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SUBJECT: Memorandum Report: *2009 H1N1 School-Located Vaccination Program Implementation,* OEI-04-10-00020

This memorandum report provides information about selected 2009 H1N1 School-Located Vaccination (SLV) programs. The Centers for Disease Control and Prevention (CDC) considers SLV to be a viable, large-scale vaccination method for children. However, CDC indicated in meetings with the Office of Inspector General (OIG) that onsite evaluations of the administration of H1N1 vaccine at SLV sites would be useful because data about local implementation of SLV programs have been limited, especially during influenza pandemics.

In November and December 2009, OIG conducted onsite interviews and observed the administration of H1N1 vaccine at 38 selected elementary SLV sites in 6 localities. Our evaluation of 2009 H1N1 vaccination programs at these selected SLV sites included three objectives: (1) to determine the extent to which SLV sites provided the first dose of the H1N1 vaccine to enrolled students, (2) to determine the extent to which and how SLV sites implemented specific vaccine administration elements, and (3) to identify challenges and lessons learned from implementing these elements across SLV sites.

We found that, by locality, selected SLV sites vaccinated an average of 28 percent of enrolled students during their 1-day programs, ranging from 14 percent to 45 percent. This compares favorably to relevant State and national vaccination rates obtained over a longer period of time and through a variety of methods. For example, the average vaccination rate in the six corresponding States was 37 percent. However, this statewide percentage reflects the number of children vaccinated over a period of approximately 3 months using multiple methods (e.g., private providers, commercial pharmacies, mass vaccination clinics, SLV) and for a wider age range. The majority of selected localities reported SLV to be a useful method to vaccinate a large number of children in a short period of time, but they also reported that they would need additional resources to implement future SLV programs.

We also found a number of challenges associated with implementing SLV programs. For example, we observed that the majority of selected SLV sites used recommended vaccine storage containers but did not monitor and record vaccine storage temperature. All selected localities reported challenges securing sufficient SLV staff and distributing them effectively across staffing functions. Additionally, selected SLV sites reported experiencing challenges communicating a clear and consistent message to parents about potential vaccination adverse reactions and the need for a second vaccine dose. Finally, the majority of selected localities had not established a billing system to bill third-party payers for the cost of H1N1 vaccine administration.

The selected localities reported a number of things they would do differently in future SLV programs. These include simplifying the consent form and educational materials; standardizing the consent form review process; devoting more staff to registration, triage, and translation; streamlining staff communication and training; developing a centralized information-sharing system; and distributing information to parents and participating schools earlier.

BACKGROUND

In June 2009, the World Health Organization declared the start of the 2009 H1N1 influenza pandemic, and Congress appropriated supplemental funds to prepare for and respond to an influenza pandemic.[1, 2] Although the pandemic was less severe than anticipated, approximately 59 million cases were estimated nationwide from April 2009 to mid-February 2010.[3] Additionally, CDC estimated 265,000 hospitalizations and 12,000 deaths within the United States. Among children 17 years of age and younger, there were an estimated 19 million cases of H1N1 influenza, 85,000 related hospitalizations, and 1,250 deaths nationwide within the same timeframe.

In July 2009, CDC announced funding to awardees through Public Health Emergency Response (PHER) grants to enhance State and local public health response capacity for emerging H1N1 influenza outbreaks.[4] CDC distributed a total of $1.35 billion through PHER grants in three phases.[5] Awardees used the grant funds to plan for their 2009 H1N1 vaccination programs,

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[1] World Health Organization, *World Now at Start of 2009 Influenza Pandemic.* Accessed at http://www.who.int/mediacentre/news/statements/2009/h1n1_pandemic_phase6_20090611/en/index.html on May 19, 2010.

[2] 2009 Supplemental Appropriation Act, P.L. 111-32, Title VIII, 123 Stat. 1884 (June 24, 2009).

[3] CDC, *CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations, and Deaths in the United States, April 2009–February 13, 2010*. Accessed at http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm on May 19, 2010.

[4] Funding Opportunity Number CDC-RFA-TP09-902-H1N109, p. 1.

[5] Phase 1: On July 31, 2009, a total of $260 million was distributed to PHER awardees to help them assess their current capabilities in pandemic influenza response and to address remaining gaps. Phase 2: On August 21, 2009, $248 million was distributed to provide additional resources for mass vaccination planning and implementation activities. Phase 3: On September 28, 2009, $846 million was given for the implementation of mass vaccination programs. CDC, *Funding Guidance and Technical Assistance to States.* Accessed at http://www.bt.cdc.gov/cdcpreparedness/coopagreement/index.asp on May 19, 2010.

including purchasing supplies and hiring additional staff, such as contractors. Compared to SLV programs for seasonal influenza, the 2009 SLV programs were unique because of delays in vaccine production and delivery, compressed timelines for planning, and additional concerns about vaccine safety.

In October 2009, upon availability of H1N1 vaccines, CDC began coordinating the distribution of limited quantities of two types of H1N1 vaccine: a nasal mist and an injection. The nasal mist was available for distribution in larger quantities before the injection, so States and localities initially received larger shipments of this type of the vaccine. According to CDC, the nasal mist should be administered only to people 2 to 49 years of age who do not have certain medical conditions, including asthma.[6] The injection can be administered to people 6 months of age and older, including those with chronic medical conditions and pregnant women.[7] Individuals with a severe allergy to eggs, or any other substance in the vaccine, should not receive either type, as they may experience adverse reactions to it.[8] Finally, children 9 years of age and younger who are eligible to receive the vaccine based on the criteria above should receive two doses of the H1N1 vaccine, separated by a minimum of 21 days.[9]

Because of the initially limited supply of the H1N1 vaccine, CDC recommended voluntary vaccination of target group members (e.g., individuals ages 6 months to 24 years) to prevent illness among those at higher risk of infection and complications.[10, 11] To implement CDC recommendations, States developed vaccination programs to reach target group members first. CDC's recommendations allowed States and localities flexibility to determine how and when to vaccinate members of these target groups. Most States chose to direct H1N1 vaccine to individuals in the 6 month to 24 years of age target group and, as of early May 2010, 40 States had elected to reach this group using SLV to some degree.[12]

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[6] CDC, *2009 H1N1 Live, Attenuated Influenza Vaccine Information Sheet*. Accessed at http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-laiv-h1n1.pdf on May 19, 2010.
[7] CDC, *2009 H1N1 Inactivated Influenza Vaccine Information Sheet.* Accessed at http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-inact-h1n1.pdf on May 19, 2010.
[8] There have been rare and mild influenza-like side effects experienced after receiving the 2009 H1N1 vaccination. However, for those people with severe allergies to chicken eggs, anaphylactic shock resulting in death is possible. CDC, *General Questions and Answers on 2009 H1N1 Influenza Vaccine Safety*. Accessed at http://www.cdc.gov/h1n1flu/vaccination/vaccine_safety_qa.htm on May 19, 2010.
[9] CDC, *Questions & Answers: Vaccine against 2009 H1N1 Influenza Virus.* Accessed at http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm on May 19, 2010.
[10] CDC, *2009 H1N1 Vaccine Recommendations.* Accessed at http://cdc.gov/h1n1flu/vaccination/acip.htm on May 19, 2010.
[11] Other target groups include pregnant women, caregivers of children younger than 6 months of age, health care and emergency medical service personnel, and persons aged 25 to 64 with certain health conditions that increased their risk of complications if infected with H1N1 influenza virus.
[12] Center for Infectious Disease Research & Policy, *H1N1 Lessons Learned: Vaccination campaign weathered rough road, paid dividends*. Accessed at http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/apr3010campaign.html on May 19, 2010.

Although some States implemented SLV programs during previous influenza seasons, the 2009 influenza season was considered the first widespread use of SLV to vaccinate children against the influenza virus. CDC considers SLV to be a viable, large-scale vaccination method for children but indicated in meetings with OIG that onsite evaluations of the administration of H1N1 vaccine at SLV sites would be useful because data about local implementation of SLV programs have been limited, especially during influenza pandemics.

School-Located Vaccination

SLV is any vaccination program that takes place on school grounds. SLV usually targets enrolled students, although vaccine may be offered to others, such as school staff and family members of students and staff. SLV can occur before, during, and/or after school hours and involves collaboration between public health departments, schools, and/or school districts.[13] SLV programs may last a month or more within a State or locality, but vaccination at individual SLV sites is typically held for 1 day only.

Several benefits are associated with conducting vaccination programs at schools. Schools provide a convenient location with large spaces, such as gymnasiums and cafeterias, to host the event. Schools also generally have well-established relationships with community members. Furthermore, school staff, including nurses, are familiar with students and their parents and can assist in contacting parents or calming nervous students.[14]

Federal Guidance for Administering H1N1 Pandemic Influenza Vaccine

Guidance from the Department of Health & Human Services (HHS) and CDC outlines elements that State and local pandemic influenza planners should consider for vaccine administration.[15, 16, 17] In a school setting, these elements include ensuring proper vaccine storage; distributing consent forms and verifying student vaccination eligibility (i.e., obtaining parental consent and verifying student medical eligibility), staffing the SLV site, communicating with parents, and billing for vaccine administration costs.

