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Recommendations of the Immunization Practices Advisory Committee (ACIP) General Recommendations on Immunization

This revision of the "General Recommendations on Immunization" updates the 1983 statement (1). Changes or new sections include 1) listing of vaccines available in the United States by type and recommended routes, 2) updated schedules for immunizing infants and children, 3) clarification of the guidelines for spacing administration of immune globulin preparations and different vaccines, 4) an updated table of recommendations for routine immunization of children infected with human immunodeficiency virus, 5) listing of conditions that are often inappropriately considered contraindications to immunization, and 6) addition of information on the National Childhood Vaccine Injury Act of 1986 and the National Vaccine Injury Compensation Program. These recommendations are not comprehensive for each vaccine; Immunization Practices Advisory Committee (ACIP) recommendations on each vaccine should be consulted for more details. INTRODUCTION Recommendations for immunizing infants, children, and adults are based on characteristics of immunobiologics, scientific knowledge about the principles of active and passive immunization, and judgments by public health officials and specialists in clinical and preventive medicine. Benefits and risks are associated with the use of all immunobiologics: no vaccine is completely safe or completely effective. Benefits of immunization range from partial to complete protection against the consequences of disease (which range from mild or asymptomatic infection to severe consequences, such as paralysis or death); risks of immunization range from common, trivial, and inconvenient side effects to rare, severe, and life-threatening conditions. Thus, recommendations for immunization practices balance scientific evidence of benefits, costs, and risks to achieve optimal levels of protection against infectious diseases. These recommendations describe this balance and attempt to minimize the risks by providing specific advice regarding dose, route, and spacing of immunobiologics and delineating situations that warrant precautions or contraindicate their use. They are recommendations for use in the United States because epidemiologic circumstances and vaccines often differ in other countries. Individual circumstances may warrant deviations from these recommendations. The relative balance of benefits and risks can change as diseases are controlled or eradicated. For example, because smallpox has been eradicated throughout the world, the risk of complications associated with smallpox vaccine now exceeds the risk of the disease; consequently, smallpox vaccination of civilians is now indicated only for laboratory workers directly involved with smallpox or closely related orthopox viruses (e.g., monkeypox and vaccinia). DEFINITIONS Immunobiologic Immunobiologics include both antigenic substances, such as vaccines and toxoids, and antibody-containing preparations, including globulins and antitoxins, from human or animal donors. These products are used for active or passive immunization or therapy. Examples include: Vaccine (Table 1): A suspension of live (usually attenuated) or inactivated microorganisms (bacteria, viruses, or rickettsiae) or fractions thereof administered to induce immunity and thereby prevent infectious disease. Some vaccines contain

