STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH

Donald E. Williamson, MD
State Health Officer

November 17, 2003

Dear Vaccines for Children (VFC) Provider:

Subject: Immunization Update

Enclosed are several points of interest regarding vaccines. After physicians and the other members of your staff have reviewed this material, the staff member responsible for the changes to the VFC manual should initial, date, and place this cover letter behind the Title Page of your VFC Manual. This procedure will indicate if you have the latest information and let our representatives know if you are missing important vaccine information.

The purpose of the article, *Standards for Child and Adolescent Immunization Practices, National Vaccine Advisory Committee*, is to present a set of standards of essential and desirable immunization policies and practices. Please note Table 1 summarizes the standards and Table 2 lists the organizations that have endorsed these standards.

2 Enclosed also is the brief report, *Association Between Thimerosal-Containing Vaccine and Autism, Journal of American Medical Association.* **The article concludes there is no causal relationship between childhood vaccination with thimerosal-containing vaccines and the development of autistic-spectrum disorders.**

3. It is not too late to order influenza vaccine for VFC-eligible children who are high-risk and 6 months through 18 years of age and VFC-eligible children 6 months through 23 months of age who come in your practice during this influenza season. On the other hand, if your practice ordered too much influenza vaccine, please call Dell at 1-800-469-4599. He will make arrangements to redistribute the excess influenza vaccine.

4. In October 2003, the Advisory Committee on Immunization Practices (ACIP) recommended influenza vaccine for infants 6-23 months of age. This upgrades the previously "encouraged" vaccine to a "recommended" vaccine. Therefore next year all VFC-eligible children 6 months through 23 months of age can receive influenza vaccine. As always, VFC-eligible children 6 months through 18 years of age who are high-risk can receive influenza vaccine. Please start thinking about 2004-2005 influenza season and the number of doses your practice will need to vaccinate the expanded number of VFC-eligible children. Enclosed is *Increasing Influenza Immunization Rates Infants and*

Children: Putting Recommendations Into Practice, National Foundation for Infectious Diseases, to assist your practice in implementing the influenza recommendations.

5. Enclosed is the October 2003 issue of *Needle Tips, Immunization Action Coalition (IAC)* This publication provides helpful current immunization education material for staff and parents.

6. The Centers for Disease Control and Prevention (CDC) requires states to have on file a list of all physicians who are administering VFC vaccine. If you have non-Medicaid physicians using VFC vaccine for VFC-eligible children, we may not have this information. Please notify us at 1-800-469-4599 if this is the case.

7. Enclosed is the new color Monthly Temperature Range Chart to assist your staff in recording daily temperatures within the proper range (35F- 46F for refrigerators and 5F or less for freezers). If your staff records a check, an "x", or the specific temperature (i.e., ✔, ✗, or 35 F) in the yellow or red area, action needs to be taken to prevent the vaccine from spoiling. You can order additional Monthly Temperature Range Charts online or write your order on the Form Requisition for Private Providers until it is updated.

8. As a reminder, VFC will not be shipping vaccine the weeks of Thanksgiving, Christmas, and New Year's.

Please call us at 1-800-469-4599 and we will be happy to discuss items mentioned in this letter and any questions regarding vaccines, or visit our web site at www.adph.org/immunization/. Thank you for your efforts to immunize Alabama's children and for participating in the Alabama VFC Program.

Sincerely,

Cindy Lesinger

Cindy Lesinger
VFC and Assessment Branch Director
Smallpox Coordinator
Registry Data Management Operations
Immunization Division

Initials _____
Date letter was place behind Title Page of the VFC Manual

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.[1,2] Second, vaccination of children has shifted markedly from the public to the private sector,[3–5] with an emphasis on vaccination in the context of primary care and the medical home.[6] 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,[7] have focused national attention on the quality of preventive care, including vaccination. Finally, high-quality 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 challenges. 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.[9]

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.

From the National Vaccine Advisory Committee, Providence, Rhode Island.
Received for publication Feb 26, 2003; accepted Apr 10, 2003.
Reprint requests to the Centers for Disease Control and Prevention, National Immunization Program Resource Center, 1600 Clifton Rd, MS E-34, Atlanta, GA 30333.
PEDIATRICS (ISSN 0031 4005).

TABLE 1. Standards for Child and Adolescent Immunization Practices

Availability of vaccines
1. Vaccination services are readily available.
2. Vaccinations are coordinated with other health care services and provided in a medical home[6] when possible.
3. Barriers to vaccination are identified and minimized.
4. 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
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.

Proper storage and administration of vaccines and documentation of vaccinations
8. Health care professionals follow appropriate procedures for vaccine storage and handling.
9. Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.
10. 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.
16. 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,[10] 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.[6] 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.[6] 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/child-schedule.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.[11] 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.

Committee members: Georges Peter, MD (Chair), Brown Medical School, Providence, RI; Ann Margaret Arvin, MD, Stanford University School of Medicine, Stanford, CA; Jeffrey P. Davis, MD, Wisconsin Division of Health, Madison, WI; Michael D. Decker, MD, MPH; Aventis Pasteur, Swiftwater, PA; Patricia Fast, MD, PhD, International AIDS Vaccine Initiative, New York, NY; Fernando A. Guerra, MD, MPH, San Antonio Metropolitan Health District, San Antonio, TX; Charles M. Helms, MD, PhD, University of Iowa Hospital and Clinics, Iowa City, IA; Alan Richard Hinman, MD, The Task Force for Child Survival and Development, Decatur, GA; Ruth Katz, JD, MPH, Yale University School of Medicine, New Haven, CT; Jerome O. Klein, MD, Boston Medical Center, Boston, MA; Mary Beth Koslap-Petraco, MS, CPNP, Suffolk County Department of Health Services, Lindenhurst, NY; Peter R. Paradiso, PhD, Wyeth-Lederle Vaccines and Pediatric American Home Products, West Henrietta, NY; William Schaffner, MD, Vanderbilt University School of Medicine, Nashville, TN; Patricia N. Whitley-Williams, MD, Robert Wood Johnson Medical School, New Brunswick, NJ; Donald E. Williamson, MD, Alabama Department of Public Health, Montgomery, AL.

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BRIEF REPORT

Association Between Thimerosal-Containing Vaccine and Autism

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Context Mercuric compounds are nephrotoxic and neurotoxic at high doses. Thimerosal, a preservative used widely in vaccine formulations, contains ethylmercury. Thus it has been suggested that childhood vaccination with thimerosal-containing vaccine could be causally related to neurodevelopmental disorders such as autism.

Objective To determine whether vaccination with a thimerosal-containing vaccine is associated with development of autism.

Design, Setting, and Participants Population-based cohort study of all children born in Denmark from January 1, 1990, until December 31, 1996 (N=467 450) comparing children vaccinated with a thimerosal-containing vaccine with children vaccinated with a thimerosal-free formulation of the same vaccine.

Main Outcome Measures Rate ratio (RR) for autism and other autistic-spectrum disorders, including trend with dose of ethylmercury.

Results During 2986 654 person-years, we identified 440 autism cases and 787 cases of other autistic-spectrum disorders. The risk of autism and other autistic-spectrum disorders did not differ significantly between children vaccinated with thimerosal-containing vaccine and children vaccinated with thimerosal-free vaccine (RR, 0.85 [95% confidence interval (CI), 0.60-1.20] for autism; RR, 1.12 [95% CI, 0.88-1.43] for other autistic-spectrum disorders). Furthermore, we found no evidence of a dose-response association (increase in RR per 25 μg of ethylmercury, 0.98 [95% CI, 0.90-1.06] for autism and 1.03 [95% CI, 0.98-1.09] for other autistic-spectrum disorders).

Conclusion The results do not support a causal relationship between childhood vaccination with thimerosal-containing vaccines and development of autistic-spectrum disorders.

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HIGH DOSES OF MERCURIC COMpounds are nephrotoxic and neurotoxic.[1] Thimerosal, an organic compound that contains ethylmercury, has been widely used since the 1930s as a preservative in certain vaccines. In the 1990s, an increasing number of different vaccines containing thimerosal were introduced in immunization schedules around the world, and thus the average cumulative exposure to thimerosal in infants has increased in recent years. This has led to the suggestion that childhood vaccination with thimerosal-containing vaccines increases the risk of neurodevelopmental disorders, such as autism, attention-deficit/hyperactivity disorder, and language and speech delay.

In a recent independent review conducted by the Immunization Safety Committee, on behalf of the Institute of Medicine, it was concluded that the evidence was inadequate to accept or reject a causal relationship between thimerosal-containing vaccine and neurodevelopmental disorders.[2] However, based on comparison with the toxicology of methylmercury, the biological plausibility of a link remained. Further research was recommended. We examined the hypothesized association by comparing children vaccinated with a thimerosal-containing pertussis vaccine with children vaccinated with the same pertussis vaccine formulated without thimerosal and following them with respect to development of autism and other autistic-spectrum disorders.

METHODS

The Danish childhood vaccination program is voluntary and free of charge to the vaccinees. Vaccines against diphtheria, tetanus, polio, measles, mumps, rubella, pertussis, and *Haemophilus influenzae* type b are administered by general practitioners.[3] From 1970, the only thimerosal-containing vaccine in the program has been the whole-cell pertussis vaccine. In late March 1992, the last batch of thimerosal-containing whole-cell pertussis vaccine was released and distributed from Statens Serum Institut. Only the whole-cell vaccine produced by Statens Serum Institut has been used in Denmark. The same vaccine was reformulated without thimerosal and used until January 1, 1997, when it was replaced with an acellular pertussis vaccine.[4] The whole-cell vaccine was administered at 5 weeks, 9 weeks, and 10 months from 1970 and until it was replaced, irrespective of thimerosal content.[3] The thimerosal formulation contained 50 μg of thimerosal (~25 μg of ethylmercury) in the first

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dose and 100 µg (~50 µg of ethylmercury) in each of the succeeding 2 doses.

Since April 1968, all persons in Denmark have been given a unique identification number in the Danish Civil Registration System.[5] Based on this registry, we constructed a cohort consisting of all children born in Denmark in the period from January 1, 1990, to December 31, 1996. Using the unique personal identification number, we were able to link information on vaccinations, diagnoses of autism, diagnoses of other autistic-spectrum disorders, other relevant diagnoses, and potential confounders to the children in the cohort. The dates of vaccination with 1, 2, or 3 doses of whole-cell pertussis vaccine were obtained from the National Board of Health. We have published details of this process in a study of autistic-spectrum disorders and measles-mumps-rubella vaccine.[6] Doses administered before June 1, 1992, were considered to contain thimerosal, and doses administered after June 1, 1992, were considered thimerosal-free. Children who received thimerosal-free vaccine after 1 or 2 doses of thimerosal-containing vaccine were classified only according to receipt of thimerosal-containing vaccine.

Information on autism and other autistic-spectrum disorder diagnoses was obtained from the Danish Psychiatric Central Register.[6,7] Child psychiatrists make the diagnosis and assign diagnostic codes for this register. In the period 1991-1993, the *International Classification of Diseases, 8th Revision (ICD-8)* was used. In the period 1994 through 2000, the *International Classification of Diseases, 10th Revision (ICD-10)* was used. All cases of autism and other autistic-spectrum disorders in our study have been ascertained using *ICD-10*. Autism was defined by *ICD-10* code F84.0, which is similar to *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)* code 299.00, and other autistic-spectrum disorders were defined by *ICD-10* codes F84.1-F84.9, which are similar to *DSM-IV* codes 299.10 and 299.80.

In 1991-1994, only inpatients were included in the Danish Psychiatric Central Register. From 1995, both inpatients and outpatients were included. Information on diagnoses of tuberous sclerosis, Angelman syndrome, fragile X syndrome, and congenital rubella, conditions associated with autism, was obtained from the National Hospital Discharge Register.[8] Information on possible confounding factors was obtained from the Danish Civil Registration System and the Danish Medical Birth Registry,[9] as follows: child's sex, child's place of birth (Copenhagen, Copenhagen suburbs, area with ≥100 000 population, area with population of 10 000-99 999, area with population of <10 000), birth weight (<2500, 2500-2999, 3000-3499, 3500-3999, ≥4000 g), 5-minute Apgar score (0-7, 8-9, 10), gestational age (<37, 37-41, ≥42 weeks), mother's age at birth of child (<20, 20-24, 25-29, 30-34, 35-39, and ≥40 years), and mother's country of birth (Danish or not). The percentage of missing values for the variables birth weight, gestational age, 5-minute Apgar score, mother's country of birth, and child's place of birth were 6.6%, 6.9%, 6.9%, 0.3%, and 0.03%, respectively.

Children in our cohort contributed person-time to follow-up from 1 year of age or January 1, 1991, whichever occurred last, until a diagnosis of autism, other autistic-spectrum disorder, tuberous sclerosis, Angelman syndrome, fragile X syndrome or congenital rubella, possible death, disappearance or emigration, 11 years of age, or until December 31, 2000, whichever occurred first. Follow-up was begun at 1 year of age because indications for an evaluation of a possible case of autistic-spectrum disorder typically occur after the first year of life. The resulting incidence rates for autism and other autistic-spectrum disorders were analyzed with Poisson regression, producing estimates of rate ratios (RRs) according to vaccination history.[10] Vaccination history was considered a time-varying variable. We estimated the dose-response relationship between thimerosal-containing vaccine and autism and other autistic-spectrum disorders as the increase in RR per 25 µg of ethylmercury. We adjusted all RRs for age (1-9 years of age, ½-year intervals; 10 years of age, 1-year interval) and calendar period (1991-1993, 1994, 1995, 1996, 1997, 1998, 1999, 2000). We further adjusted our estimates for the potential confounding variables previously listed. Statistical analysis was performed using PROC GENMOD in SAS version 6.12 (SAS Institute Inc, Cary, NC).

RESULTS

A total of 467 450 children were born in Denmark between January 1, 1990, and December 31, 1996. During 2 986 654 person-years of follow-up, we identified 440 cases of autism and 787 cases of other autistic-spectrum disorders. The mean (SD) age at diagnosis was 4.7 (1.7) years for autism and 6.0 (1.9) years for other autistic-spectrum disorders. The follow-up of 5770 children was prematurely terminated because of death (n=579), emigration (n=5035), disappearance (n=87), tuberous sclerosis (n=51), Angelman syndrome (n=17), or congenital rubella (n=1).

In our cohort, only 20 755 (4.4%) children did not receive any whole-cell pertussis vaccine, 446 695 (95.6%) were vaccinated at least once, 416 081 (89.0%) were vaccinated twice, and 293 186 (62.7%) received 3 doses of whole-cell pertussis vaccine. Among those who received at least 1 thimerosal-containing pertussis vaccine (n=138 953), 118 593 received 1 subsequent dose and 65 725 received 2 subsequent doses of thimerosal-containing vaccine. Furthermore, 42 032 children who received at least 1 dose of thimerosal-containing vaccine subsequently received at least 1 dose of thimerosal-free vaccine. In those receiving at least 1 dose of whole-cell pertussis vaccine, there were 407 cases of autism (303 receiving thimerosal-free and 104 receiving thimerosal-containing vaccine) and 751 cases of other autistic-spectrum disorders (430 receiving thimerosal-free and 321 receiving thimerosal-containing vaccine).

