Vaccine Policy Changes and Epidemiology of Poliomyelitis in the United States

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IN 1952, 3 YEARS BEFORE THE LICENSURE of the first poliomyelitis vaccine, more than 21,000 cases of paralytic poliomyelitis were documented in the United States.1 The use of inactivated poliovirus vaccine (IPV) and, later, oral poliovirus vaccine (OPV) led to a precipitous drop in reported cases of poliomyelitis.2 The last cases of poliomyelitis caused by indigenously acquired wild poliovirus occurred in 1979 during an outbreak following importation from Canada.3 Genetic studies of poliovirus isolates from the 1970s suggested that endemic circulation of wild polioviruses in the United States may have ceased by the late 1960s, and subsequent sporadic cases and small outbreaks due to wild poliovirus during the 1970s probably represented importations from neighboring countries.3

See also p 1749 and Patient Page.

Context The last case of poliomyelitis in the United States due to indigenously acquired wild poliovirus occurred in 1979; however, as a consequence of oral poliovirus vaccine (OPV) use that began in 1961, an average of 9 cases of vaccine-associated paralytic poliomyelitis (VAPP) were confirmed each year from 1961 through 1989. To reduce the VAPP burden, national vaccination policy changed in 1997 from reliance on OPV to options for a sequential schedule of inactivated poliovirus vaccine (IPV) followed by OPV. In 2000, an exclusive IPV schedule was adopted.

Objective To review the epidemiology of paralytic poliomyelitis and document the association between the vaccine schedule changes and VAPP in the United States.

Design and Setting Review of national surveillance data from 1990 through 2003 for cases of confirmed paralytic poliomyelitis.

Main Outcome Measures Number of confirmed paralytic poliomyelitis cases, including VAPP, and ratio of VAPP cases to number of doses of OPV distributed that occurred before, during, and after implementation of policy changes.

Results From 1990 through 1999, 61 cases of paralytic poliomyelitis were reported; 59 (97%) of these were VAPP (1 case per 2.9 million OPV doses distributed), 1 case was imported, and 1 case was indeterminate. Thirteen cases occurred during the 1997-1999 transitional policy period and were associated with the all-OPV schedule; none occurred with the IPV-OPV schedule. No cases occurred after the United States implemented the all-IPV policy in 2000. The last imported poliomyelitis case occurred in 1993 and the last case of VAPP occurred in 1999.

Conclusion The change in polio vaccination policy from OPV to exclusive use of IPV was successfully implemented; this change led to the elimination of VAPP in the United States.

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Monovalent OPV type 3 became available in 1961 in the United States. Trivalent OPV (offering protection against the 3 poliovirus serotypes) was licensed in the United States in 1963 and became the vaccine of choice for prevention of poliomyelitis in the United States and most of the world.3 Oral poliovirus vaccine was considered superior to IPV because of provision of better intestinal immunity, ability to indirectly vaccinate susceptible contacts through transmission of vaccine polioviruses, case of administration, and lower costs. However, a serious consequence of the use of this live-virus vaccine, vaccine-associated
paralytic poliomyelitis (VAPP), was recognized as early as 1962.6,7 From 1961 through 1989, an average of 9 cases of VAPP (range, 1-25 cases) were confirmed each year.8-10 In 1988, the World Health Assembly resolved to eradicate poliomyelitis globally by 2000.11 Universal implementation of polio eradication strategies substantially reduced the risk of poliovirus importation into the United States.12 In response to the changing risk-benefit profile associated with OPV use, the Institute of Medicine conducted independent evaluations on polio vaccine options in the United States in 1977 and 1988,13,14 and in 1995, participated in a policy review initiated by the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices.15 The discussion of changing reliance from OPV to IPV led to national debates in the mid 1990s.16 It was thought that the potential for reduced compliance due to higher costs and the increased number of injections associated with IPV, coupled with possible reduced mucosal immunity in IPV recipients, could lead to wild poliovirus outbreaks.17,18

