

# AMERICAN ACADEMY OF PEDIATRICS

Committee on Infectious Diseases

## Varicella Vaccine Update

**ABSTRACT.** Recommendations for routine varicella vaccination were published by the American Academy of Pediatrics in May 1995, but many eligible children remain unimmunized. This update provides additional information on the varicella disease burden before the availability of varicella vaccine, potential barriers to immunization, efforts to increase the level of coverage, new safety data, and new recommendations for use of the varicella vaccine after exposure and in children with human immunodeficiency virus infections. Pediatricians are strongly encouraged to support public health officials in the development and implementation of varicella immunization requirements for child care and school entry.

**ABBREVIATIONS.** AAP, American Academy of Pediatrics; ACIP, Advisory Committee on Immunization Practices; CDC, Centers for Disease Control and Prevention; CI, confidence interval; VZV, varicella-zoster virus; VZIG, varicella-zoster immune globulin.

Varicella vaccine (Varivax, Merck and Company, Inc, West Point, PA) was licensed on March 17, 1995, by the US Food and Drug Administration for use in healthy persons 12 months of age or older who have not had varicella. Recommendations for vaccine use were published by the American Academy of Pediatrics (AAP) in May 1995 and by the Advisory Committee on Immunization Practices (ACIP) in July 1996.<sup>1,2</sup> Updated recommendations of the ACIP were published in May 1999.<sup>3</sup>

Despite the recommendations, many eligible children remain unimmunized. Annualized estimates from July 1997 to June 1998 revealed that national varicella vaccine coverage of children 19 to 35 months of age was 34% with wide variations in state and urban areas, ranging from 6% to 52% (Centers for Disease Control and Prevention [CDC] unpublished data, 1999).

As a result of underutilization of varicella vaccine, hospitalizations, serious complications, and deaths attributable to varicella infection continue to occur in the United States.<sup>4,5</sup> To increase vaccine coverage and reduce the current morbidity and mortality attributable to varicella, the ACIP recently recommended that a physician's diagnosis of varicella, a reliable history of the disease, serologic evidence of immunity, or receipt of varicella vaccine be required for enrollment in child care centers and schools.<sup>3</sup> In addition, *Healthy People 2010* objectives for varicella

vaccine coverage are more than 90% for children 19 to 35 months of age and more than 95% at school entry.<sup>6</sup> Varicella deaths and severe morbidity, as well as the societal disruption of children missing 5 to 7 days of school or child care, have prompted states to consider requirements for varicella immunization for school and child care center entry. Several states and the District of Columbia already have such requirements, and a number of other states have begun the implementation process. Children 12 months of age or older without documentation of varicella immunization or infection who do not have a contraindication should receive a dose of varicella vaccine immediately. In addition, special emphasis should be placed on immunization of susceptible older children and adults, because the likelihood of severe infection increases with increasing age.

### POTENTIAL BARRIERS TO IMMUNIZATION WITH VARICELLA VACCINE

Potential barriers to achieving high rates of varicella immunization among children include the following: 1) the misconception that varicella is uniformly a mild disease; 2) concerns about vaccine effectiveness and safety; 3) concerns about waning immunity; 4) concern that universal immunization of young children will shift the disease burden to older age groups among whom the disease is more severe; 5) the stringent storage and handling requirements of the vaccine; 6) vaccine availability; 7) inadequate insurance coverage; and 8) lack of requirements for varicella vaccine for licensed child care and school entry.<sup>7</sup> In addition, there is an inherent lag time between issuance of recommendations and full incorporation of the recommendations into immunization programs. Although some of these issues are no longer barriers to immunization with varicella vaccine, others remain.

### VARICELLA DISEASE BURDEN

Varicella is a common, highly infectious disease that, in the absence of immunization, infects almost every person. Before the availability of the varicella vaccine, approximately 4 million cases occurred annually in the United States, resulting in 10 000 hospitalizations and 100 deaths.<sup>5</sup> In the United States, more than 90% of infections, two thirds of varicella-related hospitalizations, and almost half of varicella-related deaths occur in children.<sup>5</sup> In children, varicella is one of the most important risk factors for severe, invasive, group A streptococcal disease.<sup>8,9</sup> Although the incidence of disease among adults is low, the risk of complications and death attributable to

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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varicella is 10- to 20-fold higher than that for children. Despite the lower risks of severe morbidity and mortality among children, the burden of disease is greatest among children since more than 90% of cases occur in this age group. Although the incidence of disease had been highest among children 5 to 9 years of age,<sup>10</sup> in the 1990s, the highest incidence is in children 1 to 4 years of age.<sup>11,12</sup>