Comparing children vaccinated with at least 1 dose of thimerosal-containing whole-cell pertussis vaccine with

children vaccinated with a thimerosal-free formulation of the same vaccine, we found a fully adjusted RR of 0.85 (95% confidence interval [CI], 0.60-1.20) for autism and an RR of 1.12 (95% CI, 0.88-1.43) for other autistic-spectrum disorders (TABLE). Furthermore, we found no evidence of a dose-response association between the dose of ethylmercury received and autistic-spectrum disorders (increase in RR per 25 µg of ethylmercury, 0.98 [95% CI, 0.90-1.06] for autism and 1.03 [95% CI, 0.98-1.09] for other autistic-spectrum disorders).

Although doses administered after June 1, 1992, were considered thimerosal-free, it is conceivable that a few thimerosal-containing doses may have been administered during the months after this date. To assess whether misclassification of vaccine type might have biased our estimates, we reestimated the RRs, omitting children vaccinated from June 1, 1992, through December 31, 1992. We found a fully adjusted RR of 0.87 (95% CI, 0.61-1.23) for autism and an RR of 1.15 (95% CI, 0.90-1.47) for other autistic-spectrum disorders and no evidence of a dose-response association (increase in RR per 25 µg of ethylmercury, 0.98 [95% CI, 0.90-1.07] for autism and 1.04 [95% CI, 0.98-1.09] for other autistic-spectrum disorders).

In a further analysis we evaluated the robustness of our results by restricting our cohort to children born in 1991-1993, a presumably more homogeneous group with respect to diagnosis, length of follow-up, and factors not included in this study (eg, mercury exposure through food) and found a fully adjusted RR of 0.86 (95% CI, 0.53-1.39) for autism and an RR of 1.05 (95% CI, 0.77-1.44) for other autistic-spectrum disorders and no evidence of a dose-response association (increase in RR per 25 µg of ethylmercury, 0.97 [95% CI, 0.85-1.10] for autism and 1.04 [95% CI, 0.96-1.13] for other autistic-spectrum disorders).

Finally, we evaluated the impact of missing values by the method of single imputation, replacing a missing value with the most common value of the relevant variable, and found a fully adjusted RR of 0.85 (95% CI, 0.60-1.20) for autism and 1.13 (95% CI, 0.89-1.44) for other autistic-spectrum disorders.

To evaluate whether the incidence of autistic-spectrum disorders was increasing in Denmark in the study period, we calculated time period trends from our cohort. We found statistically significant increases in age-adjusted RR per calendar year for both autism and other autistic-spectrum disorders during the study period (RR, 1.24 [95% CI, 1.17-1.31] for autism; RR, 1.21 [95% CI, 1.16-1.27] for other autistic-spectrum disorders). In the period from January 1, 1995, to December 31, 2000, a period where outpatients were included, we found similar trends (RR, 1.24 [95% CI, 1.16-1.32] for autism; RR, 1.20 [95% CI, 1.13-1.26] for other autistic-spectrum disorders).

COMMENT

We found no evidence of an association between thimerosal-containing vaccine and autism in children who received thimerosal-containing vaccine compared with children who received the same vaccine formulated without thimerosal. Furthermore, there was no indication of a dose-response association between autism and the amount of ethylmercury received through thimerosal.

The hypothesis of an association between thimerosal and autism has primarily been based on biological plausibility through analogies with methylmercury.[2] Ethylmercury, however, is thought to have a shorter half-life in the human body than methylmercury, and no controlled studies of low-dose ethylmercury toxicity in humans have been conducted.[11] Pichichero and colleagues[12] measured the concentration of mercury in the blood, urine, and stool of infants who received thimerosal-containing vaccines and concluded that vaccination did not raise the blood concentration of mercury above safe limits, and that ethylmercury was rapidly

Table. Rate Ratio of Autism and Other Autistic-Spectrum Disorders Comparing Children Vaccinated With a Thimerosal-Containing Vaccine to Children Vaccinated With a Thimerosal-Free Formulation of the Same Vaccine

		Autism			Other Autistic-Spectrum Disorders		
	Person-Years at Risk	No. of Cases	RR (95% CI)*	RR (95% CI)†	No. of Cases	RR (95% CI)*	RR (95% CI)†
Vaccinations							
All thimerosal-free	1 660 159	303	1.00	1.00	430	1.00	1.00
Any containing thimerosal	1 220 006	104	0.85 (0.60-1.20)	0.85 (0.60-1.20)	321	1.12 (0.88-1.43)	1.12 (0.88-1.43)
Doses of thimerosal-containing vaccine							
None	1 660 159	303	1.00	1.00	430	1.00	1.00
1 dose (25 µg eHg)	169 920	18	0.99 (0.59-1.68)	1.01 (0.60-1.71)	40	0.96 (0.67-1.39)	0.95 (0.66-1.37)
2 doses (75 µg eHg)	447 973	33	0.71 (0.46-1.09)	0.70 (0.46-1.09)	130	1.20 (0.92-1.56)	1.20 (0.92-1.56)
3 doses (125 µg eHg)	602 113	53	0.96 (0.63-1.46)	0.96 (0.63-1.47)	151	1.11 (0.83-1.48)	1.13 (0.84-1.51)
Trend (increase in RR per 25 µg eHg)			0.98 (0.90-1.06)	0.98 (0.90-1.06)		1.03 (0.97-1.09)	1.03 (0.98-1.09)

Abbreviations: CI, confidence interval; eHg, ethylmercury; RR, rate ratio.
*Adjusted for confounders: age and calendar period.
†Fully adjusted: age, calendar period, child's sex, child's place of birth, birth weight, 5-minute Apgar score, gestational age, mother's age at birth of child, and mother's country birth.

eliminated via the stools. They estimated the blood half-life of ethylmercury at 7 days (95% CI, 4-10 days), although their study was not designed as a formal pharmacokinetic study of ethylmercury.

In 1999, when thimerosal was still widely used, children in the US childhood immunization program would have received 187.5 μg of ethylmercury by the age of 6 months and 237.5 μg of ethylmercury by the age of 2 years.[2] In Denmark, children would have received 125 μg of ethylmercury by the age of 10 months. However, in the Danish program, children received larger doses of ethylmercury per vaccine (50 μg compared with 25 μg in the United States) so that at 3 months, Danish children would have received the same amount of ethylmercury as US children (75 μg).[2]

To our knowledge, our study is the first population-based cohort study to examine the association between thimerosal and autism. In Denmark since 1970, only the whole-cell pertussis vaccine was formulated with thimerosal, and this vaccine was the only one used for pertussis immunization until it was replaced with an acellular pertussis vaccine in 1997. The unique situation has allowed a direct comparison of children vaccinated with a thimerosal-containing whole-cell pertussis vaccine with children vaccinated with the same vaccine formulated without thimerosal, and thus we have avoided confounding by contraindication and other selection bias associated with unvaccinated children. Furthermore, we have no reason to believe that the 2 groups of children differ with respect to other potential risk factors for autism.

All data used in this study were collected prospectively, eliminating concerns about recall bias. Madsen and colleagues[6] reviewed the medical records of 40 children with autism from the Danish Psychiatric Central Register and found that 37 children met the operational criteria for autism according to a systematic coding scheme developed by the Centers for Disease Control and Prevention.[13] Furthermore, Madsen and colleagues[6] found Danish prevalence rates for autism and other autistic-spectrum disorders comparable to prevalence rates found in other studies. Thus we conclude that the validity and completeness of the autism and other autistic-spectrum disorder diagnoses in the Danish Psychiatric Central Register is high. However, it is possible that the National Hospital Discharge Register is not complete with respect to a diagnosis of tuberous sclerosis, Angelman syndrome, fragile X syndrome, and congenital rubella. However, these conditions are rare in the general population and since we have compared only vaccinated children, lack of completeness is unlikely to seriously confound an association between thimerosal content and autistic-spectrum disorder.

We found statistically significant increased rates over time for both autism and other autistic-spectrum disorders. These results are compatible with a dramatic increase in the number of diagnosed cases of autistic-spectrum disorders during the study period, similar to what has been observed in other countries (eg, the United States).

In Denmark, general practitioners administer all childhood vaccinations and are reimbursed when reporting these to the National Board of Health, thus ensuring a high degree of completeness. In our cohort we found that 96%, 89%, and 63% of children were vaccinated at least once, at least twice, and 3 times with whole-cell pertussis vaccine. The low uptake of 3 doses is unexpected but can be partially explained by the transition to acellular pertussis vaccine in January 1997. Furthermore, for each dose there is a small chance of either missing the dose or the vaccination not being recorded. Even small probabilities for each dose can, if they are statistically independent, result in a significant reduction in the calculated uptake of all 3 doses.

A possible weakness of this study is that the date of diagnosis used as the incidence date may differ significantly from the "onset of symptoms" date. A diagnosis of autistic-spectrum disorder can be a lengthy process; this is reflected in the mean ages of diagnoses in this study (4.7 years for autism and 6.0 years for other autistic-spectrum disorders). However, this is more likely to be a problem in an incidence study than in a risk factor study.

In conclusion, our results are not compatible with the hypothesis of a causal association between thimerosal and autistic-spectrum disorders.

Author Contributions: *Study concept and design:* Hviid, Stellfeld, Wohlfahrt, Melbye.
Analysis and interpretation of data: Hviid, Wohlfahrt.
Drafting of the manuscript: Hviid.
Critical revision of the manuscript for important intellectual content: Stellfeld, Wohlfahrt, Melbye.
Statistical expertise: Hviid, Wohlfahrt.
Obtained funding: Hviid, Melbye.
Study supervision: Wohlfahrt, Melbye.
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Volume 13 – Number 2 October 2003

NEEDLE TIPS
and the Hepatitis B Coalition News

Published by the Immunization Action Coalition for individuals and organizations concerned about vaccine-preventable diseases

WHAT'S ON THE INSIDE:

Ask the Experts

Editor's note: The Immunization Action Coalition thanks William L. Atkinson, MD, MPH; Linda A. Moyer, RN; and Eric E. Mast, MD, of the Centers for Disease Control and Prevention (CDC) for answering the following questions for our readers. Dr. Atkinson, medical epidemiologist at the National Immunization Program, serves as a CDC liaison to the Coalition. Ms. Moyer is an epidemiologist and Dr. Mast is a medical epidemiologist, both at CDC's Division of Viral Hepatitis.

Immunization questions?

- Email nipinfo@cdc.gov
- Call CDC's Immunization Information Hotline at (800) 232-2522
- Call your state health dept. (phone numbers at: www.immunize.org/coordinators)

Immunization questions

by William L. Atkinson, MD, MPH

How can we quickly determine how to "catch up" children who have fallen behind on their shots, and can we still use combination vaccines while doing so?

As a general rule, infants or children who are more than one month or one dose behind schedule should be on an accelerated schedule, which means the intervals between doses should be reduced to the minimum allowable. Beginning with the 2003 "Recommended Childhood and Adolescent Immunization Schedule" issued by ACIP, AAP, and AAFP, a "catch-up" schedule is now included on the second page. To obtain a copy, go to www.immunize.org/cdc/child-schedule.pdf

Combination vaccines can also be used on an accelerated schedule. The minimum intervals between doses are determined by the individual components that have the longest minimum interval.

What should we do if we give an injection by the wrong route (e.g., IM instead of SC)?

Vaccines should always be given by the route recommended by the manufacturer because data regarding safety and efficacy of alternate routes are limited. However, ACIP recommends that vaccines given by the wrong route be counted as valid with two exceptions: hepatitis B or rabies vaccine given by any route other than IM should not be

(continued on page 20)

NEEDLE TIPS

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www.izcoalitions.org

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The **Immunization Action Coalition (IAC)**, a 501(c)3 nonprofit organization, publishes practical immunization information for health professionals to help increase immunization rates and prevent disease.

The **Hepatitis B Coalition,** a program of IAC, promotes hepatitis B vaccination for all children 0–18 years; HBsAg screening for all pregnant women; testing and vaccination for high-risk groups; and education and treatment for people chronically infected with hepatitis B.

What others say about IAC

It is with great pleasure and pride that we reproduce in this column a sampling of comments culled from letters of support for our work from highly respected individuals and organizations. We share these because we want you to feel comfortable placing your trust in the information IAC provides. Many thanks to those who gave us permission to share their kind words.

"I have had more than a dozen years of experience in collaborating with the dedicated IAC directors and staff in shaping and delivering messages about vaccine-preventable diseases . . . IAC has a proven track record for utilizing a broad range of communication venues to reach health professionals. These include well-written and entertaining newsletters, electronic e-mail messaging for instant updates, durable vaccine use reference tables for posting in offices for ready access by nurses, and omnibus website design with excellent links to reliable secondary sites. . . . To put it simply, no organization does it better."

Thomas N. Saari, MD, FAAP
Prof. of Pediatrics, Div. of Pediatric Inf. Disease
University of Wisconsin Medical School

"IAC is extremely effective because it has its fingers on the pulse of the immunization system in the U.S. IAC tailors its output to be useful to parents and health workers, dealing with issues of concern in real time, with practical information and advice, using a variety of media (conferences, four websites, listservs, printed materials, references, videos, Q & As, etc.). Whether the issue is a vaccine safety concern, practical problems in delivering a birth dose of hepatitis B vaccine, or the best ways to immunize difficult-to-access high-risk groups, IAC has more than a decade of experience in translating health policy into useful advice, and backing that up with the most relevant information."

Mark A. Kane, MD, MPH
Director, Children Vaccine Program at PATH

"Of special note has been your ability to prepare materials in many different languages so that families, health care workers, and the media are able to avail themselves of the most reliable information. Your collaborations with CDC as well as other groups concerned with infant, child, adolescent, and adult immunization are legendary and we constantly stand in awe of the productivity of IAC."

Samuel L. Katz, MD
Wilburt C. Davison Professor & Chairman Emeritus
Duke Children's Hospital and Health Center

"Because the goals of the Asian Liver Center are to provide health education and blood screening for Asian populations at risk for hepatitis B, we commend the IAC's efforts to reach out to diverse populations by providing Vaccine Information Statements (VISs) in 28 languages . . . IAC is uniquely situated to distribute materials to inform and motivate the health care community to meet the needs of underserved populations, high-risk groups, and the general public."

Samuel So, MD
The Lui Hac Minh Professor
Director, Asian Liver Center at Stanford University

"The Immunization Action Coalition is one of our department's most valuable partners! They help to evaluate, translate, and condense research and educational data into usable tools. They are a professional resource that we use daily because we can depend on their reliability. The IAC has helped us increase our immunization rates and prevent disease."

Marci Eckerson, RN
Nurse Consultant and Hepatitis B Coordinator
Montana Dept. of Public Health & Human Services

"Potentially harmful misinformation about immunization is circulating on the Internet, in the media, and in congressional hearings related to vaccine safety . . . IAC consistently has been an effective voice in addressing these misconceptions. IAC's publications, websites, and other educational materials are up-to-date, understandable, and effective resources for parents and the health professionals who communicate with them. . . We look forward to continuing to collaborate with IAC to provide up-to-date, science-based information about immunization to health professionals, the media, policy makers, and the public . . ."

Louis Z. Cooper, MD, FAAP
National Network for Immunization Information

"The AMA's Group on Science, Quality, and Public Health has been collaborating with the not-for-profit IAC for more than five years. . . . The AMA has found the many materials on immunization and viral hepatitis provided by the IAC such as *NEEDLE TIPS*. . . to be remarkably useful and well designed. In fact, we promote the availability of these publications on our Infectious Disease website. Our collaborations with Dr. Wexler, her staff, and IAC have been very productive and useful to both organizations."

