIQUES, AND PROCEDURES		MEETS OR EXCEEDS	NEEDS TO IMPROVE	MEETS OR EXCEEDS	PLAN OF ACTION
G	Performs proper hand hygiene prior to preparing vaccine.					
Vaccine Preparation	When removing vaccine from the refrigerator or freezer, looks at the storage unit's temperature to make sure it is in proper range.					
reparation	Checks vial expiration date. Double-checks vial label and contents prior to drawing up.					
	4. Prepares and draws up vaccines in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed.					
	<ol><li>Selects the correct needle size for IM and Subcut based on patient age and/or weight, site, and recommended injection technique.</li></ol>					
	Maintains aseptic technique throughout, including cleaning the rubber septum (stopper) of the vial with alcohol prior to piercing it.					
	7. Prepares vaccine according to manufacturer instructions. Inverts vial and draws up correct dose of vaccine. Rechecks vial label.					
	8. Prepares a new sterile syringe and sterile needle for each injection. Checks the expiration date on the equipment (syringes and needles) if present.					
	9. Labels each filled syringe or uses labeled tray to keep them identified.					
D	Verifies identity of patient. Rechecks the provider's order or instructions against the vial and the prepared syringes.					
Administering Immunizations	2. Utilizes proper hand hygiene with every patient and, if it is office policy, puts on disposable gloves. (If using gloves, changes gloves for every patient.)					
	3. Demonstrates knowledge of the appropriate route for each vaccine.					
	4. Positions patient and/or restrains the child with parent's help.					
	5. Correctly identifies the injection site (e.g., deltoid, vastus lateralis, fatty tissue over triceps).					
	6. Locates anatomic landmarks specific for IM or Subcut injections.					
	7. Preps the site with an alcohol wipe, using a circular motion from the center to a 2" to 3" circle. Allows alcohol to dry.					

CONTINUED ON THE NEXT PAGE

		Self-Ass	essment		Superviso	or Review
COMPETENCY	CLINICAL SKILLS, TECHNIQUES, AND PROCEDURES	NEEDS TO	MEETS OR EXCEEDS	NEEDS TO IMPROVE	MEETS OR EXCEEDS	PLAN OF ACTION
Administering	8. Controls the limb with the non-dominant hand; holds the needle an inch from the skin and inserts it quickly at the appropriate angle (90° for IM or 45° for Subcut).					
Immunizations	9. Injects vaccine using steady pressure; withdraws needle at angle of insertion.					
(continued)	10. Applies gentle pressure to injection site for several seconds (using, e.g., gauze pad, bandaid).					
	11. Uses strategies to reduce anxiety and pain associated with injections.					
	12. Properly disposes of needle and syringe in "sharps" container.					
	13. Properly disposes of vaccine vials.					
E	Fully documents each vaccination in patient chart: date, lot number, manufacturer, site, VIS date, name/initials.					
Records Procedures	If applicable, demonstrates ability to use state/local immunization registry or computer to call up patient record, assess what is due today, and update computerized immunization history.					
	Asks for and updates patient's vaccination record and reminds them to bring it to each visit.					

#### Plan of Action

Circle desired next steps and write in the agreed deadline for completion, as well as date for the follow-up performance review.

- a. Watch video on immunization techniques and review CDC's Vaccine Administration eLearn, available at www.cdc.gov/vaccines/hcp/admin/ resource-library.html.
- b. Review office protocols.
- c. Review manuals, textbooks, wall charts, or other guides (e.g., Key Vaccination Resources for Healthcare Professionals at www.immunize.org/catg.d/p2005.pdf)
- d. Review package inserts.
- e. Review vaccine storage and handling guidelines or video.
- f. Observe other staff with patients.

- g. Practice injections.
- h. Read Vaccine Information Statements.
- i. Be mentored by someone who has demonstrated appropriate immunization skills.
- j. Role play (with other staff) interactions with parents and patients, including age appropriate comfort measures.
- k. Attend a skills training or other appropriate courses/training.
- I. Attend healthcare customer satisfaction or cultural competency training.

m	Renew	CPR	certification.
111.	Renew	$\Gamma$	certification.

_			
Other			
			_

File the Skills Checklist in the employee's personnel folder.

PLAN OF ACT	ION DEADLINE	
DATE OF NEX	T PERFORMANCE REVIEW	•

EMPLOYEE SIGNATURE	DATE
SUPERVISOR SIGNATURE	DATE

Effective: November 18, 2021
The purpose of this document is to distinguish which cohorts of persons, present in North Carolina, are eligible for vaccine from the North Carolina Immunization Program (NCIP). NCIP vaccine is available for eligible children through the age of 18 in compliance with recommendations made by the Advisory Committee on Immunization Practices (ACIP) and the Vaccines for Children (VFC) program. Exceptions for adult vac cine usages are noted below. Additional exceptions for outbreak control purposes (if applicable) can be found in the NCIP Coverage Criteria Supplement. ACIP recommends certain vaccines for certain cohorts who are not covered by NCIP vaccine. Health care providers must use privately purchased vaccine for those cohorts who wish to have vaccine and are not covered by this coverage criteria. Questions about current recommendations for each vaccine can be found at: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html. Local Health Departments (LHD); Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) are noted throughout when there is vaccine usage specific to their facilities.

VACCINE	AGES COVERED	ELIGIBILITY	CRITERIA FOR NCIP VACCINE USAGE
DT Pediatric	≥2 months through 6 years	UNIVERSAL	DT Pediatric can be ordered for any child, >2 months through 6 years, that has a known medical contraindication to any pertussis containing vaccine.
DTaP	≥2 months through 6 years	VFC ONLY	
DTaP, Hep B, and polio combination (Pediarix®)	$\geq$ 2 months through 6 years	VFC ONLY	
DTaP, polio, and Hib combination (Pentacel®)	≥ 2 months through 4 years	VFC ONLY	
DTaP, polio, Hib, and Hep B combination (Vaxelis <sup>TM</sup> )	≥ 6 weeks through 4 years	VFC ONLY	
DTaP/IPV combination (Kinrix®; Quadracel®)	≥ 4 years through 6 years	VFC ONLY	Only to be used for children > 4 years through 6 years of age.  Kinrix as the 5th dose in the DTaP series, & as the 4th in the IPV series  Quadracel as the 5th dose in the DTaP series, & as the 4th or 5th dose in the IPV series.
Hepatitis A Pediatric use	12 months through 18 years	VFC ONLY	Hepatitis A vaccine may be given to children 12 months through 18 years of age who are VFC-eligible only.  Hepatitis A vaccine may be given to VFC -eligible infants 6 months through 11 months of age who are traveling to an area of the world except the United States, Canada, western Europe and Scandinavia, Japan, New Zealand, and Australia.
Hepatitis B Pediatric use	Birth through 18 years	VFC ONLY	The birth dose of Hepatitis B vaccine is available universally for newborns at VFC enrolled birthing hospitals.
			Other doses of hepatitis $B^*$ vaccine may be given to children through 18 years of age who are VFC-eligible only.
			LHD Only:  ♦ Children through 18 years of age, regardless of insurance status who are household, sexual, or needle sharing contacts of an acute or chronic Hepatitis B infected person may receive Hepatitis B vaccine at the LHD. All household, sexual, or needle sharing contacts of an acute or chronic Hepatitis B infected person must be referred to the LHD for testing and vaccination.  *Heplisav-B® (two-dose series can be used for eligible individuals 18 years of age and older).
Hepatitis B Pediatric Product	Certain adults 19 years of age	UNINSURED 19 YEARS OF AGE	Any uninsured adult 19 years of age may receive state-supplied Hep B if the first dose of Hep B is administered before the 19th birthday. The series must be complete before the 20th birthday if using state- supplied vaccine.
(Engerix-B®) (Recombivax®)			LHD Only:  Uninsured immigrants with refugee status who are from endemic countries who are 19 years of age may receive Hepatitis B vaccine at the LHD. All immigrants with refugee status must be referred to the LHD for testing and vaccination.
(Heplisav- B®)			Adults 19 years of age, regardless of insurance status, who are household, sexual or needle sharing contacts of an acute or chronic Hepatitis B infected person may receive Hepatitis B vaccine at the LHD. All household, sexual, or needle sharing contacts of an acute or chronic Hepatitis B infected person must be referred to the LHD for testing/vaccination.

Effective: November 18, 2021

VACCINE	AGES COVERED	ELIGIBILITY	CRITERIA FOR NCIP VACCINE USAGE
Hepatitis B Adult use	Certain adults ≥ 20 years may receive state- supplied Hep B	ADULT USE	<ul> <li>LHD Only:</li> <li>Individuals who are ≥20 years of age, regardless of insurance status, who are household, sexual or needle sharing contacts of an acute or chronic Hepatitis B infected person may receive Hepatitis B* vaccine at the LHD. All household, sexual, or needle sharing contacts of an acute or chronic Hepatitis B infected person must be referred to the LHD for testing and vaccination.</li> <li>Uninsured immigrants with refugee status who are from endemic countries who are ≥ 20 years of age may receive Hepatitis B vaccine at the LHD. All immigrants with refugee status must be referred to the LHD for testing and vaccination.</li> <li>*Heplisav-B® (two-dose series can be used)</li> </ul>
HepA/HepB Combination (Twinrix®)	≥ 18 years	UNINSURED ADULT USE	LHD/FQHC/RHC Only:  Any uninsured adult who meets one or more of the ACIP recommended coverage groups can receive a three-dose series of the combination Hep A/Hep B vaccine at the LHD, FQHC, or RHC.  State-supplied Hep A/Hep B vaccine cannot be used for the accelerated schedule, four dose series or for persons with a documented history of a completed hepatitis A or B series.
Hib	≥ 2 months through 4 years	VFC ONLY	Certain high-risk children >59 months through 18 years of age, who are not appropriately vaccinated, may receive one dose.
9vHPV (Gardasil® 9)	Females and males 9 through 18 years	VFC ONLY	State-supplied Gardasil® (9-valent) vaccines for HPV are available for males and females 9 through 18 years of age. The series must be completed prior to the 19th birthday.
Influenza Pediatric use	≥ 6 months through 18 years	VFC ONLY	
Influenza Adult use  IIV4 (Fluarix®, Fluzone®, FluLaval®, & Flucelvax® 0.5 mL pre- filled syringes only)	Certain adults, (19 and older) without insurance	UNINSURED ADULT USE	LHD/FOHC/RHC Only:  Non-Medicaid, uninsured women who are pregnant during flu season, and receiving services at the LHD, FQHC, or RHC.  Persons enrolled in the Be Smart family planning program**** receiving services at the LHD, FQHC, or RHC.  *Please refer to the seasonal influenza memo.
Meningococcal Conjugate (Menactra®)  (Menveo®) (MenQuadfi <sup>TM</sup> )	≥ 2 months through 10 years	VFC ONLY	Available for children with high-risk conditions.  Menactra® is licensed starting at 9 months of age. Menveo® starts at 2 months of age. MenQuadfi <sup>TM</sup> starts at 2 years of age.
Meningococcal Conjugate (Menactra®) (Menveo®) (MenQuadfi <sup>TM</sup> )	11 through 18 years	VFC ONLY	
Meningococcal Serogroup B	10 through 18 years	VFC ONLY	MenB vaccines are recommended & available for children ≥10 through 18 years of age at increased risk of disease.
Bexsero® Trumenba®			MenB may be administered to adolescents aged 16–18 years of age who are not at increased risk for meningococcal disease based on the provider's clinical discretion. Follow ACIP guidance.