Ensuring proper vaccine storage. To receive doses of the H1N1 vaccine, providers are required to sign the Vaccine Provider Agreement, which stipulates that they will store the vaccine according to the manufacturer's Food and Drug Administration (FDA)-approved

[13] CDC, *2009 H1N1 Influenza School-Located Vaccination (SLV): Information for Planners*. Accessed at http://cdc.gov/h1n1flu/vaccination/SLV/planners.htm on May 19, 2010.
[14] Ibid.
[15] Ibid.
[16] CDC, *Questions and Answers on 2009 H1N1 Vaccine Financing*. Accessed at http://www.cdc.gov/H1N1flu/vaccination/statelocal/vaccine_financing.htm on May 19, 2010.
[17] HHS, *HHS Pandemic Influenza Plan Supplement 6 Vaccine Distribution and Use*. Accessed at http://www.hhs.gov/pandemicflu/plan/sup6.html on May 19, 2010.

package insert.[18] The 2009 H1N1 package inserts state that both the nasal mist and the injection must be stored within the 35 degree Fahrenheit (°F) to 46°F (2° Celsius (C) to 8°C) temperature range.[19] Influenza vaccines may become less effective if they are not stored in the environmental conditions specified by the manufacturer's labeling insert.

To ensure that the H1N1 vaccine is stored properly at SLV sites, CDC recommends that SLV planners place vaccine in containers, such as hard-sided or Styrofoam insulated coolers. CDC guidance also outlines appropriate packing methods for coolers, which include placing an insulated barrier between the vaccine and cold packs and ensuring that the thermometer used to monitor temperature does not touch the cold packs. Refrigerators, while not specifically recommended, may also be used but should be monitored for a week prior to vaccine storage to ensure that the appropriate temperature range can be maintained. Additionally, a thermometer must be kept in the refrigerator and no food or drinks may be stored inside. Vaccine storage temperature should be monitored and recorded every hour for coolers and twice each day for refrigerators.[20]

Distributing consent forms and verifying student vaccination eligibility. SLV staff is required to obtain parental consent prior to vaccinating students under the age of 18.[21] To assist in this effort, CDC developed consent form templates that are available online for State and local pandemic influenza planners.[22] After modifying the template for their needs, State and local planners may translate consent forms into other languages prior to distributing them to parents. Public health and partnering school officials may distribute consent forms to parents or guardians prior to the start of an SLV program (e.g., through mass mailings, sending forms home

[18] Copies of the official Vaccine Provider Agreement are not publicly available. However, a version of the Maine Vaccine Provider Agreement is available online at http://www.maine.gov/dhhs/boh/maineflu/h1n1/provider-agreement-2009-2010.shtml. Accessed on May 11, 2010. General information is provided by CDC, *2009 Influenza (H1N1) Monovalent Vaccine: Vaccine Provider Agreement Q & A.* Accessed at http://www.cdc.gov/H1N1flu/vaccination/statelocal/provider_agreement_qa.htm on May 20, 2010.

[19] FDA, *Influenza A (H1N1) 2009 Monovalent Vaccines Descriptions and Ingredients*. Accessed at http://www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm186102.htm on May 19, 2010.

[20] CDC, *Vaccine Storage and Handling Toolkit*. Accessed at http://www2a.cdc.gov/vaccines/ed/shtoolkit/ on May 19, 2010.

[21] State laws govern the specific requirements for obtaining parental consent and SLV planners must develop consent forms in accordance with these laws. CDC, *2009 H1N1 Influenza School-Located Vaccination (SLV): Information for Planners*, op. cit., p. 4.

[22] CDC, *Template 2009 H1N1 Vaccination Consent Form*. Accessed at http://cdc.gov/h1n1flu/vaccination/slv/word/h1n1-im-consent-form.doc on May 19, 2010.

with children, and/or making forms available online).[23, 24] Alternatively, if the SLV site is conducted outside normal school hours, when parents will be present to accompany their children, planners may distribute forms onsite.

Prior to vaccinating students, SLV staff should review the consent forms to verify that parents have fully completed the forms. They can also use responses that parents provide to health history questions on the consent form to determine whether students are medically eligible to receive the vaccine and to determine whether the student should receive the nasal mist or injection. CDC's consent form template includes questions to determine whether students have conditions that increase the risks associated with H1N1 vaccination, such as an egg allergy.

Staffing. Local health departments coordinate staffing for SLV sites. However, SLV sites may have staffing needs that exceed the local health departments' capacity. Because of this, CDC recommends that SLV planners (e.g., health department officials, school officials) consider recruiting additional medical and nonmedical staff, which may include hiring contractors (e.g., commercial community vaccinators).[25] Other sources of SLV staff may include school employees (e.g., teachers, principals, school nurses) and volunteers (e.g., parents or Medical Reserve Corps members). Potential roles for these staff include distributing and collecting consent forms, communicating with parents, transporting the vaccine, assisting with patient flow, and administering the vaccine.[26] SLV planners must also consider SLV staff's training needs. This may range from onsite training for volunteers to medical training for vaccinators who do not typically treat children.

Communicating with parents. CDC guidance indicates that Vaccine Information Statements (i.e., sheets produced by CDC that explain vaccination risks and benefits) should be included in the materials provided to parents before and after vaccination.[27] These Vaccine Information Statements instruct parents how to properly respond to and report adverse reactions, if they occur. According to CDC, SLV planners can also communicate with parents about where to take their children to receive the second dose of the vaccine (e.g., at another SLV site, mass vaccination clinic, or a private provider).[28] Additionally, planners are encouraged to inform

[23] Because consent forms are governed by State law, not Federal law, some jurisdictions may not be required to collect signed parental consent forms if the parent is present at the time of vaccination. As such, SLV planners may choose whether advance dissemination of consent forms is appropriate and/or necessary for their locality. For general information about guidelines for consent forms, see CDC, *2009 H1N1 Influenza School-Located Vaccination (SLV): Information for Planners, "Parental Consent Forms*." Accessed at http://cdc.gov/h1n1flu/vaccination/SLV/planners.htm on May 19, 2010.

[24] SLV planners were permitted to distribute consent forms to parents in advance of the 2009 H1N1 Vaccine Licensure. For general information about optional advanced consent prior to vaccine licensure, see CDC, *2009 H1N1 Influenza School-Located Vaccination (SLV): Information for Planners, "Optional Advanced Consent."* Accessed at http://cdc.gov/h1n1flu/vaccination/SLV/planners.htm on May 19, 2010.

[25] CDC, *2009 H1N1 Influenza School-Located Vaccination (SLV): Information for Planners*. Accessed at http://cdc.gov/h1n1flu/vaccination/SLV/planners.htm on May 19, 2010.

[26] Ibid.

[27] Ibid., *Vaccine Information Statements.*

[28] Ibid., *Potential Sources of non-Public Health Department Staff and Ideas for Recruitment.*

parents about the date their child was vaccinated and when he or she may need to receive a second dose of the vaccine (e.g., through an Influenza Vaccination Record card).[29]

Billing for vaccine administration. States and localities received the H1N1 vaccine and ancillary supplies (e.g., needles and syringes) from the Federal Government at no cost and therefore are not allowed to charge for the vaccine or ancillary supplies. However, States and localities are permitted to bill third-party payers (e.g., Medicare, Medicaid, private insurance companies) a set rate to cover certain costs associated with administering the H1N1 vaccine, such as staff salaries and liability insurance.[30, 31, 32] To be reimbursed for these costs, SLV planners could collect health insurance information from parents (e.g., on the consent form) and submit claims to the appropriate third-party payers. CDC collaborated with the Centers for Medicare & Medicaid Services and other partners to facilitate reimbursement for H1N1 vaccine administration costs; however, some private insurance companies do not reimburse for these costs.[33] Therefore, if SLV planners opt to bill third-party payers, they must identify the private insurance companies that reimburse for these services and incorporate their various billing codes into the SLV's billing system. If SLV planners choose not to bill third-party payers for H1N1 vaccine administration costs, they can use other sources of funding (e.g., PHER grants) to cover all, or portions of, these costs.

METHODOLOGY

We determined the extent to which 38 elementary SLV sites in 6 localities provided the first dose of the H1N1 vaccine to enrolled students during their 1-day clinics. We also determined through onsite interviews and observations how these sites ensured proper vaccine storage, distributed consent forms, verified student vaccination eligibility, staffed the SLV sites, communicated with parents, and billed for vaccine administration. Additionally, we asked SLV planners to identify challenges and lessons learned from their 2009 programs, and potential changes to consider for SLV programs in future influenza seasons.