Michael J. Scotti, Jr., MD
Senior Vice President, Professional Standards
American Medical Association

Vaccine highlights

Recommendations, schedules, and more

Editor's note: The information on these pages is current as of September 22, 2003.

The next ACIP meetings

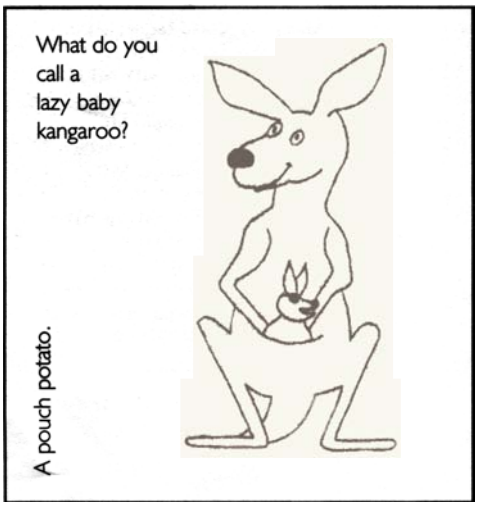
The Advisory Committee on Immunization Practices (ACIP) is a committee of 15 national experts that provides advice and guidance to the Centers for Disease Control and Prevention (CDC) regarding the most appropriate use of vaccines. ACIP meetings are held three times a year in Atlanta, Ga., and are open to the public. The next meetings will be held on Oct. 15–16, 2003, and Feb. 25–26, 2004. For more information, visit www.cdc.gov/nip/acip

ACIP statements

All clinicians should have a set of ACIP statements, the public health recommendations on vaccines, published in the *Morbidity and Mortality Weekly Report (MMWR)*. Free continuing education credits are available for reading many of the statements and completing the brief test at the end of the statement.

To obtain ACIP statements:

- Download individual statements from links on IAC's website: www.immunize.org/acip
- Download individual statements from links on CDC's website: www.cdc.gov/mmwr
- Call CDC's Immunization Information Hotline: (800) 232-2522.
- Order the "Immunization Works" CD (CDC, 2003). It contains all ACIP statements, VISs, and *The Pink Book*. Use CDC's free online ordering system: https://www2.cdc.gov/nchstp_od/PIWeb/niporderform.asp



Vaccine news

On July 7, FDA approved a supplement to the license application for Infanrix (DTaP; GlaxoSmithKline) to allow providers to give the vaccine as a fifth consecutive DTaP dose to children age 4–6 years.

On June 17, FDA approved a license application for FluMist, live attenuated influenza vaccine (LAIV). LAIV is indicated for active immunization against influenza A and B viruses in healthy persons 5–49 years of age. FluMist is a product of MedImmune Vaccines and is distributed by Wyeth Vaccines.

On June 16, Aventis Pasteur began shipping single-dose vials of Menomune (meningococcal vaccine) to its customers once again. Earlier in the year, FDA extended the shelf life of the 10-dose vials of Menomune to 35 days after reconstitution; the shelf life of single-dose reconstituted vaccine remains at 30 minutes.

On May 16, CDC announced the end of the shortage of Prevnar (pneumococcal conjugate vaccine). Providers are urged to initiate catch-up vaccination efforts to reach children who are incompletely vaccinated. The priority for catch-up is 1) to vaccinate children less than 5 years of age who are at high risk for invasive pneumococcal disease because of medical conditions and 2) to vaccinate healthy children less than 24 months who have not received any doses of PCV and those less than 12 months who have not yet received 3 doses.

On April 25, CDC published a Notice to Readers (NTR) in *MMWR* that clarified a previously published NTR concerning the use of Pediarix. The 2nd NTR clarified that according to ACIP, Pediarix may be administered to infants born to women who are hepatitis B surface antigen (HBsAg) positive or whose HBsAg status is unknown, following the birth dose of single-antigen hepatitis B vaccine. This allows for broader use of Pediarix than is included in the prescribing information.

Influenza news

In September, CDC published two influenza VISs—an updated 2003–04 Inactivated Influenza VIS and a new Live, Intranasal Influenza VIS. We have included reduced-size copies of both on pages 18–19. Full-size copies are available on the Immunization Action Coalition website at www.immunize.org/vis

On August 22, CDC announced that sufficient supplies of influenza vaccine will be available during October and November; consequently, influenza vaccination efforts can proceed this fall at the same time for all persons (high-risk as well as healthy persons). A tiered approach for vaccine delivery (vaccinating only high-risk persons first) will not be necessary this year.

In August, AMA's CPT Editorial Panel made a special exemption to allow two new CPT codes, part of the Category I Vaccine Codes for 2004, to be available during the upcoming influenza vaccination season. The panel agreed to place an effective date of November 15, 2003, on CPT code 90655 (preservative-free vaccine for individuals age 6–35 months) and CPT code 90656 (preservative-free vaccine for individuals age 3 years and older). Health professionals who will be administering preservative-free influenza vaccine should first check with their health plans to see when they will be ready to accept claims using these two new CPT codes. Other influenza ~~CPT~~ codes are as follows:

- Inactivated, for those 6–35 mos. of age: 90657
- Inactivated, for those ≥3 yrs of age: 90658
- Live, for intranasal use: 90660
- For CPT codes of preservative-free influenza vaccine, see the paragraph above.

On April 25, the ACIP statement "Prevention and Control of Influenza" was published in *MMWR* (Vol. 52, No. RR-8). The primary target groups recommended for vaccination remain the same as for the 2002–03 vaccination season. Vaccination of children age 6–23 months continues to be encouraged owing to their substantially increased risk for influenza-related hospitalization.

A supplemental ACIP statement concerning live attenuated influenza vaccine will be published in *MMWR* on September 26, 2003.

Flu & PPV news from CMS

Effective October 1, Medicare will increase maximum allowable reimbursement for pneumococcal vaccine to $18.62 per dose (previously $13.10).

Looking for your state health department immunization and hepatitis consultants?

For phone numbers of people to contact at your state (or federal project) health department for help on immunization issues, the Vaccines For Children program, or hepatitis A, B, or C, visit:

www.immunize.org/coordinators

For influenza vaccine, maximum reimbursement will be $9.95 per dose (previously $8.02). Medicare administration-fee allowances for influenza, pneumococcal, and hepatitis B vaccines are available from the Centers for Medicare & Medicaid Services (CMS) website at www.cms.hhs.gov/medlearn/2003adminrates.pdf

On August 15, the Department of Health and Human Services published the Final Rule for Electronic Submission of Medicare Claims. The Administrative Simplification Compliance Act requires nearly all claims sent to the Medicare Program be submitted electronically beginning October 16, 2003. However, providers wishing to submit paper roster bills for vaccinations are exempt from this requirement. Review the rule and the few exceptions to these requirements at http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/pdf/03-20955.pdf

New vaccine resources

On August 22, CDC released the 2003–04 edition of *Health Information for International Travel* (the Yellow Book). It is available from the Public Health Foundation at http://bookstore.phf.org/cat24.htm or by calling (877) 252-1200.

In July, the American Academy of Pediatrics (AAP) released *Red Book: 2003 Report of the Committee on Infectious Diseases*. It is available in several formats, including soft cover, CD-ROM, and PDA. Cost: $95–$175. To order, call customer service at (888) 227-1770 or visit AAP's website at www.aap.org

Current VIS dates

Here are the most current VISs and the issue date printed at the bottom of each. Make sure you are using the current ones. Please recycle old copies.

DTaP/DT/DTP	7/30/01	MMR	1/15/03
Td	6/10/94	varicella	12/16/98
polio	1/1/00	Hib	12/16/98
hepatitis A	8/25/98	hepatitis B	7/11/01
pneumo (PCV)	9/30/02	meningococcal	7/28/03
pneumo (PPV)	7/29/97	smallpox	1/16/03
yellow fever	3/14/03	anthrax	4/24/03
influenza, inactivated			5/6/03
influenza, live intranasal			9/4/03

VISs and instructions on how to use them can be obtained from CDC's website: www.cdc.gov/nip/publications/vis or from your state health department (for contact information see box on page 4). The VISs, some in 28 languages, and the VIS instruction sheet are also available on IAC's website: www.immunize.org/vis

Give these people influenza vaccine!

WHY? This year, influenza is again expected to kill more than 35,000 people in the United States.

The Centers for Disease Control and Prevention (CDC) recommends that persons in the following groups receive influenza vaccine. Check the list below and make sure you offer influenza vaccine to all who need or want it.

☐ **ALL persons 50 years of age and older**

☐ **Persons with certain high-risk medical conditions**

Any person (6 months of age or older) who is at increased risk for complications from influenza because of underlying medical conditions, including

- ✓ residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions
- ✓ adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including asthma
- ✓ adults and children who have required regular medical follow-up or hospitalization during the past year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression
- ✓ children and adolescents (age 6 months to 18 years) who are receiving long-term aspirin therapy and therefore might be at risk for developing Reye's syndrome after influenza illness
- ✓ all women who will be in the second or third trimester of pregnancy (greater than 14 weeks gestation) during the influenza season. Pregnant women who have medical conditions that increase their risk for complications from influenza should be vaccinated before the influenza season—regardless of the stage of pregnancy.

☐ **Household contacts of high-risk persons (listed above) and of children 0–23 months of age**

☐ **ALL children age 6–23 months are encouraged to be vaccinated because of their increased risk for influenza-related hospitalization**

☐ **ANY person who wishes to reduce the likelihood of becoming ill with influenza as long as the person has no contraindications to the vaccine and is at least 6 months of age**

☐ **Health care workers**

Health care workers and others in close contact with persons in high-risk groups should be vaccinated to decrease the risk of transmitting infection to persons for whom influenza could be a serious, life-threatening disease. Those who should be vaccinated include the following:

- ✓ physicians, nurses, receptionists, and other personnel who have contact with patients in both hospital and outpatient settings, including medical emergency response workers
- ✓ employees of nursing homes and chronic-care facilities who have contact with patients or residents
- ✓ employees of assisted living and other residences for persons in high-risk groups
- ✓ persons who provide home care to people high-risk groups

☐ **Other groups to consider:**

- ✓ travelers at high risk for influenza complications who were not vaccinated in the previous fall or winter and who plan to travel to the Southern hemisphere between April and September, to the tropics, or with a large tourist group at any time of the year
- ✓ persons who provide essential community services (e.g., firefighters, police)
- ✓ students or other persons in institutional settings (e.g., those who reside in dormitories)

Persons who should not be vaccinated:

Consult the current recommendations from CDC for guidance on contraindications and precautions for use of inactivated influenza vaccine and live attenuated influenza vaccine.

Note: The newly licensed live attenuated intranasal influenza vaccine (FluMist™) should only be used in healthy, nonpregnant persons 5–49 years of age.

Sources: "Prevention and Control of Influenza—Recommendations of ACIP," MMWR, April 2 2003, Vol. 52, No. RR-8; and "Using Live, Attenuated Influenza Vaccine for Prevention and Control of Influenza. Supplemental Recommendations of ACIP," anticipated publication date i MMWR: Sept 26, 2003.

Summary of Rules for Childhood Immunization*

Adapted from ACIP, AAP, and AAFP by Immunization Action Coalition, September 2003

Vaccine	Ages usually given and other guidelines	If child falls behind	Contraindications
Hepatitis B *Give IM*	• Vaccinate all newborns prior to hospital discharge. Give dose #2 at 1–4m and dose #3 at 6–18m. After the first dose, the series may be completed with single-antigen vaccine or up to 3 doses of Comvax (2m, 4m, 11–15m of age) or Pediarix (2m, 4m, 6m of age). Dose #1 can be given as late as age 2m if the mother is known to be HBsAg negative, but this is not the preferred schedule. • Vaccinate all children 0 through 18yrs of age. • For older children, schedules include: 0-, 1-, 6m; 0-, 2-, 4m; 0-, 1-, 4m. • Children born (or whose parents were born) in countries where hepatitis B virus infection is highly endemic should be vaccinated ASAP. • **If mother is HBsAg-positive:** give the newborn HBIG + dose #1 within 12hrs of birth, #2 at 1–2m, and #3 at 6m of age. • **If mother's HBsAg status is unknown:** give the newborn dose #1 within 12hrs of birth, #2 at 1–2m, and #3 at 6m of age. If mother is subsequently found to be HBsAg positive, give infant HBIG within 7d of birth. • **Note:** For premature infants, hepatitis B vaccination recommendations may be different. Consult the *2003 AAP Red Book* (pp. 66–68). • May give with all other vaccines.	• Do not restart series, no matter how long since previous dose. • 3-dose series can be started at any age. • Minimum spacing for children and teens: 4wks between #1 & #2, and 8wks between #2 & #3. Overall there must be ≥16wks between #1 & #3. • The last dose in infant hepatitis B series should not be given earlier than age 6m.	**Special Notes on Hepatitis B Vaccine** **Dosing of hepatitis B vaccines:** Vaccine brands are interchangeable for 3-dose schedules. For Engerix-B, use 10mcg for 0 through 19yrs of age. For Recombivax HB, use 5mcg for 0 through 19yrs of age. **Alternative dosing schedule for unvaccinated adolescents age 11 through 15yrs:** Give Recombivax HB two 10mcg doses (adult dosage) spaced 4–6m apart. (Engerix-B is not licensed for a 2-dose schedule.)
DTaP (Diphtheria, tetanus, acellular pertussis) *Give IM*	• Give at 2m, 4m, 6m, 15–18m, 4–6yrs of age. • May give dose #1 as early as 6wks of age. • May give #4 as early as 12m of age if 6m have elapsed since #3 and the child is unlikely to return at age 15–18m. • Do not give DTaP to children ≥7yrs of age (give Td). • May give with all other vaccines. • It is preferable but not mandatory to use the same DTaP product for all doses.	• #2 & #3 may be given 4wks after previous dose. • #4 may be given 6m after #3. • If #4 is given before 4th birthday, wait at least 6m for #5 (4–6yrs of age). • If #4 is given after 4th birthday, #5 is not needed.	**Contraindication for DTaP only:** Previous encephalopathy within 7d after DTP/DTaP. **Precautions for DTaP:** The following are precautions, not contraindications. When these conditions are present, the individual child's disease risk should be carefully assessed. In situations when the benefit outweighs the risk (e.g., community pertussis outbreak), vaccination should be considered. • T≥105°F (40.5°C) within 48hrs after previous dose. • Continuous crying lasting ≥3hrs within 48hrs after previous dose. • Previous convulsion within 3d after immunization. • Pale or limp episode or collapse within 48hrs after previous dose. • Unstable progressive neurologic problem (defer until stable).
DT *Give IM*	• Give to children <7yrs of age if child had a serious reaction to "P" in DTaP/DTP or if parents refuse the pertussis component. • May give with all other vaccines.		
Td *Give IM*	• Use Td, not tetanus toxoid (TT), for persons ≥7yrs of age for all indications • A booster dose is recommended for children 11–12yrs of age if 5yrs have elapsed since last dose. Then boost every 10yrs. • May give with all other vaccines.	• For unvaccinated patients: give dose #1 now, give 2nd dose 4wks later, give 3rd dose 6m after #2, then give booster every 10yrs.	
MMR (Measles mumps, rubella) *Give SC*	• Give #1 at 12–15m of age. Give #2 at 4–6yrs of age. • Make sure that all children and teens over 4–6yrs of age have received both doses of MMR. • If a dose was given before 12m of age, it doesn't count as the first dose, so give #1 at 12–15m of age with a minimum interval of 4wks between the invalid dose and dose #1. • May give with all other vaccines. • If MMR and Var (and/or yellow fever vaccine) are not given on the same day, space them ≥28d apart. • 2 doses of MMR are recommended for all children ≤18yrs of age.	• Dose should be given whenever it is noted that a child is behind. Exception: If MMR and Var (and/or yellow fever vaccine) are not given on the same day, space them ≥28d apart. • Dose #2 can be given at any time if at least 28d have elapsed since dose #1 and both doses are administered after 1yr of age.	• Pregnancy or possibility of pregnancy within 4 weeks. • If blood, plasma, and/or immune globulin were given in past 11m, see ACIP statement *General Recommendations on Immunization*† regarding time to wait before vaccinating. • HIV is NOT a contraindication unless severely immunocompromised. • Immunocompromised persons (e.g., because of cancer, leukemia, lymphoma). **Note:** For patients on high-dose immunosuppressive therapy, consult ACIP recommendations† regarding delay time. **Note:** MMR is not contraindicated if a PPD test was recently applied. If PPD and MMR not given on same day, delay PPD for 4–6wks after MMR.
Varicella (Var) (Chickenpox) *Give SC*	• Give at 12–18m of age. • Vaccinate all children ≥12m of age including all adolescents who have not had chickenpox. • May use as postexposure prophylaxis if given within 3–5d. • May give with all other vaccines. • If Var and MMR (and/or yellow fever vaccine) are not given on the same day, space them ≥28d apart. • Do not withhold vaccine from children of pregnant women.	• Do not give to children <12m of age. • Susceptible children <13yrs of age should receive 1 dose. • Susceptible persons ≥13yrs of age should receive 2 doses 4–8wks apart.	• Pregnancy or possibility of pregnancy within 4 weeks. • If blood, plasma, and/or immune globulin (IG or VZIG) were given in past 11m, see ACIP statement *General Recommendations on Immunization*† regarding time to wait before vaccinating. • Persons immunocompromised because of high doses of systemic steroids, cancer, leukemia, lymphoma, or immunodeficiency. **Note:** For patients with humoral immunodeficiency, HIV infection, or leukemia, or for patients on high doses of systemic steroids, see ACIP recommendations.† • For children taking salicylates, see ACIP recommendations.†

