Complete Summary

GUIDELINE TITLE

1) Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP). 2) Update: recommendations from the Advisory Committee on Immunization Practices (ACIP) regarding administration of combination MMRV vaccine.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP). Update: recommendations from the Advisory Committee on Immunization Practices (ACIP) regarding administration of combination MMRV vaccine. MMWR Morb Mortal Wkly Rep 2008 Mar 14;57(10):258-60. PubMed

Marin M, Guris D, Chaves SS, Schmid S, Seward JF, Advisory Committee on Immunization Practices, Centers for Disease Control. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2007 Jun 22;56(RR-4):1-40. [204 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Marin M, Guris D, Chaves SS, Schmid S, Seward JF, Advisory Committee on Immunization Practices, Centers for Disease Control. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2007 Jun 22;56(RR-4):1-40.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Varicella zoster viral infections: varicella (chickenpox) and herpes zoster (shingles)

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

2007 Guideline

- To advise physicians on the use of live, attenuated varicella virus vaccine and the use of varicella zoster immune globulin (VZIG) as prophylaxis against varicella
- To revise, update, and replace earlier ACIP (Advisory Committee on Immunization Practices) statements for prevention of varicella

2008 Addendum

To provide updated recommendations regarding the administration of the combination measles, mumps, rubella, and varicella (MMRV) vaccine

TARGET POPULATION

Children 12 months old or older; adolescents; and adults

INTERVENTIONS AND PRACTICES CONSIDERED

1. Vaccination with live, attenuated varicella virus (VARIVAX®, Merck and Company, Inc.)

2. Licensed combination mumps-measles-rubella-varicella vaccine (ProQuad®, Merck and Company, Inc., not licensed for use among persons aged ≥13 years)
3. Varicella zoster immune globulin (VZIG) prophylaxis (VariZIG™, Cangene Corporation, Winnipeg, Canada; available under an Investigational New Drug Application Expanded Access protocol in the United States)

MAJOR OUTCOMES CONSIDERED

- Incidence of infection by varicella zoster virus
- Efficacy and effectiveness of vaccination
- Adverse events associated with vaccination
- Annual varicella-related hospitalization rate
- Mortality from varicella infection
- Breakthrough rates for 1 and 2 does of single-antigen varicella vaccine

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In response to increasing reports of varicella outbreaks among highly vaccinated populations, the Advisory Committee on Immunization Practices (ACIP)'s measles-mumps-rubella and varicella (MMRV) workgroup first met in February 2004 to review data related to varicella vaccine use in the United States since implementation of the vaccination program in 1995 and to consider recommendation options for improving control of varicella disease. The workgroup held monthly conference calls and met in person three times a year. The workgroup reviewed data on the impact of the 1-dose varicella vaccination program, including data on vaccination coverage, changes in varicella epidemiology, transmission from vaccinated persons with varicella, vaccine effectiveness, immune response to vaccination, evidence of immunity, and potential risk factors for vaccine failure. Published and unpublished data related to correlates of protection, safety, immunogenicity, and efficacy of the new quadrivalent MMRV vaccine and the immunogenicity and efficacy of a second dose of varicella vaccine also were reviewed.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

2007 Guideline

Presentations were made to the full Advisory Committee on Immunization Practices (ACIP) meetings in October 2004, February 2005, June 2005, and June 2006. Recommendation options were developed and discussed by the measles-mumps-rubella and varicella (MMRV) workgroup. When definitive research evidence was lacking, the recommendations incorporated expert opinion of the workgroup members. The workgroup sought input from partner organizations (i.e., the American Academy of Pediatrics [AAP], the American Academy of Family Physicians [AAFP], the American College of Obstetricians and Gynecologists, the Council of State and Territorial Epidemiologists, and the Association of Immunization Managers) and from state public health professionals and immunization program directors.

2008 Addendum

On February 27, 2008, new information was presented to ACIP regarding the risk for febrile seizures among children aged 12 to 23 months after administration of the combination measles, mumps, rubella, and varicella (MMRV) vaccine (ProQuad®, Merck & Co., Inc., Whitehouse Station, New Jersey). At this meeting, ACIP considered the preliminary results from the Vaccine Safety Datalink (VSD) and Merck studies, which suggested an increased risk for febrile seizures after the first dose of MMRV vaccine. Given the availability of alternative options for vaccination against measles, mumps, rubella, and varicella and the limited supply of MMRV vaccine, ACIP voted to change the preference language for MMRV vaccine to read as follows: "Combination MMRV vaccine is approved for use among healthy children aged 12 months to 12 years. MMRV vaccine is indicated for simultaneous vaccination against measles, mumps, rubella, and varicella. ACIP does not express a preference for use of MMRV vaccine over separate injections of equivalent component vaccines (i.e., MMR vaccine and varicella vaccine)."