Effective: November 18, 2021

VACCINE	AGES COVERED	ELIGIBILITY	CRITERIA FOR NCIP VACCINE USAGE	
MMR Pediatric use	≥ 12 months through 18 years	VFC ONLY	MMR vaccine may be given to children 12 months through 18 years of age who are VFC- eligible only.  MMR vaccine may be given to VFC-eligible infants 6 months through 11 months of age who will be traveling internationally.	
MMR Adult use	Certain adults (19 and older) without insurance	UNINSURED ADULT USE	One dose of MMR vaccine is available for:  LHD only:  Uninsured immigrants with refugee status of any age without documentation of a prior MMR may receive MMR at the LHD.  LHD/FOHC/RHC only:  All uninsured susceptible persons without documentation of a prior MMR may receive MMR at the LHD, FQHC, or RHC.  Two doses of MMR vaccine are available for:  Any uninsured person entering a four-year college or university in North Carolina for the first time, in addition to, any uninsured adults attending any other post-high school educational institutions, i.e. community colleges and technical schools because:  Two doses of measles containing vaccine is required by law for all persons born in 1957 or later entering a North Carolina college/university*** for the first time on or after July 1, 1994.  Two doses of mumps are also recommended and available for all uninsured adult students attending post-high school educational institutions (i.e. community colleges and technical schools).  LHD only:  All uninsured women ages 19-44 years.	
MMRV	≥ 12 months through 12 years	VFC ONLY		
IPV-Polio	≥ 2 months through 17 years	VFC ONLY		
Pneumococcal Conjugate 13- valent (PCV13)	≥ 2 through 59 months	VFC ONLY		
Pneumococcal Conjugate 13- valent (PCV13)	≥ 60 months through 18 years	VFC ONLY	Children >60 months through 18 years with certain high-risk conditions.	
Pneumococcal Polysaccharide 23-valent (PPSV23)	≥ 2 years through 18 years	VFC ONLY	Children > 2 years through 18 years with certain high-risk conditions.	
Rotavirus	≥ 6 weeks through 7 months	VFC ONLY		
Td or Tdap Pediatric use	≥ 7 years through 18 years	VFC ONLY	When considering the use of Td and Tdap interchangeably, ensure state immunization requirements for school/college entry immunization have been met with the appropriate vaccine.	

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VACCINE	AGES COVERED	ELIGIBILITY	CRITERIA FOR NCIP VACCINE USAGE
Td or Tdap Adult use	Certain adults (19 and older) without insurance	UNINSURED ADULT USE	One or more doses of state-supplied Td/Tdap can be given to any uninsured adult 19 years of age or older as indicated by ACIP at the local health department or an VFC enrolled FQHC, or RHC.  Additionally, one or more doses as indicated by ACIP of state supplied Tdap are available for uninsured pregnant women 19 years of age and older being served in any capacity at the LHD, or an enrolled FQHC, or RHC.
Varicella (Chickenpox)	≥ 12 months through 18 years	VFC ONLY	
Varicella (Chickenpox)	Certain adults, (19 and older) without insurance	UNINSURED FEMALE ADULT USE	LHD Only:  One dose of varicella vaccine is available for uninsured, unvaccinated women ages 19 through 44 years of age at the LHD.

VFC- Vaccines for Children: Children birth through 18 years of age that meet at least one of the following criteria are eligible for VFC vaccine:

- Medicaid enrolled a child who is eligible or enrolled in the Medicaid program.
- Uninsured a child who has no medical insurance coverage
- American Indian or Alaskan Native
- Underinsured (Can only be served by deputized providers such as LHD/FQHC/RHC). Underinsured includes:
  - Children who have commercial (private) health insurance but the coverage does not include vaccines,
  - Children whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only),
  - Children whose insurance caps vaccine coverage at a certain amount once that coverage amount is reached, these children
    are categorized as underinsured

Children who are covered by North Carolina Health Choice (NCHC) are considered insured, with one exception: NCHC children who are American Indian or Alaskan Native are eligible for VFC vaccines. Note: Children whose health insurance covers vaccinations are not eligible for VFC vaccines, even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met or because the insurance did not cover the total cost of the vaccine

#### Health Care Sharing Ministries (HCSM)

HCSMs are nonprofit alternatives to purchasing health insurance from private, for-profit insurers. VFC eligibility depends primarily on recognition of the plan as insurance by the state. A child with this type of plan should be considered:

- Uninsured if the plan is not recognized as insurance by the North Carolina Department of Insurance (NCDOI)
- Insured if plan is recognized by the NCDOI and covers all ACIP-recommended vaccines
- Underinsured if plan is recognized by the NCDOI and does not cover all ACIP-recommended vaccines
   Providers are responsible for verifying the insurance plan with NCDOI prior to administration of VFC vaccine

\*\*ACIP Recommendation Highlights The ACIP recommendations for each vaccine are located on the CDC website at <a href="http://www.cdc.gov/vaccines/hcp/acip-recs/index.html">http://www.cdc.gov/vaccines/hcp/acip-recs/index.html</a>. Full and final recommendations are published as MMWR Recommendations and Reports. Updates are often sent out as Provisional Recommendations with the most pertinent information included before the final recommendations are released. There is also separate documentation for Contraindication/Precautions for all vaccines on the CDC web site at: <a href="https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html">https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html</a>.

\*\*\*Students attending colleges within the North Carolina Community College System are exempt from North Carolina Immunization Law for college/university entry. However, some programs at community colleges, such as medical programs, may have requirements specific to their program, but this does not allow them to receive state supplied vaccine unless it is specifically stated in the coverage criteria.

\*\*\*\*<u>LHD/FQHC/RHC only:</u> Persons covered by the Be Smart Family Planning Program are considered uninsured and may receive certain statesupplied vaccines as noted in this coverage criteria for uninsured adults if receiving services at a Local Health Department, Federally Qualified Health Center, or Rural Health Clinic. Unaccompanied minors (through 18 years of age) without proof of insurance presenting to a local health department

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Title X clinic can also be vaccinated with VFC vaccines.

Local health departments (LHD) who are considering using VFC vaccine for offsite clinics, must contact the Immunization Branch for specific guidance prior to scheduling the clinic. Proper storage and handling is critical at all times.

Unless specifically stated above, no NCIP vaccine may be administered to an insured individual unless the patient is an underinsured child at an FQHC, RHC, LHD, or deputized provider.

VFC vaccine cannot be used for allergy skin testing prior to vaccination.

## NORTH CAROLINA IMMUNIZATION PROGRAM (NCIP) COVERAGE CRITERIA SUPPLEMENT FOR OUTBREAK RESPONSE/PREVENTION

Effective: November 19, 2021, until further notice, unless otherwise stated below

	Пуссинс	. Troventeer 12	, 2021, until further houce, unless otherwise stated below
VACCINE	AGES COVERED	ELIGIBILITY	CRITERIA FOR NCIP VACCINE USAGE
Hepatitis A Adult use	Certain adults ≥ 19 years	UNIVERSAL	LHD/FQHC/RHC/Substance Abuse Treatment Centers Only:  A single dose of Hepatitis A vaccine is available for adults 19 years of age and older, regardless of insurance status, who meet one or more of the following high-risk criteria:  Persons who use injection and/or non-injection drugs  Persons who are homeless  Men who have sex with men  Persons with chronic liver disease, including chronic hepatitis B or C  Persons who are currently incarcerated in a county-owned facility/jail
Hepatitis A Pediatric use	Certain adolescents, through 18 years	UNIVERSAL	LHD/FQHC/RHC/Substance Abuse Treatment Centers Only:  A single dose of Hepatitis A vaccine is available for adolescents 18 years of age and younger, regardless of insurance status, who meet one or more of the following high-risk criteria:  Persons who use injection and/or non-injection drugs  Persons who are homeless  Men who have sex with men  Persons with chronic liver disease, including chronic hepatitis B or C  Persons who are currently incarcerated in a county-owned facility/jail
Influenza Adult use  Pre-filled syringes only:  Fluzone® Flucelvax® Fluarix® Fluarix®	Certain adults ≥ 19 years	UNIVERSAL	LHD/Substance Abuse Treatment Centers Only:  A single dose of flu vaccine is available during the 2021-2022 flu season for adults 19 years of age and older, regardless of insurance status who are at high risk for complications of flu and who are experiencing access to care barriers. See the Supplemental Adult Flu Vaccine memo dated November 19, 2021 for more information.
IPV		AFGHAN REFUGEES	<ul> <li>♣ One dose of IPV for all persons aged &gt;6 weeks of age (including adults), ideally during the first 7 days of U.S. entry (unless medically contraindicated), and within 12 months of travel to the United States. For children, this initial dose should be followed by the standard ACIP schedule with doses at 2, 4, and 6-18 months, and 4-6 years. Adults do not need to receive another dose after the initial dose.</li> <li>♣ See CDC Special Considerations <a href="https://www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/immunizations-guidelines.html">https://www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/immunizations-guidelines.html</a></li> </ul>
MMR		AFGHAN REFUGEES	<ul> <li>Enrolled Providers Serving Evacuees from Afghanistan:</li> <li>◇ One dose of MMR vaccine for all persons aged &gt;6 months to 64 years (born in or after 1957, and unless medically contraindicated), ideally within 7 days of U.S. entry. A first MMR dose administered between 6-11 months should be followed by the standard ACIP schedule with doses at 12-15 months and 4-6 years.</li> <li>❖ See CDC Special Considerations <a href="https://www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/immunizations-guidelines.html">https://www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/immunizations-guidelines.html</a></li> </ul>

#### **Kev Points**:

- For routine vaccination, see the full *Coverage Criteria* for eligibility requirements.
- Only one dose is available as part of these statewide initiatives.
- Vaccine availability is time limited. The NCIP will update all VFC-enrolled providers when expansion campaigns end.

# Screening Checklist for Contraindications DATE OF BIRTH Month / day / year to Vaccines for Children and Teens

For parents/guardians: The following questions will help us determine which vaccines your child may be given today. If you answer "yes" to any question, it does not necessarily mean your child should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	· · · · · · · · · · · · · · · · · · ·	yes	no	know
1. Is the child	I sick today?			
2. Does the c	hild have allergies to medications, food, a vaccine component, or latex?			
3. Has the ch	ild had a serious reaction to a vaccine in the past?			
(e.g., diabe	hild have a long-term health problem with lung, heart, kidney or metabolic disease etes), asthma, a blood disorder, no spleen, complement component deficiency, implant, or a spinal fluid leak? Is he/she on long-term aspirin therapy?			
	to be vaccinated is 2 through 4 years of age, has a healthcare provider told you ild had wheezing or asthma in the past 12 months?			
<b>6.</b> If your chil	d is a baby, have you ever been told he or she has had intussusception?			
	ild, a sibling, or a parent had a seizure; has the child had brain or other stem problems?			
8. Does the c	hild have cancer, leukemia, HIV/AIDS, or any other immune system problem?			
<b>9.</b> Does the c	hild have a parent, brother, or sister with an immune system problem?			
as prednis	3 months, has the child taken medications that affect the immune system such one, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid rohn's disease, or psoriasis; or had radiation treatments?			
•	year, has the child received a transfusion of blood or blood products, or been une (gamma) globulin or an antiviral drug?			
12. Is the child next month	l/teen pregnant or is there a chance she could become pregnant during the			
<b>13.</b> Has the ch	ild received vaccinations in the past 4 weeks?			
	FORM COMPLETED BY	DATE		
	FORM REVIEWED BY	DATE		
	Did you bring your immunization record card with you? yes on o lt is important to have a personal record of your child's vaccinations. If you don't healthcare provider to give you one with all your child's vaccinations on it. Keep it is it with you every time you seek medical care for your child. Your child will need this	n a safe	place an	d bring



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## Information for Healthcare Professionals about the Screening Checklist for Contraindications to Vaccines (Children and Teens)

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the references in **Notes** below.