However, as the likelihood of wild poliovirus importations declined, the risk of VAPP with routine use of OPV became more difficult to justify. In June 1996, a policy change was made when the Advisory Committee on Immunization Practices recommended a transition to IPV by first introducing a sequential vaccination schedule of 2 doses of IPV followed by 2 doses of OPV.17 This schedule was predicted to reduce the number of VAPP cases by 53%, with the greatest impact on recipients.19 However, more flexible policy options were supported by the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP) that allowed for an all-OPV schedule or an all-IPV schedule, provided parents were educated about the decision.20,21 In January 1999, the AAP and AAFP revised their recommendations to state that only IPV should be administered for doses 1 and 2, citing that VAPP continued to be associated with the all-OPV schedule22 and that the vaccine options were not always presented to patients and parents.20 Further progress toward global polio eradication and the desire to eliminate VAPP prompted all policy-setting groups to recommend that an all-IPV schedule be implemented in 2000,22,23

This report reviews national poliomyelitis surveillance data in the United States from 1990 through 2003, describes the epidemiology of poliomyelitis, and assesses the impact of the poliomyelitis vaccine policy changes on the occurrence of paralytic poliomyelitis in the United States.

METHODS

Sources of Data

The CDC has maintained national poliomyelitis surveillance since 1955. This system relies on voluntary reporting of suspected cases from health care providers and laboratories through local and state health departments to the CDC, the Vaccine Adverse Events Reporting System, and the National Vaccine Injury Compensation Program.10,24,25 Suspected cases are investigated and demographic, clinical, epidemiologic, and virologic data are collected. We reviewed paralytic poliomyelitis cases reported in the United States for 1990 through 2003.

National Immunization Survey (NIS) data for 1995 through 2002 were accessed to obtain vaccination coverage information and estimates of the proportion of children who received IPV or OPV26; NIS is an ongoing random-digit-dial telephone survey that provides national estimates of vaccine coverage among children aged 19 to 35 months. We obtained the number of OPV doses distributed in the 1990s from CDC Biologics Surveillance (CDC, unpublished data, January 2003).

Case Definition and Classification

The Council of State and Territorial Epidemiologists defines a clinical case of paralytic poliomyelitis as an acute onset of flaccid paralysis in 1 or more limbs, with decreased or absent tendon reflexes in the affected limbs, without apparent cause, and without sensory or cognitive loss. Confirmed cases are those that meet the clinical case definition and in which neurologic deficit continues to be present 60 days after onset of symptoms, unless death has occurred or follow-up status is unknown.27 Isolation of poliovirus is helpful but not necessary to confirm a case of paralytic poliomyelitis, and isolation of poliovirus itself does not confirm diagnosis. An expert committee of physicians, not affiliated with the CDC, reviews suspected cases to determine whether they meet the definition for a confirmed case of paralytic poliomyelitis.

Confirmed cases of paralytic poliomyelitis are classified according to the 4 main categories of the Epidemiologic and Laboratory Classification of Paralytic Poliomyelitis Cases system: sporadic (immunologically normal), epidemic, immunologically abnormal, and imported.28 Each of these categories is subdivided and includes a vaccine-associated subcategory. A paralytic poliomyelitis case is classified as VAPP if there is a temporal association between OPV receipt or contact with an OPV recipient and onset of symptoms.

Laboratory Investigations

Although laboratory technology evolved during the study period, polioviruses were isolated and identified using conventional procedures of inoculation of processed specimens onto susceptible cell cultures.29 Isolates were then determined to be vaccine-related by 1 of several standard molecular methods.30-32

VAPP Ratios and Risk

To estimate rates for VAPP in the 1990s before the implementation of the sequential schedule, we used a previously described method to calculate the ratio of VAPP cases per number of OPV doses distributed.32 We compared ratios of VAPP following exposure with the first OPV dose to ratios of VAPP following a subsequent dose. To estimate the number of first doses of OPV administered during 1990-1996, we used the annual number of births in the United States, obtained from the National Vital Statistics System,33 with the assump-
tion that every child born before 1997 received at least a first dose of OPV. To estimate the number of subsequent OPV doses administered, we subtracted the estimated number of first OPV doses from the number of all OPV doses distributed. During the sequential period (1997-1999), we could no longer assume that all infants received OPV; for this period, we used NIS data to estimate the percentage of infants who received a first dose of OPV. National Immunization Survey data were not used for the 1990-1996 period because these data were not available before 1995.