Selection of Localities and SLV Sites

We selected a purposive sample of 6 localities, which included 38 urban, elementary SLV sites. To select this sample, we first identified States conducting H1N1 SLV programs and determined whether they had previously implemented SLV programs. We selected States with varying

[29] CDC, *Influenza Vaccination Record Card*. Accessed at http://www.cdc.gov/h1n1flu/vaccination/slv/pdf/h1n1vaxrecord.pdf on May 19, 2010.
[30] CDC, *H1N1 Vaccine Administration Billing Q & As*. Accessed at http://www.cdc.gov/h1n1flu/vaccination/statelocal/vaccing_billing_qa.htm on May 19, 2010.
[31] The decision to bill for vaccine administration is made by the city, county, State, or commercial community vaccinator, not by individual schools.
[32] These set rates vary by State and provider, but are approximately $20 per vaccine administration. For an example of reimbursement rates for the 2009 H1N1 Influenza vaccine administration fees, see Highmark, *2009 Reimbursement Fees: Flu, Pneumococcal and Hepatitis B Vaccines*. Accessed at https://www.highmarkmedicareservices.com/partb/reimbursement/flu-pnu-hep-09.html on June 2, 2010.
[33] CDC, *Questions and Answers on 2009 H1N1 Vaccine Financing*, op. cit., p. 2.

levels of SLV experience to capture a range of procedures and the associated challenges and lessons learned. We then identified Metropolitan Statistical Areas (i.e., localities) within these States that had a population of at least 2.5 million residents.[34] From this sample we selected six localities that had scheduled SLV clinics to provide the first dose of the H1N1 vaccine at elementary schools within our evaluation timeline (i.e., early November to mid-December 2009). We refer to these localities consistently throughout the report as Localities A, B, C, D, E, and F. See Appendix A for an alphabetical listing of the selected localities.

We then selected six to eight elementary schools per locality based on the scheduled SLV date and time. We selected elementary schools because of their large grade range (i.e., pre-Kindergarten through sixth grade) and because their age demographics were consistent with children in an age range that CDC recommended receive a second vaccine dose (i.e., 9 years of age and younger). See Appendix B for additional characteristics of the 38 selected SLV sites, by locality.

Selection of SLV Elements

Based on our review of HHS and CDC guidance and feedback from CDC staff, we selected five SLV elements to include in our evaluation: ensuring proper vaccine storage, distributing consent forms and verifying student vaccination eligibility, staffing, communicating with parents, and billing for vaccine administration.

Data Collection

To collect data for this study, we conducted onsite interviews with SLV staff and observed vaccine administration activities during the 1-day clinic at each selected school. We also administered followup surveys to SLV planners and reviewed documents collected from each SLV site and/or locality.

Data collection instruments. We developed onsite interview and observation guides based on the five selected SLV elements. We also developed a followup survey for SLV planners to collect data regarding the number of students vaccinated and feedback regarding challenges and lessons learned from their 2009 programs and potential changes to consider for SLV programs in future influenza seasons. We coordinated with CDC to develop these data collection instruments.

Interviews and observations. Between November 4 and December 15, 2009, we met with SLV planners in the six selected localities to collect relevant information about their SLV programs. We also conducted structured onsite interviews with SLV staff on the vaccination day. SLV staff included health department employees, contracted field managers, school nurses, contracted nurses, and school principals. In addition to the onsite interviews, we observed vaccine

[34] According to the U.S. Census Bureau (Census), Metropolitan Statistical Areas are geographic entities defined by the U.S. Office of Management and Budget for use by Federal statistical agencies in collecting, tabulating, and publishing Federal statistics. These areas contain a core urban area with a population of 50,000 or more. Additionally, they include the counties containing the core urban area as well as any adjacent counties that have a high degree of social and economic integration with the urban core.

administration during the 1-day clinic at each SLV site in our sample and collected data regarding the five SLV elements we selected (e.g., whether temperature monitoring devices were present, whether there was a system in place at the SLV site for verifying parental consent, the number of SLV staff serving in each staffing function).

Followup surveys. In late December 2009, we emailed a followup survey to SLV planners in each of the six selected localities. We requested information regarding student enrollment, vaccine coverage rates for the first H1N1 dose by type of vaccine (i.e., nasal mist or injection), and information about how and where the locality would offer the second vaccine dose. We also asked SLV planners to identify challenges and lessons learned from their 2009 programs, and potential changes to consider for SLV programs in future influenza seasons. Finally, we requested supporting documentation, including SLV planning documents, onsite vaccine storage and handling procedures, parental consent form packages, and information provided to parents about potential adverse reactions and the need for a second vaccine dose.

Data Analysis

To determine the extent to which and how selected SLV sites implemented the five selected SLV elements, we analyzed interview, observation, and followup survey data. We synthesized these data from these three sources to verify accuracy and to provide a more complete analysis. We present most of these data by locality because SLV programs and activities were generally similar across SLV sites in the same locality. However, where there were differences among SLV sites within a locality, we present these data by individual SLV sites.

Percentage of enrolled students vaccinated in 1 day. To determine the extent to which selected SLV sites vaccinated enrolled students during their 1-day clinics, we calculated—across all 38 SLV sites and by locality—the percentage of enrolled students that received the H1N1 vaccine on the day of the SLV clinic.[35] We also calculated, across all six corresponding States, the estimated statewide percentage of individuals 6 months to 17 years of age vaccinated.[36] Additionally, we calculated the percentage of students vaccinated with each type of vaccine, by locality. Finally, we calculated the number of selected localities that identified SLV as a useful vaccination model and reported that they would implement SLV programs in the future.

Ensuring proper vaccine storage. We calculated the number of SLV sites that used coolers, refrigerators, or a combination of these methods to store the vaccine. We also calculated the number of SLV sites that had a temperature monitoring device and the number of SLV sites that used the device to monitor and record vaccine storage temperature. Finally—by type of storage container—we calculated the number of SLV sites that monitored and recorded vaccine storage temperature according to CDC guidelines and determined how frequently the monitoring and recording occurred.

[35] Using the enrolled student population for each locality, we weighted the percentage of students vaccinated to account for varying population sizes.

[36] Using the number of children under the age of 18 residing within the State based on 2008 Census data, we weighted the percentage of children vaccinated to account for varying population sizes.

Distributing consent forms and verifying student vaccination eligibility. We calculated the average number and range of days prior to the vaccination day that consent forms were distributed, and we identified the most common distribution methods. Additionally, we calculated the number of SLV sites that distributed reminders to parents to return consent forms and identified the most common reminder methods. Finally, we calculated the number of SLV sites that verified student vaccination eligibility and identified the verification methods they used.

Staffing. We consolidated and renamed staffing functions into the following categories based on similar job responsibilities, for consistency: vaccinator, triage, registration, special needs (which includes translators), manager, clerical, postvaccine, and other (e.g., security guards). We also consolidated and renamed the sources of onsite staff: Department of Health (i.e., local health department), Department of Education, contractor, other city agency, volunteer, and school nurse. Then, we calculated the average number and range of SLV staff across all selected SLV sites. We also identified the most common staffing sources and counted the number of SLV sites that reported using contractors. Additionally, we calculated the average number, average percentage, and range of staffing functions at all selected SLV sites.

Based on our observations and interviews with onsite staff, we also identified where there were waiting lines of people (i.e., delays) at various points in the vaccination process, and we identified those delays by staffing function. We calculated the number of minutes it took for a child to proceed through the SLV site (i.e., vaccination time) and, when the vaccination time was longer than our site visit, we asked onsite staff to estimate the vaccination time for us. We categorized vaccination times as "long" if the processing time for a student was greater than 45 minutes.

Communicating with parents. We identified the most common methods to communicate with parents about potential adverse reactions associated with vaccination and the need for children 9 years of age and younger to receive a second H1N1 vaccine dose.

Billing for vaccine administration. We calculated the number of localities that billed third-party payers for vaccine administration and identified which payers they billed. We also described alternative approaches that the remaining localities used to pay for vaccine administration costs.

See Appendix C for characteristics of SLV sites as they relate to these five selected elements.

Limitations

Our results are based on a purposive sample and therefore we cannot generalize to other SLV programs.

The 1-day selected SLV clinics occurred at various stages in the localities' H1N1 vaccination programs. For example, selected SLV sites in one locality were among the first to be held in that locality, while selected SLV sites in another locality were among the last to be held in that

locality. Because SLV planners typically adjusted their programs as time progressed, SLV sites we visited later may have had more opportunities to adjust and improve the overall program prior to our visits.

The percentage of enrolled school children vaccinated at SLV sites on the day of our visit is based on self-reported data. The reported 1-day SLV rates may underestimate overall SLV first-dose vaccination coverage rates because schools may have also offered first doses at second-dose clinics.