#### EFFECTIVENESS OF VARICELLA VACCINE

Varicella vaccine has been demonstrated to be very effective. Prelicensure, controlled, clinical trials demonstrated varicella vaccine to be 70% to 90% effective for preventing varicella and more than 95% effective for preventing severe varicella.<sup>13,14</sup> A postlicensure study of 148 children performed during an outbreak of varicella in a child care center in DeKalb County, GA, found that varicella vaccine was 86% (95% confidence interval [CI], 73%–92%) effective for preventing varicella and 100% (95% CI, 96%–100%) effective for preventing moderate to severe disease. Varicella was less severe and resulted in fewer days of absence from the day care center among immunized compared with unimmunized cases.<sup>15</sup> Two more recent studies found that varicella vaccine was 86% (95%CI, 67%–94%) and 84% effective (95% CI, 60%–94%), respectively, for preventing varicella and 100% effective for preventing severe varicella.<sup>16,17</sup> “Breakthrough” disease following exposure to wild-type varicella-zoster virus (VZV) occurs in about 1% to 4% of vaccinees per year, and the rate does not seem to increase with length of time after immunization.<sup>18</sup> “Breakthrough” disease is usually of short duration and mild with fewer than 50 lesions and low-grade or no fever.

#### DURATION OF IMMUNITY

Although there has been concern about waning immunity, follow-up evaluations of children immunized during prelicensure clinical trials in the United States revealed protection for at least 11 years, and studies in Japan indicated protection for at least 20 years.<sup>19,20</sup> However, these studies were during a period when a substantial amount of wild-type VZV was present in the community, with many opportunities for boosting of immunity by subclinical infection in immunized persons. Experience with other live virus vaccines (eg, measles, rubella) suggests that immunity remains high throughout life; the primary reason for second doses of measles vaccine is to induce protection in children who did not respond to the first dose, not because of waning immunity. Follow-up studies of clinical trials in children are being

performed to determine the need, if any, for additional doses of varicella vaccine.

#### EFFECT OF VARICELLA VACCINE ON EPIDEMIOLOGY OF VARICELLA

There has been concern that use of varicella vaccine in young children will create a cohort of adults at risk for serious varicella disease. Currently, fewer than 2% of adults older than 30 years in the United States are susceptible to varicella. As the use of varicella vaccine increases, the circulation of wild-type VZV will decrease and the likelihood that children unexposed to natural infection and unimmunized will enter adolescence and adulthood without immunity will increase. Mathematical models predict that if varicella vaccine coverage in children is more than 90%, a greater proportion of cases will occur at older ages, but the varicella disease burden will decrease for children *and* adults<sup>21</sup> (Table 1). However, if immunization rates for young children with varicella vaccine remain relatively low, the number of children who become susceptible adults will increase as will the opportunities for these susceptible adults to contract varicella from unimmunized children. Therefore, physicians who withhold varicella immunization from young children because of fear of creating a cohort of adults at risk for serious varicella disease may be creating a self-fulfilling prophecy.<sup>22</sup>

#### COST-BENEFIT OF VARICELLA VACCINE

In recent years, several cost-benefit analyses of varicella vaccine programs have been performed<sup>23–25</sup> (Table 2). In 1994, Lieu and coworkers<sup>23</sup> reported the results of a cost-benefit analysis of a program that provided varicella vaccine to all children in the United States younger than 6 years. That same year, Huse and coworkers<sup>24</sup> reported the results of a cost-benefit analysis of a program that provided routine varicella immunization to a hypothetical cohort of 100 000 children in the United States aged 15 months. In 1996, Beutels and coworkers<sup>25</sup> reported the results of a cost-benefit analysis of a program that provided routine varicella immunization to all children in Germany between 12 and 18 months of age. Although the amount of savings and cost-benefit ratios differ, each of the analyses concluded that when direct medical *and* indirect societal costs were considered, a routine varicella immunization program for healthy young children was cost-beneficial. Furthermore, both American analyses were based on morbidity and mortality data from the 1980s and on cost data from 1990. Because of the subsequent increase in hospitalization costs and the number of deaths and

**TABLE 1.** Varicella-Zoster Virus Disease Burden in Adults Related to Varicella Vaccine Coverage Among Children\*

	Coverage in Children (%)	Number of Susceptible Adults	Amount of Wild-Type Virus	Disease Burden in Adults
No vaccine	0	+	++++	++
Selective vaccine use	<90	++++	+++	++++
Universal vaccine use	>90	++	+	+

\* The plus signs indicate the relative number or disease burden.