Do not give if patient (1) has had an anaphylactic reaction to a prior dose or to any vaccine component or (2) has a moderate or severe acute illness. (Minor illness is not a reason to postpone vaccination.)

Summary of Rules for Childhood Immunization* (continued)

Vaccine	Ages usually given and other guidelines	If child falls behind	Contraindications
Polio (IPV) *Give SC or IM*	• Give at 2m, 4m, 6–18m, and 4–6yrs of age. • May give #1 as early as 6wks of age. • Not routinely recommended for those ≥18yrs of age (except certain travelers) • May give with all other vaccines.	• All doses should be separated by at least 4wks. • If #3 of an all-IPV series is given at ≥4yrs of age, dose #4 is not needed. • Those who receive a combination of IPV and OPV doses should receive all 4 doses	Do not give if patient (1) has had an anaphylactic reaction to a prior dose or to any vaccine component or (2) has a moderate or severe acute illness. (Minor illness is not a reason to postpone vaccination.)
Hib (*Haemophilus influenzae* type b) *Give IM*	• HibTITER (HbOC) & ActHib (PRP-T): give at 2m, 4m, 6m, 12–15m (booster dose). • PedvaxHIB or Comvax (containing PRP-OMP): give at 2m, 4m, 12–15m. • Dose #1 of Hib vaccine may be given as early as 6wks of age but no earlier. • The last dose (booster dose) is given no earlier than 12m of age and a minimum of 8wks after the previous dose. • May give with all other vaccines. • Hib vaccines are interchangeable; however, if different brands of Hib vaccines are administered, a total of three doses are necessary to complete the primary series in infants. • Any Hib vaccine may be used for the booster dose. • Hib is not routinely given to children ≥5yrs of age.	**Rules for all Hib vaccines:** • If #1 was given at 12–14m, give a booster dose in 8wks. • Give only 1 dose to unvaccinated children ≥15m and <5yrs of age. **Rules for HibTITER and ActHib:** • #2 and #3 may be given 4 wks after previous dose. • If #1 was given at 7–11m, only 3 doses are needed; #2 is given 4–8wks after #1 then boost at 12–15m. **Rules for PedvaxHiB and Comvax:** • #2 may be given 4wks after dose #1	
Hepatitis A *Give IM*	• Vaccinate children ≥2yrs old who live in areas with consistently elevated rates of hepatitis A, as well as children who have specific risk factors. (See ACIP statement† and column to right for details.) • Children who travel outside of the U.S. (except to Western Europe, New Zealand, Australia, Canada, or Japan). • Dose #2 is given a minimum of 6m after dose #1. • Dose #1 may not be given earlier than 2yrs of age. • May give with all other vaccines.	• Do not restart series, no matter how long since previous dose. • Hepatitis A vaccine brands are interchangeable. • Consult your local/state public health authority for information regarding your city county, or state hepatitis A rates. States with consistently elevated rates (average ≥10 cases per 100,000 population from 1987-1997) include the following: AL, AZ, AK, CA, CO, ID, MO, MT, NV, NM, OK, OR, SD, TX, UT, WA, and WY.	
Pneumococcal — **PCV** *Give IM*	• Give at 2m, 4m, 6m, and 12–15m of age. • Dose #1 may be given as early as 6wks of age. • For unvaccinated high-risk children (defined below) 24–59m of age, give 2 doses. If PPV not previously given, administer ≥8wks after final dose of PCV. • For unvaccinated moderate-risk children (defined below) 24–59m of age, consider giving 1 dose. • May give 1 dose to unvaccinated healthy children 24–59m. • PCV is not routinely given to children ≥5yrs of age. • May give with all other vaccines.	• Minimum interval between doses for infants <12m of age is 4wks, for ≥12m of age is 8wks. • For infants 7–11m of age: If unvaccinated, give dose #1 now, give 2nd dose 4–8wks later, and boost at 12–15m. If infant has had 1 or 2 previous doses, give next dose now, and boost at 12–15m. • For children 12–23m: If not previously vaccinated or only one previous dose before 12m, give 2 doses ≥8wks apart. If child previously had 2 doses, give booster dose ≥8wks after previous dose.	
	High-risk children: Those with sickle cell disease; anatomic/functional asplenia; chronic cardiac, pulmonary, or renal disease; diabetes mellitus; CSF leak; HIV infection; or immunosuppression. **Moderate-risk children:** Children age 24–35m; children age 24–59m who attend group day care centers or are of Alaska Native, American Indian, or African American descent.		
PPV *IM or SC*	Give PPV to high-risk children ≥2yrs of age as recommended in the ACIP statement *Prevention of Pneumococcal Disease* (4/4/97).†		
Influenza *Give IM or intranasally*	Vaccinate children ≥6m of age with risk factors and encourage vaccination of all children age 6–23m. Inactivated influenza vaccine (IIV) may be used for children ≥6m of age who have no contraindications. Live attenuated influenza vaccine (LAIV) may be used for children ≥5yrs of age who have no contraindications. For details, see the *2003 AAP Red Book* or CDC's current ACIP statement on influenza.†		
Meningococcal *Give SC*	Vaccinate children ≥2yrs of age with risk factors. Discuss disease risk and vaccine availability with college students. Consult ACIP statement on meningococcal disease (6/30/00) for details.†		

* Licensed combination vaccines may be used whenever any components of the combination are indicated and the vaccine's other components are not contraindicated. The following combination vaccines are currently licensed: Hib-HepB (Comvax), DTaP-HepB-IPV (Pediarix), DTaP-Hib (Trihibit), and HepA-HepB (Twinrix). Rules for use of combination vaccines consist of those applicable to each of the components.

† For more complete information, see the ACIP statements, which are published in the *MMWR*. To obtain them, visit www.cdc.gov/nip/publications/ACIP-list.htm or visit the Immunization Action Coalition's (IAC) website at www.immunize.org/acip For recommendations of the American Academy of Pediatrics (AAP), consult AAP's *2003 Red Book* and the journal *Pediatrics,* or visit www.immunize.org/aap To view the AAFP/AAP/CDC Recommended Childhood and Adolescent Immunization Schedule—U.S., visit www.immunize.org/cdc/child-schedule.pdf

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Summary of Recommendations for Adult Immunization

Adapted from the recommendations of the Advisory Committee on Immunization Practices (ACIP)* by the Immunization Action Coalition, September 2003

Vaccine name and route	For whom it is recommended	Schedule for routine and "catch-up" administration	Contraindications (mild illness is not a contraindication)
Influenza Inactivated influenza vaccine (IIV) *Give IM* Live attenuated influenza vaccine (LAIV) *Give intranasally*	[illegible] heart disease, lung disease, diabetes, renal [illegible] or people living in chronic care facilities [illegible] or 3rd trimesters during influenza season [illegible] people from [illegible]	• Given every year. • October through November is the *optimal* time to receive an annual influenza shot to maximize protection. • Influenza vaccine may be given at any time during the influenza season (typically December through March) or at other times when the risk of influenza exists. • May give with all other vaccines.	• Previous anaphylactic reaction to this vaccine, to any of its components, or to eggs. • Moderate or severe acute illness. • Do not give live attenuated influenza vaccine (LAIV) to persons ≥50 years of age, pregnant women, or to persons who have: asthma, reactive airway disease or other chronic disorder of the pulmonary or cardiovascular systems; an underlying medical condition, including metabolic diseases such as diabetes, renal dysfunction, and hemoglobinopathies; a known or suspected immune deficiency disease or who are receiving immunosuppressive therapy; a history of Guillain-Barré syndrome. **Note:** Use of inactivated influenza vaccine (IIV) is preferred for persons in close contact with immunosuppressed persons.
	Special Note on Influenza Vaccines: Inactivated influenza vaccine (IIV) may be given to any person ≥6 months of age for whom the vaccine is not contraindicated. Live attenuated influenza vaccine (LAIV) may be given to healthy, non-pregnant persons 5–49 years of age for whom the vaccine is not contraindicated.		
Pneumococcal polysaccharide (PPV23) *Give IM or SC*	• Adults who are 65yrs of age or older. • People 2–64yrs of age who have chronic illness or other risk factors, including chronic cardiac or pulmonary diseases, chronic liver disease, alcoholism, diabetes mellitus, CSF leaks, candidate for or recipient of cochlear implant, as well as people living in special environments or social settings (including Alaska Natives and certain American Indian populations). Those at highest risk of fatal pneumococcal infection are people with anatomic asplenia, functional asplenia, or sickle cell disease; immunocompromised persons including those with HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, or nephrotic syndrome; persons receiving immunosuppressive chemotherapy (including corticosteroids); and those who received an organ or bone marrow transplant. Pregnant women with high-risk conditions should be vaccinated if not done previously.	• Routinely given as a one-time dose; administer if previous vaccination history is unknown. • One-time revaccination is recommended 5yrs later for people at highest risk of fatal pneumococcal infection or rapid antibody loss (e.g., renal disease) and for people ≥65yrs of age if the 1st dose was given prior to age 65 and ≥5yrs have elapsed since previous dose. • May give with all other vaccines.	• Previous anaphylactic reaction to this vaccine or to any of its components. • Moderate or severe acute illness. **Note:** Pregnancy and breastfeeding are not contraindications to the use of this vaccine.
Hepatitis B (Hep B) *Give IM* Brands may be used interchangeably.	• All adolescents. • High-risk adults, including household contacts and sex partners of HBsAg-positive persons; users of illicit injectable drugs; heterosexuals with more than one sex partner in 6 months; men who have sex with men; people with recently diagnosed STDs; patients receiving hemodialysis and patients with renal disease that may result in dialysis; recipients of certain blood products; health care workers and public safety workers who are exposed to blood; clients and staff of institutions for the developmentally disabled; inmates of long-term correctional facilities; and certain international travelers. **Note:** Prior serologic testing may be recommended depending on the specific level of risk and/or likelihood of previous exposure. **Note:** In 1997, the NIH Consensus Development Conference, a panel of national experts, recommended that hepatitis B vaccination be given to all anti-HCV positive persons. **Ed. note:** Provide serologic screening for immigrants from endemic areas. When HBsAg-positive persons are identified, offer appropriate disease management. In addition, screen their sex partners and household members and, if found susceptible, vaccinate.	• Three doses are needed on a 0, 1, 6m schedule. • Alternative timing options for vaccination include 0, 2, 4m and 0, 1, 4m. • There must be 4wks between doses #1 and #2, and 8wks between doses #2 and #3. Overall there must be at least 16wks between doses #1 and #3. • **Schedule for those who have fallen behind:** If the series is delayed between doses, DO NOT start the series over. Continue from where you left off. • May give with all other vaccines. For Twinrix™ (hepatitis A and B combination vaccine [GSK]), three doses are needed on a 0, 1, 6m schedule.	• Previous anaphylactic reaction to this vaccine or to any of its components. • Moderate or severe acute illness. **Note:** Pregnancy and breastfeeding are not contraindications to the use of this vaccine.
Hepatitis A (Hep A) *Give IM* Brands may be used interchangeably.	• People who travel outside of the U.S. (except for Western Europe, New Zealand, Australia, Canada, and Japan). • People with chronic liver disease, including people with hepatitis C; people with hepatitis B who have chronic liver disease; illicit drug users; men who have sex with men; people with clotting-factor disorders; people who work with hepatitis A virus in experimental lab settings (not routine medical laboratories); and food handlers when health authorities or private employers determine vaccination to be cost effective. **Note:** Prevaccination testing is likely to be cost effective for persons >40yrs of age as well as for younger persons in certain groups with a high prevalence of hepatitis A virus infection.	• Two doses are needed. • The minimum interval between dose #1 and #2 is 6m. • If dose #2 is delayed, do not repeat dose #1. Just give dose #2. • May give with all other vaccines.	• Previous anaphylactic reaction to this vaccine or to any of its components. • Moderate or severe acute illness. • Safety during pregnancy has not been determined, so benefits must be weighed against potential risk. **Note:** Breastfeeding is not a contraindication to the use of this vaccine.

