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Standards for Pediatric Immunization Practices

Recommended by the National Vaccine Advisory Committee

Approved by the U.S. Public Health Service

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Standards for Pediatric Immunization Practices

Ad Hoc Working Group for the Development of the Standards for
Pediatric Immunization Practices

Recommended by the National Vaccine Advisory Committee, approved by the U.S. Public Health Service, and endorsed as of January 22, 1993, by

Advisory Committee on Immunization Practices
American Academy of Family Physicians
American Academy of Pediatrics
American Nurses Association
The ARC (formerly the Association for Retarded Citizens of the United States)
Association of Maternal and Child Health Programs
Council of State and Territorial Epidemiologists
National Association of Children's Hospitals and Related Institutions
National Association of Pediatric Nurse Associates and Practitioners

Ad Hoc Working Group for the Development of the Standards for Pediatric Immunization Practices

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Standards for Pediatric Immunization Practices

Summary

Although 97%–98% of children in the United States are vaccinated before or shortly after starting school, the proportion of preschool children who have completed a full series for all recommended vaccines is considerably lower. Although low immunization coverage among preschoolers has been attributed to difficulties in reaching certain groups, such as the urban poor and racial and ethnic minorities, more recent evaluations suggest that the health-care delivery system itself bears much of the responsibility. To eliminate barriers and obstacles (e.g., appointment-only systems and unnecessary prevaccination physical examinations) that impede efficient vaccine delivery and to encourage providers to take advantage of all health-care visits as opportunities to provide vaccinations, the National Vaccine Advisory Committee (NVAC) called for the development of standards for immunization policies and practices. Eighteen standards were developed in collaboration with a 35-member working group representing 22 public and private agencies. These 18 standards have since been recommended by the NVAC, approved by the U.S. Public Health Service, and endorsed by the American Academy of Pediatrics. The standards are presented and discussed in detail in this report.

INTRODUCTION

The resurgence of measles in the United States during the period 1989–1991 was associated with 55,622 reported cases (*1,2*), 11,251 hospitalizations, >42,000 hospital days (CDC, unpublished data), and 166 suspected deaths from measles (*3*). The cause of the epidemic was failure to vaccinate children at the recommended age of 12–15 months (*4*).

Although 97%–98% of children in the United States are vaccinated before or shortly after starting school with four doses of diphtheria and tetanus toxoids and pertussis vaccine (DTP), three doses of oral poliovirus vaccine (OPV), and one dose of measles-mumps-rubella (MMR) vaccine, series-complete immunization levels among preschool-age children are considerably lower. Recent surveys of children starting school in nine cities measured immunization status as of the second birthday and documented that only 52%–71% had been vaccinated against measles (*5*). Series-complete immunization levels ranged from 10% to 42%. These coverage levels are substantially lower than the *Healthy People 2000* national goal of 90% coverage levels by the second birthday (*6*).

Immunization of preschool-age children is intended to provide early protection to this most vulnerable group, and approximately 80% of the routine childhood vaccines are currently recommended to be administered by 15–18 months of age. In addition, the recommended vaccine series has been expanded to include three or four doses of *Haemophilus influenzae* b vaccine and three doses of hepatitis B vaccine (*7–10*).

Low immunization coverage has been attributed to difficulties in reaching certain groups in the population. These groups include the urban poor and racial and ethnic minorities. However, recent evaluations suggest that the health-care delivery system

itself bears much of the responsibility (*11,12*). Parents seeking vaccination for their children face barriers and obstacles, such as long waiting periods, appointment-only services, and prevaccination physical examinations, that impede efficient vaccine delivery. In addition, not all providers take advantage of all opportunities to administer needed vaccines, because of failure either to screen the immunization status of a child during a health-care visit or to administer simultaneously all vaccines for which a child is eligible. Inadequate or lacking third-party payment for vaccinations further reduces coverage.

The measles epidemic signaled that the immunization delivery system must be changed immediately if the nation's children are to be fully protected. The system requires both enhancement of outreach capacity and modifications of policies and practices to remove the above-mentioned barriers and improve access. The National Vaccine Advisory Committee (NVAC), therefore, made 13 recommendations to improve vaccine delivery in the United States (*4*). Recognizing that both barriers to the receipt of vaccinations and missed opportunities to vaccinate contribute to low coverage levels, NVAC in one of its recommendations called for standards to guide immunization practices.