**TABLE 2.** Cost-Benefit Analyses of Varicella Vaccine\*

	Lieu et al <sup>23</sup> /1994	Huse et al <sup>24</sup> /1994	Beutels et al <sup>25</sup> /1996
Target population	All children in United States younger than 6 y	Hypothetical cohort of 100 000 children in United States; 15 mo	All children in German; 12-18 mo
Direct medical costs (savings)†	8 million	3.13 million	4.5 million
Indirect societal costs (savings)‡	(392 million)	(9.78 million)	(96.5 million)
Annual net costs (savings)	(384 million)	(6.65 million)	(92 million)
Costs (savings) per vaccine	(\$96)	(\$66)	(\$164)
Total benefits-total costs ratio	5.40	1.38	4.60

\* Savings are given in parentheses.

† Cost of vaccine and administration minus cost of varicella disease prevented.

‡ Work-loss costs (savings).

hospitalizations due to varicella, analyses based on current data would likely demonstrate a more favorable cost-benefit ratio.

#### POSTEXPOSURE IMMUNIZATION

Studies conducted in Japan and the United States in the 1970s and 1980s demonstrated that postexposure varicella immunization was about 90% effective for preventing varicella if given within 3 days, and possibly within 5 days, of household or hospital exposure.<sup>26-28</sup> Although the vaccine formulation in these studies differed from the current formulation, data suggest that this product also may be effective for preventing or modifying varicella when given to household contacts within 3 days of the appearance of the rash in the index case. In a study of 10 susceptible siblings given varicella vaccine within 3 days of the appearance of the rash in the index case, 5 did not develop varicella disease, and 5 developed mild disease with only 1 child developing more than 20 lesions.<sup>29</sup> The AAP now recommends the vaccine for use in susceptible children after exposure to varicella. For susceptible children recently exposed to varicella, offering the varicella vaccine is logical because infected children may then be partially or completely protected against disease, and, in children who are not infected, administration of the vaccine will protect them against future exposures. Physicians should advise parents and their children in these circumstances that the vaccine may not protect against disease, and that some children may have been exposed at the same time as the index case. The vaccine will not protect in the latter instance, and some children may develop moderate or severe varicella within a few days after immunization in such situations. There is no evidence that administration of varicella vaccine during the presymptomatic or prodromal stage of illness increases the risk for vaccine-associated adverse events or more severe natural disease. For susceptible hospitalized children exposed to varicella, the decision to use varicella vaccine, varicella-zoster immune globulin (VZIG), or antiviral agents must be individualized.

#### SEROLOGIC TESTING BEFORE AND AFTER IMMUNIZATION

For adults, adolescents, and children with a reliable history of varicella, it can be assumed that they are immune and immunization is unnecessary. Because approximately 70% to 90% of adults without a

reliable history of varicella also will be immune, it may be cost-effective to perform serologic tests on persons 13 years of age or older and immunize those who are seronegative. If serologic testing is performed, a tracking system for seronegative persons should be developed to ensure that susceptible persons are immunized. However, serologic testing is not required because varicella vaccine is well tolerated by those immune from earlier disease. In some situations, universal immunization may be easier to implement than serologic testing and tracking. Most children younger than 13 years of age without a reliable history of varicella should be considered susceptible and immunized without serologic testing. However, data from some populations indicate that a large proportion of 9- to 12-year-old children with uncertain histories of varicella will be immune and that serologic testing before deciding about immunization may be cost-effective.<sup>30</sup> Seroconversion rates after 1 dose of varicella vaccine in children younger than 13 years of age and after 2 doses in adolescents and adults are so high that serologic testing after immunization is unnecessary.

Whole cell enzyme immunoassay is the most commonly used commercially available serologic test for VZV. The sensitivity of this test is sufficient to determine immunity after natural varicella, but it may not be sensitive enough to determine vaccine-induced immunity. More sensitive tests include the fluorescent antibody to membrane antigen test, but it is not commercially available, and the latex agglutination test, which is not convenient for mass testing.