highly defined antigens (e.g., the polysaccharide of Haemophilus influenzae type b or the surface antigen of hepatitis B); others have antigens that are complex or incompletely defined (e.g., killed Bordetella pertussis or live attenuated viruses). Toxoid: A modified bacterial toxin that has been rendered nontoxic but retains the ability to stimulate the formation of antitoxin. Immune globulin (IG): A sterile solution containing antibodies from human blood. It is obtained by cold ethanol fractionation of large pools of blood plasma and contains 15%-18% protein. Intended for intramuscular administration, it is primarily indicated for routine maintenance of immunity of certain immunodeficient persons and for passive immunization against measles and hepatitis A. IG does not transmit hepatitis B virus, human immunodeficiency virus (HIV), or other infectious diseases. Intravenous immune globulin (IGIV): A product derived from blood plasma from a donor pool similar to the IG pool but prepared so it will be suitable for intravenous use. IGIV does not transmit infectious diseases. It is primarily indicated for replacement therapy in antibody-deficiency disorders. Specific IG: Special preparations obtained from blood plasma from donor pools preselected for a high antibody content against a specific antigen, e.g., hepatitis B immune globulin (HBIG), varicella-zoster immune globulin, rabies immune globulin, and tetanus immune globulin. Like IG and IGIV, these preparations do not transmit infectious diseases. Antitoxin: A solution of antibodies derived from the serum of animals immunized with specific antigens (e.g., diphtheria antitoxin, botulinum antitoxin) used to achieve passive immunity or for treatment. Vaccination and Immunization These terms are often used interchangeably. Vaccination and vaccine derive from vaccinia, the virus once used as smallpox vaccine. Thus, vaccination originally meant inoculation with vaccinia virus to render a person immune to smallpox. Although some persons still prefer that vaccination be restricted to this use, most use it to denote the administration of any vaccine or toxoid. Immunization is a more inclusive term denoting the process of inducing or providing immunity artificially by administering an immunobiologic. Immunization can be active or passive. Active immunization is the production of antibody or other immune responses to the administration of a vaccine or toxoid. Passive immunization means the provision of temporary immunity by the administration of preformed antibodies. Three types of immunobiologics are administered for passive immunization: 1) pooled human IG or IGIV, 2) specific IG preparations, and 3) antitoxins. Vaccination and immunization are used interchangeably in ACIP statements in reference to active immunization. Regardless of which term is used, administration of an immunobiologic cannot be automatically equated with the development of adequate immunity for a variety of reasons, many of which are discussed below. IMMUNOBIOLOGICS The specific nature and content of immunobiologics can differ. When immunobiologics against the same infectious agents are produced by different manufacturers, active and inert ingredients in the various products are not always the same. Practitioners are urged to become familiar with the constituents of the products they use. Suspending Fluids These may be sterile water or saline or complex fluids containing small amounts of protein or other constituents derived from the medium or biologic system in which the vaccine is produced (e.g., serum proteins, egg antigens, cell-culture-derived antigens). Preservatives, Stabilizers, Antibiotics These components of vaccines, antitoxins, and globulins are used to inhibit or prevent bacterial growth in viral cultures or the final product or to stabilize the antigens or antibodies. Allergic reactions can occur if the recipient is sensitive to one of these additives (e.g., mercurials, phenols, albumin, glycine). Adjuvants Many antigens evoke insufficient immunologic responses when given in their natural state. Efforts to enhance immunogenicity include mixing antigens with a variety of substances or adjuvants (e.g., aluminum adjuvants such as aluminum phosphate). ROUTE, SITE, AND TECHNIQUE OF IMMUNIZATION Route Routes of administration are recommended for each immunobiologic (Table 1). To avoid unnecessary local or systemic effects and/or to ensure optimal efficacy, the practitioner should not deviate from the recommended routes. Vaccines containing adjuvants must be injected deep into the muscle mass; they should not be administered subcutaneously or intradermally because they can cause local irritation, inflammation, granuloma formation, or necrosis. Site Injectable immunobiologics should be administered where there is little likelihood of local, neural, vascular, or tissue injury. Subcutaneous injections are usually administered into the thigh of infants and in the deltoid area of older children and adults. Intradermal injections are generally given on the volar surface of the forearm except for human diploid cell rabies vaccine with which reactions are less severe in the deltoid area. The preferred sites for intramuscular injections are the anterolateral aspect of the upper thigh and the deltoid muscle of the upper arm. In most infants, the anterolateral aspect of the thigh provides the largest muscle mass and is therefore the preferred site. An individual decision must be made for each child based on the volume of the material to be administered and the size of the muscle into which it is to be injected. In adults, the deltoid is recommended for routine intramuscular vaccine administration, particularly for hepatitis B vaccine. The buttock should not be used routinely as a vaccination site for infants, children, or adults because of the risk of injury to the sciatic nerve. In addition, injection into the buttock has been associated with decreased