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A cost-effectiveness analysis was performed before initiation of the varicella vaccination program in the United States. The results of the study indicated a savings of $5.40 for each dollar spent on routine vaccination of preschool-aged children when direct and indirect costs were considered. When only direct medical costs were considered, the benefit-cost ratio was 0.9:1.0. Benefit-cost ratios were only slightly lower when lower estimates of the short- and long-term effectiveness of the vaccine were used.

A recent analysis was performed that used current estimates of morbidity and mortality and current direct and indirect costs. The model considered that the second dose will reduce varicella disease residual after the first dose by 79%. From a societal perspective, both 1-dose and 2-dose vaccination programs are cost saving compared with no program. The vaccine program cost was estimated at $320 million for 1 dose and $538 million for 2 doses. The savings from varicella disease prevented were estimated at approximately $1.3 billion for the 1-dose program and approximately $1.4 billion for the 2-dose program. Compared with the 1-dose program, the incremental cost for the second dose was estimated to be $96,000 per quality-adjusted life year (QALY) saved. If benefits from preventing group A streptococcus infections and herpes zoster (HZ) among vaccinated persons are added, incremental costs per QALY saved are $91,000 and $17,000, respectively. Because of the uncertainty of the modeled predictions of an increase in HZ among persons with a history of varicella and the fact that no consistent trends demonstrate an increase in HZ attributable to the varicella vaccination program in the United States, HZ among persons with a history of varicella was not included in the model.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Proposed recommendations and a draft statement were presented to the full Advisory Committee on Immunization Practices (ACIP) in June 2005 and June 2006. After deliberations, final ACIP recommendations were approved in 2005 and 2006. Modifications to the draft statement were made following CDC and external review process to update and clarify wording in the document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

2008 Addendum

On February 27, 2008, new information was presented to the Advisory Committee on Immunization Practices (ACIP) regarding the risk for febrile seizures among children aged 12 to 23 months after administration of the combination measles, mumps, rubella, and varicella (MMRV) vaccine (ProQuad®, Merck & Co., Inc.,

Whitehouse Station, New Jersey). The original addendum document summarizes current knowledge regarding the risk for febrile seizures after MMRV vaccination and presents updated ACIP recommendations that were issued after presentation of the new information. These updated recommendations remove ACIP's previous preference for administering combination MMRV vaccine over separate injections of equivalent component vaccines (i.e., measles, mumps, and rubella [MMR] vaccine and varicella vaccine).

The combination tetravalent MMRV vaccine was licensed by the Food and Drug Administration (FDA) on September 6, 2005, for use in children aged 12 months--12 years. MMRV vaccine can be used in place of trivalent MMR vaccine and monovalent varicella vaccine to implement the recommended 2-dose vaccine policies for prevention of measles, mumps, rubella, and varicella. The first vaccine dose is recommended at age 12 to 15 months and the second at age 4 to 6 years.

Consistent with ACIP General Recommendations on Immunization, the 2007 ACIP recommendations for prevention of varicella included a preference for use of combination MMRV vaccine over separate injections of equivalent component vaccines (i.e., MMR vaccine and varicella vaccine). At its February 27, 2008, meeting, ACIP considered the preliminary results from the Vaccine Safety Datalink (VSD) and Merck studies, which suggested an increased risk for febrile seizures after the first dose of MMRV vaccine. Given the availability of alternative options for vaccination against measles, mumps, rubella, and varicella and the limited supply of MMRV vaccine, ACIP voted to change the preference language for MMRV vaccine to read as follows: "Combination MMRV vaccine is approved for use among healthy children aged 12 months--12 years. MMRV vaccine is indicated for simultaneous vaccination against measles, mumps, rubella, and varicella. ACIP does not express a preference for use of MMRV vaccine over separate injections of equivalent component vaccines (i.e., MMR vaccine and varicella vaccine)." ACIP also recommended establishing a work group to conduct in-depth evaluation of the findings regarding the increased risk for febrile seizures after the first dose of MMRV vaccine to present for consideration of future policy options. CDC, FDA, and ACIP will communicate updates and implement further necessary actions based on these evaluations.

Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at http://www.vaers.hhs.gov or by telephone, 800-822-7967. Additional information on MMRV vaccine and febrile seizures is available at http://www.cdc.gov/od/science/iso/vsd/mmrv.htm and http://www.fda.gov/cber/label/proquadlbinfo.htm.

2007 Guideline

Summary of Recommendations for Varicella Vaccination

Routine Childhood Schedule

- Routine childhood vaccination should be 2 doses.
- Preschool-aged children should receive the first dose of varicella vaccine at age 12 to 15 months.

- School-aged children should receive the second dose at age 4–6 years (may be administered earlier provided ≥3 months have elapsed after the first dose)

Persons Aged ≥13 Years

- Persons aged ≥13 years should receive 2 doses of vaccine, doses (4 to 8 weeks apart).
- All adolescents and adults without evidence of immunity should be vaccinated.
- Because of their increased risk for transmission to persons at high risk for severe disease or their increased risk of exposure, vaccination is especially important for persons without evidence of immunity in the following groups:
    - Persons who have close contact with persons at high risk for serious complications (e.g., health-care personnel and household contacts of immunocompromised persons)
    - Persons who live or work in environments in which transmission of varicella zoster virus is likely (e.g., teachers, child-care workers, and residents and staff in institutional settings)
    - Persons who live and work in environments in which transmission has been reported (e.g., college students, inmates and staff members of correctional institutions, military personnel)
        - Nonpregnant women of childbearing age
        - Adolescents and adults living in households with children
        - International travelers

Prenatal Assessment and Postpartum Vaccination

Prenatal assessment of women for evidence of varicella immunity is recommended. Upon completion or termination of pregnancy, women who do not have evidence of varicella immunity should be vaccinated.

Vaccination of Human Immunodeficiency Virus (HIV)-Infected Persons

Vaccination should be considered for HIV-infected children with age-specific CD4+ T-lymphocyte percentage ≥15% and may be considered for adolescents and adults with CD4+ T-lymphocyte count ≥200 cells/microL.

Outbreak Control

- 2-dose vaccination policy

Postexposure Prophylaxis

- Recommended within 3 to 5 days

Requirements for Entry to Child Care, School, College, and Other Postsecondary Educational Institutions

All states should require that students at all grade levels (including college) and those in child care centers receive varicella vaccine unless they have other evidence of immunity of varicella.

Evidence of Immunity to Varicella

Evidence of immunity to varicella includes any of the following:

- Documentation of age-appropriate vaccination with a varicella vaccine:
  Preschool-aged children (i.e., aged ≥12 months): 1 dose
  School-aged children, adolescents, and adults: 2 doses[1]
- Laboratory evidence of immunity[2] or laboratory confirmation of disease
- Birth in the United States before 1980[3]
- Diagnosis or verification of a history of varicella disease by a health-care provider[4]
- Diagnosis or verification of a history of herpes zoster by a health-care provider

[1] For children who received their first dose at age <13 years and for whom the interval between the 2 doses was ≥28 days, the second dose is considered valid.

[2] Commercial assays can be used to assess disease-induced immunity, but they lack sensitivity to always detect vaccine-induced immunity (i.e., they might yield false-negative results).

[3] For health-care personnel, pregnant women, and immunocompromised persons, birth before 1980 should not be considered evidence of immunity.

[4] Verification of history or diagnosis of typical disease can be provided by any health-care provider (e.g., school or occupational clinic nurse, nurse practitioner, physician assistant, or physician). For persons reporting a history of, or reporting with, atypical or mild cases, assessment by a physician or their designee is recommended, and one of the following should be sought: 1) an epidemiologic link to a typical varicella case or to a laboratory-confirmed case or 2) evidence of laboratory confirmation if it was performed at the time of acute disease. When such documentation is lacking, persons should not be considered as having a valid history of disease because other diseases might mimic mild atypical varicella.

Use of Varicella Zoster Immune Globulin (VZIG) for Postexposure Prophylaxis

- VZIG provides maximum benefit when administered as soon as possible after exposure, but it might be effective if administered as late as 96 hours after exposure.
- The recommended dose of VZIG is 125 U/10 kg body weight, up to a maximum of 625 U. The minimum dose is 125 U.
- The decision to administer VZIG should be based on three factors: 1) whether the patient lacks evidence of immunity, 2) whether the exposure is likely to result in infection, and 3) whether the patient is at greater risk for complications than the general population.

