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Standards for Child and Adolescent Immunization Practices
National Vaccine Advisory Committee
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SPECIAL ARTICLE

Standards for Child and Adolescent Immunization Practices

National Vaccine Advisory Committee

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

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

Since that time, vaccine delivery in the United States has changed in several important ways. First, vaccination coverage rates among preschool children have increased substantially and are now monitored by the National Immunization Survey.[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.
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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

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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

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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-

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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,

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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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ERRATA

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

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

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

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

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