immunogenicity of hepatitis B and rabies vaccines, presumably because of inadvertent subcutaneous injection or injection into deep fat tissue. If the buttock is used when very large volumes are to be injected or multiple doses are necessary (e.g., large doses of IG), the central region should be avoided; only the upper, outer quadrant should be used. Techniques Syringes and needles used for injections must be sterile and preferably disposable to minimize the risk of contamination. For an intramuscular injection, the needle and syringe should be of sufficient length and bore to reach the muscle mass itself and prevent vaccine from seeping into subcutaneous tissue. For children, a 20- or 22-gauge needle 1 to 1-1/2 inches long is recommended. For small infants, a 25-gauge 5/8-inch-long needle may be adequate. For adults, the suggested needle length is 1-1/2 inches. For subcutaneous or intradermal injections, a 25-gauge needle 5/8-3/4 inches long is recommended. Before the injection is given, the needle is inserted in the site and the syringe plunger pulled back; if blood appears, the needle should be withdrawn and a new site selected. The process should be repeated until no blood appears. A separate needle and syringe should be used for each vaccine injected. Disposable needles and syringes should be discarded into labeled, puncture-proof containers to prevent accidental needlesticks or reuse. If more than one vaccine preparation is administered or if vaccine and IG are administered simultaneously, each should be given at a different site. DOSAGE The recommendations on dosages of immunobiologics are derived from theoretical considerations, experimental trials, and clinical experience. Administration of volumes smaller than those recommended, such as split doses or intradermal administration (unless specifically recommended), can result in inadequate protection. Use of larger than the recommended dose can be hazardous because of excessive local or systemic concentrations of antigens. The ACIP strongly discourages any variation from the recommended volume or number of doses of any vaccine. Some practitioners use smaller, divided, doses of vaccine, thereby reducing the total immunizing dose. Others use multiple smaller doses that together equal a full immunizing dose (e.g., diphtheria and tetanus toxoids and pertussis vaccine (DTP)) in an effort to reduce reactions. However, the serologic response, clinical efficacy, and/or frequency and severity of adverse reactions of such schedules have not been adequately studied. AGE AT WHICH IMMUNOBIOLOGICS ARE ADMINISTERED Several factors influence recommendations concerning the age at which vaccines are administered (Table 2); they are age-specific risks of disease, age-specific risks of complications, ability of persons of a given age to respond to the vaccine(s), and potential interference with the immune response by passively transferred maternal antibody. In general, vaccines are recommended for the youngest age group at risk whose members are known to develop an acceptable antibody response to vaccination. SPACING OF IMMUNOBIOLOGICS Multiple Doses of Same Antigen Some products require administration of more than one dose for development of an adequate antibody response. In addition, some products require periodic reinforcement (booster) doses to maintain protection. In recommending the ages and/or intervals for multiple doses, the ACIP takes into account risks from disease and the need to induce or maintain satisfactory protection (Tables 2, 3, and 4). Intervals between doses that are longer than those recommended do not lead to a reduction in final antibody levels. Therefore, it is not necessary to restart an interrupted series of an immunobiologic or to add extra doses. In contrast, giving doses of a vaccine or toxoid at less than recommended intervals may lessen the antibody response and therefore should be avoided. Doses given at less than recommended intervals should not be counted as part of a primary series. Some vaccines produce local or systemic symptoms in certain recipients when given too frequently (e.g., Td, DT, and rabies). Such reactions are thought to result from the formation of antigen-antibody complexes. Good recordkeeping, careful patient histories, and adherence to recommended schedules can decrease the incidence of such reactions without sacrificing immunity. Different Antigens Experimental evidence and extensive clinical experience have strengthened the scientific basis for giving certain vaccines at the same time. Many of the widely used vaccines can safely and effectively be given simultaneously (i.e., on the same day, not at the same site). This knowledge is particularly helpful when there is imminent exposure to several infectious diseases, preparation for foreign travel, or uncertainty that the person will return for further doses of vaccine. 1.Simultaneous administration In general, inactivated vaccines can be administered simultaneously at separate sites. However, when vaccines commonly associated with local or systemic side effects (e.g., cholera, typhoid, and plague) are given simultaneously, the side effects can be accentuated. Whenever possible, these vaccines should be given on separate occasions. Simultaneous administration of pneumococcal polysaccharide vaccine and whole-virus influenza vaccine elicits satisfactory antibody responses without increasing the incidence or severity of adverse reactions. Simultaneous administration of the pneumococcal vaccine and split-virus influenza vaccine can also be expected to yield satisfactory results. Influenza vaccine should be administered annually to the target population. In general, simultaneous administration of the most widely used live and inactivated vaccines has not resulted in impaired antibody responses or increased rates of adverse reactions. Administration of combined measles, mumps, and

