SUPPLEMENT ARTICLE

Challenges to Implementing Second-Dose Varicella Vaccination during an Outbreak in the Absence of a Routine 2-Dose Vaccination Requirement—Maine, 2006

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In June 2005, the Advisory Committee on Immunization Practices (ACIP) recommended administering a second dose of varicella vaccine during outbreaks, supplementing the routine 1-dose requirement. From October 2005 to January 2006, a varicella outbreak occurred in Maine in a highly vaccinated elementary school population. We investigated the outbreak, held a school-based vaccination clinic, and assessed costs in implementing ACIP's outbreak-response recommendation. Parents completed questionnaires and case investigation interviews. Personnel at the Maine Center for Disease Control and Prevention, the school in which the outbreak occurred ("school A"), and physician offices completed economic surveys. Forty-eight cases occurred, with no hospitalizations or deaths. Vaccine effectiveness was 86.6% (95% confidence interval, 82.0%–90.1%). Of 240 eligible students, 132 (55.0%) received second-dose vaccination. Implementing ACIP's outbreak-response recommendation was challenging and cost approximately $26,875. Additionally, the routine 1-dose varicella vaccination policy did not confer adequate population immunity to prevent this outbreak. These findings support ACIP's June 2007 recommendation for a routine 2-dose varicella vaccination program.

Before the introduction of the varicella vaccine in 1995, >90% of varicella cases, two-thirds of varicella-related hospitalizations, and almost half of varicella-related deaths occurred in persons <20 years of age [1–3]. In 1996, the Advisory Committee on Immunization Practices (ACIP) recommended that susceptible children 12 months to 12 years of age with no disease history receive 1 dose of varicella vaccine and that susceptible persons ⩾13 years of age receive 2 doses [4]. ACIP updated these recommendations in 1999 with a 1-dose school-entry varicella vaccination requirement for eligible students [5]. This requirement was implemented in stages in most states, leaving cohorts of unvaccinated students in grades not yet covered by the requirement. Maine implemented a progressive varicella vaccine school requirement in 2003 for kindergarteners and first graders, adding other grades each year. By 2007, all students in Maine's kindergarten through 12th grades were covered [6].

The varicella vaccine is ~80%–85% effective after 1 dose [7–11], resulting in many breakthrough cases (varicella disease >42 days after varicella vaccination). Although breakthrough disease is generally milder than disease in unvaccinated individuals, the persistence of cases among vaccinated individuals has contributed to school outbreaks nationwide [11–13]. Accordingly, in June 2005, the ACIP passed a recommendation for the administration of a second dose of varicella vaccine in

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an outbreak setting, resources permitting [14]. Implementation of the ACIP's outbreak-response recommendation has not been previously documented.

In January 2006, the Maine Center for Disease Control and Prevention (Maine CDC) notified the US Centers for Disease Control and Prevention (CDC) in Atlanta of a varicella outbreak in a school (hereafter referred to as "school A") that had been ongoing since October 2005. Maine CDC asked for the CDC's assistance in investigating the outbreak, implementing a vaccination clinic at school A, and evaluating the implementation of ACIP's outbreak-response recommendation from an economic standpoint. Our objectives were to (1) describe the outbreak epidemiology, (2) determine the feasibility of implementing ACIP's outbreak-response recommendation, and (3) assess the economic impact on Maine CDC, school A, and the local health care providers of implementing ACIP's second-dose vaccination recommendation during a varicella outbreak.

METHODS

Outbreak setting. School A is a public elementary school (kindergarten through fifth grade) in Maine (town population, ~22,000). Mixing of students occurred in the classrooms, lunchroom, and hallways; on school buses; and during interclass activities.

Data collection. We used 2 standard questionnaires: a parental survey and a case investigation interview form. The former was included in a packet sent home with all students before the vaccination clinic held at school A and collected information on demographics, health care provider, medical/vaccination history, and parental consent to contact the health care provider. It was completed by the parent or with the parent. ("Parent" refers to either a parent or another caregiver.) The parents of all children who developed rash illness after 1 September 2005 (the start of the school year) completed a follow-up case investigation telephone interview in which information on varicella exposure, underlying medical conditions, treatment with prescription medications at the time of rash onset, clinical illness characteristics, and household transmission was obtained.

Personnel at pediatric/family practice offices, Maine CDC, and school A completed logs prospectively and/or retrospectively on the economic impact of the outbreak response by recording the number of telephone inquiries, miles traveled, and time spent on the outbreak.