The resulting Standards for Pediatric Immunization Practices (see box on page 3) were developed by CDC in collaboration with a 35-member working group representing 22 public and private agencies that had input from state and local health departments, physician and nursing organizations, and public and private providers involved in clinical care and in prevention health services. The Standards represent the consensus of the NVAC and the working group that address the most essential and desirable immunization policies and practices for an immunization service. The Standards are accompanied by a Guide to Contraindications and Precautions to Immunization (Table 1), which reflects the current recommendations of the Advisory Committee on Immunization Practices (ACIP), as well as the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP) (*7,8*).

The Standards have been endorsed by several medical and public health organizations. These organizations encourage adherence to the Standards for Pediatric Immunization Practices as a key element in our national strategy to administer vaccines more efficiently and effectively to the nation's children.

THE STANDARDS

Ideally, immunizations should be administered as part of comprehensive child health care. Overall improvement in our primary-care delivery system requires intensive effort and will take time. However, providing effective immunization programs should not depend on changes in this system before vaccinations are delivered more effectively to U.S. children.

Current health-care policies and practices in all settings result in the failure to deliver vaccines on schedule to many vulnerable preschool-age children. This failure is due primarily to barriers that impede vaccine delivery and to missed opportunities during clinic visits. Changes in policies and practices can immediately improve coverage. The present system should be geared to "user-friendly," family-centered, culturally sensitive, and comprehensive primary health care that can provide rapid, efficient, and consumer-oriented services to the users, i.e., children and their parents.

Standards for Pediatric Immunization Practices

1. Immunization services are readily available.
2. There are no barriers or unnecessary prerequisites to the receipt of vaccines.
3. Immunization services are available free or for a minimal fee.
4. Providers utilize all clinical encounters to screen and, when indicated, vaccinate children.
5. Providers educate parents and guardians about immunization in general terms.
6. Providers question parents or guardians about contraindications and, before vaccinating a child, inform them in specific terms about the risks and benefits of the vaccinations their child is to receive.
7. Providers follow only true contraindications.
8. Providers administer simultaneously all vaccine doses for which a child is eligible at the time of each visit.
9. Providers use accurate and complete recording procedures.
10. Providers co-schedule immunization appointments in conjunction with appointments for other child health services.
11. Providers report adverse events following vaccination promptly, accurately, and completely.
12. Providers operate a tracking system.
13. Providers adhere to appropriate procedures for vaccine management.
14. Providers conduct semi-annual audits to assess immunization coverage levels and to review immunization records in the patient populations they serve.
15. Providers maintain up-to-date, easily retrievable medical protocols at all locations where vaccines are administered.
16. Providers practice patient-oriented and community-based approaches.
17. Vaccines are administered by properly trained persons.
18. Providers receive ongoing education and training regarding current immunization recommendations.

The failure to do so is evidenced by the recent resurgence of measles and measles-related childhood mortality, which may be a precursor of other vaccine-preventable disease outbreaks. The following Standards for Pediatric Immunization Practices and the accompanying discussions address these issues.

Standard 1. Immunization services are readily available.

Discussion: Immunization services should be responsive to the needs of patients. For example, in large urban areas, public immunization clinic services should be available daily, 8 hours per day. In smaller cities and rural areas, clinics may operate less frequently. To be fully responsive, providers in many locations should consider offering immunization services each working day as well as during some off-hours (e.g., weekends, evenings, early mornings, or lunch hours). Immunization services should be considered for all days and at all hours that other child health services at the same site are offered (e.g., the Special Supplemental Food Program for Women, Infants, and Children [WIC]). Private providers who offer primary care to infants and children should always include immunization services as a routine part of that care.

Ready availability of immunization services also requires that the supply of vaccines be adequate at all times.

Standard 2. There are no barriers or unnecessary prerequisites to the receipt of vaccines.

Discussion: Appointment-only systems often act as barriers to immunization in both public and private settings. Immunization services should be available on a walk-in basis at all times for both routine and new enrollee visits. Waiting time should be minimized and generally should not exceed 30 minutes. Furthermore, administration of needed vaccines should not be contingent on enrollment in a well-baby program unless enrollment is immediately available. Children coming only for vaccinations should be rapidly and efficiently screened without requiring other comprehensive health services. However, children who receive vaccinations in such an "express lane" fashion and who do not have a primary-care provider should be referred to one.