NOTE: For supporting documentation on the answers given below, go to the specific ACIP vaccine recommendation found at the following website: www.cdc.gov/vaccines/hcp/acip-recs/index.html

1. Is the child sick today? [all vaccines]

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (such as otitis media, upper respiratory infections, and diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Does the child have allergies to medications, food, a vaccine component, or latex? [all vaccines]

An anaphylactic reaction to latex is a contraindication to vaccines that contain latex as a component or as part of the packaging (e.g., vial stoppers, prefilled syringe plungers, prefilled syringe caps). If a person has anaphylaxis after eating gelatin, do not administer vaccines containing gelatin. A local reaction to a prior vaccine dose or vaccine component, including latex, is not a contraindication to a subsequent dose or vaccine containing that component. For information on vaccines supplied in vials or syringes containing latex, see www.cdc.gov/vaccines-pubs/pinkbook/downloads/appendices/B/latex-table.pdf; for an extensive list of vaccine components, see www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. People with egg allergy of any severity can receive any recommended influenza vaccine (i.e., any IIV, RIV, or LAIV) that is otherwise appropriate for the patient's age and health status. With the exception of ccIIV and RIV (which do not contain egg antigen), people with a history of severe allergic reaction to egg involving any symptom other than hives (e.g., angio-edema, respiratory distress), or who required epinephrine or another emergency medical intervention, the vaccine should be administered in a medical setting, such as a clinic, health department, or physician office; vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

- 3. Has the child had a serious reaction to a vaccine in the past? [all vaccines]

  History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses. History of encephalopathy within 7 days following DTP/DTaP is a contraindication for further doses of pertussis-containing vaccine. There are other adverse events that might have occurred following vaccination that constitute contraindications or precautions to future doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).
- 4. Does the child have a long-term health problem with lung, heart, kidney, or metabolic disease (e.g., diabetes), asthma, a blood disorder, no spleen, complement component deficiency, a cochlear implant, or a spinal fluid leak? Is he/she on long-term aspirin therapy? [MMR, MMRV, LAIV, VAR]

A history of thrombocytopenia or thrombocytopenic purpura is a precaution to MMR and MMRV vaccines. The safety of LAIV in children and teens with lung, heart, kidney, or metabolic disease (e.g., diabetes), or a blood disorder has not been established. These conditions, including asthma in children ages 5 years and older, should be considered precautions for the use of LAIV. Children with functional or anatomic asplenia, complement deficiency, cochlear implant, or CSF leak should not receive LAIV. Children on long-term aspirin therapy should not be given LAIV; instead, they should be given IIV. Children with CSF leak, anatomic or functional asplenia, or cochlear implant, or on long-term aspirin therapy should not be given LAIV; instead, they should be given IIV. Aspirin use is a precaution to VAR.

- 5. If the child to be vaccinated is 2 through 4 years of age, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months? [LAIV]

  Children ages 2 through 4 years who have had a wheezing episode within the past 12 months should not be given LAIV. Instead, these children should be given IIV.
- 6. If your child is a baby, have you ever been told that he or she has had intussusception? [Rotavirus]

  Infants who have a history of intussusception (i.e., the telescoping of one portion of the

intants who have a history of intussusception (i.e., the telescoping of one portion of the intestine into another) should not be given rotavirus vaccine.

7. Has the child, a sibling, or a parent had a seizure; has the child had brain or other nervous system problem? [DTaP, Td, Tdap, IIV, LAIV, MMRV]

DTaP and Tdap are contraindicated in children who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to the use of DTaP and Tdap. For children with stable neurologic disorders (including seizures) unrelated to vaccination, or for children with a family history of seizures, vaccinate as usual (exception: children with a personal or family [i.e., parent or sibling] history of seizures generally should not be vaccinated with MMRV; they should receive separate MMR and VAR vaccines). A history of Guillain-Barré syndrome (GBS) is a consideration with the following:

1) Td/Tdap: if GBS has occurred within 6 weeks of a tetanus-containing vaccine and decision is made to continue vaccination, give Tdap instead of Td if no history of prior Tdap;

NOTE: For summary information on contraindications and precautions to vaccines, go to the ACIP's General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

2) Influenza vaccine (IIV, LAIV, or RIV): if GBS has occurred within 6 weeks of a prior influenza vaccination, vaccinate with IIV if at high risk for severe influenza complications.

8. Does the child have cancer, leukemia, HIV/AIDS, or any other immune system problem? [LAIV, MMR, MMRV, RV, VAR]

Live virus vaccines (e.g., MMR, MMRV, VAR, RV, LAIV) are usually contraindicated in immuno-compromised children. However, there are exceptions. For example, MMR is recommended for asymptomatic HIV-infected children who do not have evidence of severe immuno-suppression. Likewise, VAR should be considered for HIV-infected children age 12 months through 8 years with age-specific CD4+ T-lymphocyte percentage at 15% or greater, or for children age 9 years or older with CD4+ T-lymphocyte counts of greater than or equal to 200 cell/µL. VAR should be administered (if indicated) to persons with isolated humoral immunodeficiency. Immunosuppressed children should not receive LAIV. Infants who have been diagnosed with severe combined immunodeficiency (SCID) should not be given a live virus vaccine, including RV. Other forms of immunosuppression are a precaution, not a contraindication, to RV. For details, consult ACIP recommendations (see references in **Notes** above).

9. Does the child have a parent, brother, or sister with an immune system problem? [MMR, MMRV, VAR]

MMR, VAR, and MMRV vaccines should not be given to a child or teen with a family history of congenital or hereditary immunodeficiency in first-degree relatives (i.e., parents, siblings) unless the immune competence of the potential vaccine recipient has been clinically substantiated or verified by a laboratory.

10. In the past 3 months, has the child taken medications that affect the immune system such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or had radiation treatments? [LAIV, MMR, MMRV, VAR]

Live virus vaccines (e.g., LAIV, MMR, MMRV, VAR) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, consult the ACIP statement. Some immune mediator and immune modulator drugs (especially the antitumor-necrosis factor agents adalimumab, infliximab, and etanercept) may be immunosuppressive. A comprehensive list of immunosuppressive immune modulators is available in CDC Health Information for International Travel (the "Yellow Book") available at wwwnc.cdc.gov/travel/yellowbook/2020/travelers-with-additional-considerations/immunocompromised-travelers. The use of live vaccines should be avoided in persons taking these drugs. To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see General Best Practice Guidelines for Immunization (referenced in **Notes** above). LAIV, when recommended, can be given only to healthy non-pregnant people ages 2 through 49 years.

- 11. In the past year, has the child received a transfusion of blood/blood products, or been given immune (gamma) globulin or an antiviral drug? [MMR, MMRV, LAIV, VAR] Certain live virus vaccines (e.g., MMR, MMRV, LAIV, VAR) may need to be deferred, depending on several variables. Consult the most current ACIP recommendations (referenced in Notes above) for the most current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines.
- 12. Is the child/teen pregnant or is there a chance she could become pregnant during the next month? [HPV, IPV, LAIV, MenB, MMR, MMRV, VAR]

Live virus vaccines (e.g., MMR, MMRV, VAR, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active young women who receive a live virus vaccine should be instructed to practice careful contraception for one month following receipt of the vaccine. On theoretical grounds, IPV and MenB should not be given during pregnancy; however, it may be given if there is a risk of exposure. IIV and Tdap are both recommended during pregnancy. HPV vaccine is not recommended during pregnancy.

13. Has the child received vaccinations in the past 4 weeks? [LAIV, MMR, MMRV, VAR, yellow fever]

Children who were given either LAIV or an injectable live virus vaccine (e.g., MMR, MMRV, VAR, yellow fever) should wait 28 days before receiving another vaccination of this type (30 days for yellow fever vaccine). Inactivated vaccines may be given at the same time or at any spacing interval.

#### VACCINE ABBREVIATIONS

LAIV = Live attenuated influenza vaccine HPV = Human papillomavirus vaccine IIIV = Inactivated influenza vaccine ccIIV - cell culture inactivated influenza vaccine IPV = Inactivated poliovirus vaccine MMR = Measles, mumps, and rubella vaccine

MMRV = MMR+VAR vaccine RIV = Recombinant influenza vaccine RV = Rotavirus vaccine Td/Tdap = Tetanus, diphtheria, (acellular pertussis) vaccine VAR = Varicella vaccine

## Healthcare Personnel Vaccination Recommendations<sup>1</sup>

#### **VACCINES AND RECOMMENDATIONS IN BRIEF**

- **Hepatitis B** If previously unvaccinated, give a 2-dose (Heplisav-B) or 3-dose (Engerix-B or Recombivax HB) series. Give intramuscularly (IM). For HCP who perform tasks that may involve exposure to blood or body fluids, obtain anti-HBs serologic testing 1–2 months after dose #2 (for Heplisav-B) or dose #3 (for Engerix-B or Recombivax HB).
- **Influenza** Give 1 dose of influenza vaccine annually. Inactivated injectable vaccine is given IM. Live attenuated influenza vaccine (LAIV) is given 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 subcutaneously (Subcut).
- **Varicella (chickenpox)** For HCP who have no serologic proof of immunity, prior vaccination, or diagnosis or verification of a history of varicella or herpes zoster (shingles) by a healthcare provider, give 2 doses of varicella vaccine, 4 weeks apart. Give Subcut.
- **Tetanus, diphtheria, pertussis** Give 1 dose of Tdap as soon as feasible to all HCP who have not received Tdap previously and to pregnant HCP with each pregnancy (see below). Give Td or Tdap boosters every 10 years thereafter. Give IM.
- **Meningococcal** Give both MenACWY and MenB to microbiologists who are routinely exposed to isolates of *Neisseria meningitidis*. As long as risk continues: boost with MenB after 1 year, then every 2–3 years thereafter; boost with MenACWY every 5 years. Give MenACWY and MenB IM.

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

#### **Hepatitis B**

Unvaccinated healthcare personnel (HCP) and/or those who cannot document previous vaccination should receive either a 2-dose series of Heplisav-B at 0 and 1 month or a 3-dose series of either Engerix-B or Recombivax HB at 0, 1, and 6 months. HCP who perform tasks that may involve exposure to blood or body fluids should be tested for hepatitis B surface antibody (anti-HBs) 1–2 months after dose #2 of Heplisav-B or dose #3 of Engerix-B or Recombivax HB to document immunity.

- If anti-HBs is at least 10 mIU/mL (positive), the vaccinee is immune. No further serologic testing or vaccination is recommended.
- If anti-HBs is less than 10 mIU/mL (negative), the vaccinee is not protected from hepatitis B virus (HBV) infection, and should receive another 2-dose or 3-dose series of HepB vaccine on the routine schedule, followed by anti-HBs testing 1–2 months later. A vaccinee whose anti-HBs remains less than 10 mIU/mL after 2 complete series is considered 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 or blood with unknown HBsAg status. It is also possible that non-responders are people who are HBsAg positive. HBsAg testing is recommended. HCP found

to be HBsAg positive should be counseled and medically evaluated.

For HCP with documentation of a complete 2-dose (Heplisav-B) or 3-dose (Engerix-B or Recombivax HB) vaccine series but no documentation of anti-HBs of at least 10 mIU/mL (e.g., those vaccinated in childhood): HCP who are at risk for occupational blood or body fluid exposure might undergo anti-HBs testing upon hire or matriculation. See references 2 and 3 for details.

#### 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 be given only to non-pregnant healthy HCP age 49 years and younger. Inactivated injectable influenza vaccine (IIV) is preferred over LAIV for HCP who are in close contact with severely immunosuppressed patients (e.g., stem cell transplant recipients) when they 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 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 and separated by 28 days or more, and at least 1 dose of live rubella vaccine). HCP with 2 documented doses of MMR are not recommended to be serologically tested for immunity; but if they are tested and results are negative or equivocal for measles, mumps, and/or rubella, these HCP should be considered to have presumptive evidence of immunity to measles, mumps, and/or rubella and are not in need of additional MMR doses.
- Although birth before 1957 generally is considered acceptable evidence of measles, mumps, and rubella immunity, 2 doses of MMR vaccine should be considered for unvaccinated HCP born before 1957 who do not have laboratory evidence of disease or immunity to measles and/or mumps. One dose of MMR vaccine should be considered for HCP with no laboratory evidence of disease or immunity to rubella. For these same HCP who do not have evidence of immunity, 2 doses of MMR vaccine are recommended 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, laboratory evidence of immunity, laboratory confirmation of disease, or diagnosis or verification of a history of varicella or herpes zoster (shingles) by a healthcare provider.

#### 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 dose of Tdap as soon as feasible, without regard to the interval since the previous dose of Td. Pregnant HCP should be revaccinated during each pregnancy. All HCPs should then receive Td or Tdap boosters every 10 years thereafter.