A number of factors influence vaccination rates, and we were not able to assess the effect of all of these variables. Such factors include the SLV date (e.g., relative to the timing and impact of H1N1 illness within the community), time (e.g., during or after school), and the type of vaccine available (i.e., injection or mist). Other factors may include the timing and methods of consent form distribution, collection, and review; as well as lack of knowledge about the vaccine. Additionally, community demographics and variations in media coverage of the influenza pandemic may influence vaccination rates. For example, in one locality, SLV planners observed an increase in returned consent forms after a number of local news stations extensively covered a child's death because of H1N1.

Standards

This evaluation was conducted in accordance with the *Quality Standards for Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

RESULTS

Selected SLV Sites Vaccinated an Average of 28 Percent of Enrolled Students During Their 1-Day Clinics

Selected SLV sites vaccinated an average of 28 percent of enrolled students in 1 day. Additionally, they administered a slightly higher percentage of the H1N1 injection than nasal mist. Finally, the majority of localities reported that SLV is a useful vaccination method but said that they would not implement future SLV programs without additional resources.

We found that, by locality, selected SLV sites vaccinated an average of 28 percent of enrolled students (5,910 of 20,862) in 1 day, ranging from 14 percent to 45 percent.[37] Table 1 presents the average percentage and range of students vaccinated in 1 day at selected SLV sites by locality. The vaccination rate at selected SLV sites (28.3 percent) reflects the number of children vaccinated during a 1-day period using one method (i.e., SLV). In comparison, the average vaccination rate in the six corresponding States (37.3 percent) reflects the number of children vaccinated over a period of approximately 3 months using multiple methods (e.g., private

[37] Some of the percentages for individual SLV sites may be overestimated or underestimated if SLV planners expanded the group of people eligible to receive the vaccine (e.g., school-aged siblings) or if only a portion of the enrolled students (e.g., only certain grades) were eligible to receive the vaccine on the day of our site visit. See Appendix B for the groups eligible to receive the vaccine, by SLV site.

providers, commercial pharmacies, mass vaccination clinics, SLV) and for a wider age range.[38] The national median vaccination coverage rate for children aged 6 months to 18 years in the same 3-month period—nearly 37 percent—is similar to the average in these six States.[39]

Table 1: Average Percentage and Range of Students Vaccinated at Selected SLV Sites in 1 Day, by Locality

Locality	Average Percentage of Students Vaccinated at Selected SLV Sites	Range of Percentage of Students Vaccinated at Selected SLV Sites
A	44.7%	28.0%–67.4%
B	29.6%	20.9%–37.6%
C	28.1%	16.9%–41.0%
D	22.6%	4.3%–37.9%
E	17.5%	7.1%–25.1%
F	14.4%	9.0%–33.2%
Weighted Average	**28.3%**	**N/A**

Source: OIG analysis of H1N1 SLV data, 2010.

Of the reported total number of students vaccinated at selected SLV sites, approximately 42 percent received the nasal mist and 59 percent received the injection. Table 2 shows the percentage of students vaccinated with each type of vaccine. Four localities offered both the nasal mist and injection to all students. Of these localities, three administered the nasal mist as the primary vaccine, provided that the student was eligible (e.g., had no underlying medical conditions, such as asthma), while the fourth locality gave parents the opportunity to choose which type of vaccine their child received. The remaining two localities chose to offer only the injection to certain elementary school grades because of high rates of these underlying conditions. Finally, three of the six localities reported a difference in demand between the injection and nasal mist because of parental and staff misconceptions about the safety of the nasal mist. For example, there were incorrect messages circulating in the media that the H1N1 nasal mist could make recipients sick with influenza because it is a "live, attenuated vaccine."[40] Localities reported that, as a result, some parents did not allow their children to receive the nasal mist.

[38] Estimate is based on data from CDC, *Interim Results: State-Specific Influenza A (H1N1) 2009 Monovalent Vaccination Coverage—United States, October 2009–January 2010*. Accessed at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5912a2.htm?s_cid=mm5912a2_e on May 20, 2010.

[39] Ibid.

[40] Live, attenuated vaccines contain a weakened version of the influenza virus that is activated but will not cause illness. CDC, *2009 H1N1 Live, Attenuated Influenza Vaccine Information Sheet*. Accessed at http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-laiv-h1n1.pdf on May 19, 2010.

Table 2: Percentage of Vaccinated Students That Received Nasal Mist or Injection on Day of Site Visit, by Locality

Locality	Percentage of Students Vaccinated With Nasal Mist*	Percentage of Students Vaccinated With Injection*
E	73.8%	26.2%
F	61.4%	38.6%
B	58.8%	41.2%
D	33.5%	66.5%
C	28.7%	71.3%
A	26.9%	73.1%
Weighted Average	**41.5%**	**58.5%**

* Differences in quantities and availabilities of each type of vaccine, along with parental preference, may have affected these percentages.

Source: OIG analysis of H1N1 SLV data, 2010.

The majority of selected localities reported that SLV is a useful method to vaccinate a large number of children in a short period of time, but some said they will need additional resources to implement future SLV programs. Three of the six selected localities reported that they are likely to offer SLV in the future. Another two localities reported that they would consider offering SLV programs in the future only if they received Federal funding. These localities reported that SLV programs are very resource intensive and require dedicated full-time staff, sufficient funding to cover both vaccine and administrative costs, and ample planning time. One of these localities reported that it might choose to vaccinate school-aged children using a more traditional vaccination model that requires fewer resources, such as a community-wide, large-scale vaccination clinic. Finally, the remaining locality reported that it might offer SLV in the future, but only in a pandemic influenza scenario.

The Majority of Selected SLV Sites Used Recommended Vaccine Storage Containers but Did Not Monitor or Record Vaccine Storage Temperature

CDC recommends that SLV sites use hard-sided or Styrofoam coolers with cold packs to maintain vaccine storage temperature. Refrigerators, while not specifically recommended, may also be used to store vaccine if they can reliably maintain the required temperature range and have met other requirements described in CDC's vaccine storage guidance.[41] Twenty-nine of the thirty-eight SLV sites used coolers to store the vaccine. Three SLV sites used a combination of coolers and refrigerators, and all six SLV sites in one locality relied only on refrigerators. SLV planners in this locality reported experiencing some problems with faulty refrigerators that did not maintain the required temperature range. This caused some SLV sites to be rescheduled and compromised small amounts of the vaccine. Another locality considered using refrigerators at its SLV sites but opted against this because of concerns about cost and immobility.

[41] CDC, *Vaccine Storage and Handling Toolkit*, loc. cit.

The required temperature storage range for both types of the H1N1 vaccine is between 35 and 46°F (2–8°C).[42] CDC's vaccine storage guidelines state that vaccine may become less effective if not stored in the temperature range required by its labeling.[43] If SLV staff is not monitoring the vaccine storage temperature, they cannot ensure that the vaccine is stored properly and will be effective when administered. Approximately half of SLV sites (20 of 38) had temperature monitoring devices in the cooler or refrigerator with the vaccine. Of these sites, the majority (16 of 20) used thermometers. The remaining four sites used a color-coded temperature indicator that would change color if the temperature went outside of the required range.

CDC also recommends that vaccine storage temperature be recorded, but only 12 SLV sites did so. Of the nine SLV sites that stored vaccine in coolers and recorded vaccine storage temperature, six did so hourly (i.e., consistent with the interval recommended by CDC), while the remaining three recorded the temperature every 2 hours. The three SLV sites that used refrigerators to store vaccines recorded temperature twice daily as recommended by CDC.

Finally, we observed some vaccine storage procedures that were inconsistent with CDC's vaccine storage and handling guidelines, which specify how coolers should be packed, monitored, and used.[44] For example, we observed some SLV site staff leaving coolers open for extended time periods without monitoring temperature. We also observed tightly packed coolers that were missing spacers between the vaccine and cold packs, which could have caused the vaccine to become too cold. Additionally, we observed food items stored beside the vaccine and thermometers placed directly on top of or next to cold packs within the coolers, which can cause inaccurate temperature readings.

All Selected Localities Used Parental Consent Forms To Verify Student Vaccination Eligibility, Although Most Reported That They Would Revise Their Procedures for Future Programs

All selected SLV sites verified student vaccination eligibility prior to administering the H1N1 vaccine and used various consent form distribution and eligibility verification procedures. SLV planners also reported a number of changes they would make to their consent form development, distribution, and review processes for future SLV programs.

<u>All SLV sites distributed, collected, and verified parental consent forms prior to vaccinating students</u>.

Consent Form Distribution, Collection, and Parent Reminders: The majority of SLV sites (32 of 38) made consent forms available to parents prior to the day of vaccination. These SLV sites made consent forms available an average of 29 days in advance (ranging from 7 to 61 days). In some cases, SLV sites reported that distributing consent forms before the day of vaccination

[42] FDA, *Influenza A (H1N1) 2009 Monovalent Vaccines Descriptions and Ingredients*, loc. cit.
[43] CDC, *Vaccine Storage and Handling Toolkit*, loc. cit.
[44] Ibid.

presented vaccination challenges. For example, some students were vaccinated elsewhere (e.g., by a private provider) between the time the consent form was returned and the day of vaccination. Therefore, SLV staff had to determine whether the information parents provided on the consent form regarding immunization status was current. This typically was accomplished by calling the parents, which localities reported was time and labor intensive.