Summary of Recommendations for Adult Immunization (continued)

Vaccine name and route	For whom it is recommended	Schedule for routine and "catch-up" administration	Contraindications (mild illness is not a contraindication)
Td (Tetanus, diphtheria) *Give IM*	• All adolescents and adults. • After the primary series has been completed, a booster dose is recommended every 10yrs. Make sure your patients have received a primary series of 3 doses. • A booster dose as early as 5yrs later may be needed for the purpose of wound management, so consult ACIP recommendations.* • Use Td, not tetanus toxoid (TT), for all indications.	• Give booster dose every 10yrs after the primary series has been completed. • For those who are unvaccinated or behind, complete the primary series (spaced at 0, 1–2m, 6–12m intervals). Don't restart the series, no matter how long since the previous dose. • May give with all other vaccines.	• Previous anaphylactic or neurologic reaction to this vaccine or to any of its components. • Moderate or severe acute illness. **Note:** Pregnancy and breastfeeding are not contraindications to the use of this vaccine.
MMR (Measles, mumps, rubella) *Give SC*	• Adults born in 1957 or later who are ≥18yrs of age (including those born outside the U.S.) should receive at least one dose of MMR if there is no serologic proof of immunity or documentation of a dose given on or after the first birthday. • Adults in high-risk groups, such as health care workers, students entering colleges and other post–high school educational institutions, and international travelers, should receive a total of two doses. • Adults born before 1957 are usually considered immune but proof of immunity may be desirable for health care workers. • All women of childbearing age (i.e., adolescent girls and premenopausal adult women) who do not have acceptable evidence of rubella immunity or vaccination. • Special attention should be given to immunizing women born outside the United States in 1957 or later.	• One or two doses are needed. • If dose #2 is recommended, give it no sooner than 4wks after dose #1. • May give with all other vaccines. • If varicella vaccine and MMR are both needed and are not administered on the same day, space them at least 4wks apart. • If a pregnant woman is found to be rubella-susceptible, administer MMR postpartum.	• Previous anaphylactic reaction to this vaccine or to any of its components. • Pregnancy or possibility of pregnancy within 4 weeks (use contraception). • Persons immunocompromised because of cancer, leukemia, lymphoma, immunosuppressive drug therapy, including high-dose steroids or radiation therapy. **Note:** HIV positivity is NOT a contraindication to MMR except for those who are severely immunocompromised. • If blood, plasma, and/or immune globulin were given in past 11m, see ACIP statement *General Recommendations on Immunization** regarding time to wait before vaccinating. • Moderate or severe acute illness. **Note:** Breastfeeding is not a contraindication to the use of this vaccine. **Note:** MMR is not contraindicated if a tuberculin skin test (i.e., PPD) was recently applied. If PPD and MMR not given on same day, delay PPD for 4–6wks after MMR.
Varicella (Var) (Chickenpox) *Give SC*	All susceptible adults and adolescents should be vaccinated. It is especially important to ensure vaccination of the following groups: susceptible persons who have close contact with persons at high risk for serious complications (e.g., health care workers and family contacts of immunocompromised persons) and susceptible persons who are at high risk of exposure (e.g., teachers of young children, day care employees, residents and staff in institutional settings such as colleges and correctional institutions, military personnel, adolescents and adults living with children, non-pregnant women of childbearing age, and international travelers who do not have evidence of immunity). **Note:** People with reliable histories of chickenpox (such as self or parental report of disease) can be assumed to be immune. For adults who have no reliable history, serologic testing may be cost effective since most adults with a negative or uncertain history of varicella are immune.	• Two doses are needed. • Dose #2 is given 4–8wks after dose #1. • May give with all other vaccines. • If varicella vaccine and MMR are both needed and are not administered on the same day, space them at least 4wks apart. • If the second dose is delayed, do not repeat dose #1. Just give dose #2.	• Previous anaphylactic reaction to this vaccine or to any of its components. • Pregnancy or possibility of pregnancy within 4 weeks (use contraception). • Persons immunocompromised because of malignancies and primary or acquired cellular immunodeficiency including HIV/AIDS. (See *MMWR* 1999, Vol. 48, No. RR-6.) **Note:** For those on high-dose immunosuppressive therapy, consult ACIP recommendations regarding delay time.* • If blood, plasma, and/or immune globulin (IG or VZIG) were given in past 11m, see ACIP statement *General Recommendations on Immunization** regarding time to wait before vaccinating. • Moderate or severe acute illness. **Note:** Breastfeeding is not a contraindication to the use of this vaccine. **Note:** Manufacturer recommends that salicylates be avoided for 6wks after receiving varicella vaccine because of a theoretical risk of Reye's syndrome.
Polio (IPV) *Give IM or SC*	Not routinely recommended for persons 18yrs of age and older. **Note:** Adults living in the U.S. who never received or completed a primary series of polio vaccine need not be vaccinated unless they intend to travel to areas where exposure to wild-type virus is likely. Previously vaccinated adults can receive one booster dose if traveling to polio endemic areas.	• Refer to ACIP recommendations* regarding unique situations, schedules, and dosing information. • May give with all other vaccines.	• Previous anaphylactic or neurologic reaction to this vaccine or to any of its components. • Moderate or severe acute illness. **Note:** Pregnancy and breastfeeding are not contraindications to the use of this vaccine.
Meningococcal *Give SC*	Vaccinate people with risk factors. Discuss disease risk and vaccine availability with college students. Consult ACIP statement* on meningococcal disease (6/30/00) for details.		

* For specific ACIP immunization recommendations, refer to the statements, which are published in *MMWR*. To obtain a complete set of ACIP statements, call (800) 232-2522, or to access individual statements, visit CDC's website: www.cdc.gov/nip/publications/ACIP-list.htm or visit IAC's website: www.immunize.org/acip

This table is revised yearly because of the changing nature of U.S. immunization recommendations. Visit the Immunization Action Coalition's website at www.immunize.org/adultrules to make sure you have the most current version. We extend our thanks to William Atkinson, MD, MPH, from CDC's National Immunization Program, and Linda Moyer, RN, from the Division of Viral Hepatitis, at CDC's National Center for Infectious Diseases for their assistance. This table is published by the Immunization Action Coalition, 1573 Selby Avenue, St. Paul, MN 55104, (651) 647-9009. Email: admin@immunize.org

Hepatitis B and the health care worker

CDC answers frequently asked questions about how to protect health care workers

Editor's note: The Immunization Action Coalition thanks Linda A. Moyer, RN, epidemiologist, and Eric E. Mast, MD, medical epidemiologist, both from the Division of Viral Hepatitis, National Center for Infectious Diseases, Centers for Disease Control and Prevention, for reviewing and updating the following questions and answers about hepatitis B and the health care worker.

You may need more shots than just hepatitis B! To find which ones, read the ACIP statement "Immunization of Health-Care Workers."

It's available online at ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4618.pdf or by calling CDC's National Immunization Information Hotline at (800) 232-2522

Which workers in the health care setting need hepatitis B vaccine?

Health care workers (HCWs) who have a reasonable expectation of being exposed to blood on the job should be offered hepatitis B vaccine. This does not include receptionists, clerical and billing staff, etc., as these individuals are not expected to be at risk for blood exposure.

What is the appropriate administration site for hepatitis B vaccine and what needle size should be used?

A deep intramuscular (IM) injection into the deltoid muscle is recommended for adult hepatitis B vaccination. A 22–25 gauge, 1–1½" needle should be used, but a longer needle may be needed to reach deep into the muscle of obese persons.

If a HCW's only dose of hepatitis B vaccine was four months ago, should the series be restarted?

No. The hepatitis B vaccine series should not be restarted when doses are delayed; rather, the series should be continued from where it left off. The vaccine recipient should receive the second dose of vaccine now and the third dose 2–5 months later.

Is it safe for HCWs to be vaccinated during pregnancy?

Yes. Pregnant women in occupations with a high risk of hepatitis B virus (HBV) infection (e.g., HCWs who have a potential for exposure to blood) should be vaccinated. Hepatitis B vaccine contains no components that have been shown to pose a risk to the fetus at any time during gestation. An acute (or chronic) HBV infection in a pregnant woman poses a significant risk to the fetus or newborn for perinatal or *in utero* infection.

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

All HCWs should have serologic testing 1–2 months following the final dose of the hepatitis B vaccine series. An anti-HBs serologic test result of ≥10mIU/mL indicates immunity. No further routine doses or testing are indicated.

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

You should repeat the 3-dose series and then test for anti-HBs 1–2 months after the last dose of vaccine. If the HCW is still negative after the second vaccine series, the HCW is considered a non-responder to hepatitis B vaccination. The HCW should be counseled that non-response to the vaccination series most likely means the HCW is susceptible to HBV infection. The HCW should then be counseled to discuss what non-response to the vaccination series means for that specific HCW and what steps should be taken in the future to protect his/her health. It is also possible that the non-responder is chronically infected with HBV. HBsAg testing can be offered or suggested to determine if this is the case. HBsAg test results should remain confidential.

How often should I test health care workers after they've received the hepatitis B vaccine series to make sure they're protected?

Postvaccination testing should be done 1–2 months after the last dose of hepatitis B vaccine.

(continued on page 12)

Recommended postexposure prophylaxis for exposure to hepatitis B virus

Vaccination and antibody response status of exposed workers*	Treatment		
	Source HBsAg† positive	Source HBsAg negative	Source unknown or not available for testing
Unvaccinated	HBIG§ x 1 and initiate HB vaccine series¶	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated			
Known responder**	No treatment	No treatment	No treatment
Known nonresponder††	HBIG x 1 and initiate revaccination or HBIG x 2§§	No treatment	If known high risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs¶¶ 1. If adequate,** no treatment is necessary 2. If inadequate,†† administer HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate,** no treatment is necessary 2. If inadequate,†† administer vaccine booster and recheck titer in 1–2 months

* Persons who have previously been infected with HBV are immune to reinfection and do not require postexposure prophylaxis.

† Hepatitis B surface antigen

§ Hepatitis B immune globulin; dose is 0.06 mL/kg intramuscularly.

¶ Hepatitis B vaccine

** A responder is a person with adequate levels of serum antibody to HBsAg (i.e., anti-HBs ≥10 mIU/mL).

†† A nonresponder is a person with inadequate response to vaccination (i.e., serum anti-HBs <10 mIU/mL).

§§ The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

¶¶ Antibody to HBsAg

Source: "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis," MMWR, June 29, 2001, Vol. 50 (RR-11): 22

If adequate anti-HBs is present (≥10mIU/mL), nothing more needs to be done. Periodic testing or boosting is not needed. If the postvaccination test result is less than 10 mIU/mL, the vaccine series should be repeated and testing done 1–2 months after the second series. This information should be recorded in the person's health record.

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

No. Postvaccination testing needs to be done only once at 1–2 months after the vaccine series is completed. If a HCW's test result indicated protection (anti-HBs ≥10mIU/mL) as a result of the original vaccination series, no further serologic testing is indicated. Data show that adequate response to the 3-dose series of hepatitis B vaccine provides long-term immunologic memory that gives long-term protection. Only immunocompromised persons (e.g., hemodialysis patients, HIV-positive persons) need to have anti-HBs testing and booster doses of vaccine to maintain their anti-HBs concentrations of at least 10mIU/mL to be protected against HBV infection.

If HCWs were vaccinated for hepatitis B in the past and not tested for immunity, should they be tested now?

No. In this scenario, a HCW does not need to be tested unless he or she has an exposure. If an exposure occurs, refer to the table on the first page for management guidelines. In addition to following these guidelines, if prophylaxis (HBIG and a booster dose of vaccine) is indicated, the person should receive postvaccination testing 3–6 months afterwards. It is necessary to do postvaccination testing at 3–6 months because testing earlier may only measure antibody from HBIG. This postvaccination test result should be recorded in the person's health record.

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

Unfortunately, inadequate documentation of vaccination is common. Even if these physicians think they may have been fully vaccinated, but it is not documented, the three-dose vaccination series should be administered. Postvaccination testing should be performed 1–2 months after the three-dose series. There is no harm in receiving extra doses of vaccine.

Some might suggest giving only one dose of vaccine followed by postvaccination testing. Although 30% of previously unvaccinated healthy adults will have a protective antibody response after only one dose of vaccine, these individuals will not have the long-term protection afforded by the three-dose series.

Each organization (hospital, clinic, etc.) should develop policies or guidelines about the documentation required to demonstrate valid hepatitis B vaccination. If policies are in place and documentation is not present, revaccination should be instituted. Care should always be taken to document vaccine lot, date, manufacturer, route, and vaccine dosages. Postvaccination testing results should also be documented, including the date serologic testing was performed.

I'm a nurse who received the hepatitis B vaccine series over 10 years ago and had a positive follow-up titer. At present, my titer is negative. What should I do now?

You don't need to do anything further. Current data show that vaccine-induced anti-HBs levels may decline over time; however, immune memory (anamnestic anti-HBs response) remains intact indefinitely following immunization. Persons with declining antibody levels are still protected against clinical illness and chronic disease. For health care workers with normal immune status who have demonstrated an anti-HBs response following vaccination, booster doses of vaccine are not recommended nor is periodic anti-HBs testing.

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

If the person is a true non-responder (i.e., failed to produce adequate anti-HBs after two full vaccine series), it seems illogical to give a third hepatitis B vaccine series. The two-dose HBIG regimen would be the better choice. The first dose of HBIG (0.06ml/kg) should be given as soon as possible after exposure and the second dose (same dosage)given one month later. If the person has failed only one hepatitis B vaccine series, the second option (HBIG x 1 and initiate revaccination) should be used. Postvaccination testing with anti-HBs should be done 1–2 months after the second series of vaccine.

If an employee does not respond to hepatitis B vaccination, does s/he need to be removed from activities that expose her/him to bloodborne pathogens? Does the employer have a responsibility in this area beyond providing the vaccine? Where can I get further information on this subject?

No regulations demand removal from the job situations described. It is up to each organization to develop a policy concerning non-responders. The Occupational Safety and Health Administration (OSHA) requires that employees in jobs where there is a reasonable risk of exposure to blood be offered hepatitis B vaccine. In addition, the regulation states that adequate personal protective equipment be provided and that standard precautions be followed. Check with your state OSHA regarding more stringent requirements. If there is no state OSHA, federal OSHA regulations should be followed. Adequate documentation should be placed in the employee record regarding non-response to vaccination. The employee should be counseled that non-response to the vaccination series most likely means the employee is susceptible to HBV infection, and if an exposure to HBV occurs, HBIG should be used for postexposure prophylaxis. HBsAg testing should be recommended as it is possible the employee is chronically infected with HBV. The employee should then be counseled to discuss what non-response to the vaccination series means for her/him and what steps should be taken in the future to protect her/his health.

Does being chronically infected with HBV preclude one from becoming a health professional?

No. All health professionals should practice standard precautions. However, there is one caveat concerning HBV-infected health professionals. Those who are HBsAg-positive and HBeAg-positive should not perform exposure-prone invasive procedures (e.g., gynecologic, cardiothoracic surgery) unless they have been counseled by an expert review panel and been advised under what circumstances, if any, they may perform these procedures.

Such circumstances might include notifying prospective patients of the health professional's seropositivity before they undergo exposure-prone invasive procedures. For more information on this issue, see the 1991 *MMWR Recommendations and Report* "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures." This document is available at www.cdc.gov/mmwr/preview/mmwrhtml/00014845.htm ♦

www.immunize.org/catg.d/2109! • Item #P2109 (9/03)

Keep your own vaccination history!

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

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

See ad for IAC adult vaccination record cards on page 3.

Hepatitis B
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QUESTIONS FREQUENTLY ASKED ABOUT HEPATITIS B

What is hepatitis B?

Hepatitis B is a serious public health problem that affects people of all ages in the United States and around the world. In 2001, an estimated 78,000 people contracted hepatitis B virus (HBV) infection in the United States. Hepatitis B is caused by a highly infectious virus that attacks the liver and can lead to severe illness, liver damage, and in some cases, death.

The best way to be protected from hepatitis B is to be vaccinated with hepatitis B vaccine, a vaccine used in the U.S. for more than two decades and proven safe and effective.

Who is at risk for HBV infection?