#### HEALTH AND CHILD CARE WORKERS

Health and child care workers who do not have a history of varicella should be tested serologically, and those who are seronegative and without a contraindication should be immunized. Immunized health and child care workers should be advised to monitor themselves for the infrequent occurrence of a vaccine-associated rash that may occur during the 6 weeks after immunization. This rash may appear at the injection site or may be generalized. Because vaccine virus that may be infectious to susceptible contacts has been recovered rarely from skin lesions of immunized persons, institutions should develop guidelines for personnel in whom a rash develops after immunization. Immunized persons who do not develop a rash may continue to work in their assigned patient or child care areas. Health and child

care workers should be considered immune from varicella infection after receiving their second dose of varicella vaccine and need not be excluded from work if subsequently exposed to VZV infection. However, immunized health and child care workers should be informed of the risk of breakthrough varicella infections and told to report close contacts with natural VZV infection to infection control personnel. The role of serologic testing of exposed immunized persons is controversial, but whether tested or not, they should be advised to watch for the appearance of skin lesions during the 2- to 3-week incubation period. Any rashes that develop during this period should be evaluated by infection control personnel before the health or child care worker provides direct care to children.

#### ADVERSE EVENTS

Varicella vaccine is safe; reactions are generally mild and occur with an overall frequency of approximately 5% to 35%. Approximately 20% of immunized persons will experience minor injection site reactions (eg, pain, redness, swelling). Approximately 3% to 5% of immunized children will develop a localized rash, and an additional 3% to 5% will develop a generalized varicella-like rash. These rashes typically consist of 2 to 5 lesions and may be maculopapular rather than vesicular; lesions usually appear 5 to 26 days after immunization. However, most varicella-form rashes that occur within the first 2 weeks after varicella immunization are due to wild-type VZV.<sup>31</sup> Although a temperature higher than 38.9°C (102°F) has been observed from 1 to 42 days after immunization in 15% of healthy immunized children, fever also occurs in a similar percentage of children receiving placebo and is not considered to be a significant adverse event of immunization.<sup>32</sup> A temperature higher than 37.8°C (100°F) has been reported in 10% of adolescents and adults who are immunized with the vaccine. Serious adverse events, such as encephalitis, ataxia, erythema multiforme, Stevens-Johnson syndrome, pneumonia, thrombocytopenia, seizures, neuropathy, and death, have been reported rarely in temporal association with varicella vaccine. In some cases, wild-type VZV or another causal agent has been identified. In most cases, data are insufficient to determine a causal association.

#### HERPES ZOSTER AFTER IMMUNIZATION

The varicella vaccine virus has been demonstrated to cause herpes zoster in immunocompetent and immunocompromised persons within 25 to 722 days after immunization. Data from postlicensure surveillance indicate that the age-specific risk of herpes zoster seems to be lower in immunocompetent children immunized with varicella vaccine than in children who have had natural infection. A population-based study indicated that the incidence of herpes zoster after natural varicella infection among immunocompetent children younger than 20 years of age was 68 per 100 000 person-years<sup>33</sup> while the reported rate of herpes zoster after varicella immunization among immunocompetent persons was approximately 2.6 per 100 000 vaccine doses distributed

(CDC, unpublished data, 1998). However, these rates should be compared cautiously because the former rates are based on populations monitored actively for longer periods than the passive surveillance after immunization. Wild-type VZV also has been identified in persons with herpes zoster after immunization, indicating that herpes zoster in immunized persons also may result from antecedent natural varicella infection.

#### TRANSMISSION OF VACCINE-ASSOCIATED VIRUS

Experience during the past 4 years with more than 14 million doses of varicella vaccine distributed in the United States indicates that vaccine-associated virus transmission to contacts is extremely rare (only 3 well-documented cases to date) and occurs only if the immunized person develops a rash (Merck and Company, Inc, unpublished data, 1999).

The role of VZIG or acyclovir as prophylaxis for high-risk persons exposed to immunized persons with lesions will be difficult to evaluate given the rarity of transmission. If contact inadvertently occurs, the routine use of VZIG is not recommended because transmission is rare, and disease, if it were to develop, would be expected to be mild. However, some experts believe that immunocompromised persons who develop skin lesions possibly related to vaccine virus should receive acyclovir treatment.

#### PREGNANCY

The vaccine manufacturer, in collaboration with the CDC, has established the Varivax Pregnancy Registry to monitor maternal and fetal outcomes of women who are inadvertently immunized with varicella vaccine 3 months or less before pregnancy or anytime during pregnancy (800-986-8999). The registry, which contains data from more than 300 deliveries, indicates no defects compatible with congenital varicella syndrome. However, the small number of pregnancies followed-up to date gives low power to detect a rare effect, and the serologic status of the majority of the women was unknown, but the majority were likely to be immune. A 12-month-old infant who developed approximately 30 vesicular lesions after receiving the currently licensed varicella vaccine transmitted vaccine virus to his previously healthy mother who was 5 to 6 weeks pregnant.<sup>34</sup> After an elective abortion, polymerase chain reaction testing of fetal tissue did not reveal VZV.