#### Meningococcal

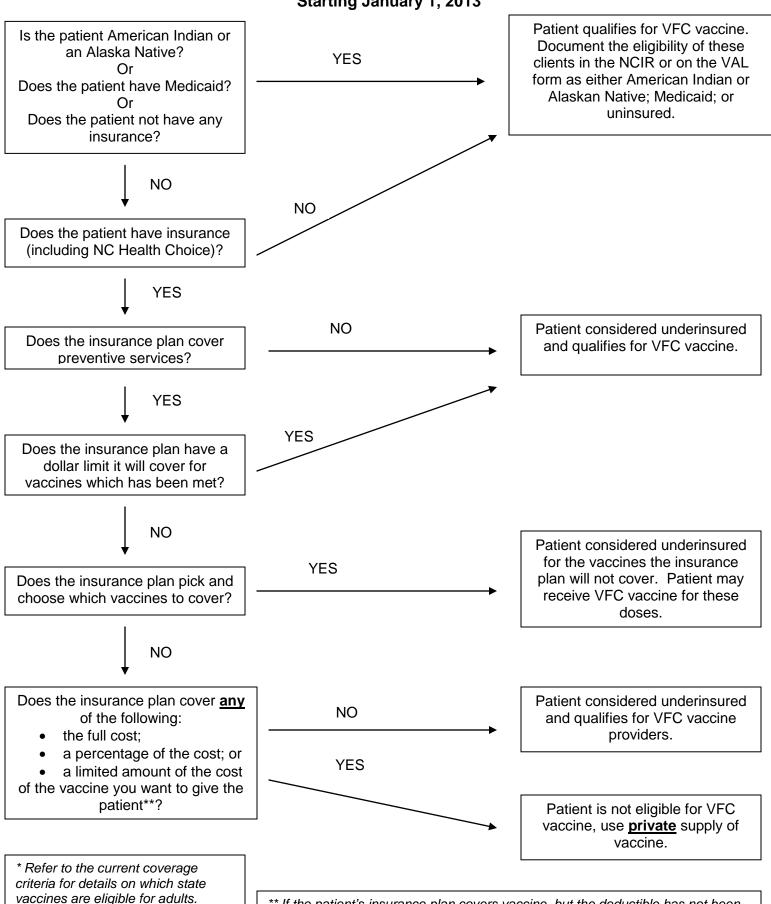
Vaccination with MenACWY and MenB is recommended for microbiologists who are routinely exposed to isolates of *N. meningitidis*. The two vaccines may be given concomitantly but at different anatomic sites, if feasible.

#### REFERENCES

- 1 CDC. Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR, 2011; 60 (RR-7).
- 2 CDC. Prevention of Hepatitis B Virus Infection in the United States. Recommendations of the Advisory Committee on Immunization Practices. MMWR, 2018; 67(RR1):1–30.
- 3 IAC. Pre-exposure Management for Healthcare Personnel with a Documented Hepatitis B Vaccine Series Who Have Not Had Post-vaccination Serologic Testing. Accessed at www.immunize.org/catg.d/p2108.pdf.

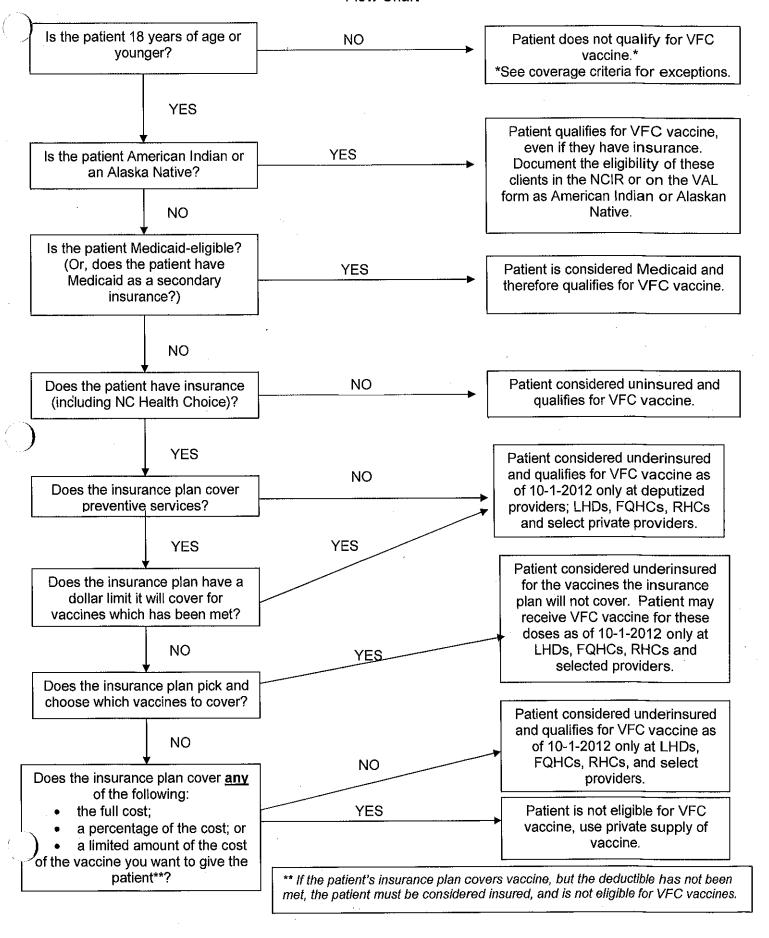
For additional specific ACIP recommendations, visit CDC's website at www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html or visit IAC's website at www.immunize.org/acip.

# For LHDs, FQHCs, RHCs, and deputized Private Providers Determining Eligibility for VFC Vaccines Flow Chart (Patients 18 years of age or less\*) Starting January 1, 2013

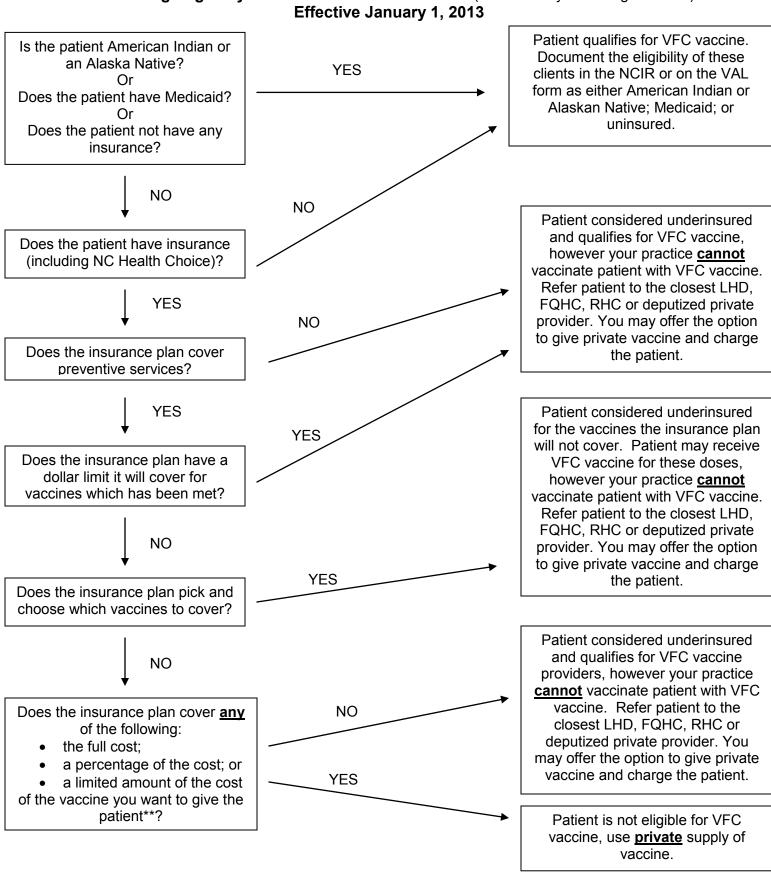


<sup>\*\*</sup> If the patient's insurance plan covers vaccine, but the deductible has not been met, the patient must be considered insured, and is not eligible for VFC vaccines.

## Determining Eligibility for VFC Vaccines Flow Chart



## For Private Providers (Not deputized) Determining Eligibility for VFC Vaccines Flow Chart (Patients 18 years of age or less\*) Effective January 1, 2013



<sup>\*\*</sup> If the patient's insurance plan covers vaccine, but the deductible has not been met, the patient must be considered insured, and is <u>not eligible</u> for VFC vaccines.

\* Refer to the current coverage criteria for details on which state vaccines are eligible for adults.

## You Must Provide Patients with **Vaccine Information Statements** (VISs) - It's Federal Law!

#### What are Vaccine Information Statements (VISs)?

Vaccine Information Statements (VISs) are documents produced by the Centers for Disease Control and Prevention (CDC), in consultation with panels of experts and parents, to properly inform vaccinees (or their parents/legal representatives) about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should address any questions or concerns that the vaccinee (or parent/legal representative) may have.

#### Using VISs is legally required!

Federal law (under the National Childhood Vaccine Injury Act) requires a healthcare professional to provide a copy of the current VIS to an adult patient or to a child's parent/legal representative before vaccinating an adult or child with a dose of the following vaccines: diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, Haemophilus influenzae type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox).

#### Where to get VISs

All available VISs can be downloaded from the websites of the Immunization Action Coalition at www.immunize.org/vis or CDC at www.cdc.gov/vaccines/hcp/vis/index.html. Ready-to-copy versions may also be available from your state or local health department.

Translations: You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis.

To obtain translations of VIS in languages other than English, go to www.immunize.org/vis.

#### According to CDC, the appropriate VIS must be given:

- Prior to the vaccination (and prior to each dose of a multi-dose series);
- Regardless of the age of the vaccinee;
- Regardless of whether the vaccine is given in a public or private healthcare setting.

#### Top 10 Facts About VISs



#### It's federal law! You must provide current\* VISs to all your patients before vaccinating them.

Federal law requires that VISs must be used for patients of **ALL** ages when administering these vaccines:

DTaP (includes DT)

· influenza (inactivated

and live, intranasal)

- Td and Tdap
- hepatitis A
- hepatitis B
- Hib
- · HPV

- MMR and MMRV
- meningococcal (MenACWY, MenB)
- pneumococcal conjugate
- polio
- rotavirus
- varicella (chickenpox)

For the vaccines not covered under the National Childhood Vaccine Injury Act (i.e., adenovirus, anthrax, Japanese encephalitis, pneumococcal polysaccharide, rabies, typhoid, yellow fever, and zoster), providers are not required by federal law to use VISs unless they have been purchased under CDC contract. However, CDC recommends that VISs be used whenever these vaccines are given.

\*Federal law allows up to 6 months for a new VIS to be used.

## FACT

#### VISs can be given to patients in a variety of ways.

In most medical settings, VISs are provided to patients (or their parents/legal representatives) in paper form. However, VISs also may be provided using electronic media. Regardless of the format used, the goal is to provide a current VIS just prior to vaccination.

CONTINUED ON NEXT PAGE ▶

#### Most current versions of VISs (table)

As of February 1, 2021, the most recent versions of the VISs are as follows:

Adenovirus	1/8/20
Anthrax	1/8/20
Cholera	.10/30/19
DTaP	4/1/20
Hepatitis A	7/28/20
Hepatitis B	8/15/19
Hib	.10/30/19
HPV	.10/30/19
Influenza	8/15/19
Japanese enceph	8/15/19
MenACWY	8/15/19
MenB	8/15/19
MMR	8/15/19

8/15/19
4/1/20
10/30/19
10/30/19
10/30/19
1/8/20
10/30/19
4/1/20
4/1/20
10/30/19
8/15/19
4/1/20
10/30/19

A handy list of current VIS dates is also available at www.immunize.org/catg.d/p2029.pdf.



(For information on special circumstances involving vaccination of a child when a parent/legal representative is not available at the time of vaccination, see CDC's *Frequently Asked Questions* at www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html.)

Prior to vaccination, VIS may be:

- Provided as a paper copy
- Offered on a permanent, laminated office copy
- Downloaded by the vaccinee (parent/legal representative) to a smartphone or other electronic device (VISs have been specially formatted for this purpose)
- Made available to be read before the office visit, e.g., by giving the patient or parent a copy to take home during a prior visit, or telling them how to download or view a copy from the Internet. These patients must still be offered a copy in one of the formats described previously to read during the immunization visit, as a reminder.