About 5% of people in the U.S. will get infected with HBV sometime during their lives. If you engage in certain behaviors, your risk may be much higher. You may be at risk if you:

- have a job that exposes you to human blood
- share a household with someone who has lifelong HBV infection
- inject drugs
- have sex with a person infected with HBV
- have sex with more than one partner during a six-month period
- received blood transfusions in the past before excellent blood testing was available (1975)
- are a person whose parents were born in Asia, Africa, the Amazon Basin in South America, the Pacific Islands, Eastern Europe, or the Middle East
- were born in an area listed above
- were adopted from an area listed above
- are an Alaska native
- have hemophilia
- are a patient or worker in an institution for the developmentally disabled
- are an inmate of a long-term correctional facility
- travel internationally to areas with a high prevalence of hepatitis B

The largest outbreak of hepatitis B in the U.S. occurred in 1942 in military personnel who were given vaccine to protect them from yellow fever. It was unknown at the time that this vaccine contained a human blood component that was contaminated with HBV. The outbreak caused 28,585 cases of hepatitis B with jaundice.

How is HBV spread?

HBV is found in blood and certain body fluids—such as serum, semen, and vaginal secretions—of people infected with HBV. HBV is *not* found in sweat, tears, urine, or respiratory secretions. Contact with even small amounts of infected blood can cause infection.

Hepatitis B virus can be spread by:

- unprotected sex
- injecting drug use
- an infected mother to her child during birth
- contact with the blood or open sores of an infected person
- human bites
- sharing a household with a chronically infected person
- sharing items such as razors, toothbrushes, or washcloths
- pre-chewing food for babies or sharing chewing gum
- using unsterilized needles in ear or body piercing, tattooing, or acupuncture
- using the same immunization needle on more than one person

Hepatitis B virus IS NOT spread by:

- casual contact like holding hands
- eating food prepared by an infected person
- kissing or hugging
- sharing silverware, plates, or cups
- visiting an infected person's home
- sneezing or coughing

What are the symptoms of hepatitis B?

Most people who get HBV infection as babies or children don't look or feel sick at all. Similarly, almost half of adults who get infected don't have any symptoms or signs of the disease. If people do have signs or symptoms, they may experience any or all of the following:

- loss of appetite
- yellowing of skin and eyes (jaundice)
- nausea, vomiting
- fever
- weakness, tiredness, inability to work for weeks or months
- abdominal pain and/or joint pain
- dark urine

I'm not in a risk group. How did I get HBV infection?

Many people don't know when or how they acquired the infection. When they get the blood test results indicating they've been infected with HBV, they are taken by surprise. Studies have demonstrated that 30–40% of people who acquire HBV infection are unable to iden-

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tify their own risk factors explaining why they have the disease.

Do people usually recover from HBV infection?

Nearly 95% of adults recover after several months. They clear the infection from their bodies and become *immune*. This means they won't get infected with HBV again. They are no longer contagious and cannot pass HBV on to others.

Unfortunately, of those who become newly infected with HBV, about 5% of adults and up to 90% of children under age five are unable to clear the infection from their bodies; they become chronically infected.

How do I know if I have or have had HBV infection?

The only way to know if you are currently infected with HBV, have recovered, are chronically infected, or are susceptible, is by having blood tests. The three standard blood tests are the following:

HBsAg (hepatitis B surface antigen): when this is "positive" or "reactive," it means the person is currently infected with HBV and is able to pass the infection on to others.

Anti-HBc [or HBc-Ab] (antibody to hepatitis B *core* antigen): when this is "positive" or "reactive," it *may* mean the person has had contact with HBV. This is a very complicated test to explain because the "anti-HBc" could possibly be a "false-positive" test result. The interpretation of this positive test usually depends on the results of the other two blood tests (see Interpretation table at right). Blood banks routinely run an "anti-HBc," but they do not routinely run an "anti-HBs."

Anti-HBs [or HBs-Ab] (antibody to hepatitis B *surface* antigen): when this is "positive" or "reactive," it means the person is *immune* to HBV infection, either from vaccination or from past infection. If the person was previously infected, s/he cannot pass the disease on to others. (To repeat, this test is not routinely done by blood banks.)

Interpretation of the Hepatitis B Blood Test Results

Tests	Results	Interpretation
HBsAg anti-HBc anti-HBs	negative negative negative	susceptible
HBsAg anti-HBc anti-HBs	negative negative positive with ≥10mIU/mL*	immune due to vaccination
HBsAg anti-HBc anti-HBs	negative positive positive	immune due to natural infection
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	newly infected
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	chronically infected
HBsAg anti-HBc anti-HBs	negative positive negative	four interpretations possible†

*Postvaccination testing, when it is recommended, should be done 1–2 months after the final dose.

†1. May be recovering from acute HBV infection.
2. May be distantly immune, and the test is not sensitive enough to detect a very low level of anti-HBs in serum.
3. May be susceptible with a "false positive" anti-HBc.
4. May be chronically infected and have an undetectable level of HBsAg present in the serum.

What does it mean if my blood bank said I tested positive for hepatitis B and can no longer donate blood?

If the blood bank told you your test was "positive," it is important to find out *which* test was positive. If the "HBsAg" was positive, this means that you are either *chronically infected* with HBV or were recently infected. If *only* the "anti-HBc" was positive, it is most likely that you either had a "false-positive" test or are *immune* to hepatitis B. It is important that you understand the full meaning of your test results. If you are not sure how to interpret these test results, call your blood bank for an explanation or have the blood bank send the test results to your physician. You may need to provide written permission for the blood bank to release these results to your physician. Your physician may want to repeat the blood tests or perform additional tests such as an "anti-HBs." Bring this information sheet along with you to your doctor visit.

And remember, you cannot contract HBV from donating blood because the equipment used during blood donation is sterile.

CHRONIC HEPATITIS B VIRUS INFECTION

What does it mean to be chronically infected with hepatitis B virus?

People who do not recover from HBV infection are chronically infected, and there are over one million chronically infected people in the United States today. A chronically infected person is someone who has had HBV in her/his blood for more than six months. While approximately 5% of adults who acquire HBV infection become chronically infected, children less than five years of age have a greater risk. The younger the child is at the time of infection, the greater the risk that the child will have a lifelong infection. Many babies born to chronically infected mothers will also become chronically infected with HBV unless the babies are given two shots in the hospital and at least two more during the 6 months after birth to protect them from the infection.

A chronically infected person usually has no signs or symptoms of HBV infection but remains infected for years or for a lifetime and is capable of passing HBV on to others. Sometimes chronically infected people will spontaneously clear the infection from their bodies, but most will not. Although most chronically infected people have no serious problems with hepatitis B and lead normal, healthy lives, some develop liver problems later. Chronically infected people are at significantly higher risk than the general population for liver failure or liver cancer.

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How can I take care of myself if I am chronically infected with HBV?

A person with HBV infection should see a physician knowledgeable about the management of liver disease every 6–12 months. The physician will do blood tests to check the health of the liver as well as test for evidence of liver cancer. It is best for chronically infected people to avoid alcohol because alcohol can injure the liver. Additionally, your physician should know about all the medicines you are taking, even over-the-counter drugs, because some medicines can hurt the liver. If there are any liver test abnormalities, consultation with a liver specialist regarding your need for further testing and treatment is important.

If your liver disease has progressed...

If your physician tells you your liver disease has progressed, here are some extra precautions you should take:

- Get a yearly influenza vaccination. Patients with severe liver disease (cirrhosis) should also receive pneumococcal vaccine.
- Get vaccinated against hepatitis A. Hepatitis A can further damage your liver.
- Don't eat raw oysters. They may carry the bacteria *Vibrio vulnificus*, which can cause serious blood infections in people with liver disease. Approximately 40% of people with this blood infection die.

What can I do to protect others from HBV infection?

People with HBV infection might feel healthy but are still capable of passing the infection on to other people. To protect others from getting HBV infection, it is important to protect them from contact with your infected blood and other infectious body fluids, including semen and vaginal secretions. Sweat, tears, urine, and respiratory secretions do not contain hepatitis B virus. Hepatitis B virus transmission via saliva has only been documented through biting.

Important DOs and DON'Ts for people with chronic HBV infection

DO:

- Cover all cuts and open sores with a bandage.
- Discard used items such as bandaids and menstrual pads carefully so no one is accidentally exposed to your blood.
- Wash your hands well after touching your blood or infectious body fluids.
- Clean up blood spills. Then reclean the area with a bleach solution (one part household chlorine bleach to 10 parts water).
- Tell your sex partner(s) you have hepatitis B so they can be tested and vaccinated (if not already infected). Partners should be tested after the three doses are completed to be sure the vaccine worked.
- Use condoms (rubbers) during sex unless your sex partner has had hepatitis B or has been immunized and has had a blood test demonstrating immunity. (Condoms may also protect you from other sexually transmitted diseases.)
- Tell household members to see their doctors for testing and vaccination for hepatitis B.
- Tell your doctors that you are chronically infected with HBV.
- See your doctor every 6–12 months to check your liver for abnormalities including cancer.
- If you are pregnant, tell your doctor that you have HBV infection. It is critical that your baby is started on the hepatitis B shots within a few hours of birth.

DON'T:

- Share chewing gum, toothbrushes, razors, washcloths, needles for ear or body piercing, or anything that may have come in contact with your blood or infectious body fluids
- Pre-chew food for babies
- Share syringes and needles
- Donate blood, plasma, body organs, tissue, or sperm

What are the long-term effects of HBV infection?

Each year, approximately 5,000 people in the U.S. die of HBV-related liver failure and another 1,500 die from HBV-related liver cancer. HBV infection is the most common cause of liver cancer worldwide and ranks second only to cigarettes as the world's leading cause of cancer.

Is there a cure for hepatitis B?

As of this writing, there are three FDA-approved medications (interferon, lamivudine, and adefovir) that can help a person who is already infected with HBV. Their use is reserved for people who have certain blood test abnormalities. Be sure to ask your doctor if you are a candidate for treatment or if you might benefit from enrolling in a clinical trial. Researchers continue to seek additional cures for hepatitis B.

Why is hepatitis B so serious in pregnant women?

Pregnant women who are infected with HBV can transmit the disease to their babies. Many of these babies develop lifelong HBV infections, and up to 25% will develop liver failure or liver cancer later in life. All pregnant women should be tested early in pregnancy to determine if they are infected with HBV. If the blood test is positive, the baby should be vaccinated at birth with two shots, one of hepatitis B immune globulin (HBIG) and one of hepatitis B vaccine. The infant will need at least two additional doses of hepatitis B vaccine by 6 months of age.

How can hepatitis B be prevented?

The vaccine can provide protection in 90–95% of healthy young adults. The vaccine can be given safely to infants, children, and adults usually in three doses over an approximate 6-month period. Even pregnant women can be safely given these shots if their risk factors warrant it. Hepatitis B shots are very safe, and side effects are rare. Hepatitis B vaccine is our first vaccine that prevents cancer—liver cancer.

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At what age are hepatitis B shots routinely given?

In the U.S., hepatitis B shots are routinely recommended for all children 0–18 years of age. For babies, the first hepatitis B shot is recommended to be given in the hospital at birth. Older children and teens should be vaccinated at the earliest opportunity. Any adult who is at risk for HBV infection should start the vaccine series immediately.

Where can I get hepatitis B shots?

Check with your clinic first. Children's health insurance usually covers the cost of this vaccine since it is routinely recommended for all U.S. children. If your child is uninsured, ask your local health department for assistance. For adults, contact your health provider first to find out if the vaccine is covered under your health plan. If you are uninsured, call your local health department for advice.

How many shots are needed?

Usually three shots are needed for the best protection against HBV, but some protection is provided from receiving as little as one dose. The shots are usually given on a schedule of 0, 1, and 6 months, but there is great flexibility in the timing of these injections. As with all other vaccines, if you fall behind on the schedule, you just continue from where you left off. Hepatitis B shots will not help or cure a person who is already infected with the hepatitis B virus.

What should I do if I'm in a risk group?

If you are in a risk group for hepatitis B (risk groups are listed on page 1), get vaccinated! All people in risk groups should protect themselves from HBV infection. Every day you delay getting vaccinated increases your chances of getting this highly contagious liver disease. The problems caused by hepatitis B—liver cancer and liver failure—are too great. See your doctor or visit your health department.

How does hepatitis B differ from hepatitis A and C?

Hepatitis A, B, and C are all viruses that attack and injure the liver, and all can cause similar symptoms. Usually, people get hepatitis A from household or sexual contact with a person who has hepatitis A. Hepatitis C, formerly known as hepatitis non-A non-B, is caused by the hepatitis C virus and is spread in much the same way as HBV. Both hepatitis B and C can cause lifelong liver problems while hepatitis A does not. Vaccines to prevent hepatitis A are now available. There is no vaccine yet for hepatitis C. If you've had hepatitis A or C in the past, it is still possible to get hepatitis B.

Where can I receive more information about hepatitis B?

Contact your local and state health departments for more information. You can also contact the following organizations:

Immunization Action Coalition
Hepatitis B Coalition
(651) 647-9009
www.immunize.org
www.vaccineinformation.org

American Liver Foundation
(800) 465-4837
www.liverfoundation.org

Centers for Disease Control and Prevention
(888) 443-7232 Hepatitis Hotline, automated
(800) 232-2522 Immunization Hotline
www.cdc.gov/hepatitis
www.cdc.gov/nip

Hepatitis B Foundation
(215) 489-4900
www.hepb.org

Hepatitis Foundation International
(800) 891-0707
www.hepfi.org

Parents of Kids with Infectious Diseases (PKIDS)
(877) 557-5437
www.pkids.org

What is the Immunization Action Coalition (IAC)?

The Immunization Action Coalition is a nonprofit organization that works to prevent hepatitis B and all other vaccine-preventable diseases in people of all ages. The Hepatitis B Coalition, a program of IAC, promotes vaccination for children 0–18 years of age, screening for all pregnant women, testing and vaccination for risk groups, and education and treatment for chronically infected people.

IAC relies on financial support from the Centers for Disease Control and Prevention, corporations, foundations, health professionals, and other private citizens to maintain its activities. Financial contributions are always needed, greatly appreciated, and tax-deductible. You can send your check to IAC at the address below or donate online at www.immunize.org/join

Deborah L. Wexler, MD
Executive Director
Immunization Action Coalition
1573 Selby Ave., Suite 234
St. Paul, MN 55104
www.immunize.org
www.vaccineinformation.org

This article was written in response to more than 5,000 letters sent to Dr. Wexler after she wrote a letter to "Dear Abby" about hepatitis B in 1993. It was updated in September 2003.

How's your state doing?