#### RECOMMENDATIONS FOR VARICELLA VACCINE USE

The AAP reaffirms the recommendations for varicella vaccine use presented in the initial statement from the Committee on Infectious Diseases.<sup>1</sup>

Routine immunization of all susceptible children and adolescents without a contraindication is recommended. A reliable history of varicella should be sought at every childhood visit and persons 12 months of age or older without a history of disease should be immunized. Evidence of immunity or record of immunization should be documented in the medical record. Evidence of immunity should consist of a physician's diagnosis of varicella, a reli-

able history of varicella, or serologic evidence of immunity. Special emphasis should be placed on the immunization of susceptible older children before entry into middle school, because the likelihood of severe infection increases with age.

The AAP strongly encourages pediatricians to support public health officials in the development and implementation of varicella immunization requirements for child care and school entry.

In addition, the following new recommendations are presented:

- 1. HIV-infected and other children with altered immunity.** Children with impaired humoral immunity may be immunized with varicella vaccine. However, varicella vaccine should not be administered routinely to children who have cellular immunodeficiencies including persons with leukemia, lymphoma, other malignancies affecting the bone marrow or lymphatic systems, and congenital T-cell abnormalities. Exceptions include children with acute lymphocytic leukemia, to whom vaccine may be given through a research protocol, and certain children infected with HIV. Children infected with HIV may be at increased risk of morbidity from varicella and herpes zoster. Limited data on immunization of HIV-infected children in CDC class I (CD4<sup>+</sup> T-lymphocyte percentage of 25% or more) indicate that the vaccine is safe, immunogenic, and effective. Therefore, weighing potential risks and benefits, varicella vaccine should be considered for HIV-infected children in CDC class I with mild or no signs or symptoms. With the increased use of varicella vaccine and the resulting decrease in incidence of varicella in the community, exposure of immunocompromised hosts to VZV will decrease. As the risk of exposure decreases and more data are generated on the use of varicella vaccine in high-risk populations, the risk versus benefit of varicella immunization in HIV-infected children will need to be reassessed.
- 2. Postexposure immunization.** Varicella vaccine may be effective for preventing or modifying varicella when given to household contacts within 3 days of the appearance of the rash in the index case. The use of varicella vaccine in susceptible children after exposure to varicella is recommended.
- 3. Storage and administration.** The vaccine should be stored in a freezer with an average temperature of  $-15^{\circ}\text{C}$  ( $+5^{\circ}\text{F}$ ) or colder; however, recent data indicate that it is acceptable to store vaccine at refrigerator temperature ( $2^{\circ}\text{C}$ – $8^{\circ}\text{C}$  [ $36^{\circ}\text{F}$ – $46^{\circ}\text{F}$ ]) for up to 72 continuous hours before administration. Once reconstituted, the vaccine must be used within 30 minutes or discarded.

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## ERRATUM

For the practice guideline entitled, "Practice Parameter: The Diagnosis, Treatment, and Evaluation of the Initial Urinary Tract Infection in Febrile Infants and Young Children" (1999;103:843–852), the table below replaces the previously published Table 2 (1999;104:118) and should be used in conjunction with this practice guideline.

**TABLE 2.** Criteria for the Diagnosis of Urinary Tract Infection<sup>53</sup>

Method of Collection	Colony Count (Pure Culture)	Probability of Infection (%)
Suprapubic aspiration	Gram-negative bacilli: any number Gram-positive cocci: more than a few thousand	>99%
Transurethral catheterization	>10 <sup>5</sup>	95%
	10 <sup>4</sup> – 10 <sup>5</sup>	Infection likely
	10 <sup>3</sup> – 10 <sup>4</sup> <10 <sup>3</sup>	Suspicious; repeat Infection unlikely
Clean void	>10 <sup>4</sup>	Infection likely
	Boy	95%
	Girl	90%
	3 specimens ≥10 <sup>5</sup> 2 specimens ≥10 <sup>5</sup> 1 specimen ≥10 <sup>5</sup>	80%
	5 × 10 <sup>4</sup> – 10 <sup>5</sup> 10 <sup>4</sup> – 5 × 10 <sup>4</sup>	Suspicious; repeat Symptomatic: suspicious; repeat Asymptomatic: infection unlikely
	<10 <sup>4</sup>	Infection unlikely