To calculate the risk of VAPP among immunologically abnormal children younger than 1 year, we estimated that 390 children are born each year with primary immunodeficiency disease (1 case per 10000 births). We calculated the risk of VAPP for children with primary-type immunodeficiency because this type of immunodeficiency disease is a known risk factor for VAPP, whereas VAPP is not known to be associated with acquired immunodeficiency, such as human immunodeficiency virus infection.36

**Table 1.** Epidemiologic and Laboratory Classifications of Paralytic Poliomyelitis Cases, United States, 1990-2003

<table>
<thead>
<tr>
<th>Classification</th>
<th>No. of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sporadic</td>
<td>44</td>
</tr>
<tr>
<td>Wild virus</td>
<td>0</td>
</tr>
<tr>
<td>Vaccine-associated</td>
<td></td>
</tr>
<tr>
<td>Recipient</td>
<td>27</td>
</tr>
<tr>
<td>Household contact</td>
<td>10</td>
</tr>
<tr>
<td>Nonhousehold contact</td>
<td>3</td>
</tr>
<tr>
<td>Community-acquired</td>
<td>3</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>1</td>
</tr>
<tr>
<td>Epidemic</td>
<td>0</td>
</tr>
<tr>
<td>Immunodeficient</td>
<td>16</td>
</tr>
<tr>
<td>Wild virus</td>
<td>0</td>
</tr>
<tr>
<td>Vaccine-associated</td>
<td></td>
</tr>
<tr>
<td>Recipient</td>
<td>14</td>
</tr>
<tr>
<td>Household contact</td>
<td>1</td>
</tr>
<tr>
<td>Nonhousehold contact</td>
<td>1</td>
</tr>
<tr>
<td>Community-acquired</td>
<td>0</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>0</td>
</tr>
<tr>
<td>Imported</td>
<td>1</td>
</tr>
<tr>
<td>Wild virus</td>
<td>0</td>
</tr>
<tr>
<td>Vaccine-associated</td>
<td>0</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>61</td>
</tr>
</tbody>
</table>

**Impact of Vaccine Policy Change**

We compared the frequency of VAPP per year before the polio vaccine schedule change (1990-1996) with the frequency of VAPP while the sequential schedule was in effect (1998 and 1999) and determined the percentage reduction in the number of cases between the 2 periods. Vaccine-associated paralytic poliomyelitis cases with onset in 1997 were noted but not included in this analysis because we considered this a transition period between changes in the polio vaccine policies.

**RESULTS**

One hundred thirty suspected poliomyelitis cases were reported for 1990-2003. Sixty-one (47%) of these were confirmed as paralytic poliomyelitis (Table 1), 59 of which were classified as VAPP. Of the 2 cases not associated with OPV, neither had virus isolated: 1 case (1993), in a girl who arrived ill from Nigeria, was classified as imported-indeterminate and 1 case (1991), in a teenaged Mexican-born boy, was classified as sporadic-indeterminate. The last imported poliomyelitis case occurred in 1993 and the last VAPP case in 1999 (FIGURE 1).

Of the 59 cases of confirmed VAPP, 43 (73%) were classified as sporadic in immunocompetent persons: 27 (46%) in OPV recipients, 13 (22%) in contacts of OPV recipients, and 3 (5%) in persons with unknown history of OPV exposure (community-acquired cases). Sixteen cases (27%) occurred in immunologically abnormal persons: 14 in recipients of OPV, and 2 in contacts. The immunologically abnormal cases all had primary immunodeficiency disease but none were known to have the disease prior to administration of OPV.

Forty-seven (80%) of the 59 VAPP cases had cultures performed for virus isolation; of these, 39 cases (83%) had vaccine-like poliovirus isolated. Poliovirus types 2 and 3 were isolated with similar frequencies. Type 3 poliovirus was the most common type isolated from sporadic cases (52%), whereas type 2 poliovirus was isolated from 73% of immunologically abnormal individuals.

Thirty-five (59%) of the VAPP cases occurred in males. Cases of VAPP were reported from 25 states. The highest number was reported in California, with 10 cases (17%), followed by Texas, with 6 cases (10%); 1 case occurred overseas at a US military base.