Of the SLV sites that made consent forms available to parents prior to the day of vaccination (32 of 38), 5 used multiple methods to do so. The most common methods for making consent forms available in advance included sending them home with students (14 of 32) and making them available online (10 of 32). However, 3 of the 10 SLV sites that posted forms online also had forms available at the site because some parents did not have access to a computer and could not provide consent in advance through the online system.

The majority of SLV sites (27 of 32) that distributed parental consent forms in advance also sent reminders to parents to return the consent forms. Approximately one-third (11 of 32) of SLV sites used more than 1 reminder method. These methods included mailing reminders home to parents and making personal or automated phone calls (10 of 32 SLV sites for each method). Finally, more than two-thirds (23 of 32) of SLV sites that distributed consent forms in advance collected completed forms by having students return them to their teachers or school nurses.

The remaining six SLV sites distributed consent forms to parents on the day of vaccination. All of these sites were held after school. Distributing consent forms on the day of vaccination allowed parents to ask questions while completing the form. However, at most SLV sites that distributed consent forms on the day of vaccination, we observed long lines at registration. This appeared to be because of the amount of time it took for a parent to complete the consent form and ask questions.

Consent Form Verification: Most of the selected SLV sites were held during school hours and did not require parents to be present. More than half of the SLV sites that distributed consent forms in advance (20 of 32) had nurses review the form upon receipt to identify any missing information. Additionally, all SLV sites conducted onsite reviews of the consent forms, which typically took place at registration and again immediately prior to vaccination. As a result of these review processes, several SLV sites also needed to call parents on the day of vaccination to complete or verify the information on the parental consent form. School nurses generally made these phone calls, which facilitated the process because they often knew the child and/or parent. However, planners reported that the additional step of calling parents required a substantial amount of time and is something they would try to avoid in future programs by standardizing the review process and training staff to use this process. The SLV sites that distributed consent forms on the day of vaccination were able to ensure completeness of consent forms more easily because the registration staff could verify the necessary fields while the parents were present.

All 28 SLV sites held during school hours had procedures to match students to their consent forms, since the parents were typically not present. Approximately one-half of these SLV sites

(15 of 28) created a roster or list of students to identify those with parental consent. These SLV sites generally provided the roster to teachers or volunteers, who used it to determine which children to bring to the vaccination area. Other methods included relying on school staff to manually match children to their signed consent forms (8 of 28) and using both a roster and nametags (5 of 28) to identify those children with parental consent.

All 38 SLV sites had procedures to identify children who had medical conditions that increased the risk of adverse reactions associated with H1N1 vaccination or a particular type of vaccine. For example, all of the consent forms included questions related to egg allergies and asthma. Across SLV sites, the vaccinators verified whether students had risk factors related to the vaccine and in some cases asked children additional questions (e.g., "Do you eat eggs for breakfast?" and "Do you use an inhaler?") to ensure that they received the appropriate type of vaccine.

SLV sites in all but one locality would change some aspects of their consent form development, distribution, and review processes for future SLV programs. SLV planners reported multiple consent form distribution methods and a high degree of collaboration between the Department of Health and the Department of Education to develop, print, and distribute program materials as overall program strengths. They also relied on schools' past experiences communicating with parents. However, SLV planners specified a number of overall program challenges, including:

- involving multiple agencies and/or individuals in the distribution, collection, and review of the consent forms;
- formatting the consent forms to accommodate parents' varying reading levels;
- translating the consent forms; and
- not adhering to the consent form return deadline.

For future SLV programs, planners reported that they would simplify consent form packets by making the forms shorter and at a lower reading level and include only those materials that are medically and legally necessary. Planners would also make the consent form more versatile by including a field to record the second vaccine dose or creating an annual vaccination form that included influenza. Finally, planners would provide SLV staff with standardized training for collecting and reviewing consent forms.

All Selected Localities Used Similar Staffing Functions and Sources; However, Each Encountered Challenges Securing Sufficient SLV Staff and Distributing Them Effectively Across Functions

SLV planners in all six localities indicated that having sufficient staff was integral to the success of their H1N1 SLV programs. All selected SLV sites hired contractors to supplement staff from other sources. The three most commonly staffed functions at SLV sites were vaccinators, triage, and registration. Those sites that reported not having enough staff most often needed more registration staff, translators, and vaccinators. Table 3 presents the average number, average percentage, range, and a description of staffing functions at selected SLV sites. SLV planners

reported that they would make staffing changes for future SLV programs, including changing the distribution of staff across functions, improving staff communication, and providing additional training for SLV staff.

Table 3: Staffing Functions at the 38 Selected SLV Sites

Staff Function	Average		Range	Description of Staff Duties
	Number*	Percentage*		
Vaccinator	4	31%	1–8	Vaccinate patients
Triage	3	23%	0–14	Facilitate patient flow
Registration	2	15%	0–5	Review consent forms and confirm patient identity
Special Needs	1	8%	0–10	Provide services to patients with special needs, such as translation or learning disabilities
Manager	1	8%	0–5	Control the operation of the SLV site
Clerical	0	0%	0–4	Provide clerical services at the SLV site, such as data entry
Postvaccine	0	0%	0–2	Monitor patients for potential adverse reactions after vaccination
Other	1	8%	0–18	Provide services that did not fall into any other category, such as security guards and quality assurance reviewers
All Staff	13		4–33	

* Sums of columns do not equal totals because of rounding.

Source: OIG analysis of H1N1 SLV data, 2010.

All localities used contractors at SLV sites to supplement staff from other sources and reported challenges obtaining sufficient staff. SLV sites used an average of 13 staff, ranging from 4 to 33. All SLV sites used contractors in addition to staff from other sources, such as the local Department of Health, Department of Education, other city agencies, and/or volunteers. Contractors made up the largest source of staff at most SLV sites (27 of 38), averaging 50 percent of staff across selected sites. The local Department of Health contributed the second largest average number of staff at SLV sites.

SLV planners reported challenges obtaining a sufficient number of SLV staff. As a result, some SLV sites (7 of 38) encountered long vaccination times. Additionally, several localities reported problems with staff turnover or staff not showing up at the SLV sites; this resulted in a loss of experienced and trained staff, delays, and challenges with managing and redistributing staff. Additionally, two localities reported that the success of their SLV programs was dependent on school staff. However, schools in these two localities were not able to provide a sufficient number of staff because of budget constraints and lack of communication between SLV planners and school administrators.

Localities experienced challenges distributing SLV staff across necessary staffing functions. SLV staff performed a variety of functions, and localities differed in how they distributed staff among these functions. Across all SLV sites, there was an average of four vaccinators, ranging from one to eight. The next most frequently staffed function was triage. SLV sites had an average of 3 staff performing triage functions, ranging from 0 to 14. The third most frequently staffed function at SLV sites was registration. SLV sites had an average of two registrars, ranging from zero to five. Two localities reported that it was helpful to use nurses at registration to prescreen children and review consent forms for completeness and accuracy because of their specialized training and knowledge of medical terminology and potential adverse reactions.

SLV planners cited challenges related to staff composition, such as not having an effective distribution of staff members across functions. Some of the SLV sites (8 of 38) appeared to have sufficient staff but distributed them in such a way that delays occurred, usually at registration. We observed that all of the observed delays were because of a lack of registrars to review consent forms, translators to facilitate communication, or triage staff to help ensure clinic flow. Additionally, two localities reported that having an insufficient number of trained staff to review consent forms slowed the vaccination process. Delays at registration were especially apparent at after-school SLV clinics, where parents and siblings posed additional challenges with communication and crowd control. Appendix D includes the average percentage of staff in each SLV function, and the number of SLV sites that encountered long vaccination times and delays, by locality.

The majority of localities reported that they would make changes to their staffing procedures in future SLV programs. For SLV programs in future influenza seasons, SLV planners reported that they would streamline communication among planners, school staff, and onsite staff. SLV planners in several localities reported challenges communicating, which resulted in misinformation and duplication of efforts. To remedy this, SLV planners said that they would clarify the roles of health department staff, school staff, and SLV site staff early in the process to ensure that all staff members knew with whom to communicate.

SLV planners also recognized the need to provide more extensive guidance and training for SLV staff. SLV planners reported that they would provide additional guidance to school staff to help them better prepare for and operate the vaccination clinic. Additionally, they would provide more advanced training to nurses and clerical staff about the SLV process, vaccine storage and handling protocols, and how to more effectively review consent forms.

Finally, SLV planners in one selected locality reported that allocating staff to the SLV program resulted in the interruption of regular school health services. In future programs, they plan to implement “continuity of operations plans to cover day-to-day school health operations” to more effectively allocate available staff for both activities.