Case patient ascertainment. A case patient was defined as any student attending school A who developed acute onset of diffuse maculopapulovesicular rash without other apparent cause or any vaccinated student who developed a maculopapular rash with few or no vesicles [15] after 1 September 2005 and was either laboratory confirmed or epidemiologically linked to another case patient. We used school nurse reports, parental surveys, and provider case listings to identify case patients. The parental survey asked whether the child had chickenpox or rash, bumps, or insect bites in the past and, specifically, since 1 September 2005. We obtained a varicella case listing from local health care providers from 1 September 2005 to 26 January 2006.

Specimen collection and laboratory methods. Community health care providers collected lesion specimens on all reported varicella case patients for 2 incubation periods (42 days) after the vaccination clinic on 12 January, to determine whether any students had vaccine-induced disease. Specimens were sent to the CDC National Varicella Zoster Virus (VZV) laboratory for confirmation by polymerase chain reaction (PCR) analysis and genotyping using previously described methodology [16, 17]. The first specimen collected was also confirmed by PCR at the Maine Health and Environmental Testing Laboratory.

Disease severity. Varicella severity was determined clinically as the reported number of skin lesions. Fewer than 50 lesions was classified as mild disease, 50–249 lesions was classified as mild/moderate disease, 250–500 lesions was classified as moderate/severe disease, and >500 lesions or complications such as pneumonia or encephalitis was classified as severe disease. Because of small numbers, severe and moderate/severe cases were analyzed as 1 group.

Vaccination status ascertainment and disease history. We obtained vaccination and disease history data from parental surveys and school vaccination records, with priority given to school vaccination records if discordant information was given. If no information was available from these 2 sources, we looked up vaccination history in the Maine immunization registry. We reviewed provider records after parental consent was obtained, as a last resort.

Vaccine effectiveness of a single dose. Vaccine effectiveness represents the percentage reduction in disease incidence during the outbreak attributable to 1-dose vaccination coverage among students at the outbreak onset. We calculated the attack rates among unvaccinated students with no or unknown varicella disease history (ARU) and among vaccinated students with no or unknown disease history (ARV). We assessed vaccine effectiveness for prevention of disease of any severity accordingly: % vaccine effectiveness = $[(ARU - ARV)/ARU] \times 100$. We excluded students with varicella disease history ($n = 57$) and with information on neither vaccination status nor disease history ($n = 11$) from the calculation of attack rates and vaccine effectiveness.

Outbreak response and control. On 12 January 2006, a vaccination clinic was held on site for school A students with no or unknown history of varicella disease who had no previous varicella vaccination or only 1 dose. Notification materials and vaccination consent forms were sent home with students on

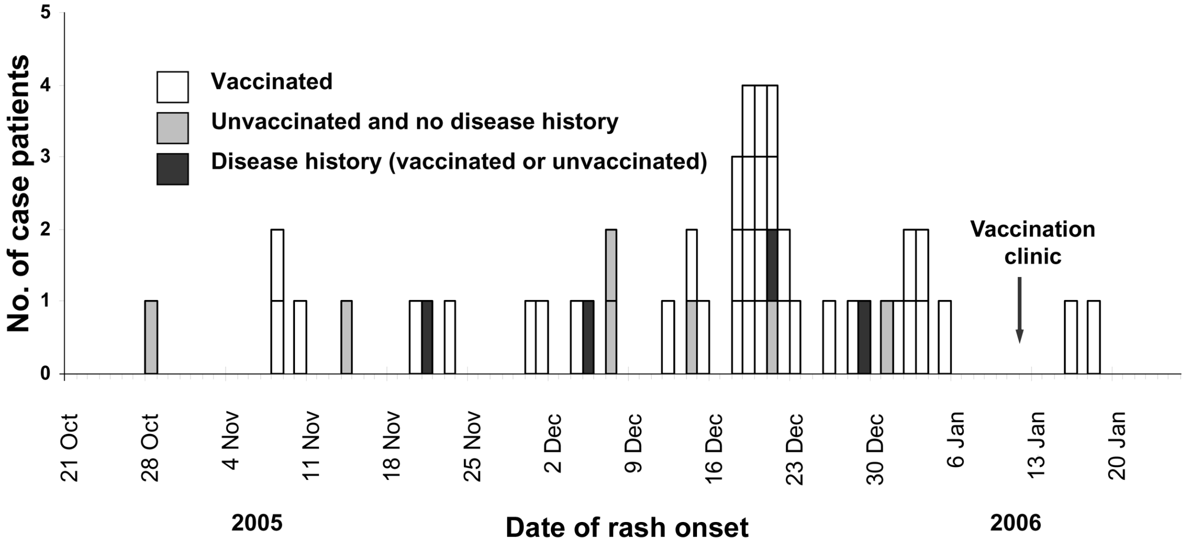

Figure 1. Distribution of varicella case patients (n = 48), by rash onset date, school A, Maine, 28 October 2005–18 January 2006