Twenty-five (93%) of the 27 sporadic cases in vaccine recipients occurred in infants; median age at onset was 3 months (range, 2 months to 5 years). The median age among the 13 sporadic cases among contacts was 27 years (range, 2 months to 69 years); only 2 (15%) occurred in infants. The

**FIGURE 1.** Reported Cases of Paralytic Poliomyelitis, United States, 1953-2003

Shaded region in the inset is represented in the larger graph, which shows both total number of cases of paralytic poliomyelitis and number of cases of vaccine-associated paralytic poliomyelitis (VAPP) from 1961 (first reported VAPP case) through 2003. Asterisk in the inset graph indicates data for 1955 do not include VAPP cases associated with inactivated poliovirus vaccine.

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median age of cases among immunologically abnormal recipients was 5.5 months (range, 2-19 months), whereas cases among immunologically abnormal contacts ranged in age from 1 month to 57 years, with a median of 29 years. The 3 sporadic community-acquired cases had a median age of 6 years (range, 9 months to 34 years).

The first OPV dose was associated with paralytic poliomyelitis in 23 (85%) of the 27 sporadic cases among recipients and was the implicated dose in 7 (54%) of 13 sporadic cases among contacts but in only 5 (31%) of the 16 immunologically abnormal cases (Table 2). In terms of vaccination status of sporadic contact and community-acquired cases, 10 (63%) of 16 had no history or an unknown history of poliomyelitis vaccination.

The interval from vaccine exposure to onset of paralysis in OPV recipients was 26 days (range, 3-61 days). In cases among contacts of vaccine recipients, when the exposure date was known, the median interval was 28 days (range, 10-39 days). The median interval of 63 days (range, 2-398 days) was much longer for immunologically abnormal cases.

At 60 days after onset of illness, the following outcomes were documented among the 59 VAPP cases: 11 (19%) had minor sequelae such as foot drop, 31 (53%) had major sequelae involving 2 limbs, 13 (22%) had severe sequelae in 3 or more limbs and/or respiratory involvement, and 3 (5%) had died; 1 case status was unknown.

Estimation of VAPP Ratios
In 1990-1996, an average of 20 million doses of OPV were distributed per year, after which the distribution declined to 10 million doses in 1999. No doses have been distributed since 1999 (Figure 2). The overall ratio was 1 VAPP case per 2.9 million doses of OPV distributed, or 0.34 cases per 1 million doses of OPV distributed. The ratio of VAPP associated with the first dose of OPV was 1 case per 0.9 million doses, a 6.6-fold greater risk than that following exposure to subsequent doses. Immunocompetent recipients were 25 times more likely to develop VAPP after the first dose than after subsequent doses (Table 3). Overall, immunologically abnormal persons had a high risk for VAPP, with 3077 cases annually per 1 million population with primary immunodeficiency disease.

Impact of Vaccine Policy Change
The sequential schedule was increasingly accepted each year. Based on NIS data, an estimated 54% of infants received OPV as their first dose of poliovirus vaccine in 1997, 29% in 1998, and only 9% in 1999. An estimated 53% received OPV as their second dose in 1997, 31% in 1998, and 10% in 1999. Coverage with 2 doses of poliovirus vaccine among 13-month-old children reported by the NIS was 93.4% in 1997, 93.8% in 1998, and 94.6% in 1999. Coverage continued to increase slightly each year and reached 95.2% in 2002.29 No imported cases of paralytic poliomyelitis have been confirmed since implementation of the sequential schedule. During 1997-1999, 13 VAPP cases occurred, 7 in 1997 and 3 each in 1998 and 1999. None of these cases occurred in persons who had followed the sequential IPV-OPV or all-IPV schedules. Nine cases occurred in OPV recipients (6 of which were associated with a first OPV dose), 2 among contacts of OPV recipients (who had not followed the sequential schedule), and 2 among immunologically abnormal OPV recipients (both associated with a second dose).