Selected SLV Sites Experienced Challenges Communicating a Clear and Consistent Message to Parents, Regardless of the Communication Method Used

SLV sites informed parents about potential vaccine adverse reactions and the need for a second H1N1 vaccine dose in a number of ways. The majority sent information packets to parents by mail or home with students. However, most SLV planners reported that distributing this information was challenging, primarily because of a lack of clear guidance and procedures for communicating with parents. For future SLV programs, planners reported that they would make a number of changes, including providing additional training for those responsible for communication.

SLV sites used similar methods for communicating with parents about potential adverse reactions and the need for a second vaccine dose. The most common method (23 of 38) of educating parents about potential vaccination adverse reactions was by sending information by mail or home with students. SLV sites also educated parents onsite (15 of 38) and through informational forums, television advertisements, and Web sites (11 of 38). Similarly, the most common method (16 of 38) used to educate parents about the need for children 9 years of age and younger to receive a second dose was by sending information to parents (e.g., on a vaccination card or information sheet), either by mail or home with students. Another method SLV sites reported using was making automated calls to parents (5 of 38).

More than one-third of SLV sites (15 of 38) had not decided if and when they would offer the second dose. At these sites, no communication with parents about the provision of a second dose clinic occurred at the time of our site visit, and the only communication about the need for a second dose was a reference within the Vaccine Information Statements. However, by the time of our followup survey 2–6 weeks later, all six localities planned to conduct followup clinics to provide the second dose of the H1N1 vaccine to children 9 years of age and younger. Five localities planned to conduct followup clinics at the same school where they administered the first dose. The remaining locality planned to administer the second dose at mass vaccination clinics open to the entire community.

SLV planners reported challenges conveying a clear and consistent message about vaccine safety and effectiveness and the need for a second vaccine dose. SLV planners reported that two significant communication challenges were not having (1) a procedure in place to share clear and consistent messages and (2) sufficient training for SLV staff. Our observations supported these reported challenges. For example, we observed an SLV staff member telling a school staff member that the nasal mist was a weaker type of the vaccine and she would need to receive multiple doses for it to be effective.

One challenge specific to communicating with parents about the need for a second dose was a lack of quality control processes to ensure that children received the appropriate number of vaccine doses at the recommended time interval. For example, SLV planners in three localities reported that there was no centralized information-sharing system for private and public providers to be informed of a child's vaccination status if the parent did not share that

information.[45] A second related challenge reported by SLV planners was misinformation in the media, which made communicating a clear message to parents more difficult. For instance, SLV planners reported seeing or hearing inaccurate time intervals between the first and second doses, as well as the overall need for children 9 years of age and younger to receive a second dose.

To improve overall communication and encourage more parents to vaccinate their children, SLV planners suggested:

- developing a centralized information-sharing system or utilizing existing systems;
- establishing timelines for communication (e.g., when to distribute consent forms to parents, when to send reminders);
- distributing information earlier (e.g., beginning of school year, up to 1 month prior to the vaccination clinic date);
- providing more training to individuals responsible for communication; and
- notifying participating schools when vaccinators will be onsite, what resources will be requested, and what responsibilities school staff members will have (e.g., contacting parents, collecting consent forms, setting up vaccination areas).

The Majority of Selected Localities Did Not Bill Third-Party Payers for H1N1 Vaccine Administration

Four of six localities had not established a billing system to bill for H1N1 vaccine administration and instead used Public Health Emergency Response grant funding to cover vaccine administration costs. One of these four localities gathered health insurance information but had not decided whether it would bill third-party payers at the time of our visit. Another of these localities paid its contractor a lump sum for vaccine administration costs instead of an amount based on the actual cost of vaccinating the number of students that received the vaccine. SLV planners in this locality calculated this sum by assuming that 50 percent of the student body would be vaccinated and multiplying that number by a negotiated reduced fee.[46]

The remaining two localities billed third-party payers for H1N1 vaccine administration. However, while Medicare and Medicaid reimbursed vaccination administration costs, some private insurance companies did not. One locality collected the vaccination fee from parents (i.e., $15 in the locality) when a child's insurance did not cover the vaccine administration cost.[47] The other locality reimbursed its contractor for the vaccine administration costs incurred by uninsured children and those children whose insurance did not cover the administration cost.

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[45] Immunization registries can be used to share information regarding a child's immunization status. However, we did not assess whether data from the selected SLV sites were entered into immunization registries.

[46] SLV planners reported that the negotiated per person fee ($10) is approximately half of the Medicare vaccine administration fee in that region.

[47] CDC guidance states that public health clinics and mass vaccination sites conducted on behalf of a public health entity should not charge out-of-pocket expenses to patients. CDC, *H1N1 Vaccine Administration Billing Q & As*, Response to Question 2," op. cit.

Both localities that billed for vaccine administration used contracted companies that specialized in providing vaccination services to the community (i.e., commercial community vaccinators) with established billing systems. However, these commercial community vaccinators reported that it was challenging to get insurance companies to reimburse for vaccine administration costs. For example, commercial community vaccinators found it time consuming to identify insurance companies who would reimburse for vaccine administration fees and to adapt their billing system to accommodate each third-party payer's billing codes and reimbursement rates. Additionally, SLV planners commented that it was difficult for SLV staff to fill out all of the necessary billing paperwork onsite.

CONCLUSION

We found that, by locality, selected SLV sites vaccinated an average of 28 percent of enrolled students during their 1-day programs, ranging from 14 percent to 45 percent. This compares favorably to relevant State and national vaccination rates obtained over a longer period of time and through a variety of methods. For example, the average vaccination rate in the six corresponding States was 37 percent. However, this statewide percentage reflects the number of children vaccinated over a period of approximately 3 months using multiple methods (e.g., private providers, commercial pharmacies, mass vaccination clinics, SLV) and for a wider age range. The majority of selected localities reported SLV to be a useful method to vaccinate a large number of children in a short period of time, but they also reported that they would need additional resources to implement future SLV programs.

We also found a number of challenges associated with implementing SLV programs. For example, we observed that the majority of selected SLV sites used recommended vaccine storage containers but did not monitor and record vaccine storage temperature. All selected localities reported challenges securing sufficient SLV staff and distributing them effectively across staffing functions. Additionally, selected SLV sites reported experiencing challenges communicating a clear and consistent message to parents about potential vaccination adverse reactions and the need for a second vaccine dose. Finally, the majority of selected localities had not established a billing system to bill third-party payers for the cost of H1N1 vaccine administration.

The selected localities reported a number of things they would do differently in future SLV programs. These include simplifying the consent form and educational materials; standardizing the consent form review process; devoting more staff to registration, triage, and translation; streamlining staff communication and training; developing a centralized information-sharing system; and distributing information to parents and participating schools earlier.

Our data indicate that SLV can be a viable strategy for vaccinating a large number of students in a short period of time. However, SLV programs require a significant amount of planning and resources. To help mitigate challenges in future SLV programs, SLV planners will need specific, timely guidance for each of the SLV elements we reviewed and sufficient lead time to

address them. See Appendix E for a list of SLV planning considerations that CDC may take into account when determining useful SLV practices and assisting States and localities that are interested in conducting SLV programs.

This report is being issued directly in final form because it contains no recommendations. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-04-10-00020 in all correspondence.

Appendix A

Selected Localities*
Locality (State)
Alexandria (VA) and Arlington (VA)
Baltimore (MD)
Minneapolis (MN)
New York City (NY)
Phoenix (AZ)
St. Louis (MO)

* Selected localities are listed in alphabetical order and do not appear in this order throughout the rest of the report.
Source: Office of Inspector General analysis of H1N1 School-Located Vaccination data, 2010.