rubella (MMR) vaccine yields results similar to administration of individual measles, mumps, and rubella vaccines at different sites. Therefore, there is no medical basis for giving these vaccines separately for routine immunization instead of the preferred MMR combined vaccine. There are equivalent antibody responses and no clinically significant increases in the frequency of adverse events when DTP, MMR, and oral polio vaccine (OPV) or inactivated polio vaccine (IPV) are administered either simultaneously at different sites or separately. As a result, routine simultaneous administration of MMR, DTP, and OPV (or IPV) to all children greater than or equal to15 months who are eligible to receive these vaccines is recommended. Administration of MMR at 15 months followed by DTP and OPV (or IPV) at 18 months remains an acceptable alternative, especially for children with caregivers known to be generally compliant with other health-care recommendations. Data are lacking on concomitant administration of Haemophilus influenzae b conjugate vaccine (HbCV) or Haemophilus influenzae b polysaccharide vaccine (HbPV) and MMR and OPV vaccine. If the child might not be brought back for future immunizations, the simultaneous administration of all vaccines (including DTP, OPV, MMR, and HbCV or HbPV) appropriate to the age and previous vaccination status of the recipient is recommended. Hepatitis B vaccine given with DTP and OPV or given with yellow fever vaccine is as safe and efficacious as these vaccines administered separately. The antibody responses of both cholera and yellow fever vaccines are decreased if given simultaneously or within a short time of each other. If possible, cholera and yellow fever vaccinations should be separated by at least 3 weeks. If there are time constraints and both vaccines are necessary, the injections can be given simultaneously or within a 3-week period with the understanding that antibody response may not be optimal. Decisions on the need for yellow fever and cholera immunizations should take into account the amount of protection afforded by the vaccine, the possibility that environmental or hygienic practices may be sufficient to avoid disease exposure, and the existence of vaccination requirements for entry into a country. 2.Nonsimultaneous administration Inactivated vaccines do not interfere with the immune response to other inactivated vaccines or to live vaccines except, as noted above, with cholera and yellow fever vaccines. In general, an inactivated vaccine can be given either simultaneously or at any time before or after a different inactivated vaccine or a live vaccine. There are theoretical concerns that the immune response to one live-virus vaccine might be impaired if given within 30 days of another. Whenever possible, live-virus vaccines not administered on the same day should be given at least 30 days apart (Table 5). Live-virus vaccines can interfere with the response to a tuberculin test. Tuberculin testing can be done either on the same day that live-virus vaccines are administered or 4-6 weeks afterwards. Immune Globulin If administration of an IG preparation becomes necessary because of imminent exposure to disease, live-virus vaccines can be given simultaneously with the IG product, with the recognition that vaccine-induced immunity might be compromised. The vaccine should be administered at a site remote from that chosen for the IG inoculation. Vaccination should be repeated about 3 months later unless serologic testing indicates that specific antibodies have been produced. OPV and yellow fever vaccines are exceptions, however, and are not affected by administration of IG at any time. Live, attenuated vaccine viruses might not replicate successfully, and antibody response could be diminished when the vaccine is given after IG or specific IG preparations. Whole blood or other antibody-containing blood products can interfere with the antibody response to measles, mumps, and rubella vaccines. In general, these parenterally administered live vaccines should not be given for at least 6 weeks, and preferably 3 months, after IG administration. However, the postpartum vaccination of susceptible women with rubella vaccine should not be delayed because of receipt of anti-Rho(D) IG (human) or any other blood product during the last trimester of pregnancy or at delivery. These women should be vaccinated immediately after delivery and, if possible, tested in 3 months to ensure that rubella immunity was established. If administration of IG preparations becomes necessary after a live-virus vaccine has been given, interference can occur. Usually, vaccine virus replication and stimulation of immunity will occur 1-2 weeks after vaccination. Thus, if the interval between administration of live-virus vaccine and subsequent administration of an IG preparation is less than 14 days, vaccination should be repeated at least 3 months after the IG product was given, unless serologic testing indicates that antibodies were produced. In general, there is little interaction between IG preparations and inactivated vaccines. Therefore, inactivated vaccines can be given simultaneously or at any time before or after an IG product is used. For example, postexposure prophylaxis with simultaneously administered hepatitis B, rabies, or tetanus IG and the corresponding inactivated vaccine or toxoid does not impair the immune response and provides immediate protection and long-lasting immunity. The vaccine and IG should be given at different sites, and standard doses of the corresponding vaccine should be used. Increasing the vaccine dose volume or number of immunizations is not indicated (Table 6). HYPERSENSITIVITY TO VACCINE COMPONENTS Vaccine components can cause allergic reactions in some recipients. These reactions can be local or systemic, including mild to severe