Comparing 1990-1996 with 1998-1999, the average number of VAPP cases per year decreased from 6.6 to 3.0, a reduction of 54.3% (Table 4). The average number of cases among sporadic recipients was similar during the 2 periods. The average number of sporadic contact cases decreased from 1.6 per year to 0.5 per year, a reduction of 68%; community-acquired cases decreased by 100%. Immunologically abnormal cases decreased from an average of 2 per year to 0, a reduction of 100%. The proportion of contact cases changed from 65% of the sporadic cases during 1990-1996 to 14% of the sporadic cases in 1998-1999.

COMMENT
In response to the declining risk of poliomyelitis balanced against the continued occurrence of VAPP each year, the United States transitioned from OPV to exclusive use of IPV, the most con-
tentitious change in vaccination policy made since OPV replaced IPV in the early 1960s. The transition was gradually accepted with no decreases in vaccination coverage or increases in adverse events. Following this change, all forms of poliomyelitis have been eliminated in the United States; the last imported case occurred in 1993 and the last VAPP case in 1999. The only threats from polio in the United States are from laboratories and the few remaining polio-endemic areas in Africa and Asia.

Globally, estimates for overall risk of VAPP are reported as cases of VAPP per number of OPV doses distributed. Our overall estimate of 1 VAPP case per 2.9 million OPV doses distributed during 1990-1999 is similar to other published US studies and data from other industrialized countries, as is our finding that there is a substantially higher risk of VAPP in immunocompetent children following the first dose of OPV compared with subsequent doses. Our estimate of 1 contact VAPP case per 13.3 million OPV doses distributed, however, is more than 50% lower than that estimated for the United States in the 1970s and 1980s, perhaps because of increasing immunization coverage during the past 2 to 3 decades. The distribution of the poliovirus serotypes that were isolated, with type 2 being the predominant type in immunodeficient cases and type 3 in immunocompetent cases, is also consistent with previous findings but is not fully understood.

No cases of VAPP were confirmed in persons who followed the IPV-OPV schedule, which is greater than the predicted reduction of 53%. Contrary to expectations, the schedule options appeared to provide most benefit in preventing contact, community-acquired, and immunodeficient cases, with no change in the risk of sporadic recipient cases. However, the short period that the sequential schedule was in effect and the rarity of VAPP occurrence in the 3 years make comparisons with data from the previous decades difficult. The predicted reduction assumed that the IPV-OPV schedule was the only acceptable schedule and that it was followed uniformly. We speculate that the decline in cases among those exposed to an OPV recipient (contact and community-acquired) may be due to the fact that IPV-vaccinated infants shed less virus for shorter periods when later given OPV.

Our method of calculating VAPP risk using OPV doses distributed and US births may underestimate the risk in recipients. Until 1996, we assumed that all OPV doses distributed each year were administered and that all infants received at least 1 dose. Certainly, not all doses were administered, and an analysis of the data from the NIS demonstrated that about 1.6% of children born in 1992-1996 received no dose of poliomyelitis vaccine. For estimated doses during the sequential schedule period, we used available data from the NIS; therefore, our estimated denominator for case–to–vaccine dose ratio calculations may be more accurate than those previously reported.

Although the United States does not conduct active surveillance for paralytic poliomyelitis cases but instead relies on clinicians investigating suspected poliomyelitis cases to conduct an appropriate clinical workup for poliovirus and notify the local or state health department, no evidence suggests that cases of paralytic poliomyelitis have been missed. On the contrary, the US poliomyelitis case definition may detect paralytic illnesses with causes other than poliovirus, especially cases in which no poliovirus was isolated. Acute flaccid paralysis cases unrelated to poliovirus infection may have been misdiagnosed as poliomyelitis; furthermore, confirmed poliomyelitis cases may have been misclassified as vaccine-associated.