10 January 2006. On 11 January 2006, school personnel called parents who did not return a consent form. Community health care providers were alerted via fax and through Maine's Health Alert Network of the ACIP 2-dose varicella vaccination recommendation for outbreaks and of the upcoming school A vaccination clinic. Case patients were excluded from school until lesions had crusted or faded. Unvaccinated students with no disease history were excluded from school until 3 weeks after the last case patient's rash onset.

Burden/impact. We examined personnel time and direct costs from a health care perspective for 1 incubation period extending from 10 January, 2 days before the vaccination clinic when information packets were sent home with students, until 31 January. All Maine CDC personnel (n = 17), community health care providers (n = 21), and school A personnel (n = 6) who were directly involved with the outbreak response completed surveys of person-time hours spent retrospectively and ongoing until 31 January 2006, with a response rate of 100%. We calculated personnel costs by multiplying the individual's gross wage by the time spent on the outbreak. Unit costs included expenses for vaccines and miles traveled. We calculated overhead costs, defined as costs related to the amount of resources needed (e.g., equipment, buildings, stationery, and utilities) to support the work of a person, as a proportion of wages.

RESULTS

Outbreak population. Of the 352 students attending school A, 282 (80.1%) students returned parental surveys. Age and sex data were available for 78.4% and 78.7%, respectively, of the 352 students. The median age of the students was 8 years (range, 5–11 years), and 47.7% of the students were male. We obtained data on disease and/or vaccination status for 341 students (96.9%). Before the outbreak, 277 students were vaccinated and had no or unknown disease history, 57 had disease history with or without vaccination history, and 7 had neither disease nor vaccination history (11 students had no data on disease and vaccination history).

Outbreak. The outbreak lasted ~3 months, from 28 October 2005 to 18 January 2006, and peaked between 19 and 21 December 2005 (figure 1). Case interviews were completed with all 48 identified case patients (100%): 38 (79.2%) had breakthrough disease (including 1 with disease history), 7 (14.6%) were unvaccinated with no disease history, and 3 (6.3%) had disease history with no/unknown vaccination status. The median age of case patients was 8 years (range, 5–11 years); 21 case patients (43.8%) were male. Case patients attended all grades in 17 of 18 classrooms. Nine additional cases occurred among non–school A siblings of case patients.

Of the 341 students for whom we had vaccination and/or disease history response, there were 284 with no or unknown reported disease history. Of these 284 students, first-dose vaccination coverage was 97.5% (277/284). Vaccination coverage by grade ranged from 93.0% to 100.0%. Attack rates by grade ranged from 7.1% to 25.7% (table 1). Only 1 of the 2 case patients with rash onset after the vaccination clinic had been vaccinated at the clinic. This patient was laboratory confirmed by PCR as being infected with wild-type VZV. A total of 5 lesion specimens were collected, 3 of which tested positive for VZV.

Disease severity. Two (20%) unvaccinated case patients had moderate/severe or severe disease, but no vaccinated case patients had moderate/severe or severe disease ($P < .05$). Dif-

Table 1. Attack rates by grade and vaccination status—school A, Maine, 28 October 2005–18 January 2006.

	Attack rate, no./total (%)	
Grade	Vaccinated children[a]	Unvaccinated children[b]
K	5/56 (8.9)	NA
1	5/49 (10.2)	NA
2	9/35 (25.7)	NA
3	12/53 (22.6)	4/4 (100.0)
4	3/42 (7.1)	3/3 (100.0)
5	3/42 (7.1)	NA
Total[c]	37/277 (13.4)	7/7 (100.0)

NOTE. K, kindergarten; NA, not applicable.
[a] No. of case patients vaccinated with 1 dose before 1 September 2005 (the beginning of the school year) with no or unknown disease history, as a percentage of all children vaccinated before 1 September 2005 with no or unknown disease history
[b] No. of case patients unvaccinated before 1 September 2005 (the beginning of the school year) with no or unknown disease history, as a percentage of all children unvaccinated before 1 September 2005 with no or unknown disease history.
[c] Four additional case patients who had a history of disease or history of both disease and vaccination are not included in either column.

ferences between vaccinated and unvaccinated case patients for median days of school missed (2 vs. 4 days, respectively) and average duration of rash (5.4 vs. 6.5 days, respectively) did not reach statistical significance. Neither group reported complications.