anaphylaxis (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock). The responsible vaccine components can derive from: 1) animal protein, 2) antibiotics, 3) preservatives, and 4) stabilizers. The most common animal protein allergen is egg protein found in vaccines prepared using embryonated chicken eggs or chicken embryo cell cultures (e.g., yellow fever, mumps, measles, and influenza vaccines). Ordinarily, persons who are able to eat eggs or egg products safely can receive these vaccines; persons with histories of anaphylactic allergy to eggs or egg proteins should not. Asking persons whether they can eat eggs without adverse effects is a reasonable way to screen for those who might be at risk from receiving measles, mumps, yellow fever, and influenza vaccines. Protocols requiring extreme caution have been developed for testing and vaccinating with measles and mumps vaccines those persons with anaphylactic reactions to egg ingestion (4). A regimen for administering influ- enza vaccine to children with egg hypersensitivity and severe asthma has also been developed (5). Rubella vaccine is grown in human diploid cell cultures and can safely be given to persons with histories of severe allergy to eggs or egg proteins. Some vaccines contain trace amounts of antibiotics to which patients may be hypersensitive. The information provided in the vaccine package insert should be carefully reviewed before a decision is made whether the rare patient with such hypersensitivity should be given the vaccine(s). No currently recommended vaccine contains penicillin or its derivatives. MMR and its individual component vaccines contain trace amounts of neomycin. Although the amount present is less than would usually be used for the skin test to determine hypersensitivity, persons who have experienced anaphylactic reactions to neomycin should not be given these vaccines. Most often, neomycin allergy is a contact dermatitis, a manifestation of a delayed-type (cell-mediated) immune response rather than anaphylaxis. A history of delayed-type reactions to neomycin is not a contraindication for these vaccines. Bacterial vaccines, such as cholera, DTP, plague, and typhoid, are frequently associated with local or systemic adverse effects, such as redness, soreness, and fever. These reactions are difficult to link with a specific sensitivity to vaccine components and appear to be toxic rather than hypersensitive. On rare occasions, urticarial or anaphylactic reactions in DTP, DT, or Td recipients have been reported. When such events are reported, appropriate skin tests should be performed to determine sensitivity to tetanus toxoid before its use is discontinued (6). ALTERED IMMUNOCOMPETENCE Virus replication after administration of live, attenuated-virus vaccines can be enhanced in persons with immunodeficiency diseases and in persons with suppressed capacity for immune response as occurs with leukemia, lymphoma, generalized malignancy, symptomatic HIV infections, or therapy with alkylating agents, antimetabolites, radiation, or large amounts of corticosteroids. Severe complications have followed vaccination with live, attenuated-virus vaccines and with live-bacteria vaccines (e.g., BCG) in patients with leukemia, lymphoma, or suppressed immune responses. In general, these patients should not be given live vaccines, with the exceptions noted below. If polio immunization is indicated for immunosuppressed patients, their household members, or other close contacts, these persons should be given IPV rather than OPV. Although a protective immune response cannot be assured in the immunocompromised patient, some protection may be provided. Because of the possibility of immunodeficiency in other children born to a family in which one such case has occurred, no family members should receive OPV unless the immune statuses of the intended recipient and all other children in the family are known. Patients with leukemia in remission whose chemotherapy has been terminated for at least 3 months can be given live-virus vaccines. Short-term, low-to-moderate dose systemic corticosteroid therapy (less than 2 weeks), topical steroid therapy (e.g., nasal, skin), long-term alternate-day treatment with low to moderate doses of short-acting systemic steroids, and intra-articular, bursal, or tendon injection with corticosteroids are not immunosuppressive in their usual doses and do not contraindicate live-virus vaccine administration. The growing number of infants and preschoolers infected with HIV has directed special attention to the appropriate immunization of such children. The evaluation and testing for HIV infection of asymptomatic children presenting for vaccines is not necessary before decisions concerning immunization are made. The inactivated childhood vaccines (e.g., DTP or HbCV) should be given to HIV-infected children regardless of whether HIV symptoms are present. Although OPV has not been harmful when administered to asymptomatic HIV-infected children, IPV is the vaccine of choice if the child is known to be infected. The use of IPV not only eliminates any theoretical risk to the vaccinee but also prevents the possibility of vaccine virus spread to immunocompromised close contacts. Asymptomatically infected persons in need of MMR should receive it. Also, MMR should be considered for all symptomatic HIV-infected children since measles disease can be severe in symptomatic HIV-infected children. Limited studies of MMR immunization in both asymptomatic and symptomatic HIV-infected patients have not documented serious or unusual adverse events. In addition, pneumococcal vaccine is recommended for any child infected with HIV. Influenza vaccine is recommended for children with symptoms of HIV infection (Table 7). FEBRILE ILLNESS The decision to administer or delay