Regardless of the way the patient is given the VIS to read, providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take home following the vaccination. However, the vaccinee may decline.



## VISs are required in both public and private sector healthcare settings.

Federal law requires the use of VISs in both public and private sector settings, regardless of the source of payment for the vaccine.



## You must provide a current VIS *before* a vaccine is administered to the patient.

A VIS provides information about the disease and the vaccine and must be given to the patient **before** a vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide a current VIS right before administering vaccines.



## You must provide a current VIS for *each* dose of vaccine you administer.

The most current VIS must be provided before **each dose** of vaccine is given, including vaccines given as a series of doses. For example, if 5 doses of a single vaccine are required (e.g., DTaP), the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.



### You must provide VISs whenever you administer combination vaccines.

If you administer a combination vaccine that does not have a stand-alone VIS (e.g., Kinrix, Quadracel, Pediarix, Pentacel, Twinrix) you should provide the patient with individual VISs for the component vaccines, or use the Multi-Vaccine VIS (see below).

The Multi-Vaccine VIS may be used in place of the individual VISs for DTaP, Hib, hepatitis B, polio, and pneumococcal when two or more of these vaccines are administered during the same visit. It may be used for infants as well as children through 6 years of age. The Multi-Vaccine VIS should not be used for adolescents or adults.



## VISs should be given in a language / format that the recipient can understand, whenever possible.

For patients who don't read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive a VIS, regardless of their ability to read English. To obtain VISs in more than 30 languages, visit the Immunization Action Coalition website at www.immunize.org/vis. Providers can supplement VISs with visual presentations or oral explanations as needed.



## Federal law does not require signed consent in order for a person to be vaccinated.

Signed consent is not required by federal law for vaccination (although some states may require it).



#### To verify that a VIS was given, providers must record in the patient's medical record (or permanent office log or file) the following information:

- The edition date of the VIS (found on the back at the right bottom corner)
- In addition, providers must record:
- The office address and name and title of the person who administers the vaccine
- (i.e., the date of the visit when the vaccine is administered)

• The date the VIS is provided

• The vaccine manufacturer and lot number

• The date the vaccine is

administered



## VISs should not be altered before giving them to patients, but you can add some information.

Providers should not change a VIS or write their own VISs. However, it is permissible to add a practice's name, address, and contact information to an existing VIS.

### Additional resources on VISs and their use are available from the following organizations:

#### **Immunization Action Coalition**

- VIS general information and translations in more than 30 languages: www.immunize.org/vis
- Current Dates of Vaccine Information Statements: www.immunize.org/catg.d/p2029.pdf

#### **Centers for Disease Control and Prevention**

- VIS website: www.cdc.gov/vaccines/hcp/vis
- VIS Facts: www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html
- VIS FAQs: www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html

## Administering Vaccines to Adults: Dose, Route, Site, and Needle Size

Vaccine	Dose	Route
Honetitic A (HonA)	≤18 yrs: 0.5 mL	IM
Hepatitis A (HepA)	≥19 yrs: 1.0 mL	IIVI
Hepatitis B (HepB)	Engerix-B; Recombivax HB ≥20 yrs: 1.0 mL ≤19 yrs: 0.5 mL	IM
Specific ( Sp. )	Heplisav-B ≥18 yrs: 0.5 mL	
HepA-HepB (Twinrix)	≥18 yrs: 1.0 mL	IM
Human papillomavirus (HPV)	0.5 mL	IM
Influenza, live attenuated (LAIV)	0.2 mL (0.1 mL in each nostril)	Intranasal spray
Influenza, inactivated (IIV) and recombinant (RIV)	0.5 mL	IM
Influenza, inactivated, high-dose (HD-IIV)	0.7 mL	IM
Measles, Mumps, Rubella (MMR)	0.5 mL	Subcut
Meningococcal serogroups A, C, W, Y (MenACWY)	0.5 mL	IM
Meningococcal serogroup B (MenB)	0.5 mL	IM
Pneumococcal conjugate (PCV13)	0.5 mL	IM
Pneumococcal polysaccharide (PPSV 23)	0.5 mL	IM or Subcut
Tetanus, Diphtheria (Td) with Pertussis (Tdap)	0.5 mL	IM
Varicella (VAR)	0.5 mL	Subcut
Zoster (Zos)	Shingrix: 0.5* mL	IM

<sup>\*</sup> The vial might contain more than 0.5 mL. Do not administer more than 0.5 mL.

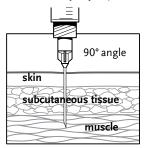
## Injection Site and Needle Size

**Subcutaneous (Subcut) injection** – Use a 23–25 gauge, <sup>5</sup>/8" needle. Inject in fatty tissue over triceps.

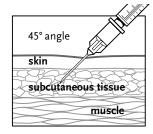
Intramuscular (IM) injection – Use a 22–25 gauge needle. Inject in deltoid muscle of arm. Choose the needle length as indicated below:

deitola masele of arm. enoose in	e necale length a	s marcated below.
Gender/Weight	Needle Length	
Female or male less than 130 lbs	<sup>5</sup> /8"*-1"	* A <sup>5</sup> /8" needle may be used for patients weigh-
Female or male 130-152 lbs	1"	ing less than 130 lbs
Female 153-200 lbs	1-1 <sup>1</sup> /2"	(<60 kg) for IM injection in the deltoid muscle
Male 153–260 lbs	1-1 72	only if the subcutaneous tissue is not bunched
Female 200+ lbs	11/2"	and the injection is made at a 90-degree angle.
Male 260+ lbs	1 /2	

#### Intramuscular (IM) injection



#### Subcutaneous (SubCut) injection



## Intranasal (NAS) administration of Flumist (LAIV) vaccine



NOTE: Always refer to the package insert included with each biologic for complete vaccine administration information. CDC's Advisory Committee on Immunization Practices (ACIP) recommendations for the particular vaccine should be reviewed as well. Access the ACIP recommendations at www.immunize.org/acip.



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

Vaccine	Dose	Route
COVID-19	Pfizer-BioNTech ≥16 yrs: 0.3 mL  Moderna; Janssen ≥18 yrs: 0.5 mL	IM
<b>Diphtheria, Tetanus, Pertussis</b> (DTaP, DT, Tdap, Td)	0.5 mL	IM
Haemophilus influenzae type b (Hib)	0.5 mL	IM
Hepatitis A (HepA)	≤18 yrs: 0.5 mL ≥19 yrs: 1.0 mL	IM
Hepatitis B (HepB) Persons 11–15 yrs may be given Recombivax HB (Merck) 1.0 mL adult formulation on a 2-dose schedule.	Engerix-B; Recombivax HB ≤19 yrs: 0.5 mL ≥20 yrs: 1.0 mL  Heplisav-B ≥18 yrs: 0.5 mL	IM
Human papillomavirus (HPV)	0.5 mL	IM
Influenza, live attenuated (LAIV)	0.2 mL (0.1 mL in each nostril)	Intranasal spray
	Afluria: 0.25 mL	
Influenza, inactivated (IIV); for ages	Fluzone: 0.25 or 0.5 mL	IM
6–35 months	FluLaval; Fluarix: 0.5 mL	
Influenza, inactivated (IIV), 3 yrs & older; recombinant (RIV), 18 yrs & older;	0.5 mL	IM
high-dose (HD-IIV) 65 yrs & older	FluZone HD: 0.7 mL	
Measles, Mumps, Rubella (MMR)	0.5 mL	Subcut
Meningococcal serogroups A, C, W, Y (MenACWY)	0.5 mL	IM
Meningococcal serogroup B (MenB)	0.5 mL	IM
Pneumococcal conjugate (PCV)	0.5 mL	IM
Pneumococcal polysaccharide (PPSV)	0.5 mL	IM or Subcut
Polio, inactivated (IPV)	0.5 mL	IM or Subcut
Rotavirus (RV)	Rotarix: 1.0 mL Rotateq: 2.0 mL	Oral
Varicella (VAR)	0.5 mL	Subcut
Zoster (Zos)	Shingrix: 0.5* mL	IM
Combination Vaccines		
DTaP-HepB-IPV (Pediarix) DTaP-IPV/Hib (Pentacel) DTaP-IPV (Kinrix; Quadracel) DTaP-IPV-Hib-HepB (Vaxelis)	0.5 mL	IM
MMRV (ProQuad)	≤12 yrs: 0.5 mL	Subcut
( )		

 $<sup>\</sup>star\,$  The Shingrix vial might contain more than 0.5 mL. Do not administer more than 0.5 mL.

Intranasal (NAS) administration of Flumist (LAIV) vaccine



#### Injection Site and Needle Size

#### Subcutaneous (Subcut) injection

Use a 23-25 gauge needle. Choose the injection site that is appropriate to the person's age and body mass.

AGE	NEEDLE LENGTH	INJECTION SITE
Infants (1–12 mos)	5/8"	Fatty tissue over anterolateral thigh muscle
Children 12 mos or older, adolescents, and adults	5/8"	Fatty tissue over anterolateral thigh muscle or fatty tissue over triceps

#### Intramuscular (IM) injection

Use a 22–25 gauge needle. Choose the injection site and needle length that is appropriate to the person's age and body mass.

AGE	NEEDLE LENGTH	INJECTION SITE
Newborns (1st 28 days)	5/8"1	Anterolateral thigh muscle
Infants (1–12 mos)	1"	Anterolateral thigh muscle
Toddlore (1. 2 years)	1–11⁄4"	Anterolateral thigh muscle <sup>2</sup>
Toddlers (1–2 years)	5/8-1"1	Deltoid muscle of arm
Children	5/8-1"1	Deltoid muscle of arm <sup>2</sup>
(3–10 years)	1–11⁄4"	Anterolateral thigh muscle
Adolescents and teens	5/8-1"1	Deltoid muscle of arm <sup>2</sup>
(11–18 years)	1–11/2"	Anterolateral thigh muscle
Adults 19 years or older		
Female or male <130 lbs	5/8-1"†	Deltoid muscle of arm
Female or male 130–152 lbs	1"	Deltoid muscle of arm
Female 153–200 lbs Male 153–260 lbs	1–11/2"	Deltoid muscle of arm
Female 200+ lbs Male 260+ lbs	11/2"	Deltoid muscle of arm

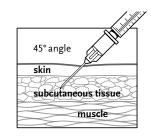
A 5/8" needle may be used in newborns, preterm infants, and patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

NOTE: Always refer to the package insert included with each biologic for complete vaccine administration information. CDC's Advisory Committee on Immunization Practices (ACIP) recommendations for the particular vaccine should be reviewed as well. Access the ACIP recommendations at www.immunize.org/acip.

#### Intramuscular (IM) injection

# 90° angle skin subcutaneous tissue muscle

#### Subcutaneous (Subcut) injection



<sup>&</sup>lt;sup>2</sup> Preferred site

## Tdap or DTaP

## Tdap

Tetanus toxoid, Reduced Diphtheria toxoid, Acellular Pertussis vaccine

7 YEARS OR **OLDER** 



## DTaP

Diphtheria and Tetanus toxoid, Acellular Pertussis vaccine

6 WEEKS -**6 YEARS** 

#### **DTaP only**





**DAPTACEL®** (sanofi pasteur).

#### Ages 6 weeks – 4 years



**Infanrix®** (GlaxoSmithKline)

#### **Combination: DTaP + Others**

DTaP + HepB + IPV Ages 6 weeks - 6 years



**Pediarix®** (GlaxoSmithKline) DTaP + IPV + Hib

Ages 6 weeks – 4 years





Pentacel® (sanofi pasteur)

DTaP + IPV

Ages 4 years - 6 years



Kinrix® (GlaxoSmithKline) Ages 4 years - 6 years



Quadracel™ (sanofi pasteur)



Report Month:	Ψ Σ	<b>≻</b> ∐	<b>≻</b> □								>	AC	N N	Z	B	VACCINES ADMINISTERED LOG				2				ŏ	(7)							ш.	Page				ا ا		$\vdash$	
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These logs must be received by the Immunization Branch by the 10th of each month. See back for other instructions.