Physical examinations and temperature measurements before vaccination should not be required if they delay or impede the timely receipt of vaccinations (e.g., appointments for physical examination in some facilities may take weeks to months to schedule). A reliable decision to vaccinate can be based exclusively on the information elicited from a parent or guardian and on the provider's observations and judgment about the child's wellness at the time of vaccination. At a minimum, children should have prevaccination assessments, including a) observing the child's general state of health, b) asking the parent or guardian if the child is well, and c) questioning the parent or guardian about potential contraindications (Table 1).

In public clinic settings, the administration of vaccines should not depend on individual written orders or on a referral from a primary-care provider. Rather, standing orders should be developed and implemented.

Standard 3. Immunization services are available free or for a minimal fee.

Discussion: In the public sector, vaccinations should be free of charge. If fees must be collected, they should be kept to a minimum. In the private sector, charges should include the cost of the vaccine and a reasonable administration fee.

Affordable vaccinations will limit fragmentation of care and help assure immunization of the greatest number of children. Public and private providers who charge a fee to administer vaccines obtained through a consolidated federal contract should prominently display a state-approved sign indicating that no one will be denied immunization services because of inability to pay the fee.

Standard 4. Providers utilize all clinical encounters to screen for needed vaccines and, when indicated, vaccinate children.

Discussion: Each encounter with a health-care provider, including an emergency room visit or hospitalization, is an opportunity to screen vaccination status and, if indicated, administer needed vaccines. Before discharge from the hospital, children should receive vaccinations for which they are eligible by age or health status. The child's regular health-care provider should be informed about the vaccinations administered. Implementation of this standard minimizes the number of missed opportunities to vaccinate.

In addition, children accompanying parents or siblings who are seeking any service should also be screened and, when indicated, should be administered needed vaccines. Providers in subspecialty clinics (e.g., oncology) who care for children should pay particular attention to the vaccination status of their patients and vaccinate or refer them to immunization services or primary health-care providers as appropriate.

Providers in other specialties should also note the vaccination status of children and refer or vaccinate as appropriate.

Standard 5. Providers educate parents and guardians about immunization in general terms.

Discussion: Providers should educate parents and guardians in a culturally sensitive way, preferably in their own language, about the importance of immunizations, the diseases they prevent, the recommended vaccination schedules, the need to receive vaccinations at recommended ages, and the importance of bringing their child's immunization record to each visit. Parents should be encouraged to take responsibility for ensuring that their child completes the full series. Providers should answer all questions parents and guardians may have and provide appropriate educational materials at suitable reading levels in the parents' or guardians' own language.

Standard 6. Providers question parents or guardians about contraindications and, before vaccinating a child, inform them in specific terms about the risks and benefits of the vaccinations their child is to receive.

Discussion: Minimal acceptable screening procedures for precautions and contraindications include asking questions to elicit a possible history of adverse events following prior immunizations and determining any existing precautions or contraindications (Table 1).

The Vaccine Information Pamphlets (required by regulation to be used universally beginning April 15, 1992, for measles, mumps, rubella, diphtheria, tetanus, pertussis, and poliomyelitis by all providers administering vaccine purchased from the federal contract) should be provided and reviewed with parents or guardians. Private physicians who purchase their own vaccines must use these pamphlets or must develop and use alternative vaccine information materials that meet all legal requirements. Similar information contained in the Important Information Statements for other vaccines (e.g., hepatitis B and *Haemophilus influenzae* type b) should be provided to all parents or guardians in public clinics, and use of these statements should be considered by private providers. Providers should ensure that information materials are current and available in appropriate languages. Providers should ask parents or guardians if they have questions about what they have read and should ensure that they receive satisfactory answers to their questions.

Providers should explain where and how to obtain medical care during both day and evening hours in case of an adverse event following vaccination.

Standard 7. Providers follow only true contraindications.