**Table 3.** OPV Doses Distributed per VAPP Case by Dose Administered, United States, 1990-1999

<table>
<thead>
<tr>
<th>Epidemiologic Classification</th>
<th>No. of OPV Doses per VAPP Case, in Millions</th>
<th>Ratio*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Doses</td>
<td>First Dose</td>
</tr>
<tr>
<td>Sporadic</td>
<td>4.0</td>
<td>1.1</td>
</tr>
<tr>
<td>Recipient</td>
<td>6.4</td>
<td>1.4</td>
</tr>
<tr>
<td>Contact</td>
<td>13.3</td>
<td>4.5</td>
</tr>
<tr>
<td>Community-acquired</td>
<td>57.7</td>
<td>NA†</td>
</tr>
<tr>
<td>Immunodeficient</td>
<td>10.8</td>
<td>6.3</td>
</tr>
<tr>
<td>Recipient</td>
<td>12.4</td>
<td>7.9</td>
</tr>
<tr>
<td>Contact</td>
<td>88.6</td>
<td>31.7</td>
</tr>
<tr>
<td>Community-acquired</td>
<td>0</td>
<td>NA†</td>
</tr>
<tr>
<td>Total</td>
<td>2.9</td>
<td>0.9</td>
</tr>
</tbody>
</table>

**Table 4.** Reduction of VAPP Cases by Poliovirus Vaccine Policy Changes in the 1990s, United States

<table>
<thead>
<tr>
<th>Epidemiologic Classification</th>
<th>No. of VAPP Cases (Mean per Year)</th>
<th>Reduction, 1990-1996 to 1998-1999, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sporadic</td>
<td>32 (4.6)</td>
<td>5</td>
</tr>
<tr>
<td>Recipient</td>
<td>18 (2.6)</td>
<td>4</td>
</tr>
<tr>
<td>Contact</td>
<td>11 (1.6)</td>
<td>1</td>
</tr>
<tr>
<td>Community-acquired</td>
<td>3 (0.4)</td>
<td>0</td>
</tr>
<tr>
<td>Immunodeficient</td>
<td>14 (2.0)</td>
<td>2</td>
</tr>
<tr>
<td>Recipient</td>
<td>12 (1.7)</td>
<td>0</td>
</tr>
<tr>
<td>Contact</td>
<td>2 (0.3)</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>46 (6.6)</td>
<td>7</td>
</tr>
</tbody>
</table>

Abbreviations: OPV, oral poliovirus vaccine; VAPP, vaccine-associated paralytic poliomyelitis.

*Ratio = subsequent dose/first dose.
Delays in reporting or confirmation of cases may result in previously unidentified cases of VAPP being reported. In 1992, Strebel et al reported 81 VAPP cases for 1980-1989. Since that report, an additional 13 cases have been confirmed for that period; 6 of these were reported by the National Vaccine Injury Compensation Program after the program was initiated. Although we cannot be certain that no other cases will be reported in the United States, as of September 2004, the CDC currently has no suspected cases that are pending confirmation. The completeness of reporting was estimated at 81% in 1994 and 85% in 1996; it is unlikely that completeness has changed. Any VAPP occurring after 1999 would most likely be imported from a country still using OPV.

Elimination of VAPP is an important public health accomplishment in the United States. However, it is crucial that the United States continue to maintain high vaccination coverage and a sensitive surveillance system to rapidly detect and respond to cases of suspected paralytic poliomyelitis, either from imported virus or from possible breaches in laboratory containment that could introduce laboratory strains. Poliovirus—from any source—that reaches communities with low vaccine coverage may result in endemic or epidemic transmission.

Author Contributions: Ms. Alexander had full access to all polio case data in the study and Dr. Santibanez to National Immunization Survey data and each takes responsibility for the integrity of these data, respectively, and the accuracy of the data analysis. Study concept and design: Alexander, Seward, Wharton, Sutter. Acquisition of data: Alexander, Pallansch, Kew, Prevots, Strebel, Cono, Sutter. Analysis and interpretation of data: Alexander, Seward, Santibanez, Prevots, Sutter. Drafting of the manuscript: Alexander, Seward, Santibanez, Pallansch, Prevots, Sutter. Critical revision of the manuscript for important intellectual content: Alexander, Seward, Santibanez, Pallansch, Kew, Prevots, Strebel, Cono, Wharton, Orenstein, Sutter. Statistical analysis: Alexander, Santibanez. Administrative, technical, or material support: Pallansch, Prevots, Strebel, Cono, Wharton, Orenstein. Supervision: Seward, Sutter. Acknowledgment: We thank the following individuals from the National Immunization Program at the CDC: Rex Ellington, for providing Biologics Surveillance data; Barry Sirokin, MSc, for maintaining historical data; Mary McCauley, MSc, for editorial comments; and Patti Smith, for assistance with graphics.

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