A qeH \8 qeH

Men B

MMRV

НЬΛ

A q9H

Rotavirus Таар

**MenACWY** 

ЬСΛ

пJ

Var

Heb B

MMR

ΛЫ

Hib (all types)

DT (pediatric)

DTaP/IPV/Hib

Td (adult)

V9I/9sT0

**DTaP** 

DTaP/HB/IPV

PPV23 (Pneumo)

COLUMN TOTALS:

LAST

FIRST NOTES

FIRST NOTES Part 1 (white) Immunization Branch, Part 2 (yellow) Immunization Branch, Part 3 (pink) Provider

VACCINES ADMINISTERED LOG, VAL122, 10/2019

(1) To improve accuracy of doses administered reporting; (2) to meet state and federal requirements; (3) to fulfill Vaccines for Children (VFC) PURPOSE:

DO NOT USE PENCIL OR FELT-TIP PENS. documentation requirements; and (4) to provide patient specific immunization information to local health departments. ONLY USE BLUE OR BLACK BALLPOINT PEN.

INSTRUCTIONS:

\*Report Month:

\*Federal ID and

Fill in month and year on every page. Please do not include more than one MONTH on a VAL form. Additions and corrected copies from different

months should be documented on separate VAL forms rather than on the VAL form(s) for the current month being reported.

Immunization Branch as an identifier. The two-digit number is necessary to differentiate between facilities owned by the same group. Record the 9-digit federal tax identification number and the two-digit site number for the FACILITY assigned to you by the Record the 11-digit number on every page. two-digit site number

Record the official name of your FACILITY on every page of the log. For example, if Dr. Jones is the solo physician in a facility called "Jones Family Practice" record "Jones Family Practice."

Record the street address and city for your facility on the first page of the logs. Only required on the first page.

Print the name and telephone number of the contact person 1) whose responsibility it is to ensure the logs are received by the North Carolina Immunization Program (NCIP) by the 10th of each month, and 2) whom you want the Immunization Branch to call with questions. Number every page. Include total number of pages on the first and last page submitted, i.e. "Page 1 of 24" or "Page 24 of 24."

\*Contact Person:

\*Contact Phone:

\*Birth Date:

\*Eligibility

fnsurance:

\*Provider Name:

\*Address: \*Page\_\_

If no vaccines were given during the month, complete the top of the form. Fill in the circle indicating that zero doses were given in this month and Only required on the first page. \*Zero Doses Given:

Legibly print the first and last INITIALS ONLY of the patient in the appropriate areas. DO NOT include the full first and/or last name of the patient. mail form to the Immunization Branch by the 10th of the month. \*Patient Name:

Fill in the appropriate circle. Only fill in one circle. If a patient qualifies under more than one eligibility category, fill in the first eligibility category for which the patient is eligible. For example: if the patient is American Indian and Medicaid, fill in "A." If you cannot obtain information as to Print the date of birth as "MM DD YYYY." Fill in the full year i.e., "1999, 2000, etc." (ex: 03-25-2000). whether a patient's insurance covers immunizations, fill in "I."

A = American Indian or Alaskan Native U = Underinsured (only at LHD, FQHC, RHC & Deputized Providers-include specific underinsured language)

 $\mathbf{H} = NC$  Health Choice for Children (NC = s CHIP plan) I = Insured (insurance covers immunizations) N = Not insured (no health insurance)M= Medicaid

Print the service date as "MM DD YY." \*Service Date:

For each patient, record the vaccine type given to a patient on that date. Use this column for state supplied vaccine only. Do not record any historical data or privately purchased vaccine in this column. For example: \*Vaccine Type

Record privately purchased vaccine given to a patient who does not meet the coverage criteria under the NCIP. ◆ If you give a patient a dose of MMR, please fill in the circle under MMR. \*Notes:

Space can also be used to document lot number, manufacturer name, expiration date, date printed on Vaccine Information Statement (VIS), date VIS given, chart number, brand/type, etc. Use of this space is not required.

Total the number of doses given in each vaccine column. Record column totals at the bottom of every page.

1. Complete the log and return Part 1 (white copy) and Part 2 (yellow copy) to the Immunization Branch. Keep Part 3 (pink copy) for your files. \*Column Totals: \*Preparation:

must be received by the Immunization Branch by the 10th of each month. The Immunization Branch will mail the copy to the local health 2. MAIL Part 1 (white copy) and Part 2 (yellow copy) to: Immunization Branch, 1917 Mail Service Center, Raleigh, NC 27699-1917. The logs department in your county. DO NOT FAX OR EMAIL. Faxes or emails will not be accepted.

If you make a mistake, draw a line through the entire row that includes the incorrect data. You must keep your copy, Part 3 (pink copy) for three years. \*Disposition: \*Mistakes:



NC Department of Health and Human Services • Division of Public Health • Women's and Children's Health Section • Immunization Branch • www.ncdhhs.gov/divisions/dph • NCDHHS is an equal opportunity employer and provider. • 2,000 copies of this document were printed at a cost of \$339.91 or \$0.169957 each. • 1/2020

1. Last Name	First Name			MI
2. Patient Number				— н
3. Date of Birth		Month	Day	Year
4. Race	Maskan Nat <u>iv</u> e		Hispani 1. Yes	c Origin? ☐ 2. No
5. Sex 1. Male 2. Fen	nale			
6. County of Residence				

NC Department of Health and Human Services
Division of Public Health
Immunization Branch

## Vaccine Administration Record

\* I/parental designee have received the "Vaccine Information Statements" (VIS) about the disease(s) and vaccine(s). I have had a chance to review the VIS(s) and to ask questions that were answered to my satisfaction. I understand the benefits and risks of the vaccine(s) and request the vaccine(s) indicated below be given to me or the person named above for whom I am authorized to make this request.

Eligi- bility Status¹	Vaccine Administered (circle one)	Date Admin.	Admin. Site²/ Route³	Mfr. and Lot No.	Expiration Date	Contra- indica- tion	*Consent or Authorization Signature	**Provider's Signature	Date Printed on VIS
	DTaP/DTP/DT #1								
	DTaP/DTP/DT #2								
	DTaP/DTP/DT #3								
	DTaP/DTP/DT #4								
	DTaP/DTP/DT #5								
	Hib #1								
	Hib #2								
	Hib #3								
	Hib #4								
	IPV/OPV #1								
	IPV/OPV #2								
	IPV/OPV #3								
	IPV/OPV #4								
	Hep B #1								
	Hep B #2								
	Hep B #3								
	MMR #1								
	MMR #2								
	Varicella #1								
	Varicella #2								
	PCV #1								
	PCV #2								
	PCV #3								
	PCV #4								
	Td #1								
	Td #2								
	Td #3								
	PPV23 #1								
	PPV23 #2								
	Influenza								
	Influenza								
	Hep A #1								
	Hep A #2								
	RV #1								
	RV #2								
	RV #3								
	Tdap								
	Meningococcal #1								
	Meningococcal #2								
	HPV #1								
	HPV #2								
	HPV #3				1				

#### **Vaccine Administration Record**

Name:							DC	DB:/_	/	
	(Last)			(First)		(Middle)		Mo.	Day	Year
review	the VIS(s) and t	o ask question	s that we	ine Information Stater ere answered to my sa e or the person named	itisfaction. I u	nderstan	d the benefits and	risks of the	vaccine(s	d a chance to s) and request
Eligi- bility Status¹	Vaccine Administered (circle one)	Date Admin.	Admin. Site²/ Route³	Mfr. and Lot No.	Expiration Date	Contra- indica- tion	*Consent or Authorization Signature	**Provid		Date Printed on VIS
	Men B #1									
	Men B #2									
Allergies	s, TB Skin Test, N	lotes:								
	e asked about imr	nunizations and tatus: A – Am M – Me	prior read	on standing in loco parer ctions. According to infor dian /Alaskan Native		ve occurre		Arm Arm	ons for the	e child.
		U – Un any	derinsure portion of Health C	ed (insurance does not co of the cost of the vaccine Choice for Children		<sup>3</sup> Admin.	LT = Left T Route: IM = Intran SC = Subco	high nuscular		
Purpose	<b>5</b> .	To docume	nt vaccii	nes administered.						
Prepara		Update der	nograph	ic information and cor		h vaccin	e administration. [	Directions: C	omplete	all requested
Distribut	tion:			er will maintain Vaccir		tion Rec	ord in individual'e i	medical reco	ord	
Disposit		This form is	s to be re	etained in accordance C Division of Archives	with the Red					edical records
Ordering	g Information:	Additional f	orms ma vision of	ay be ordered from: f Public Health – Immu tment of Health and H	unization Bra					

1917 Mail Service Center Raleigh, NC 27699-1917 Phone (877) 873-6247 FAX (800) 544-3058

1. Last Name		ı	First	Nam	e					MI	
2. Patient Number											Н
3. Date of Birth											
o. Bate of Birth						Мо	nth	D	ay	Ye	ar
4. Race	Indian	ı/Al	aska	n Na	tive		Ē			Oriç	
5. Sex  1. Male	☐ 2. F	em	ale								
6 County of Posido	nco										

N.C. Department of Health and Human Services Division of Public Health Immunization Branch

#### **Adult Vaccine Administration Record**

Before administering any vaccines, give the patient copies of all pertinent Vaccine Information Statements (VISs) and make sure he/she understands the risks

			Site	Vac	ccine				Signature/
Vaccine	Date given (mo/day/yr)	Route	given (RA, LA)	lot#	mfr.	Expiration date	Date on VIS <sup>1</sup>	Consent signature	initials of vaccinator
Tetanus and	, , ,								
Diphtheria									
(e.g., Td)									
Tetanus, Diphtheria, Pertussis									
(Tdap)									
Hepatitis A² (e.g., HepA, HepA-HepB)									
Hepatitis B <sup>2</sup>									
(e.g., HepB, HepA-HepB)									
Measles, Mumps,									
Rubella (MMR)									
<b>Varicella</b> (Var)									
Pneumococcal									
Conjugate (PCV13)									
Pneumococcal									
Polysaccharide (PPSV23)									
Zoster (Shingles) (Zos)									
Meningococcal									
Conjugate (MCV4)									
Human									
Pappillomavirus (HPV)									
,									
Influenza									
(Flu)									
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}									
					1				

Record the publication date of each VIS given to the patient. According to federal law, VISs must be given to patients before administering each dose of vaccine.

<sup>2</sup>For combination vaccines, fill in the row for each individual antigen composing the combination.

#### **Adult Vaccine Administration Record**

Name:				DOB://
	(Last)	(First)	(Middle)	Mo. Day Year

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). Update the patient's personal record card or provide a new one whenever you administer the vaccine.

		Route	Site given (RA, LA)	Vaccine					Signature initials of
Vaccine	Date given (mo/day/yr)			lot#	mfr.	Expiration date	Date on VIS¹	Consent signature	initials of vaccinator
									-
									1
									1
		1							

Purpose: To document vaccines administered.

Preparation: Update demographic information and complete at each vaccine administration.

Directions: Complete all requested information for each vaccine administered.

Distribution: Health Care Provider will maintain Vaccine Administration Record in individual's medical record.

Disposition: This form is to be retained in accordance with the *Records Retention and Disposition Schedule* of medical records

as issued by the NC Division of Archives and History.