The following patient groups are at risk for severe disease and complications from varicella and should receive VZIG (refer to the original guideline document for additional details):

- *Immunocompromised patients*. VZIG is used primarily for passive immunization of immunocompromised persons without evidence of immunity after direct exposure to varicella or disseminated herpes zoster (HZ) patients, including persons who 1) have primary and acquired immune-deficiency

disorders, 2) have neoplastic diseases, and 3) are receiving immunosuppressive treatment.
- *Neonates whose mothers have signs and symptoms of varicella around the time of delivery*. VZIG is indicated for neonates whose mothers have signs and symptoms of varicella within 5 days before and 2 days after delivery.
- *Premature neonates exposed postnatally*. Premature infants who have substantial postnatal exposure should be evaluated on an individual basis. The risk for complications of postnatally acquired varicella in premature infants is unknown. However, because the immune system of premature infants is not fully developed, administration of VZIG to premature infants born at ≥28 weeks of gestation who are exposed during the neonatal period and whose mothers do not have evidence of immunity is indicated. Premature infants born at <28 weeks of gestation or who weigh ≤1000 g at birth and were exposed during the neonatal period should receive VZIG regardless of maternal immunity, because such infants may not have acquired maternal antibody. The majority of premature infants born at ≥28 weeks of gestation to immune mothers have enough acquired maternal antibody to protect them from severe disease and complications.
- *Pregnant women*. VZIG should be strongly considered for pregnant women without evidence of immunity who have been exposed. Neonates born to mothers who have signs and symptoms of varicella within 5 days before to 2 days after delivery should receive VZIG regardless of whether the mother received VZIG.

Interval Between Administration of VZIG and Varicella Vaccine

Any patient who receives VZIG to prevent varicella should receive varicella vaccine subsequently, provided the vaccine is not contraindicated. Varicella vaccination should be delayed until 5 months after VZIG administration. Varicella vaccine is not needed if the patient has varicella after administration of VZIG.

Antiviral Therapy

Because VZIG might prolong the incubation period by ≥1 week, any patient who receives VZIG should be observed closely for signs or symptoms of varicella for 28 days after exposure. Antiviral therapy should be instituted immediately if signs or symptoms of varicella disease occur. The route and duration of antiviral therapy should be determined by specific host factors, extent of infection, and initial response to therapy.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Prevention of varicella infection and complications
- Modification of varicella severity

POTENTIAL HARMS

Varicella Vaccine

Vaccinated persons might develop modified varicella disease with atypical presentation. Varicella disease that develops >42 days after vaccination (i.e., breakthrough varicella) typically is mild, with <50 skin lesions, low or no fever, and shorter (4-6 days) duration of illness. The rash is more likely to be predominantly maculopapular rather than vesicular. Nevertheless, breakthrough varicella is contagious.

Since 1999, when varicella deaths became nationally notifiable, two deaths from breakthrough varicella disease have been reported to the Centers for Disease Control and Prevention (CDC); one of a girl aged 9 years with a history of asthma who was receiving steroids when she had the breakthrough infection, and the other of a girl aged 7 years with a history of malignant ependymoma who also was under steroid therapy at the time of her death.

Other Adverse Events

- Pain, tenderness, soreness, erythema, and/or swelling at the injection site
- Localized and systemic rash, including varicelliform rash
- Fever

Not all adverse events that occur after vaccination are reported, and many reports describe events that might have been caused by confounding or unrelated factors (e.g., medications and other diseases). Because varicella disease continues to occur, wild-type virus might account for certain reported events. For serious adverse events for which background incidence data are known, Vaccine Adverse Event Reporting System (VAERS) reporting rates are lower than expected after natural varicella or than background rates of disease in the community. Inherent limitations of passive safety surveillance impede comparing adverse event rates after vaccination reported to VAERS with those from complications after natural disease. Nevertheless, the magnitude of these differences suggests that serious adverse events occur at a substantially lower rate after vaccination than after natural disease.

Rare Events - Laboratory Confirmed

- Pneumonia
- Hepatitis
- Severe disseminated varicella infection
- Secondary varicella transmission

Except for the secondary transmission cases, these cases all occurred in immunocompromised patients or in persons who had other serious medical conditions that were undiagnosed at the time of vaccination.