Discussion: Accepting conditions that are not true contraindications (Table 1) often results in the needless deferment of indicated immunizations. The table of true contraindications is based on the recommendations of the ACIP and the recommendations of the Committee on Infectious Diseases (Red Book Committee) of the AAP. These recommendations may vary from those contained in the manufacturer's package inserts. For more detailed information, providers should consult the published recommendations of the ACIP, the AAP, the American Academy of Family Physicians (AAFP), and the manufacturer's package inserts.

Standard 8. Providers administer simultaneously all vaccine doses for which a child is eligible at the time of each visit.

Discussion: Available evidence suggests that the simultaneous administration of childhood vaccinations is safe and effective. In addition, evidence suggests that the simultaneous administration of multiple needed vaccines can potentially raise immunization coverage by 9%–17%. If providers elect not to administer a needed vaccine simultaneously with others (based either on their judgment that this action will not compromise the timely immunization of the child or on a request by the parent or guardian), they should document such actions and the reasons why the vaccine was not administered. The record should be flagged with an automatic recall for an appointment so that the child can receive the needed vaccine(s). This next appointment should be discussed with the parent or guardian of the child.

MMR vaccine should always be used in combined form when routine childhood vaccinations are provided.

Standard 9. Providers use accurate and complete recording procedures.

Discussion: Providers are required by statute to record what vaccine was administered, the date of administration (month, day, year), the name of the manufacturer of the vaccine, the lot number, the signature and title of the person who administered the vaccine, and the address where the vaccine was administered. In addition, providers

should record on the child's personal immunization record card (preferably the official state version) what vaccine was administered, the date the vaccine was administered, and the name of the provider. Providers should encourage parents or guardians to maintain a copy of their child's personal immunization record card. This card should be updated at each visit for vaccinations. If a parent fails to bring a child's card, a new one should be issued. It should contain all previous immunizations and should be identified as a replacement record card. When accepting data about previous immunizations from parents, providers should confirm that prior doses of vaccines have actually been administered, either by reviewing immunization record cards or by contacting former providers and entering this verified information onto their records. When a provider who does not routinely vaccinate or care for a child administers a vaccine to that child, the regular provider should be informed.

Providers with manual recordkeeping systems should maintain separate or easily retrievable files of the immunization records of preschool-age children to facilitate assessment of coverage as well as the identification and recall of children who miss appointments. In addition, immunization files of preschool-age children should be sorted periodically, with inactive records placed into a separate file. Providers should indicate in their records or in an appropriately identified place all primary care services that each child receives in order to facilitate co-scheduling with other services.

Standard 10. Providers co-schedule immunization appointments in conjunction with appointments for other child health services.

Discussion: Providers of immunization-only services that require an appointment should co-schedule immunization appointments with other needed health-care services such as WIC, dental examinations, or developmental screening, provided such scheduling does not create a barrier by delaying needed immunizations.

Standard 11. Providers report adverse events following vaccination promptly, accurately, and completely.

Discussion: Providers should encourage parents or legal guardians to inform them of adverse events following immunization. Providers should report all such clinically important events, including those required by law, to the Vaccine Adverse Event Reporting System, regardless of whether they believe the events are caused by the vaccines. Report forms and assistance are available by calling 1-800-822-7967. Providers should document fully the adverse event in the medical record at the time of the event or as soon as possible thereafter.

Standard 12. Providers operate a tracking system.

Discussion: A tracking system should generate reminders of upcoming immunizations as well as recalls for children who are overdue for their vaccinations. A system may be automated or manual and may include mailed or telephone messages. In the public sector, health department staff may also make home visits. All providers should identify, for additional intensive tracking efforts, children considered at high risk for failing to complete the immunization series on schedule (e.g., children who start their series late).

Standard 13. Discussion: Providers adhere to appropriate procedures for vaccine management.

Discussion: Vaccines should be handled and stored as recommended in the manufacturer's package inserts. The temperatures at which vaccines are stored and transported should be monitored daily, and the expiration date for each vaccine should be noted.

Providers using publicly purchased vaccine should periodically report usage, wastage, loss, and inventory, as required by state or local public health authorities.

Standard 14. Providers conduct semi-annual audits to assess immunization coverage levels and to review immunization records in the patient populations they serve.