Ordering Information: Additional forms may be ordered from:

Division of Public Health – Immunization Branch NC Department of Health and Human Services

1917 Mail Service Center Raleigh, NC 27699-1917 Phone (877) 873-6247 FAX (800) 544-3058

### North Carolina Department of Health and Human Services Women's and Children's Health Section • Immunization Branch

#### **NC MEDICAL EXEMPTION STATEMENT FORM DHHS 3987**

Purpose: To provide physicians licensed to practice medicine in North Carolina, a mechanism to certify, pursuant to G.S. 130A-156, a medical exemption to a required immunization(s) due to a contraindication adopted by the NC Commission for Public Health. As set out in 10A NCAC 41A .0404, the NC Commission for Public Health has adopted the contraindications that are recommended by the Advisory Committee on Immunization Practices (ACIP). These contraindications are listed on this form. This form does not need to be submitted for approval to the State Health Director and may be accepted by agencies that require proof of immunizations. For medical exemptions NOT listed in the table below, submit the Physician's Request for Medical Exemption form (DHHS 3995) to the State Health Director for approval, available at <a href="https://www.immunize.nc.gov/schools/ncexemptions.htm">https://www.immunize.nc.gov/schools/ncexemptions.htm</a>

Instruc	ctions:
1. Complete and sign the form.	
2. Attach a copy of the most current immunization record.	
3. Retain a copy for the patient's medical record.	
4. Return the original to the person requesting this form.	
Name of Patient	DOB
Name of Parent/Guardian	
Home Address (Patient/Parent)	County
Name of Child Care/School/College/University	
A <b>contraindication</b> is a condition in a recipient that increases the risk for a s	serious adverse reaction. A vaccine should not be administered when a

A **contraindication** is a condition in a recipient that increases the risk for a serious adverse reaction. A vaccine should not be administered when a contraindication is present. Medical contraindications for immunizations are described in the most recent recommendations by the ACIP, available at <a href="https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html">https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html</a>

Vaccine		Check all contraindications that apply to this patient below:						
	Diphtheria, tetanus, pertussis (DTaP) Tetanus, diphtheria, pertussis (Tdap) Tetanus, diphtheria (DT, Td)	<ul> <li>□ Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</li> <li>□ For pertussis-containing vaccines: encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of a previous dose of DTaP or DTP (for DTaP); or of previous dose of DTaP, DTP, or Tdap (for Tdap)</li> </ul>						
	Measles, mumps, rubella (MMR)	<ul> <li>□ Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</li> <li>□ Severe immunodeficiency (e.g., hematologic and solid tumors, chemotherapy, congenital immunodeficiency or long-term immunosuppressive therapy), or persons with human immunodeficiency virus [HIV] infection who are severely immunocompromised</li> <li>□ Family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents and siblings), unless the immune competence of the potential vaccine recipient has been substantiated clinically or verified by a laboratory test</li> <li>□ Pregnancy</li> </ul>						
	Varicella (Var)	<ul> <li>Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component.</li> <li>Severe immunodeficiency (e.g., hematologic and solid tumors, chemotherapy, congenital immunodeficiency or long-term immunosuppressive therapy), or persons with HIV infection who are severely immunocompromised</li> <li>Family history of congenital or hereditary immunodeficiency in first degree relatives (e.g., parents and siblings), unless the immune competence of the potential vaccine recipient has been substantiated clinically or verified by a laboratory test</li> <li>Pregnancy</li> </ul>						

	Inactivated Polio Virus (IPV)	☐ Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component						
	Hepatitis B (Hep B)	<ul> <li>□ Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</li> <li>□ Hypersensitivity to yeast</li> </ul>						
	Haemophilus influenza type B (HiB)	<ul> <li>□ Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component</li> <li>□ Age younger than 6 weeks</li> </ul>						
	Pneumococcal Conjugate (PCV13)	☐ Severe allergic reaction (e.g., anaphylaxis) after a previous dose of PCV13 or any diphtheria-toxoid—containing vaccine or to a component of a vaccine (PCV13 or any diphtheria-toxoid—containing vaccine), including yeast						
	Meningococcal Conjugate (MenACWY)	□ Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component, including yeast						
Date		(M.D. or D.O) licensed to practice medicine in North Carolina must complete and sign this form.						
	·	print) Phone						
	AddressPrioriePriorie							
N.C.	.C. Physician's Signature Date							

For questions, please contact the North Carolina Immunization Branch Nurse On-Call at (919) 707-5575. Additional copies of this form can be accessed at: <a href="https://www.immunize.nc.gov/schools/ncexemptions.htm">https://www.immunize.nc.gov/schools/ncexemptions.htm</a>

#### NC PHYSICIAN'S REQUEST FOR MEDICAL EXEMPTION FORM DHHS 3995

Purpose: To provide physicians licensed to practice medicine in North Carolina with a mechanism to request a medical exemption to a required immunization(s), pursuant to <u>G.S. 130A-156</u>, for a contraindication not adopted by the NC Commission for Public Health under <u>10A NCAC 41A .0404</u> and, therefore, not included on the NC Medical Exemption Statement Form DHHS 3987. Physicians shall state the specific vaccine(s) the individual should not receive, the basis of the request, and the length of time the requested exemption will apply for the individual. This request is subject to review by the State Health Director. The State Health Director may grant or deny a medical exemption to the requested vaccine(s). Additional copies of this form and the NC Medical Exemption Statement Form DHHS 3987 can be accessed at: https://www.immunize.nc.gov/schools/ncexemptions.htm

	<u>INSTRUCTIONS</u>									
1. Complete and sign the form.										
2. Provide documentation necessary to support the		c.).								
3. Attach a copy of the most current immunization	on record.									
4. Retain a copy for the patient's file.										
5. Provide a copy to the person requesting the medical exemption.										
6. Send the completed form, supporting documer										
·	ment of Health and Human Serv	vices								
	f Public Health									
1	tion Branch									
	Service Center									
Raieign, N	C 27699-1917									
Name of Patient		DOB								
Name of Parent/Guardian		Primary Phone ( )								
Home Address (Patient/Parent)		County								
Name of Child Care/School/College/University										
Please mark the vaccine(s) that the proposed med	disal axamption(s) applies to:									
*, , , ,	, .,	□ Haratitia D								
	☐ MMR	☐ Hepatitis B	/LI:D)							
□ Tdap □ DT/Td	□ Varicella □ IPV	☐ Haemophilus influenza type B☐ Meningococcal Conjugate (Me	· · ·							
□ Pneumococcal Conjugate (PCV13)		ivieningococcai conjugate (ivie	HACWT							
- Theamococcar conjugate (1 CV 13)	<u> </u>									
For each vaccine marked above, please describe tl	as contraindication(s) and the	aronacad langth of time that would apply (attach	additional							
pages if necessary):	· · · · · · · · · · · · · · · · · · ·		auuitioilai							
pages in necessary).										
A <u>physician</u> (M.D. or D.O.) licensed to practice me	dicine in NC must complete and	d sign this form.								
N.C. Physician's Name (please print)		Phone								
Mailing Address										
N.C. Physician's Signature		Date								

For questions, please contact the North Carolina Immunization Branch Nurse Call Line at (919) 707-5575.







Adverse events are possible reactions or problems that occur during or after vaccination. Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use Continuation Page if needed)									
1. Patient name: (first) (last)				9. Prescriptions, over-the-counter medications, dietary supplements, or					
Street address:				herbal remedies being taken at the time of vaccination:					
City: County:									
P code: Phone: Email:			10. Allergies to medications, food, or other products:						
2. Date of birth: (mm/dd/yyyy)	<mark>B.</mark> Sex: 🗆 Male 🗆 Fema	ale 🗆 Unknown							
4. Date and time of vaccination: (mm/dd/yyyy)	math Time:	□AM □PM	11. Ot	her illnesses at the	time of vaccinatio	n and up to one i	month prior:		
<b>5.</b> Date and time adverse event started: (mm/dd/yyyy)	Time:	□AM □PM							
6. Age at vaccination:Years Months 7. Too	lay's date: (mm/dd/yyyy)	<b></b>	12. Chronic or long-standing health conditions:						
8. Pregnant at time of vaccination?:   Yes   (If yes, describe the event, any pregnancy complications, and		ı item 18)							
INFORMATION ABOUT THE PERSON COMPLI	TING THIS FORM	INFORM	/ATION	ABOUT THE FACI	LITY WHERE VAC	CCINE WAS GIV	/EN		
13. Form completed by: (name)		15. Facility/clinic			_	facility: (Check o			
	7 D-4:4/ 10		□ Doctor's office, urgent care, or hospita						
Relation to patient: Healthcare professional/staff Definition Parent/guardian/caregiver	□ Patient (yourself) □ Other:	Fax:	□ Pharmacy or store						
i archigadididi/caregivei	dilici.	Street address:		☐ Check if same as item 13 ☐ Workplace clinic					
Street address:	☐ Check if same as item 1				Depuision   D				
	ZIP code:				□ Nursing h	nome or senior liv	ing facility		
Phone: Email:		City:				r student health			
14. Best doctor/healthcare professional to contact		State:	ZIP	code:					
about the adverse event:	Ext:	Phone:			Unknowr				
WHIC	CH VACCINES WERE GIVE	N? WHAT HAPPEN	NFD TO	THE PATIENT?					
17. Enter all vaccines given on the date listed in item 4:					Use Continuation	Page if needed	Dose number		
Vaccine (type and brand name)	Manufacturer		Lot number Route Body site in series						
18. Describe the adverse event(s), treatment, and outcome	no(a) if any: (aumntame sign	a time source etc.)		21. Result or outc	ome of adverse av	ant(a): (Check all	that apply)		
Describe the adverse event(s), treatment, and outcome	iic(s), ii aiiy. (syiiiptoiiis, sigii	s, time course, etc./		☐ Doctor or other					
			☐ Emergency room/department or urgent care						
			☐ Hospitalization: Number of days (if known)						
			Hospital name:						
			City: State:						
			☐ Prolongation of existing hospitalization (vaccine received during existing hospitalization)						
10 Modical tasta and laboratory recults related to the		Continuation Page if	needed	☐ Life threatening		risk of death from	tne event)		
19. Medical tests and laboratory results related to the a	uverse event(s): (Include date:	S)		<ul><li>□ Disability or pe</li><li>□ Patient died – I</li></ul>	ū	olddhar)			
	11 4	Continuation Dans 16	noode d		•				
20. Has the patient recovered from the adverse event(s)		Continuation Page if  Unknown	neeaea	<ul><li>□ Congenital and</li><li>□ None of the about</li></ul>		il			
20. Has the patient recovered from the adverse event(s)	:. L 163 L NO	Olikilowii		INOTIC OF THE AD-	JVG				
		NAL INFORMATIO	N				_		
22. Any other vaccines received within one month prior	to the date listed in item 4:  Manufacturer	Lot number		Use Continua Route	Rody site	Dose number in series	Date Given		
Vaccine (type and brand name)	Manuracturer	Lot number		noute	Body site	III SEITES	diveii		
00 11 11 11 11 11 11 11 11 11 11 11 11 1									
23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name)  □ Yes □ Yes □ No □ Unknown									
24. Patient's race: American Indian or Alaska Na (Check all that apply) White	ative		or Africa	n American	□ Native Haw	aiian or Other Pa	acific Islander		
			nmuniz.	proj. report number:	(Health Dept use on	ily)			
	V FOR II C THE TANK	DARTHERIT	FFMCT	(D. D) DELIZED	DODTO				
COMPLETE ONL	Y FOR U.S. MILITARY/DEI	PAKIMENI OF DE	FENSE	(DOD) KELATED RE	PUKIS				

SAVE

27. Status at vaccination: □ Active duty □ Reserve □ National Guard □ Beneficiary □ Other:

VAERS CONTINUATION PAGE (Use only if you need more space from the front page)									
17. Enter all vaccines given on the date listed in item 4 (or Vaccine (type and brand name)	ontinued): Manufacturer		Lot nur	mber	Route		Во	dy site	Dose number in series
22. Any other vaccines received within one month prior t	o the date listed in item 4 (contin	nued):						Dose number	Date
Vaccine (type and brand name)	Manufacturer Lot number			Route		Body site		in series	Given
Use the space below to provide any additional informatio	n (indicate item number):							<u></u>	
ose the space below to provide any additional infollitation	m (mulcate item number).								



#### COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

#### GENERAL INSTRUCTIONS

- Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile/.
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
- If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an
  email to info@vaers.org.
- Fill out the VAERS form as completely as possible and use the Continuation Page if needed. Use a separate VAERS form for
  each individual patient.
- If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
- You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether
  the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at <a href="www.vaers.hhs.gov/reportable.html">www.vaers.hhs.gov/reportable.html</a> for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who
  administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

#### **SPECIFIC INSTRUCTIONS**

Items 2, 3, 4, 5, 6, 17, 18 and 21 are ESSENTIAL and should be completed.