Appendix B

Characteristics of Selected School-Located Vaccination Sites

Locality	School-Located Vaccination (SLV) Site	SLV Date	Number of Students Enrolled at SLV Site	Number of First H1N1 Vaccine Doses Administered at SLV Site	Type of Vaccine Available	Groups Eligible To Receive Vaccine in Addition to Enrolled Students	SLV Site Timing (i.e., held during or after school)
A	School 1	11/4/09	688	369	Inj & Mist	Staff	After
	School 2	11/4/09	534	187	Inj & Mist	Nonenrolled students; Staff	After
	School 3	11/5/09	490	269	Inj & Mist	Staff	During
	School 4	11/5/09	900	314	Inj & Mist	Staff	During
	School 5	11/5/09	950	266	Injection	Staff	During
	School 6	11/5/09	694	374	Inj & Mist	Nonenrolled students; Staff	During
	School 7	11/5/09	572	222	Inj & Mist	Staff	After
	School 8	11/5/09	687	463	Inj & Mist	Staff	After
	Locality A		**5,515**	**2,464**			
B	School 1	11/23/09	494	167	Inj & Mist	N/A	During
	School 2	11/23/09	607	228	Inj & Mist	N/A	During
	School 3	11/24/09	794	166	Inj & Mist	N/A	During
	School 4	11/24/09	624	194	Inj & Mist	N/A	During
	School 5	11/24/09	351	111	Inj & Mist	N/A	During
	School 6	11/24/09	560	150	Inj & Mist	N/A	During
	Locality B		**3,430**	**1,016**			
C	School 1	11/12/09	410	111	Inj & Mist	N/A	During
	School 2	11/12/09	580	98	Inj & Mist	N/A	During
	School 3	11/13/09	485	89	Inj & Mist	N/A	During
	School 4	11/12/09	421	128	Injection	N/A	During
	School 5	11/12/09	681	279	Injection	Staff (pregnant)	During
	School 6	11/13/09	390	130	Injection	N/A	During
	Locality C		**2,967**	**835**			
D	School 1	12/14/09	192	20	Inj & Mist	N/A	During
	School 2	12/14/09	284	49	Inj & Mist	N/A	During
	School 3	12/14/09	360	123	Inj & Mist	N/A	During
	School 4	12/15/09	483	21	Inj & Mist	Staff	During
	School 5	12/15/09	285	88	Inj & Mist	N/A	During
	School 6	12/15/09	404	153	Injection	N/A	During
	Locality D		**2,008**	**454**			
E	School 1	11/20/09	555	96	Inj & Mist	Siblings; Nonenrolled students	After
	School 2	11/19/09	651	46	Inj & Mist	Siblings	After
	School 3	11/19/09	616	70	Inj & Mist	Siblings	After
	School 4	11/19/09	610	96	Inj & Mist	Siblings	After
	School 5	11/19/09	903	227	Inj & Mist	Siblings	After
	School 6	11/20/09	1,245	267	Inj & Mist	Siblings; Nonenrolled students	After
	Locality E		**4,580**	**802**			
F	School 1	12/03/09	268	24	Inj & Mist	N/A	During
	School 2	12/03/09	821	81	Inj & Mist	N/A	During
	School 3	12/03/09	372	52	Inj & Mist	N/A	During
	School 4	12/04/09	357	49	Inj & Mist	N/A	During
	School 5	12/04/09	294	50	Inj & Mist	N/A	During
	School 6	12/04/09	250	83	Inj & Mist	N/A	During
	Locality F		**2,362**	**339**			

Source: Office of Inspector General analysis of H1N1 SLV data, 2010.

Appendix C

School-Located Vaccination Site Characteristics Based on Interview and Observation Data

		Vaccine Storage		Staffing	Consent Form Distribution & Verification of Eligibility		Communicating With Parents			Third-Party Billing
Locality	**School-Located Vaccination (SLV) Site**	**Type of Vaccine Storage at SLV Site**	**Vaccine Storage Temperature Monitored & Recorded**	**Number of Staff at SLV Site**	**Method of Distributing Consent Forms**	**Days Between Consent Form Distribution & Vaccination**	**Method of Distributing Vaccine Information Statements**	**Method of Informing About Second Dose**	**Will Locality Offer Second Dose at Same SLV Sites?**	**How Did Locality Cover Vaccine Administration Costs?**
A	School 1	Cooler	No	12	Online; onsite	Unknown by respondent	Online; onsite; other	Online; vaccination card		
	School 2	Cooler	No	8	Online	9	Email; phone; other	Undecided		
	School 3	Cooler	No	7	Online	Unknown by respondent	Email; onsite; other	Undecided		
	School 4	Cooler	No	13	Online	11	Other; answer questions	Online; vaccination card		
	School 5	Cooler	No	10	Online	8	Other	Undecided		
	School 6	Cooler	No	8	Online	Unknown by respondent	Online; onsite	Onsite		
	School 7	Cooler	No	8	Online; onsite	14	Email; answer questions	Undecided		
	School 8	Cooler	No	16	Online; onsite	7	Unknown	Unknown by respondent		
	Locality A			**10 (avg.)**		**10 days (avg.)**			**Yes**	**Bill third-party payers**
B	School 1	Fridge	Yes	9	Unknown by respondent	35	Consent form	Vaccination card		
	School 2	Fridge	No	14	Mail	29	Consent form	Vaccination card		
	School 3	Fridge	Yes	8	Unknown by respondent	28	Consent form	Undecided		
	School 4	Fridge	Yes	11	Unknown by respondent	31	Consent form	Undecided		
	School 5	Fridge	No	15	Child	27	Email; answer questions	Email		
	School 6	Fridge	No	15	Child	61	Consent form	Phone; vaccination card		
	Locality B			**12 (avg.)**		**35 days (avg.)**			**Yes**	**Undecided at the time of our visit**

Continued on next page

Appendix C

School-Located Vaccination Site Characteristics Based on Interview and Observation Data (Continued)

		Vaccine Storage		Staffing	Consent Form Distribution & Verification of Eligibility		Communicating With Parents			Third-Party Billing
Locality	**SLV Site**	**Type of Vaccine Storage at SLV Site**	**Vaccine Storage Temperature Monitored & Recorded**	**Number of Staff at SLV Site**	**Method of Distributing Consent Forms**	**Days Between Consent Form Distribution & Vaccination**	**Method of Distributing Vaccine Information Statements**	**Method of Informing About Second Dose**	**Will Locality Offer Second Dose at Same SLV Sites?**	**How Did Locality Cover Vaccine Administration Costs?**
C	School 1	Cooler & fridge	No	17	Mail	27	Consent form; other; answer questions	Vaccination card		
	School 2	Cooler & fridge	No	15	Online; mail	24	Consent form; onsite; other	Vaccination card		
	School 3	Cooler & fridge	No	16	Mail; online	23	Consent form; phone	Vaccination card		
	School 4	Cooler	Yes	9	Child	28	Consent form	N/A: vaccinated only children >9 years old		
	School 5	Cooler	Yes	13	Child	18	Other; answer questions	Undecided		
	School 6	Cooler	Yes	10	Child	29	Consent form; other; answer questions	Vaccination card		
	Locality C			**13 (avg.)**		**25 days (avg.)**			**Yes**	**Public Health Emergency Response (PHER) funding**
D	School 1	Cooler	No	5	Child	30	Consent form	Vaccination card; Undecided		
	School 2	Cooler	No	5	Child	34	Consent form; onsite	Undecided		
	School 3	Cooler	No	6	Child	28	Consent form; onsite	Undecided		
	School 4	Cooler	No	7	Child	8	Consent form; onsite	Undecided		
	School 5	Cooler	No	4	Child	30	Consent form; onsite	Undecided		
	School 6	Cooler	Yes	6	Child	30	Consent form	Undecided		
	Locality D			**6 (avg.)**		**27 days (avg.)**			**Yes**	**Lump sum to contractors; PHER funding**

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Appendix C

School-Located Vaccination Site Characteristics Based on Interview and Observation Data (Continued)

		Vaccine Storage		Staffing	Consent Form Distribution & Verification of Eligibility		Communicating With Parents			Third-Party Billing
Locality	**SLV Site**	**Type of Vaccine Storage at SLV Site**	**Vaccine Storage Temperature Monitored & Recorded**	**Number of Staff at SLV Site**	**Method of Distributing Consent Forms**	**Days Between Consent Form Distribution & Vaccination**	**Method of Distributing Vaccine Information Statements**	**Method of Informing About Second Dose**	**Will Locality Offer Second Dose at Same SLV Sites?**	**How Did Locality Cover Vaccine Administration Costs?**
E	School 1	Cooler	Yes	33	Onsite	0	Onsite	Undecided		
	School 2	Cooler	Yes	31	Onsite	0	Onsite	Phone; vaccination card		
	School 3	Cooler	Yes	33	Onsite	0	Onsite	Phone; vaccination card		
	School 4	Cooler	No	30	Onsite	0	Onsite	Phone		
	School 5	Cooler	Yes	30	Onsite	0	Onsite	Undecided		
	School 6	Cooler	Yes	30	Onsite	0	Onsite	Phone; vaccination card		
	Locality E			**31 (avg.)**		**0 days**			**Yes**	**Bill third-party payers**
F	School 1	Cooler	No	7	Child	39	Consent form	Vaccination card		
	School 2	Cooler	No	8	Child	49	Consent form	Vaccination card		
	School 3	Cooler	No	6	Other	49	Consent form	Vaccination card		
	School 4	Cooler	No	7	Unknown by respondent	50	Consent form	Vaccination card		
	School 5	Cooler	No	6	Child	50	Consent form	Vaccination card		
	School 6	Cooler	No	5	Unknown by respondent	29	Consent form	Vaccination card		
	Locality F			**7 (avg.)**		**44 days (avg.)**			**No**	**PHER funding**

Source: Office of Inspector General analysis of H1N1 SLV data, 2010.