Current U.S. immunization information by state

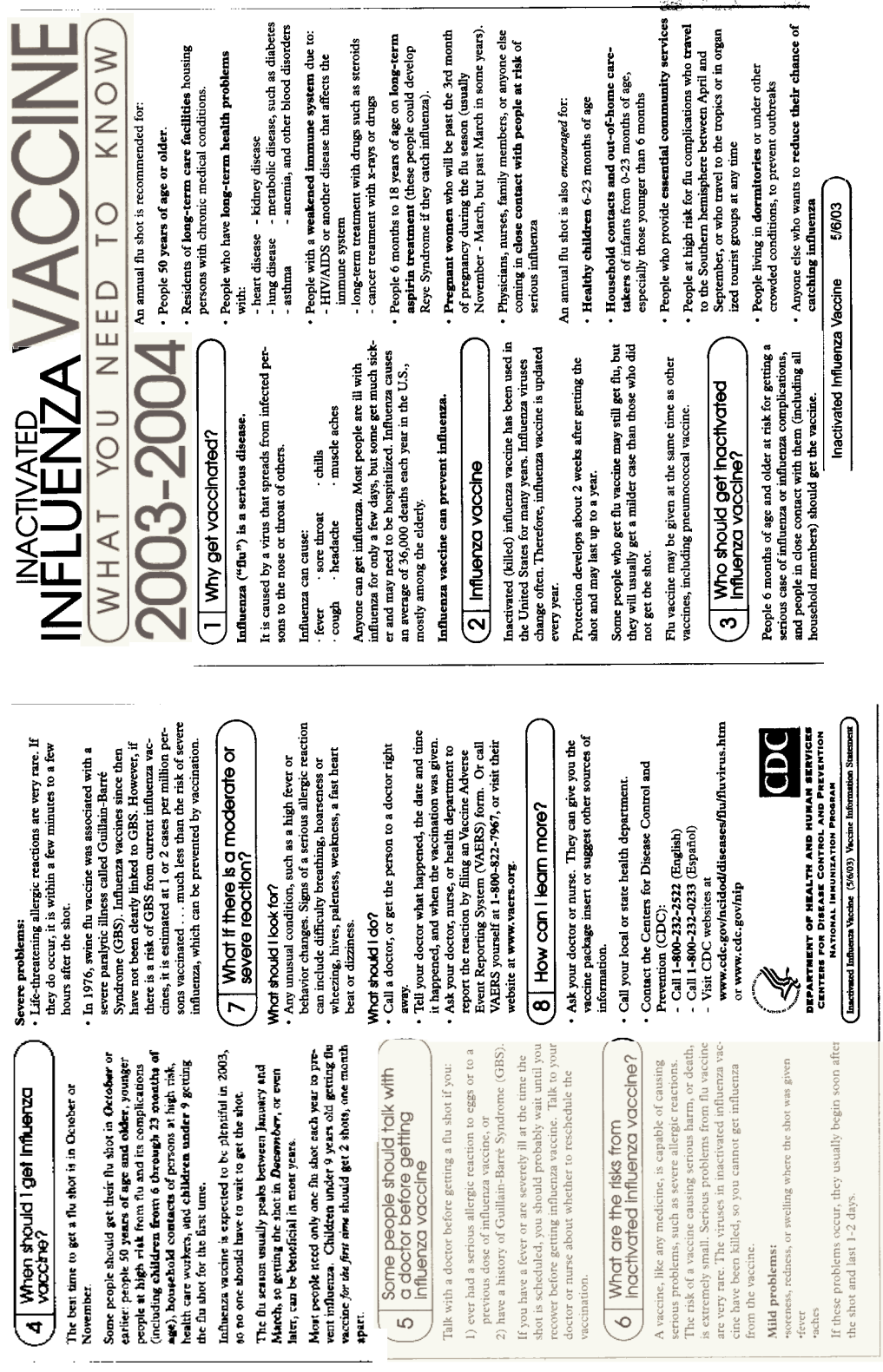
State	% of children with 4:3:1:3:3:1 series complete*†	% of children with ≥3 doses of hepatitis B vaccine*	% of children given ≥1 dose of varicella vaccine*	Hepatitis B childhood vaccination mandates, with year implemented‡				Varicella childhood vaccination mandates, with implementation dates‡			
				Mandate?	Daycare	Elementary School	Middle School	Mandate?	Daycare	Elementary School	Middle School
AL	73.3	91.7	89.3					yes	2000	2001§	
AK	56.2	88.8	63.6	yes	2001	2001	2001	yes	2001		
AZ	59.0	89.2	78.6	yes	1997	1997	2000				
AR	68.3	91.6	88.7	yes	2000	2000	2000	yes	2000	2000	
CA	67.1	88.2	85.1	yes	1997	1997	1999	yes	2001	2001	
CO	56.1	92.4	79.8	yes	1997	1997	1997	yes	2000	2000	2006
CT	72.8	91.4	86.5	yes	1995	1996	2000	yes	2000	2000	2000
DE	69.7	92.4	86.0	yes	1999	1999	1999	yes	9/02	9/03	9/03
DC	68.3	91.0	91.1	yes	1997	1997§	1997§	yes	1997	1997§	1997§
FL	66.4	89.9	80.8	yes		1998§	1997§	yes	2001	2001§	
GA	76.5	92.4	89.2	yes	1997	1997		yes	2000	2000	2001
HI	69.1	90.7	81.6	yes	1998	1998	7/02	yes	2002	2002	2002
ID	52.6	89.5	65.9	yes	1995	1995	born >11/22/91				
IL	58.1	92.5	69.9	yes	1997	1997§	1997§	yes	7/02	7/02§	
IN	59.4	93.2	70.0	yes		1999		yes	1/03	9/04	
IA	58.2	90.6	66.5	yes		1999		yes	1/04	1/04	
KS	55.1	86.9	76.2								
KY	63.6	90.5	78.3	yes	1998	1998	2001	yes	2001	2001	
LA	61.9	90.7	83.4	yes	1998	1998		yes	9/03	9/03	
ME	62.1	93.7	73.0	yes	2002			yes	11/02	9/03§	9/04§
MD	70.7	93.0	87.7	yes	2000	2001§	2007§	yes	2000	2001§	2007§
MA	78.0	93.7	87.0	yes	1993	1997§	1999§	yes	1998	1999§	1999§
MI	71.7	93.1	83.0	yes	1997	2001	9/02	yes	2000	9/02	9/02
MN	61.5	87.9	73.6	yes		2000	2001	yes	9/04	9/04	9/04
MS	63.9	88.3	77.5	yes		1999		yes	9/02	9/02	
MO	60.1	87.7	77.1	yes	1995	1997	1999	yes	2001		
MT	49.4	82.0	59.2								
NE	64.3	91.2	74.8	yes		1999	2000				
NV	65.3	90.1	74.7	yes		7/02		yes		7/03	
NH	66.2	93.7	73.9	yes	1996	born >1/1/93	born >1/1/93	yes	1/03	9/03	9/03
NJ	65.5	90.5	80.2	yes		2001	2001				
NM	59.1	85.9	80.5	yes	2000	9/02	1999	yes	2000	9/02	
NY	67.3	92.3	81.0	yes	1995	1998	2000	yes	2001	9/03	
NC	69.7	91.4	81.8	yes	1994	1999	9/05	yes	4/02	2006	2012
ND	56.3	93.5	67.4	yes		2000§		yes	tbd¶	tbd¶	
OH	63.5	88.0	75.4	yes	1999	1999					
OK	60.3	86.5	81.0	yes	1999	1998§	1997§	yes	1998	1998§	2004§
OR	60.3	85.5	73.7	yes	1998	1998	2000	yes	2000	2000	2000
PA	67.6	92.1	84.7	yes	1994	1997	2002	yes	1997	9/02	9/02
RI	80.7	97.0	88.9	yes	1998	1999	2000	yes	1999	1999§	2000§
SC	73.8	93.8	86.0	yes	1994	1998	1998	yes	2000	2001	2007§
SD	62.0	90.6	71.2					yes		2000	
TN	67.3	93.0	81.1	yes	1998	1999	7/02	yes	1999	7/02	
TX	65.0	86.2	82.9	yes	1998	1998	2000	yes	2000	2000§	2000§
UT	61.4	92.1	78.1	yes		1999§		yes		7/02§	
VT	57.7	89.8	66.5	yes			1999				
VA	64.8	83.2	83.0	yes	1994	1994	2001	yes	born >1/97	born >1/97	
WA	51.9	84.9	65.1	yes	1997§	1997§					
WV	65.8	89.9	81.8	yes	2000			yes	2000		
WI	67.5	93.3	79.8	yes	1997	1997	1997§	yes	2001§	2001§	2004§
WY	54.1	88.8	65.2	yes	1999	1999	1998				

*From the 2001 National Immunization Survey (NIS). *MMWR*, 8/8/03, Vol. 52, No. 31, pp. 728–732.
† Comprises ≥4 doses of DTP/DT/DTaP, ≥3 doses of polio, ≥1 dose of measles-containing vaccine, ≥3 doses of Hib, ≥3 doses of hepatitis B, and ≥1 dose of varicella vaccine.
‡ Immunization Action Coalition (IAC) data; updates appear on the IAC website throughout the year at www.immunize.org/laws
§ Signifies a "progressive" law in which a successive grade becomes covered by the law in each new school year (e.g., grade 7 in 2000, grades 7–8 in 2001)
¶ tbd = Date to be determined

Vaccine Information Statement (VIS): Inactivated Influenza Vaccine

CDC recommends that all providers use the VIS shown below when administering inactivated influenza vaccine to patients. Translations of this VIS and instructions for use are available at www.immunize.org/vis

To obtain a ready-to-copy 8½" x 11" version of this VIS, visit www.immunize.org/vis/2flu.pdf



INACTIVATED
INFLUENZA VACCINE

WHAT YOU NEED TO KNOW

2003-2004

1 Why get vaccinated?

Influenza ("flu") is a serious disease.

It is caused by a virus that spreads from infected persons to the nose or throat of others.

Influenza can cause:
· fever · chills
· cough · muscle aches
· sore throat
· headache

Anyone can get influenza. Most people are ill with influenza for only a few days, but some get much sicker and may need to be hospitalized. Influenza causes an average of 36,000 deaths each year in the U.S., mostly among the elderly.

Influenza vaccine can prevent influenza.

2 Influenza vaccine

Inactivated (killed) influenza vaccine has been used in the United States for many years. Influenza viruses change often. Therefore, influenza vaccine is updated every year.

Protection develops about 2 weeks after getting the shot and may last up to a year.

Some people who get flu vaccine may still get flu, but they will usually get a milder case than those who did not get the shot.

Flu vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

3 Who should get inactivated influenza vaccine?

People 6 months of age and older at risk for getting a serious case of influenza or influenza complications, and people in close contact with them (including all household members) should get the vaccine.

An annual flu shot is recommended for:

- People **50 years of age or older.**
- Residents of **long-term care facilities** housing persons with chronic medical conditions.
- People who have **long-term health problems** with:
  - heart disease - kidney disease
  - lung disease - metabolic disease, such as diabetes
  - asthma - anemia, and other blood disorders
- People with a **weakened immune system** due to:
  - HIV/AIDS or another disease that affects the immune system
  - long-term treatment with drugs such as steroids
  - cancer treatment with x-rays or drugs
- People 6 months to 18 years of age on **long-term aspirin treatment** (these people could develop Reye Syndrome if they catch influenza).
- **Pregnant women** who will be past the 3rd month of pregnancy during the flu season (usually November - March, but past March in some years).
- Physicians, nurses, family members, or anyone else coming in **close contact with people at risk of** serious influenza

An annual flu shot is also *encouraged* for:

- **Healthy children** 6-23 months of age
- **Household contacts and out-of-home caretakers** of infants from 0-23 months of age, especially those younger than 6 months
- People who provide **essential community services**
- People at high risk for flu complications who **travel** to the Southern hemisphere between April and September, or who travel to the tropics or in organized tourist groups at any time
- People living in **dormitories** or under other crowded conditions, to prevent outbreaks
- Anyone else who wants to **reduce their chance of catching influenza**

Inactivated Influenza Vaccine 5/6/03

4 When should I get influenza vaccine?

The best time to get a flu shot is in October or November.

Some people should get their flu shot in ***October*** or earlier: people **50 years of age and older**, younger people **at high risk** from flu and its complications (including **children from 6 through 23 months of age**), **household contacts** of persons at high risk, health care workers, and **children under 9** getting the flu shot for the first time.

Influenza vaccine is expected to be plentiful in 2003, so no one should have to wait to get the shot.

The flu season usually peaks between January and ***March***, so getting the shot in ***December***, or even later, can be beneficial in most years.

Most people need only one flu shot each year to prevent influenza. Children under 9 years old getting flu vaccine *for the first time* should get 2 shots, one month apart.

5 Some people should talk with a doctor before getting influenza vaccine

Talk with a doctor before getting a flu shot if you:

1) ever had a serious allergic reaction to eggs or to a previous dose of influenza vaccine, or
2) have a history of Guillain-Barré Syndrome (GBS).

If you have a fever or are severely ill at the time the shot is scheduled, you should probably wait until you recover before getting influenza vaccine. Talk to your doctor or nurse about whether to reschedule the vaccination.

6 What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small. Serious problems from flu vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:
- soreness, redness, or swelling where the shot was given
- fever
- aches

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Severe problems:
- Life-threatening allergic reactions are very rare. If they do occur, it is within a few minutes to a few hours after the shot.
- In 1976, swine flu vaccine was associated with a severe paralytic illness called Guillain-Barré Syndrome (GBS). Influenza vaccines since then have not been clearly linked to GBS. However, if there is a risk of GBS from current influenza vaccines, it is estimated at 1 or 2 cases per million persons vaccinated . . . much less than the risk of severe influenza, which can be prevented by vaccination.

7 What if there is a moderate or severe reaction?

What should I look for?
- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?
- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to report the reaction by filing an Vaccine Adverse Event Reporting System (VAERS) form. Or call VAERS yourself at **1-800-822-7967**, or visit their website at **www.vaers.org**.

8 How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-2522** (English)
  - Call **1-800-232-0233** (Español)
  - Visit CDC websites at **www.cdc.gov/ncidod/diseases/flu/fluvirus.htm** or **www.cdc.gov/nip**

CDC

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL IMMUNIZATION PROGRAM

Inactivated Influenza Vaccine (5/6/03) Vaccine Information Statement

Vaccine Information Statement (VIS): Live Intranasal Influenza Vaccine

CDC recommends that all providers use the VIS shown below when administering live, intranasal influenza vaccine to patients. Instructions for its use are available at www.immunize.org/vis

To obtain a ready-to-copy 8½" x 11" version of this VIS, visit www.immunize.org/vis/liveflu03.pdf

LIVE, INTRANASAL INFLUENZA VACCINE

WHAT YOU NEED TO KNOW

2003-2004

1 Why get vaccinated?

Influenza ("flu") is a serious disease.

It is caused by a virus that spreads from infected persons to the nose or throat of others.

Influenza can cause:

- fever
- cough
- sore throat
- headache
- chills
- muscle aches

Anyone can get influenza. Most people are ill with influenza for only a few days, but some get much sicker and may need to be hospitalized. Influenza causes an average of 36,000 deaths each year in the U.S., mostly among the elderly.

Influenza vaccine can prevent influenza.

2 Live, intranasal influenza vaccine

Two types of influenza vaccine are now available. Live, intranasal influenza vaccine (trade-name FluMist™) was licensed in 2003. FluMist is an attenuated (weakened) live vaccine. It is sprayed into the nostrils rather than injected into the muscle.

Inactivated (killed) influenza vaccine, sometimes called the "flu shot," has been used for many years, and is given by injection.

3 Who can get live, intranasal influenza vaccine?

Live, intranasal influenza vaccine is approved for healthy children and adults from 5 through 49 years of age, including household contacts of some people at high risk for influenza complications. However, because its safety has not yet been studied in some other groups, FluMist should not be used by many people at risk for flu or its complications (see Section 4).