Rare Events - Not Laboratory Confirmed

- Thrombocytopenia
- Acute cerebellar ataxia
- Acute hemiparesis consistent with varicella angiopathy (two cases)
- Recurrent papular urticaria
- Herpes zoster from latent viral infection
- Neuroblastoma with severe, chronic, drug-resistant zoster (one case)

Subgroups Most Likely to be Harmed

Persons with:

- Impaired cellular immunity or who have persons with impaired cellular immunity in their households
- Acute severe illness, including untreated, active tuberculosis
- Thrombocytopenia
- Recently administered blood, plasma, or immune globulin
- Requirement for salicylates within 6 weeks after receiving varicella vaccines

Refer to the original guideline document for additional information on adverse effects and precautions during use of varicella vaccines.

2008 Addendum

The administration of the combination measles, mumps, rubella, and varicella (MMRV) vaccine is associated with risk for febrile seizures.

CONTRAINDICATIONS

CONTRAINDICATIONS

General

Adequate treatment provisions for anaphylactic reactions, including epinephrine injection (1:1000), should be available for immediate use should an anaphylactic reaction occur. Before administering a vaccine, health-care providers should obtain the vaccine recipient's vaccination history and determine whether the individual had any previous reactions to any vaccine including Varivax, ProQuad or any measles, mumps, or rubella containing vaccines.

Allergy to Vaccine Components

The administration of live varicella-containing vaccines rarely results in hypersensitivity. The information in the package insert should be reviewed carefully before vaccine is administered. Vaccination is contraindicated for persons

who have a history of anaphylactic reaction to any component of the vaccine, including gelatin. Single-antigen varicella vaccine does not contain preservatives or egg protein; these substances have caused hypersensitive reactions to other vaccines. For the combination measles-mumps-rubella-varicella (MMRV) vaccine, live measles and live mumps vaccines are produced in chick embryo culture. However, among persons who are allergic to eggs, the risk for serious allergic reactions after administration of measles- or mumps-containing vaccines is low. Because skin testing with vaccine is not predictive of allergic reaction to vaccination, skin testing is not required before administering combination MMRV vaccine to persons who are allergic to eggs. The majority of anaphylactic reactions to measles- and mumps-containing vaccines are associated not with hypersensitivity to egg antigens but with other vaccine components. Neither single-antigen varicella nor combination MMRV vaccines should be administered to persons who have a history of anaphylactic reaction to neomycin. However, neomycin allergy usually is manifested as a contact dermatitis, which is a delayed-type immune response rather than anaphylaxis. For persons who experience such a response, the adverse reaction, if any, would appear as an erythematous, pruritic nodule or papule present 48 to 96 hours after vaccination. A history of contact dermatitis to neomycin is not a contraindication to receiving varicella vaccines.

Altered Immunity

Single-antigen varicella and combination MMRV vaccines are not licensed for use in persons who have any malignant condition, including blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems. Combination MMRV vaccine should not be administered to persons with primary or acquired immunodeficiency, including immunosuppression associated with acquired immunodeficiency syndrome (AIDS) or other clinical manifestations of human immunodeficiency virus (HIV) infections, cellular immunodeficiencies, hypogammaglobulinemia, and dysgammaglobulinemia. Combination MMRV vaccine should not be administered as a substitute for the component vaccines when vaccinating HIV-infected children.

Varicella vaccines should not be administered to persons who have a family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents and siblings) unless the immune competence of the potential vaccine recipient has been clinically substantiated or verified by a laboratory.

Varicella vaccines should not be administered to persons receiving high-dose systemic immunosuppressive therapy, including persons on oral steroids $\geq$2 mg/kg of body weight or a total of $\geq$20 mg/day of prednisone or equivalent for persons who weigh >10 kg, when administered for $\geq$2 weeks. Such persons are more susceptible to infections than healthy persons. Administration of varicella vaccines can result in a more extensive vaccine-associated rash or disseminated disease in persons receiving immunosuppressive doses of corticosteroids. This contraindication does not apply to persons who are receiving inhaled, nasal, or topical corticosteroids or low-dose corticosteroids as are used commonly for asthma prophylaxis or for corticosteroid-replacement therapy (see "Situations in Which Some Degree of Immunodeficiency Might Be Present" in the original guideline document).

Pregnancy

Because the effects of the varicella virus vaccine on the fetus are unknown, pregnant women should not be vaccinated. Nonpregnant women who are vaccinated should avoid becoming pregnant for 1 month after each injection. For persons without evidence of immunity, having a pregnant household member is not a contraindication to vaccination.