vaccination because of a current or recent febrile illness depends largely on the severity of symptoms and on the etiology of the disease. Although a moderate or severe febrile illness is reason to postpone immunizations, minor illnesses such as mild upper-respiratory infections (URI) with or without low-grade fever are not contraindications for vaccination. In persons whose compliance with medical care cannot be assured, it is particularly important to take every opportunity to provide appropriate vaccinations. Children with moderate or severe febrile illnesses can be vaccinated as soon as the child has recovered. This precaution to wait avoids superimposing adverse effects of the vaccine on the underlying illness or mistakenly attributing a manifestation of the underlying illness to the vaccine. Routine physical examinations or measuring temperatures are not prerequisites for vaccinating infants and children who appear to be in good health. Asking the parent or guardian if the child is ill, postponing vaccination in those with moderate or severe febrile illnesses, and immunizing those without contraindications to vaccination are appropriate procedures in childhood immunization programs. VACCINATION DURING PREGNANCY Because of a theoretical risk to the developing fetus, pregnant women or women likely to become pregnant within 3 months after vaccination should not be given live, attenuated-virus vaccines. With some of these vaccines--particularly rubella, measles, and mumps--pregnancy is a contraindication. Both yellow fever vaccine and OPV, however, can be given to pregnant women who are at substantial risk of exposure to natural infection. When a vaccine is to be given during pregnancy, waiting until the second or third trimester is a reasonable precaution to minimize concern over teratogenicity. Although there are theoretical risks, there is no evidence of congenital rubella syndrome in infants born to susceptible mothers who inadvertently were given rubella vaccine during pregnancy. Persons given measles, mumps, or rubella vaccines can shed but not transmit these viruses. These vaccines can be administered safely to the children of pregnant women. Although live polio virus is shed by persons recently immunized with OPV (particularly after the first dose), this vaccine can also be administered to the children of pregnant women because experience has not revealed any risk of polio vaccine virus to the fetus. There is no convincing evidence of risk to the fetus from immunizing the pregnant woman with inactivated virus or bacteria vaccines or toxoids. Previously immunized pregnant women who have not received a Td immunization within the last 10 years should receive a booster dose once past the first trimester. Women who are unimmunized or only partially immunized against tetanus should complete as much of the primary series as possible during the last two trimesters of the pregnancy. Depending on when the woman seeks prenatal care and the required interval between doses, one or two doses of Td can be administered before delivery. Eligible women who do not complete the required three-dose series during pregnancy should be followed after delivery to assure they receive the doses necessary for protection. All pregnant women should be evaluated for immunity to rubella. Women susceptible to rubella should be immunized immediately after delivery. In addition, a woman's status as a carrier of hepatitis B should also be assessed during pregnancy. A woman infected with hepatitis B virus should be followed carefully so that her child can receive HBIG and the hepatitis B vaccine series shortly after delivery. There is no known risk to the fetus from passive immunization of pregnant women with IG. Further information regarding immunization of pregnant women is available in the American College of Obstetricians and Gynecologists Technical Bulletin Number 64, May 1982. MISCONCEPTIONS CONCERNING CONTRAINDICATIONS TO VACCINATION Some health-care providers inappropriately consider certain conditions or circumstances contraindications to vaccination. Conditions most often inappropriately regarded as routine contraindications include the following:

1. Reaction to a previous dose of DTP vaccine that involved only soreness, red- ness, or swelling in the immediate vicinity of the vaccination site or temperature of less than 105 F (40.5 C).

2. Mild acute illness with low-grade fever or mild diarrheal illness in an otherwise well child.

3. Current antimicrobial therapy or the convalescent phase of illnesses.

4. Prematurity. The appropriate age for initiating immunizations in the prematurely born infant is the usual chronologic age. Vaccine doses should not be reduced for preterm infants.

5. Pregnancy of mother or other household contact.

6. Recent exposure to an infectious disease.

7. Breastfeeding. The only vaccine virus that has been isolated from breast milk is rubella vaccine virus. There is no good evidence that breast milk from women immunized against rubella is harmful to infants.

8. A history of nonspecific allergies or relatives with allergies.

9. Allergies to penicillin or any other antibiotic, except anaphylactic reactions to neomycin (e.g., MMR-containing vaccines) or streptomycin (e.g., OPV). None of the vaccines licensed in the United States contain penicillin.

10. Allergies to duck meat or duck feathers. No vaccine available in the United States is produced in substrates containing duck antigens.