Vaccine effectiveness. Vaccine effectiveness against disease of any severity was 86.6% (95% confidence interval [CI], 82.0%–90.1%), corresponding to attack rates of 13.4% (37/277) among vaccinated students with no or unknown disease history and 100% (7/7) among unvaccinated students with no or unknown disease history (table 1). Vaccine effectiveness for prevention of moderate or severe disease was 100% (LaPlace estimate, 99.6% [1-sided exact 95% CI, 98.9%]).

Transmission to household members. Secondary transmission (rash onset in another household member 10–21 days after the first household case patient's rash onset) occurred in 12 households (2 of these households had 2 generations of spread, and 1 household had 3); in 10 of these households, the primary case patient was vaccinated. In 1 of these households with a vaccinated primary case patient, secondary transmission occurred in an infant who was too young to be vaccinated. The age range of the individuals infected from secondary spread was 3 months to 13 years of age.

Vaccination clinic. Of the 240 (70.4%) students eligible for vaccination at the school clinic (i.e., students with no or unknown varicella disease history and no or 1 dose of varicella vaccination as of 12 January 2006), 132 (55%) were vaccinated. All vaccinations were second doses. Ninety-nine (28.1%) students were ineligible because of disease history, and 2 (0.6%) were ineligible because they had already received 2 doses.

Economic impact. In aggregate, the outbreak-response activities totaled ~528 person-hours, with 240 telephone calls, 408 miles driven, and 134 doses of varicella vaccine administered (table 2). The outbreak response is estimated to have cost Maine CDC, school A, and community health care providers $26,875. More than 90% ($24,310) of the costs were incurred by Maine CDC.

DISCUSSION

Varicella outbreaks continue to occur in highly vaccinated school-aged populations [11–13]. Even with a 97.5% first-dose vaccination coverage rate for school A students with no or unknown disease history, this outbreak was sustained for 4 generations of transmission over 3 months. Although the intervention was costly and occurred late in the outbreak, Maine CDC followed ACIP's 2005 recommendation for administering a second dose of varicella vaccine in an outbreak setting and implemented a vaccination clinic for school A students, which required >500 h of planning, coordination, and follow-up and redirected resources from other projects.

Responding to this outbreak cost more than $26,000, with most of the economic burden placed on Maine CDC. Both Maine CDC and school A experienced a disruption of routine activities. ACIP's outbreak-response recommendation for administering a second dose of varicella vaccine in an outbreak setting was not only resource intensive but also a challenge to effectively implement.

Breakthrough cases are often missed, because they do not resemble classic varicella and are usually mild with atypical clinical presentation [20]. As a result, parents may not recognize breakthrough disease as varicella. Additionally, parents may not report cases to the school nurse if the child becomes ill over a weekend or a holiday break. Thus, varicella outbreaks are often reported to the health department toward the end of the outbreak cycle, which prevents an effective outbreak response [21].

The response rate to the special vaccination clinic most likely was aided by the telephone calls made to the parents by school staff the night before the clinic. Federal regulations require that contact information on students not be released to outside entities except under specific circumstances that were not met [22]. These restrictions precluded health department personnel from assisting with the notification and should be a consideration when planning similar school-based clinics.

An additional barrier to implementing ACIP's outbreak-response recommendation was defining who should be included in the outbreak zone. Because of cost considerations, only students attending school A, the location with the highest burden of disease, were determined by Maine CDC to be eligible for vaccination. This left siblings, parents, day care playmates, and other susceptible contacts ineligible for vaccination. Parents

Table 2. Estimated cost of personnel time and materials used during the varicella outbreak response, Maine, 10–31 January 2006.

Cost	School A	Maine CDC	Health care providers	Total
Personnel directly involved, no.	6	17	21	44
Personnel time per activity,[a] h				
Investigation	…	19	…	19
Public health response	91	326	7	424
Laboratory	…	3	…	3
Other	…	82	…	82
Total	91	430	7	528
Materials, no.				
Phone calls	100	56	84	240
Varicella vaccine, doses	…	134	…	134
Miles	…	408	…	408
Estimated monetary costs,[b] $				
Personnel (wages + salaries)[c]	2029	14,406	202	16,637
Overhead[d]	304	2161	30	2495
Varicella vaccine	0	7625	0	7625
Miles[e]	0	118	0	118
Total cost	2333	24,310	232	26,875
Proportion of total, %	8.7	90.5	0.9	100.0

NOTE. Maine CDC, Maine Center for Disease Control and Prevention.