- Items 4 and 5: Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don't know the day). If you do not know the exact time, but know it was in the morning ("AM") or afternoon or evening ("PM"), please provide that information.
- Item 6: If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient's date of birth (item 2) and date and time of vaccination (item 4).
- Item 8: If the patient who received the vaccine was pregnant at time of vaccination, select "Yes" and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select "No" or "Unknown."
- Item 9: List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/alternative medicines being taken by the patient when the vaccine(s) was given.
- Item 10: List any allergies the patient has to medications, foods, or other products.
- Item 11: List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does **NOT** include the adverse event you are reporting.
- Item 12: List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- Item 13: List the name of the person who is completing the form. Select the "Check if same as item 1" box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.
- Item 14: List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
- Item 15: Select the "Check if same as item 13" box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
- Item 16: Select the option that best describes the type of facility where the vaccine(s) was given.



- Item 17: Include only vaccines given on the date provided in item 4. The vaccine route options include:
  - Injection/shot (intramuscular, subcutaneous,
- By mouth/oral
- Other (specify)

- intradermal, jet injection, and unknown)
- In nose/intranasal

Unknown

For body site, the options include:

• Right arm

• Right thigh

- Nose
- Other (specify)

Left arm

Left thigh

- Mouth
- Unknown

Arm (side unknown)

Thigh (side unknown)

For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose number in series."

- Item 18: Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- Item 19: List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- Item 20: Select "Yes" if the patient's health is the same as it was prior to the vaccination or "No" if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select "Unknown" if the patient's present condition is not known.
- Item 21: Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.
- Item 22: List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.
- Item 23: Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.
- Item 24: Check all races that apply.
- Item 25: Check the single best answer for ethnicity.
- Item 26: For health department use only.
- Items 27 and 28: Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

#### **GENERAL INFORMATION**

- VAERS (www.vaers.hhs.gov) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

## Report Vaccine Errors

The Institute for Safe Medication Practices Vaccine Error Reporting Program (ISMP VERP) now gives practitioners a way to provide crucial information on the unique causes and consequences of errors with vaccines. The data collected helps ISMP develop practical prevention strategies to share with the entire healthcare community.

The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field.

#### **How to Report**

Go online to: http://verp.ismp.org. All reports are kept confidential; ISMP is a federally recognized Patient Safety Organization (PSO), which confers privilege and high level protection for all information reported.

#### **Who Should Report**

Healthcare professionals from all practice settings—including physician's offices—are encouraged to report mistakes related to vaccines, regardless of whether harm resulted.

#### **How Reports Are Used**

Information from the ISMP VERP is shared with the U.S. Food and Drug Administration (FDA), and forwarded to the vaccine manufacturer when applicable.

#### **Non-Vaccine Errors**

ISMP also runs the National Medication Error Reporting Program (ISMP MERP); to report a medication error that does not involve a vaccine, go to: https://www.ismp.org/orderforms/reporterrortoismp.asp

#### What Is ISMP?

We are a multidisciplinary healthcare nonprofit organization dedicated to preventing medication errors. We are not a government, regulatory, licensing, inspecting, or accrediting agency. While we work collaboratively with these types of agencies, we do not set or enforce healthcare standards.



Report errors, close calls or hazardous conditions involving vaccines to the ISMP Vaccine Error Reporting Program http://verp.ismp.org





#### North Carolina Immunization Program (NCIP) VACCINES FOR CHILDREN PROGRAM (VFC)

Determining VFC Eligibility & Billing Guidance 02/17/2020

#### Who is eligible for Vaccines for Children (VFC) vaccines?

A child is eligible for the VFC Program from birth through 18 years of age (under 19) and is one of the following:

Medicaid-eligible (the VFC program uses the terms "Medicaid-eligible" and "Medicaid-enrolled" interchangeably)

Uninsured: a child that has NO health insurance coverage

Underinsured [1]

American Indian or Alaska Native

#### [1] \*Underinsured is defined as:

Underinsured means the child has health insurance, but it

- Doesn't cover vaccines, or
- Doesn't cover certain vaccines, or
- Covers vaccines but has a fixed dollar limit or cap for vaccines. Once that fixed dollar amount is reached, a child is then eligible.

\*Not having met a deductible or having to pay a co-payment does **not** make a patient underinsured for VFC purposes. If these conditions were met, and their insurance covers vaccines, they would be considered insured, and therefore, not VFC eligible.

With the implementation of the Affordable Care Act (ACA) it is rare that children fall under this category. Providers should follow the below guidance for vaccinating underinsured children.

**Note**: Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC), or Local Health Department in North Carolina. (LHD) under an approved deputization agreement.

For underinsured children, whose medical home is not with a FQHC, RHC, or LHD, the provider should notify the parent /guardian that the patient is VFC eligible and could receive VFC vaccines at one of these designated provider types.

If the parent/guardian chooses to receive vaccines for their child at their non-deputized medical home, the patient would receive private purchased vaccine, and would be financially responsible for the cost of the purchased vaccine and the associated administration fees.

## Are children whose families participate in a Health Care Sharing Ministries (HCSMs), such as Medi-Share, eligible for VFC vaccines?

HCSMs are nonprofit alternatives to purchasing health insurance from private, for-profit insurers. VFC eligibility depends primarily on recognition of the plan as insurance by the state. A child with this type of plan should be considered:

- Uninsured if the plan is not recognized as insurance by the North Carolina Department of Insurance (NCDOI)
- Insured if the plan is recognized by the NCDOI and covers all ACIP-recommended vaccines
- Underinsured if the plan is recognized by the NCDOI and does not cover all ACIP-recommended vaccines Providers are responsible for verifying the insurance plan prior to administration of VFC vaccine.

#### North Carolina Immunization Program (NCIP) VACCINES FOR CHILDREN PROGRAM (VFC)

Determining VFC Eligibility & Billing Guidance 02/17/2020

#### When do we screen for VFC eligibility?

The CDC Provider agreement states that providers will screen patients and document eligibility status **at each** immunization encounter for VFC eligibility. Eligibility screening and documentation must take place at each immunization visit prior to immunization administration. Providers that administer VFC vaccines to ineligible children will be required to replace the doses with private vaccine.

#### Are children who are covered by North Carolina Health Choice (NCHC) eligible for VFC vaccines?

**No-** for VFC purposes, the CDC considers patients **insured** who are covered by a state's Children's Health Insurance Program (CHIP). In North Carolina, the CHIP is known as NCHC.

#### Are there any special considerations for children that are American Indian or Alaska Native (AI/AN)?

Yes- AI/AN children are always VFC-eligible. However, VFC is an entitlement program and participation is not mandatory for an eligible child. For AI/AN patients who are Medicaid eligible, either eligibility may be documented but Medicaid should be billed the administration fee as it is the least costly out of pocket expense. Providers should also consider the least costly out of pocket expense for AI/AN patients enrolled in NC Health Choice or other private insurance plans.

#### What if a child presents and has Insurance and Medicaid as Secondary Coverage?

Children from birth through 18 years who are covered by both Medicaid's Health Check and another insurance plan (for example, BC/BS, Prudential, etc.) simultaneously (on the same date of service) are considered Medicaid-eligible, and therefore, are eligible for VFC vaccines. The CDC says that providers must offer the family a choice of what is the most cost effective for them: either 1) provide VFC vaccine and bill Medicaid (admin fee only), or 2) provide purchased vaccine and bill the insurance plan (for both the vaccine and the admin fee). The provider should honor the family's request.

#### What about 19 & 20-year-old patients that are on Medicaid (NC Health Check)

Individuals of this age on Medicaid are *NOT* eligible for VFC vaccines. Because these two age groups are not eligible for VFC vaccine, Medicaid will cover the cost of the vaccine and the vaccine administration fee. Per the 2018 Health Check Billing Guide providers must use privately purchased vaccines and bill Medicaid for the cost of the vaccine and the vaccine administration fee. Once the individual turns 21 years of age they fall under Adult Medicaid. Please contact the CSRA Call Center at 800-688-6696 if you have any questions.

## We have a family that has a new insurance company that does not allow us to be in their network of providers, but the family would like to remain with us for continuity of care. Can the child automatically be considered underinsured and receive VFC vaccines?

**No-** Because VFC eligibility status must be determined at each immunization encounter, the provider needs to evaluate whether vaccines are covered by the plan to determine if the patient is underinsured and is therefore eligible for VFC vaccine at a *Federally Qualified Health Center (FQHC)*, *Rural Health Clinic (RHC)*, *or Local Health Department (LHD)*. \*See page 1 for details on Underinsured patients.

If the insurance plan will cover the cost of vaccines at an in-network provider, patients should be referred to in-network providers who accept their insurance. These patients are not considered un-insured or underinsured for the VFC program.

## We are aware that we may not charge for VFC vaccines, but are there any services involving VFC vaccines that we may charge for?

**Yes-** For VFC Eligible children on Medicaid, providers may bill Medicaid a vaccine administration fee. Providers must accept the reimbursement for immunization administration set by the state Medicaid agency. The vaccine administration fee is per vaccine, NOT per antigen.

#### North Carolina Immunization Program (NCIP) VACCINES FOR CHILDREN PROGRAM (VFC)

Determining VFC Eligibility & Billing Guidance 02/17/2020

For **Uninsured** children, the provider may charge the child's parent/guardian the vaccine administration fee out -of-pocket but the following must be observed:

- Providers cannot charge the parent/guardian any amount that exceeds the administration fee cap per vaccine
  dose above the maximum medical billable rate. \*See your current CDC Provider Agreement for the dollar
  amount.
- Providers cannot deny administration of VFC vaccines to a VFC eligible child because the parent /guardian of the VFC eligible child is unable to pay the administration fee.
- Providers must waive the administration fee if the VFC eligible child's parent/guardian of the VFC eligible child is unable to pay the administration fee.
- Providers who choose to bill for the vaccine administration fee after the date of service may issue only a single bill to the patient within 90 days of vaccine administration.
- Providers cannot send unpaid administration fees to collections.

**Note**: The parent/guardian of an **Underinsured** child that receives VFC vaccine at a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or Local Health Department (LHD) can also be charged an out-of-pocket fee, but the same criteria above must be followed.

#### Local Health Departments(LHD's)

#### Are there any services involving VFC vaccines that LHD's may charge for?

LHD's may charge the patient an out-of-pocket administration fee for VFC vaccines unless the patient is Uninsured or Underinsured **AND** the family income is below 200% of the federal poverty level. If these two conditions apply the patient's vaccine administration fee must be waived.

If the LHD chooses to charge an out-of-pocket vaccine administration fee the following must be observed:

- LHDs cannot charge the parent/guardian any amount that exceeds the administration fee cap per vaccine dose above the maximum medical billable rate. \*See your current CDC Provider Agreement for the dollar amount.
- LHDs cannot deny administration of VFC vaccines to a VFC eligible child because the parent/guardian is unable to pay the administration fee.
- LHDs must waive the administration fee if the VFC eligible child's parent/guardian is unable to pay the administration fee.
- LHDs who choose to bill for the vaccine administration fee after the date of service may issue only a single bill to the patient within 90 days of vaccine administration.
- LHDs cannot send unpaid administration fees to collections.

Where can providers find detailed information about billing Medicaid for immunization-related services? For complete billing guidance for Medicaid-eligible children you can refer to the most current N.C. Health Check Program Guide which can be found on the NC DMA web site under the Health Check Section: <a href="https://files.nc.gov/ncdma/documents/Medicaid/EPSDT/09-20-2018\_Health-Check\_Program%20Guide%20Final.pdf">https://files.nc.gov/ncdma/documents/Medicaid/EPSDT/09-20-2018\_Health-Check\_Program%20Guide%20Final.pdf</a>

Details on billing procedures for all Health Check services, including details such as vaccine CPT® codes and ICD-10® (diagnosis) codes are included in the billing guide. You can also find Medicaid Bulletins and other important information on this site: https://www2.ncdhhs.gov/DMA/healthcheck/index.htm

#### Are we limited in what we may charge an insurance company for the administration of vaccine?

Questions about commercial insurance plans and administration reimbursement charges should be addressed with the insurance carrier directly.

#### Who can providers contact if we have questions?

The CSRA Call Center is dedicated to assisting with inquiries regarding enrollment, claim status, recipient eligibility, and other information needed by providers to support their service to NC DHHS recipients. The contact number is **800-688-6696**. For eligibility related questions, please contact the Helpdesk at 1-877-873- 6247.