11. Family history of convulsions in persons considered for pertussis or measles vaccination (7,8).

12. Family history of sudden infant death syndrome in children considered for DTP vaccination.

13. Family history of an adverse event, unrelated to immunosuppression, following vaccination. ADVERSE EVENTS FOLLOWING VACCINATION

Modern vaccines are safe and effective but not completely so. Adverse events have been reported following the administration of all vaccines. These events range from frequent, minor, local reactions to extremely rare, severe, systemic illness, such as paralysis associated with OPV. It is often impossible to establish evidence for cause-and-effect relationships when untoward events occur after vaccination because temporal association alone does not necessarily indicate causation. More complete information on adverse reactions to a specific vaccine may be found in the ACIP recommendations for each vaccine.

The National Vaccine Injury Compensation Program established by the National Childhood Vaccine Injury Act of 1986 requires physicians and other health-care providers who administer vaccines to maintain permanent immunization records and to report occurrences of certain adverse events to the U.S. Department of Health and Human Services. Recording and reporting requirements took effect on March 21, 1988. Reportable reactions include those listed in the Act for each vaccine (9,10) and events specified in the manufacturer's vaccine package insert as contraindications to further doses of that vaccine.

Although there will be one system for reporting adverse events following im- munizations in the future, at present there are two separate systems. The appropriate method depends on the source of funding used to purchase the vaccine. Events that occur after receipt of a vaccine purchased with public (federal, state, and/or local government) funds must be reported by the administering health provider to the appropriate local, county, or state health department. The state health department completes and submits the correct forms to CDC. Reportable events that follow administration of vaccines purchased with private money are reported by the health-care provider directly to the Food and Drug Administration (FDA). PATIENT INFORMATION

Parents, the responsible caregiver, or adult patients should be informed about the benefits and risks of vaccine in understandable language. Ample opportunity for questions and answers should be provided before each immunization. CDC has developed "Important Information Statements" for use with federally purchased vaccines given in public health clinics, but similar statements have not been uni- versally adopted for the private medical-care sector.

An Important Information Statement must be developed for each vaccine covered by the National Childhood Vaccine Injury Act (DTP or component antigens, MMR or component antigens, IPV, and OPV). These statements are to be used by all public and private providers of vaccines. Until the Important Information Statements established by the Act become available, the current CDC Important Information Statements should be used in public health clinics and other settings where publicly purchased vaccines are used. The use of similar statements in the private sector is encouraged. VACCINE PROGRAMS The best way to reduce vaccine-preventable diseases is to have a highly immune population. Universal immunization is an important part of good health care and should be accomplished through routine and intensive programs carried out in physicians' offices