Appendix D

Staff and Staffing Functions at Selected School-Located Vaccination Sites, Long Vaccination Times, and Delays, by Locality

Locality	Average Number of Staff at Each Selected School-Located Vaccination (SLV) Site	Average Percentage of Staff in Each School-Located Vaccination Staffing Function*								SLV Site Timing (i.e., held during or after school)	Number of Selected SLV Sites That Encountered Long Vaccination Times	Number of Selected SLV Sites That Encountered Delays
		Vaccinator	Triage	Registration	Special Needs	Manager	Clerical	Post-vaccine	Other			
A	10	54%	9%	26%	6%	6%	0%	0%	0%	During & After	3	3**
B	12	39%	31%	19%	0%	7%	0%	3%	0%	During	1	0
C	13	36%	30%	14%	0%	6%	5%	3%	6%	During	0	0
D	6	36%	33%	15%	0%	12%	3%	0%	0%	During	0	2**
E	31	15%	25%	11%	18%	8%	0%	2%	20%	After	2	3**
Total Average	**13**	**31%**	**23%**	**17%**	**8%**	**8%**	**3%**	**2%**	**9%**			

* Sums of percentages do not equal 100 percent because of rounding.

** Delays occurred at registration and were because of insufficient staffing in various roles related to processing consent forms and registration, as well as communication with parents, including providing translation services.

Source: Office of Inspector General analysis of H1N1 SLV data, 2010.

Appendix E

School-Located Vaccination Planning Considerations

The following planning considerations are based on observations, interviews, and surveys conducted at 38 selected School-Located Vaccination (SLV) sites in 6 localities during the 2009 H1N1 influenza pandemic. The Centers for Disease Control and Prevention may consider this document when determining useful SLV practices and assisting States and localities that are interested in conducting SLV programs. Items are listed in semichronological order and cover topics that are important to consider when planning and implementing SLV programs.

1. **Identify school districts/individual schools that are interested in participating in the SLV program and involve parents and school staff early in the planning process**. Once schools are identified, hold meetings with principals, teachers, school nurses, Parent Teacher Association members, providers, and other relevant stakeholders. For example, health department staff can give an overview of the SLV method and identify the respective responsibilities of the health department and schools during the program. These responsibilities may include:

    a. *Health Department*
        i. Provide a diagram of the clinic, including setup and patient flow
        ii. Provide vaccine and related supplies
        iii. Identify and provide staff (e.g., managers, vaccinators)
        iv. Develop the consent form and educational materials

    b. *Schools*
        i. Provide dedicated space for the SLV clinic and set up the space according to diagram provided by health department.
        ii. Identify and provide staff and/or parent volunteers (e.g., triage, translators).
        iii. Develop a plan for communicating with parents (e.g., informing them of the SLV program, distributing consent forms and educational materials provided by the health department).

2. **Consider that staffing needs are affected by SLV timing**. We observed that SLV sites held during school hours tended to have lower attendance, possibly because of the fact that parents could not accompany students. However, we also observed that these sites were generally more organized because SLV staff could control the number of people in the vaccination area at any one time (e.g., by bringing one class in at a time). Alternatively, SLV sites held after school tended to have higher attendance because parents and siblings could accompany the enrolled student and, at some SLV sites, receive the H1N1 vaccine. However, we also observed that these sites were often overcrowded and poorly organized, which resulted in longer wait times.

3. **Provide online and paper versions of the consent form**. Online systems for completing consent forms can be convenient and efficient (e.g., because the system checks the consent form for completeness and eligibility before allowing parents to submit it). However, not all parents have access to a computer to complete the consent form online. Therefore, it may be beneficial to give parents the option to complete the online consent form at home and/or during a scheduled time in the school's computer lab. Paper consent forms can also be provided to parents who would prefer this format over the online method. These paper forms should be reviewed in advance for completeness, preferably by one person within the health department or the school nurse to ensure consistency.

   To determine which method parents will use to complete the consent forms (e.g., online or hard copy), schools can communicate with parents to:

   (1) notify parents of the scheduled SLV clinic;
   (2) ask parents if they would like to complete the form online at home, online at the school, or use the paper format; and
   (3) provide parents the option to decline vaccination and explain why. Understanding why parents do not want their children vaccinated may allow SLV staff to dispel misinformation and improve future programs.

4. **Conduct a walk through of the SLV site prior to the event.** This will give health department and school staff a chance to review the logistics for the event and address any concerns prior to the vaccination day. Health department and school officials may also want to schedule this time for parents to come in and complete the consent forms online. By scheduling these events at the same time, health department staff can answer questions or concerns that parents may have and eliminate the need for SLV planners and/or staff to make several trips to the school.

5. **Use automated phone calls and/or emails to remind parents to complete and return consent forms.** This task may be delegated to the health department or the schools, depending on resources. Automated calls can be used to remind a large number of parents and may include information regarding the date parents can come to the school to complete forms, as well as the actual vaccination date. Automated email reminders (generated by the online registration system) may also be sent to parents who completed forms online.

6. **Pack vaccine coolers and supply kits the day before and have couriers deliver these items the day of the SLV clinic.** Packing these items the day before and having couriers or other non-SLV staff deliver the items to the schools the day of the program saves time by eliminating the need for SLV staff to go to the health department before and after the event. Couriers can deliver the vaccine daily from the initial storage site (i.e., health

department or contractor's office) to the SLV site. SLV planners in two of the three localities that used couriers reported that this method worked well for transporting the vaccine and supplies to the correct site without relying on SLV site staff. Other SLV sites used onsite staff to transport the vaccine or had the vaccine delivered directly from the manufacturer. SLV planners in three localities also noted that having health department employees prepackage the vaccines and supplies was helpful in saving time and ensuring that all needed supplies reached the SLV site.

7. **Monitor and record vaccine storage temperature according to the guidelines appropriate for the storage container (i.e., cooler or refrigerator)**. Once coolers have been transported to the SLV sites, the temperature inside the coolers should be monitored and recorded every hour; if vaccines are placed in refrigerators, the temperature should be monitored and recorded twice each day. SLV planners considering using refrigerators to store the vaccine should be aware of the additional cost, as well as accompanying mobility and storage issues (e.g., thermometer calibration).

8. **Ask school staff to set up the vaccination room, including privacy and waiting areas, before the health department or contracted vaccinators arrive.** It may be more comfortable for students if privacy is provided for those being vaccinated. This may be done using screens or folding mats to create temporary walls between vaccination stations. Vaccination rooms can also have a waiting area for students to sit in before and after vaccination. Waiting areas may include toys, books, or videos to keep children occupied. Ensuring privacy and providing distractions in the waiting area can help calm students who may be nervous or upset. The day before, the health department may want to call schools to discuss any last-minute questions or concerns.

9. **Include principals, teachers, and/or school nurses when organizing SLV staff, and provide an adequate number of registrars, triage, health educators, and translators, based on community needs.** Including the school staff can be helpful as they typically know the children's parents and medical history. Additionally, school staff can often help as translators if non-English-speaking students or parents will be participating. By providing additional registrars, triage, and health educators, planners can avoid potential delays in patient flow.

10. **Ask registrars to use a roster that includes all of the students who returned a signed consent form.** At the registration desk, students can be matched to the roster and asked to verify their identity. Once the student has been correctly identified, the registrar can give each student a copy of his or her consent form before he or she is escorted to the vaccination station. Planners may decide to use a color-coded system to identify which form of the vaccine, if any, a student should receive. For example, SLV sites in one locality used a color-coded sticker system to ensure that students received the proper type of vaccine; administrative staff placed a green, yellow, or red sticker on the consent form to indicate whether the student should receive the injection, mist, or no vaccine. For

example, a form might receive a red sticker for "no vaccine" because the parent changed his or her mind, the child was vaccinated by his or her private provider in the interim, or the child was exhibiting influenza-like symptoms (e.g., fever).

11. **Make communication materials developed by Federal, State, and/or local agencies available to parents when they complete the consent forms as well as on the day of vaccination.** It may be helpful if these materials are available in every language spoken by families at the school. Health departments can develop a sheet of frequently asked questions that dispels any rumors or misconceptions about the vaccine. Planners may want to review the reasons, if any, parents gave on consent forms for not vaccinating their children when developing this document. Once vaccinated, students should receive a Vaccine Information Statement that includes information about possible adverse reactions and a phone number to call if there are any questions. This sheet can also be sent home to parents of children who will need a second dose of the vaccine and include information regarding when and where the second dose will be administered. Once the child receives his or her second dose, he or she could take home a vaccination card including the administration date of both doses. Children who do not need a second dose can be sent home with the vaccination card or record the day that they are vaccinated.

12. **Determine whether it is beneficial to bill third-party payers for vaccine administration costs.** Vaccine administration costs are typically paid through grant funding, State funds, or by billing third-party payers. While billing insurance companies enables health departments or contracted vaccinators to recoup some of their expenditures, it can be time consuming and requires a billing system to be in place, as well as a method for collecting insurance information (e.g., requesting that parents provide insurance information on the consent form).