Discussion: In both the public and private sectors, the assessment of immunization services for preschool-age patients should include audits of immunization records or inspection of a random sample of records a) to determine the immunization coverage level (i.e., the percentage of 2-year-old children who are up to date), b) to identify how frequently opportunities for simultaneous immunization are missed, and c) to assess the quality of documentation. The results of such assessments should be discussed by providers as part of their ongoing quality assurance reviews and used to develop solutions to the problems identified.

Standard 15. Providers maintain up-to-date, easily retrievable medical protocols at all locations where vaccines are administered.

Discussion: Providers administering vaccines should maintain a protocol which, at a minimum, discusses the appropriate vaccine dosage, vaccine contraindications, and the recommended sites and techniques for vaccine administration, as well as possible adverse events and their emergency management. Such protocols should specify the necessary emergency medical equipment, drugs (including dosage), and personnel to safely and competently manage any medical emergency that may arise after the administration of a vaccine. All providers should be familiar with the content of these protocols, their location, and how to follow them. Vaccines can be administered in any setting (e.g., schools, churches) where providers can adhere to these protocols.

Standard 16. Providers practice patient-oriented and community-based approaches.

Discussion: Public providers should routinely seek the input of their patients on specific approaches to better serve their immunization needs and implement the changes necessary to provide more user-friendly services.

Public providers should adopt a community-based approach to the provision of immunization services that recommends reaching high coverage levels in their catchment area populations and not only in the active patient populations they serve. Such a community-based approach requires all public providers to publicize the availability of their immunization services and to conduct community outreach activities to increase demand for them. Private providers should cooperate with local health officials in their efforts to assure high coverage levels throughout the community. Without high immunization coverage levels, no community is completely protected against

vaccine-preventable diseases. All providers share responsibility for achieving the highest possible degree of community protection.

Standard 17. Vaccines are administered by properly trained persons.

Discussion: Only properly trained persons should administer vaccines. However, the task of administering vaccines need not be assigned exclusively to physicians and nurses. With appropriate training, including the management of emergency situations, and under professional supervision, other personnel can skillfully and safely administer vaccines. In some jurisdictions, statutory requirements may limit the administration of vaccines to licensed physicians and/or nurses and may therefore create barriers to immunization. If so, legal opinion should be sought locally to determine the necessary steps to overcome this barrier.

Standard 18. Providers receive ongoing education and training regarding current immunization recommendations.

Discussion: Providers include all persons who are involved in the administration of vaccines, the management of immunization clinics, or the support of these functions. Training and education should cover current guidelines and recommendations of the ACIP, AAP, and the AAFP, as well as the Standards for Pediatric Immunization Practices and other immunization information sources, such as the manufacturer's package inserts. Providers should also receive information about ongoing national efforts to reach the year 2000 goal of 90% series-complete immunization by the second birthday.

COMMENT

These Standards are recommended for use by all health professionals in the public and private sector who administer vaccines to or manage immunization services for infants and children. These Standards represent the most desirable immunization practices that health-care providers should strive to achieve to the extent possible. By adopting these Standards, providers can begin to enhance and change their own policies and practices. Not all providers will have the funds necessary to fully implement the Standards immediately. Nevertheless, providers and programs lacking the resources to implement the Standards fully should find them a useful tool in better delineating immunization needs and in obtaining additional resources to achieve the *Healthy People 2000* immunization objective.

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Association of State and Territorial Health Officials
Centers for Disease Control and Prevention
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National Association of Pediatric Nurse Associates and Practitioners
National Migrant Resource Program
National Vaccine Injury Compensation Program
United States Conference of Local Health Officers
State and Local Health Departments

Membership in the Ad Hoc Working Group does not necessarily imply organizational endorsement.