and in public health clinics. Programs aimed at ensuring that all children are immunized at the recommended ages should be established and maintained in all communities. In addition, appropriate immunizations should be available for all adults. Every visit to a health-care provider is an opportunity to update a patient's immunization status with needed vaccines. All adults should complete a primary series of tetanus and diphtheria toxoids, then receive a booster dose every 10 years. Persons greater than or equal to65 years old and all adults with medical conditions that place them at risk for pneumococcal disease or serious complications of influenza should receive one dose of pneumococcal polysaccharide vaccine and annual injections of influenza vaccine. In addition, immunization programs for adults should provide MMR vaccine whenever possible to anyone believed susceptible to measles, mumps, or rubella. Use of MMR ensures that the recipient has been immunized against three different diseases and causes no harm if the vaccinee is already immune to one or more of its components. Official health agencies should take necessary steps, including developing and enforcing school immunization requirements, to assure that students at all grade levels, including college students, and those in child-care centers are protected against vaccine-preventable diseases. Agencies should also encourage institutions such as hospitals and extended-care facilities to adopt policies regarding the appropriate immunization of residents and employees. Dates of immunization (day, month, and year) should be recorded on institutional immunization records, such as those kept in schools and child-care centers. This will facilitate assessments that a primary vaccine series has been completed according to an appropriate schedule and that needed boosters have been obtained at the correct time. Tickler or recall systems can identify children who are due for immunizations or are behind schedule so parents can be contacted and reminded to have their children immunized. The ACIP recommends the use of these systems by all health-care providers. Such systems should also be developed by health-care providers who treat adults to ensure that at-risk persons receive influenza vaccine annually. IMMUNIZATION RECORDS Documentation of patient immunizations will help ensure that persons in need of vaccine receive it and that adequately vaccinated patients are not overimmunized with increased risk of hypersensitivity (e.g., tetanus toxoid hypersensitivity). Patient's Personal Record Official immunization cards have been adopted by every state and the District of Columbia to encourage uniformity of records and to facilitate the assessment of immunization status by schools and child-care centers. The records are also important tools in immunization education programs aimed at increasing parental and patient awareness of the need for vaccines. A permanent immunization record card should be established for each newborn infant and maintained by the parent. In many states, these cards are distributed to new mothers before discharge from the hospital. Provider Records The National Vaccine Injury Compensation Program requires each health-care provider to record in the vaccine recipient's permanent medical record (or in a permanent office log or file) the provider's name, address, and title (if appropriate), the type of immunobiologic administered, the manufacturer, lot number, and date of administration. Health-care provider is any licensed health-care professional, organization, or institution, whether private or public (including federal, state, and local departments and agencies), under whose authority a specified vaccine is administered. The vaccines covered under this new law include: DTP and MMR (or any of their components given singly or in combination), OPV, and IPV. A permanent immunization record should also be established and maintained for adults and children who receive vaccines not covered by the National Vaccine Injury Act. The ACIP recommends use of standard records that note the type, manufacturer, lot number, and date of administration for each immunobiologic administered. Serologic test results for vaccine-preventable diseases, such as those for rubella screening, as well as documented episodes of adverse events, should also be recorded in the vaccine recipient's permanent medical record. SOURCES OF VACCINE INFORMATION In addition to these general recommendations, the practitioner can draw on a variety of sources for specific data and updated information including: Official vaccine package circulars. Manufacturer-provided product-specific information approved by the FDA with each vaccine. Some of these materials are reproduced in the Physician's Desk

Reference (PDR).

Morbidity and Mortality Weekly Report (MMWR). Published weekly by CDC, MMWR contains regular and special ACIP recommendations on vaccine use and statements of vaccine policy as they are developed and reports of specific disease activity. Subscriptions are available through Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. Also available through MMS Publications, C.S.P.O. Box 9120, Waltham, MA 02254. Health Information for International Travel. Booklet published annually by CDC as a guide to national requirements and with recommendations for specific immunizations and health practices for

travel to foreign countries. Purchase from the Superintendent of Documents (address above). Advisory memoranda are published as needed by CDC to advise international travelers or persons who provide information to travelers about specific outbreaks of communicable diseases abroad. They include health information for prevention and specific recommendations for immunization. Memoranda and/or placement on mailing list are available from Division of Quarantine, Center for Prevention Services (CPS), CDC, Atlanta, GA 30333. The Report of the Committee on Infectious Diseases of the American Academy of Pediatrics (Red Book). This report, which contains recommendations on all licensed vaccines, is updated every 2-3 years, most recently in 1988. Policy changes for individual recommendations for immunization practices are published as needed by the American Academy of Pediatrics in the journal Pediatrics. They are available from American Academy of Pediatrics, Publications Division, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927. Control of Communicable Diseases in Man is published by the American Public Health Association every 5 years, most recently in 1985 (14th ed.) The manual contains information about infectious diseases, their occurrence worldwide, diagnoses and therapy, and up-to-date recommendations on isolation and other control measures for each disease presented. It is available from the American Public Health Association, 1015 Fifteenth St. N.W., Washington, DC 20005. Guide for Adult Immunization (1985) is produced by the American College of Physicians for physicians caring for adults. It emphasizes use of vaccines in healthy adults and adults with specific disease problems. It is available from American College of Physicians, Division of Scientific Activities, Health and Public Policy, 4200 Pine Street, Philadelphia, PA 19104. Technical bulletins of the American College of Obstetricians and Gynecologists are updated periodically. These bulletins contain important information on immunization of pregnant women. They are available from American College of Obstetricians and Gynecologists, Attention: Resource Center, 409 12th Street S.W., Washington, DC 20024-2188. State and many local health departments frequently provide technical advice, printed information on vaccines and immunization schedules, posters, and other educational materials. Division of Immunization, CPS, CDC, Atlanta, GA 30333, telephone (404) 639-3311, offers technical advice on vaccine recommendations, disease outbreak control, and sources of immunobiologics. In addition, a course on the epidemiology, prevention, and control of vaccine preventable diseases is offered each year in Atlanta and, on occasion, in different states. References

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