If a pregnant woman is vaccinated or becomes pregnant within 1 month of vaccination, she should be counseled about potential effects on the fetus. Wild-type varicella poses a low risk to the fetus (see "Prenatal and Perinatal Exposure" in the original guideline document). Because the virulence of the attenuated virus used in the vaccine is less than that of the wild-type virus, the risk to the fetus, if any, should be even lower. In 1995, Merck and Co., Inc., in collaboration with the Centers for Disease Control and Prevention (CDC), established the VARIVAX Pregnancy Registry to monitor the maternal-fetal outcomes of pregnant women who were inadvertently administered varicella vaccine 3 months before or at any time during pregnancy (to report, call: 1-800-986-8999). During the first 10 years of the pregnancy registry no cases of congenital varicella syndrome or birth defects compatible with congenital varicella syndrome have been documented. Among 131 live-born infants of prospectively reported seronegative women (82 of whom were born to mothers vaccinated during the highest risk period [i.e., the first or second trimester of pregnancy]), no birth defects consistent with congenital varicella syndrome have been documented (prevalence rate = 0; CI = 0 to 6.7%), and three major birth defects were reported (prevalence rate = 2.3%; CI = 0.5% to 6.7%). The rate of occurrence of major birth defects from prospective reports in the registry was similar to the rate reported in the general United States population (3.2%), and the defects indicated no specific pattern or target organ. Although the study results do not exclude the possibility of risk for women who received inadvertent varicella vaccination before or during pregnancy, the potential risk, if any, is low.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP). Update: recommendations from the Advisory Committee on Immunization Practices (ACIP) regarding administration of combination MMRV vaccine. MMWR Morb Mortal Wkly Rep 2008 Mar 14;57(10):258-60. PubMed

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 May (revised 2007 Jun 22; addendum released 2008 14 Mar)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Advisory Committee on Immunization Practices (ACIP)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Advisory Committee on Immunization Practices Varicella Working Group Members

Chairperson: Judith R. Campbell, MD, Houston, Texas; Ann M. Arvin, MD, Stanford, California; David W. Kimberlin, MD, Birmingham, Alabama; James L. Hadler, MD, Hartford, Connecticut; Barbara Watson, MB ChB, Philadelphia, Pennsylvania; Penina Haber, MPH, Atlanta, Georgia; William Atkinson, MD, Atlanta, Georgia; Anne A. Gershon, MD, New York, New York; Tracy Lieu, MD, Boston, Massachusetts; Teresa Thornton, Des Moines, Iowa; Myron J. Levin,

Denver, Colorado; John F. Modlin, MD, Lebanon, New Hampshire; Dale L. Morse, MD, Albany, New York; Reginald Finger, MD, Colorado Springs, Colorado; Dalya Guris, MD, Atlanta, Georgia; Mona Marin, MD, Atlanta, Georgia; Sandra S. Chaves, MD, Atlanta, Georgia; Paul Gargiullo, PhD, Atlanta, Georgia; John W. Glasser, PhD, Atlanta, Georgia; Rafael Harpaz, MD, Atlanta, Georgia; Gregory Wallace, MD, Atlanta, Georgia; Jane F. Seward, MBBS, Atlanta, Georgia; Scott Schmid, PhD, Atlanta, Georgia; Philip LaRussa, MD, New York, New York; Angela Calugar, MD, Atlanta, Georgia; H. Cody Meissner, MD, Boston, Massachusetts; Philip R. Krause, MD, Bethesda, Maryland; Keith Powell, MD, Akron, Ohio; Gustavo H. Dayan, MD, Atlanta, Georgia

Advisory Committee on Immunization Practices Membership List, June 2006

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Executive Secretary: Larry Pickering, MD, CDC, Atlanta, Georgia

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GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Marin M, Guris D, Chaves SS, Schmid S, Seward JF, Advisory Committee on Immunization Practices, Centers for Disease Control. Prevention of varicella: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2007 Jun 22;56(RR-4):1-40.

GUIDELINE AVAILABILITY

2007 Guideline

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325.

2008 Addendum

Available from the Centers for Disease Control and Prevention (CDC Web site).

AVAILABILITY OF COMPANION DOCUMENTS

A Continuing Education activity is available from the Centers for Disease Control and Prevention (CDC) Web site.

PATIENT RESOURCES

None available

NGC STATUS

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