[a] Activities included in "investigation" are case finding and case interviewing; activities included in "public health response" are response planning/coordination, specimen collection, database development/analysis, development of information for the public, preparing reports, answering public inquiries, and working with the media; the activity included in "laboratory" is specimen testing.

[b] All costs are measured in 2005 US dollars.

[c] Personnel costs (wages and salaries) are calculated using the estimated hourly earnings for specific occupations, as reported in the Bureau of Labor Statistics [18].

[d] Overhead costs are calculated using 15% over personnel costs, as in [19].

[e] Mile costs are from [19] and are calculated by multiplying $0.29 by the total no. of miles.

were unable to receive free vaccinations for siblings of school A students, because Maine is a universal-purchase state (i.e., the state immunization program purchases vaccines for all children in the state and distributes these vaccines to the providers for children free of charge), but a second dose of free varicella vaccine was not in the program's budget, unless the individual was considered to be in the outbreak zone.

There were also challenges in determining how to deal with unvaccinated students with no or unknown history of disease. At the time of this outbreak, there was no policy requiring exclusion from school of unvaccinated students. Although the overall varicella vaccination coverage in the school before the outbreak was high, there were some students not yet covered by the phased-in school-entry vaccination requirement. School and public health officials agreed that if an extensive amount of time and resources were going to be invested in a vaccination clinic, new regulations were needed to exclude from school students with no or unknown history of disease during an outbreak.

Parental perception of varicella remains mixed, as evidenced by the 55% participation rate of eligible students in the vaccination clinic. Varicella is often perceived as a common disease with few serious adverse effects, and there is an underestimation of the potential serious disease sequelae [23, 24]. With a vaccine effectiveness of ~80%–85% after 1 dose [7–11], antivaccine literature claims that the vaccine is not working, because children are still becoming infected [25]. Some parents are losing confidence in the vaccine and are choosing to expose their children to natural disease to confer lifelong immunity, especially because the long-term immunity from vaccination is unknown [25].

There were several limitations to the investigation. This outbreak occurred in a predominantly white, middle- to upper-class, well-educated community and may not be reflective of varicella outbreaks in other areas. We had only an 80% response rate to the parental survey of school A students. We accepted parental and school nurse reporting of varicella history as valid without laboratory confirmation. We may have had incomplete case patient ascertainment because of the failure of the parents, school nurse, or community health care providers to recognize mild cases of breakthrough disease. This may have led to an overestimation of vaccine effectiveness. Intervention with a second dose of vaccine may also have increased our estimated vaccine effectiveness. However, because the intervention took place late in the outbreak, many of the susceptible individuals were likely exposed to the virus before the second dose of vaccine; thus, the impact on the vaccine effectiveness estimate would have been minimal. We also did not explore risk factors for vaccine failure, because the numbers were too small to assess confounding. Additionally, outbreak-response costs were measured retrospectively and did not include indirect costs (e.g., costs associated with productivity lost when parents of case patients missed work to take care of their sick child).

This investigation provided information on the challenges involved with implementing ACIP's outbreak-specific 2-dose varicella vaccine recommendation in one community. The constraints to effectively implementing ACIP's outbreak-response recommendation provided support for changing the focus of the varicella vaccine policy from outbreak response to prevention. This was accomplished through a routine second-dose varicella vaccination recommendation for all school-aged children, by ACIP in June 2007 [26]. The availability of a combination measles-mumps-rubella-varicella vaccine provides an opportunity to offer a routine first and second dose of varicella vaccine along with the widely accepted 2 doses of measles-mumps-rubella vaccine at 12–15 months and 4–6 years of age and may improve compliance.

The substantial economic impact and resource drain required to implement a vaccination clinic in an outbreak setting were also supporting evidence in favor of the new vaccination policy change for a routine second dose for school-aged children. More importantly, the routine 1-dose policy for varicella vaccination was not enough to confer adequate population immunity. This investigation highlighted the importance of implementing ACIP's June 2007 recommendation for a routine second dose of varicella vaccine for school-aged children to strengthen vaccine-induced immunity and protect against varicella disease.

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