4 Who should *not* get live, intranasal influenza vaccine?

The following people should not get intranasal influenza vaccine. They should check with their health care provider about getting inactivated influenza vaccine.

- **Adults 50 years of age or older or children younger than 5.**
- People who have **long-term health problems** with:
  - heart disease
  - kidney disease
  - lung disease
  - metabolic disease, such as diabetes
  - asthma
  - anemia, and other blood disorders
- People with a **weakened immune system** due to:
  - HIV/AIDS or another disease that affects the immune system
  - long-term treatment with drugs that weaken the immune system, such as steroids
  - cancer treatment with x-rays or drugs
- Children or adolescents on **long-term aspirin treatment** (these people could develop Reye syndrome if they catch influenza).
- **Pregnant women.**
- Anyone with a history of **Guillain-Barré Syndrome** (GBS).

The flu shot (inactivated vaccine) is preferred over live, intranasal influenza vaccine for physicians, nurses, family members, or anyone else coming in close contact with anyone with a weakened immune system.

The following people should talk with a doctor before getting *either* flu vaccine:

- Anyone who has ever had a serious allergic reaction to **eggs** or to a **previous dose** of influenza vaccine.
- If you have a fever or are severely ill at the time the vaccination is scheduled, you should probably wait until you recover before getting influenza vaccine. Talk to your doctor or nurse about whether to reschedule the vaccination.

5

The best time to get flu vaccine is in **October** or **November**. But live, intranasal flu vaccine may be given as soon as the vaccine is available. The flu season usually peaks anywhere from January through March, so getting the vaccine in December, or even later, can be beneficial in most years.

Most people need only one flu vaccination each year to prevent influenza. But children through 8 years of age getting influenza vaccine *for the first time* should get 2 doses of vaccine. For the live, influenza vaccine, these doses should be 6-10 weeks apart. These children should get their first dose in October or earlier.

Live, intranasal flu vaccine may be given at the same time as other vaccines. This includes other live vaccines, such as MMR or chickenpox. But if two live vaccines are not given on the same day, they should be given at least 4 weeks apart.

Influenza viruses change often. Therefore, influenza vaccines are updated every year, and an annual vaccination is needed.

6 What are the risks from live, intranasal influenza vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live, intranasal influenza vaccine can cause mild symptoms (see below).

Mild problems:
Some children and adolescents 5-17 years of age reported mild reactions during clinical studies, including:

- runny nose or nasal congestion
- fever
- headache and muscle aches
- abdominal pain or occasional vomiting

These problems usually happened after the first dose and went away on their own.

Some adults 18-49 years of age reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

During clinical studies with live, intranasal influenza vaccine, many of these symptoms occurred whether or not the person was vaccinated. Even when they occurred after vaccination, they may not have been caused by the vaccine.

Severe problems:

- Life-threatening allergic reactions are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.
- No life-threatening reactions were reported during clinical trials of live, intranasal influenza vaccine. However, rare reactions may not be identified until thousands or millions of people have used any new product. Monitoring for unusual or severe problems is being done.

7 What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to report the reaction by filing an Vaccine Adverse Event Reporting System (VAERS) form. Or call VAERS yourself at **1-800-822-7967**, or visit their website at **www.vaers.org**.

8 How can I learn more?

- Ask your immunization provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-2522** (English)
  - Call **1-800-232-0233** (Español)
  - Visit CDC websites at **www.cdc.gov/ncidod/diseases/flu/fluvirus.htm** or **www.cdc.gov/nip**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL IMMUNIZATION PROGRAM

IAC's "Ask the Experts" team from CDC

William L. Atkinson, MD, MPH

Linda A. Moyer, RN

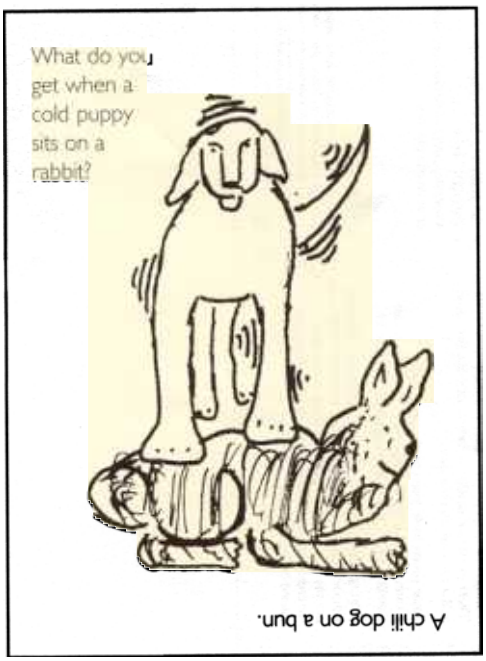
Eric E. Mast, MD

counted as valid and should be repeated. This and other information on vaccine administration is available in the 2002 *General Recommendations on Immunization* (www.cdc.gov/mmwr/pdf/rr/rr5102.pdf).

We are unable to locate 7/8" needles for IM injections given to infants and young children. Should we use 5/8" or 1"?
If 7/8" needles are not available, you should use a 1" needle.

Is a parent signature required for vaccination?
Usually not. Federal law mandates the recording of certain information about each vaccination (e.g., manufacturer, lot #) but does not require a parent signature to vaccinate. However, providers should check with their state immunization program to determine whether additional requirements exist under state law. For phone numbers, go to: www.immunize.org/coordinators

Where can I get the most up-to-date information on vaccination recommendations for people who travel outside the U.S.?



You can get this information from the CDC publication *Health Information for International Travel* ("Yellow Book") and biweekly updates, *Summary of Health Information for International Travel,* ("Blue Sheet"). Both are available on the CDC travel website, www.cdc.gov/travel To order a copy of the book, call (877) 252-1200.

Influenza

by William L. Atkinson, MD, MPH

How serious a problem is influenza in the U.S.?
Influenza is the most frequent cause of death from a vaccine-preventable disease in this country. From 1990 through 1999, an average of approximately 36,000 influenza-associated pulmonary and circulatory deaths occurred during each influenza season. In addition to fatalities, influenza is also responsible for an average of 114,000 hospitalizations per year.

Who should be vaccinated against influenza?
ACIP recommends annual influenza vaccination for all persons 50 years of age or older; persons ≥6 months of age with chronic cardiovascular or pulmonary disease (including asthma), a chronic disease of the blood, kidneys, or immune system (including HIV) or diabetes; residents of long-term care facilities; pregnant women who will be in the 2nd or 3rd trimester of pregnancy during the influenza season; and children and teens who are on long-term aspirin therapy. In addition, persons who are likely to transmit influenza to persons at high risk should be vaccinated (e.g., health care workers, caregivers, or household members) as well as household contacts and out-of-home caretakers of children 0–23 months of age. Vaccination of children 6–23 months of age is encouraged because of their higher risk of hospitalization from influenza. And, lastly, any other (healthy) person ≥6 months of age who wishes to reduce the likelihood of becoming ill with influenza may be vaccinated.

For whom can the new intranasal flu vaccine be used?
The new live attenuated influenza vaccine (LAIV), FluMist,™ is currently approved for use only for healthy non-pregnant persons 5–49 years of age. It should not be used for anyone with an underlying medical condition that increases the person's risk of complications of influenza (inactivated vaccine should be used for these groups). It also cannot be given to pregnant women or to immunosuppressed persons.

How is LAIV administered?
The vaccine dose (0.5mL) comes frozen inside a special sprayer device. A plastic clip on the plunger divides the dose into two equal parts. The vaccine is thawed by holding it in your hand for 3-5 minutes. Once the vaccine is thawed, the patient is seated in an upright position with head tilted back. Half of the contents of the sprayer (0.25mL) is sprayed into each nostril.

Are there special storage issues for LAIV vaccine?
Yes. The vaccine is extremely fragile so proper storage and handling are critical. The vaccine must be stored continuously at -15°C (+5°F) or below. The vaccine cannot tolerate the temperature fluctuations in a frost-free freezer, so it must be stored in a manual defrost freezer. If a manual defrost freezer is not available, you must store the vaccine in a special manufacturer-supplied container that is placed inside the self-defrosting freezer. The container is designed to maintain a constant internal temperature consistent with the freezer's own temperature. (If the freezer in which you store vaccine does not reach -15°C (+5°F) or lower, the container will not hold the vaccine at the proper temperature.) If the vaccine is removed from the freezer, it can be stored in the refrigerator for 24 hours; it must be discarded if not used within this time period.

Can LAIV be given to contacts of immunosuppressed patients?
Like other live vaccines, LAIV should not be administered to immunosuppressed persons. There are currently no data assessing the risk of transmission of LAIV from vaccine recipients to immunosuppressed contacts. As a result, ACIP has stated a preference for using inactivated influenza vaccine for household members, health care workers, and others who have close contact with immunosuppressed individuals because of the theoretical risk that the live attenuated vaccine virus could be transmitted to the immunosuppressed individual and cause disease.

Can LAIV be administered to persons with minor acute illnesses, such as a mild URI with or without fever?
Yes, however, if clinical judgment suggests nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration should be considered until the congestion resolves.

Why do people who received a flu shot last year still need to get vaccinated this year when the viruses haven't changed?
Although the strains are the same as in last year's vaccine, you should NOT use the 2002–2003 vaccine you might still have in your refrigerator. All of last season's vaccine expired on June 30, 2003; expired vaccine should NEVER be administered. Secondly, antibody titers that persons might have achieved from last year's vaccination have waned and need to be boosted with a dose this year.

Hepatitis A and B

by Linda Moyer, RN, and Eric E. Mast, MD

I have seen patients (adults >18 years old) who have had one or two doses of Twinrix® (HepA-HepB combination vaccine from GlaxoSmithKline), but we only carry single-antigen vaccine in our practice. How should we complete their vaccination series with single-antigen vaccines?
Twinrix is licensed as a 3-dose series.

If one dose of Twinrix® was given, complete the series with two adult doses of hepatitis B vaccine and two adult doses of hepatitis A vaccine.

If two doses of Twinrix® were given, the schedule can be completed with one adult dose of hepatitis A vaccine and one adult dose of hepatitis B vaccine.

How should we complete the series if a 12-year-old starts the 2-dose Recombivax HB® adult formulation (from Merck) series but fails to receive dose #2 before the 16th birthday?
The 2-dose Recombivax HB® schedule (using adult formulation vaccine) is only licensed for use in 11 through 15-year-olds. Thus, a 16-year-old would need two additional doses of pediatric hepatitis B vaccine to complete a 3-dose series.

I'm a pediatrician and support the use of the birth dose of hepatitis B vaccine. I give it routinely, but a few parents object. In my practice, almost 100% of my infant patients' mothers are tested for HBsAg and almost all are reported to be negative. Could you tell me how many cases of hepatitis B virus (HBV) infection occur each year in babies who are born to documented HBsAg-negative mothers?
Because infants born to "documented" HBsAg-negative mothers are usually not tested for HBV infection, and because virtually all HBV infections occurring among infants are asymptomatic, it is not possible to quantify the number of HBV-infected infants born to mothers believed to be HBsAg negative. However, we know that many unvaccinated newborns have been left needlessly at risk of infection because of errors in maternal hepatitis B testing and reporting. In two surveys conducted by IAC covering the period from July 1999 to October 2002, state and local hepatitis B coordinators reported more than 500 medical errors discovered through their perinatal hepatitis B prevention programs. Many of these errors involved misinterpreting or mistranscribing hepatitis screening test results, or ordering the wrong hepatitis B screening test. Such errors can lead to a mother being documented as HBsAg-negative, when she is actually HBsAg-positive.

Another issue is preventing possible transmission of HBV in early childhood. Seroprevalence data from the National Health and Nutrition Examination Surveys has provided estimates of the number of early HBV infections. Based on these data, approximately 16,000 children under 10 years of age were infected with HBV beyond the post-natal period each year before routine infant vaccination was recommended in 1991 (Armstrong GL, Mast EE, Wojczynski M, Margolis HS. Childhood hepatitis B virus infections in the United States before hepatitis B immunization. Ped. 2001;108(5):1123-28). Although these infections represented only 5%–10% of all persons with chronic infections in the United States at that time, it is estimated that 18% of all persons with chronic infection acquired their infections postnatally during early childhood. In some populations, childhood transmission was more important than perinatal transmission as a cause of chronic HBV infection before infant hepatitis B immunization was widely implemented. For example, in studies conducted among U.S.-born children of Southeast Asian refugees during the 1980s, approximately 60% of chronic infections in young children were among children born to HBsAg-negative mothers.

Use of the hepatitis B vaccine birth dose safeguards against maternal hepatitis B testing and reporting errors and also prevents early childhood HBV infections. The birth dose also protects the infants of women who become HBV infected after having been screened in early pregnancy and not tested later in pregnancy.

NEEDLE TIPS correction policy

The Immunization Action Coalition works tirelessly to ensure the accuracy of the information we make available. At times, however, mistakes occur and we welcome your review of our content. If you find an error, please notify us immediately. We publish notification of significant errors in ***NEEDLE TIPS*** and on our e-mail announcement service ***IAC EXPRESS.*** Be sure you're signed up for this service. Visit www.immunize.org/express to sign up, or subscribe by sending an e-mail to express@immunize.org Enter the word SUBSCRIBE in the "Subject:" field. No message is needed.

Natalie Joy Smith, MD, MPH
Dec. 28, 1961 – Aug. 22, 2003

Our friend and colleague who worked tirelessly to expand the use of childhood and adult vaccines throughout the United States.

Dr. Smith died after a struggle with cancer while Deputy Director of the National Immunization Program, Centers for Disease Control and Prevention.

We will always remember Natalie for the dedication she brought to the field of immunization during her brief tenure at CDC, as Chief of the Immunization Branch at the California Department of Health Services, as a member of CDC's Advisory Committee on Immunization Practices, and as a member of many state and national committees focused on immunization.

Q: What's just about the best investment an immunization provider can make?

A: A $60 contribution to the Immunization Action Coalition!

Typically $60 doesn't go far in a provider's immunization practice. But when you contribute $60 or more to IAC, you get a much sought-after, valuable commodity: print copies of reliable, extensively reviewed, continually updated immunization information. Contribute $60 or more, and here's what you'll receive:

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Deborah L. Wexler, MD
IAC Executive Director

Dear Colleague,

As you know, in today's economy, there are few "extra" dollars. Therefore, to reduce our costs, we have had to trim our *NEEDLE TIPS'* mailing list, removing the names of people we haven't heard from in several years. By eliminating "out-of-touch" recipients, we are better able to serve readers we ***know*** value *NEEDLE TIPS'* up-to-date, practical immunization information. (See page 2 for some opinions about the value of our work.)

To ensure you continue to receive *NEEDLE TIPS* in 2003–04, please show your interest by supporting us during these difficult financial times. ***Your contribution is vital!***

The most helpful way to support us is to send a generous contribution today. You can contribute online at www.immunize.org/join, or you can fill out the form below and fax or mail it to us. Our fax number is (651) 647-9131, and an envelope is enclosed. Your contribution to IAC is tax deductible! (IAC is a non-profit 501[c]3 organization.) With a contribution of $60 or more, you'll receive our extensive collection of patient- and staff-education print materials.

Please keep in touch, and we'll keep *NEEDLE TIPS* coming!

Deborah L. Wexler MD

Deborah L. Wexler, MD
Executive Director

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Oct. 2003

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