TABLE 1. Guide to Contraindications and Precautions to Vaccinations*

True contraindications and precautions	Not true (vaccines may be administered)
General for all vaccines (DTP/DTaP, OPV, IPV, MMR, Hib, HBV)	
Contraindications	Mild to moderate local reaction (soreness, redness, swelling) following a dose of an injectable antigen
Anaphylactic reaction to a vaccine contraindicates further doses of that vaccine	Mild acute illness with or without low-grade fever
Anaphylactic reaction to a vaccine constituent contraindicates the use of vaccines containing that substance	Current antimicrobial therapy
Moderate or severe illnesses with or without a fever	Convalescent phase of illnesses
	Prematurity (same dosage and indications as for normal, full-term infants)
	Recent exposure to an infectious disease
	History of penicillin or other nonspecific allergies or family history of such allergies
DTP/DTaP	
Contraindications	Temperature of <40.5 C (105 F) following a previous dose of DTP
Encephalopathy within 7 days of administration of previous dose of DTP	Family history of convulsions§
Precautions†	Family history of sudden infant death syndrome
Fever of ≥40.5°C (105°F) within 48 hrs after vaccination with a prior dose of DTP	Family history of an adverse event following DTP administration
Collapse or shocklike state (hypotonic-hyporesponsive episode) within 48 hrs of receiving a prior dose of DTP	
Seizures within 3 days of receiving a prior dose of DTP§	
Persistent, inconsolable crying lasting ≥3 hrs within 48 hrs of receiving a prior dose of DTP	
OPV¶	
Contraindications	Breast-feeding
Infection with HIV or a household contact with HIV	Current antimicrobial therapy
Known altered immunodeficiency (hematologic and solid tumors; congenital immunodeficiency; and long-term immunosuppressive therapy)	Diarrhea
Immunodeficient household contact	
Precaution†	
Pregnancy	

DTP = Diphtheria-tetanus toxoid and pertussis vaccine
DTaP = Diphtheria and tetanus toxoids and acellular pertussis vaccine
OPV = Oral poliovirus vaccine
IPV = Inactivated poliovirus vaccine
MMR = Measles-mumps-rubella vaccine
Hib = *Haemophilus influenzae* type b vaccine
HBV = Hepatitis B vaccine

TABLE 1. Guide to Contraindications and Precautions to Vaccinations* — Continued

True contraindications and precautions	Not true (vaccines may be administered)
IPV	
Contraindication Anaphylactic reaction to neomycin or streptomycin	
Precaution† Pregnancy	
MMR¶	
Contraindications Anaphylactic reactions to egg ingestion and to neomycin** Pregnancy Known altered immunodeficiency (hematologic and solid tumors; congenital immunodeficiency; and long-term immunosuppressive therapy)	Tuberculosis or positive skin test Simultaneous TB skin testing†† Breast-feeding Pregnancy of mother of recipient Immunodeficient family member or household contact
Precaution† Recent (within 3 months) immune globulin administration	Infection with HIV Nonanaphylactic reactions to eggs or neomycin
Hib	
None identified	
HBV	
None identified	Pregnancy

*This information is based on the recommendations of the Advisory Committee on Immunization Practices (ACIP) and those of the Committee on Infectious Diseases (Red Book Committee) of the American Academy of Pediatrics (AAP) as of October 1992. Sometimes these recommendations vary from those contained in the manufacturer's package inserts. For more detailed information, providers should consult the published recommendations of the ACIP, AAP, American Association of Family Practice Physicians, and the manufacturer's package inserts.

†The events or conditions listed as precautions, although not contraindications, should be carefully reviewed. The benefits and risks of administering a specific vaccine to an individual under the circumstances should be considered. If the risks are believed to outweigh the benefits, the vaccination should be withheld; if the benefits are believed to outweigh the risks (for example, during an outbreak or foreign travel), the vaccination should be administered. Whether and when to administer DTP to children with proven or supected underlying neurologic disorders should be decided on an individual basis. It is prudent on theoretical grounds to avoid vaccinating pregnant women. However, if immediate protection against poliomyelitis is needed, OPV, not IPV, is recommended.

§For children with a personal or family (siblings or parents) history of convulsions, acetaminophen should be considered before DTP is administered and thereafter every 4 hours for 24 hours.

¶There is a theoretical risk that the administration of multiple live-virus vaccines (OPV and MMR) within 30 days of one another if not administered on the same day will result in a suboptimal immune response. There are no data to substantiate this lack of response.

**Persons with a history of anaphylactic reactions following egg ingestion should be vaccinated only with extreme caution. Protocols that have been developed for vaccinating such persons should be consulted (J Pediatr 1983;102:196–9, J Pediatr 1988;113:504–6).

††Measles vaccination may temporarily suppress tuberculin reactivity. If testing cannot be done the day of MMR vaccination, the test should be postponed for 4–6 weeks.

MMWR

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