Promising Practices for School-located Vaccination Clinics—Part II: Clinic Operations and Program Sustainability

abstract

A school-located mass vaccination program can enable rapid vaccination of a large number of students while minimizing disruption of their school activities. During 3 consecutive influenza seasons beginning in 2005, the Knox County Health Department conducted school-located mass vaccination clinics using live attenuated influenza vaccine. Overall, the proportion of elementary schoolchildren vaccinated with live attenuated influenza vaccine exceeded 40% each year. We describe key lessons learned in clinic operations, including obtaining informed consent, defining the organizational structure and roles, preparing the school, staffing, training, supplies, vaccine management, team communication, and data management. We conclude by discussing program costs and sustainability. Pediatrics 2012;129:S81–S87
During a 4-week period in fall 2005, 2006, and 2007, the Knox County Health Department (KCHD) conducted school-located mass influenza vaccination (SLV) clinics in 100 public and private schools for more than 65,000 students in grades K through 12. We developed protocols for handling its many functions, and revised these using a continuous quality improvement program. In this article, we consider the logistical and operational elements needed to conduct this program. These elements included obtaining informed consent, defining the organizational structure and roles, preparing the school, staffing, training, supplies, vaccine management, team communication, and data management. We conclude with considerations of cost and issues of sustainability.

**OBTAINING INFORMED CONSENT**

One of the most challenging aspects of an SLV program is obtaining informed consent from a parent or guardian. This process includes notifying him or her about the program, providing the necessary information about the nature and safety profile of the vaccine (required by federal law), determining the presence of any contraindication to administering whatever vaccine product is being used, determining Vaccines for Children (VFC) program eligibility, and obtaining written parental informed consent for each child to be vaccinated, as required by state, local, or school requirements.

The first step in obtaining informed consent is sending program information, vaccine information, and consent documents home. Teachers in elementary schools usually do this by sending such material home in each student’s courier pack each week. Beyond elementary school age, though, older children commonly are handed the information and consent sheets at school and are asked to take them home to their parents. Older youth commonly discard, lose, or hide the forms, so they may not reach a parent.

The legal requirements of the Family Educational Rights and Privacy Act make this task a burden for those not employed by the official school system, to the extent that obtaining a student directory is discouraged. Accordingly, any others wishing to contact parents individually by phone or mail, or obtaining a directory list of children in the school, will likely not obtain this information from the school district. Once the school system sends such a consent form home, however, any information provided by it can be used by project personnel.

The second step involves reading and understanding the material provided. For this to succeed, parents need to receive sufficient information written in their native language (or one in which they are fluent) that is written at their reading level. Parents then need to make the decision a high enough priority for themselves and their child. Many parents do not perceive influenza vaccination to be a high priority. Others may want to confer first with their primary medical provider for advice. If that discussion does not happen immediately, the parent may then forget the matter in the midst of the myriad of other family obligations. Finally, parents must fill out the form properly, and their child must return it to the school. This elaborate process can break down at any point along its path, resulting in the school receiving an incomplete form or no form at all. This again emphasizes the special value of the school staff, especially the principal’s office staff and the school nurse, who are adept at following up with families, particularly those of older children.

To manage these potential impediments, some schools have made project information and consent forms available at their open house at the school at the beginning of the school year. There, teachers and project staff can help educate parents and obtain their informed consent. In many school districts, the beginning of the school year is also an optimal time to send the documents home, because parents are accustomed to receiving a great deal of important school information at that time and are alert and receptive of its content. If the packets are not sent home when school starts, they should be sent out at least 2 weeks before the scheduled day of the clinic. Our information and consent packet contained a letter from the health department and school administrators that gave the parent an overview of the project, a live attenuated influenza vaccine (LAIV) information sheet created by the Centers for Disease Control and Prevention,2 Frequently Asked Questions, and a consent form. These packets should both provide program information specific to the child’s school and direct parents to additional resources for more information (eg, Web sites, family physician or pediatrician, other trustworthy sources). Parents commonly appreciate receiving information from several sources and often use it to make decisions about their child. This is especially important if the intranasal formulation of influenza vaccine is to be used, because most parents are not as familiar with it as the injectable formula.

Each school in the Knox County program was responsible for managing its own consent process. The school sent its information and consent packets home to parents with other unrelated school information, received it back, and collated the signed consent forms. These were then reviewed by school and other project personnel before the day of the clinic. This advance work should increase the vaccination rate by allowing time to both review the forms for completeness and accuracy and, when needed, to contact parents to resolve questions about eligibility.
Schools can offer incentives to increase consent form return rates and vaccination rates. In 2006, 3 Knox County elementary schools offered either a pencil eraser or free ice cream cups during lunch for the return of a consent form, regardless of whether the parent gave consent. Elementary schools that offered simple and inexpensive classroom-based incentives had higher return rates of consent forms (range 75%–95%) compared with those schools that did not offer incentives (range 68%–76%).

DEVELOPING THE ORGANIZATIONAL STRUCTURE AND ROLE DEFINITIONS

For such a large program to operate efficiently, we needed clear role definition and delegation of authority. We found it helpful to form a small core leadership team at the outset to plan, coordinate, and implement operational and logistical needs of the clinics. Our project leader designated 4 core lead persons to direct vaccines, supplies, training, and staffing. They supervised other personnel assigned the tasks of data entry; public relations; consent form screening; education of school staff, students, and parents; and other activities. A clinic leader was designated for each site. The leader was responsible for overall clinic management, interaction with school officials there, and making the final determination about whether a child should be vaccinated. We found that our health department clinic manager (a registered nurse) was well suited to serve as the clinic team leader because this clinic manager was familiar with conducting mass clinics for bioterrorism preparedness and influenza vaccination at the health department, and also was accustomed to vaccinating young children.

Each school principal was given a project plan and a set of operational guidelines to assist him or her in coordinating and implementing the vaccination clinic(s) at that school. We found it helpful to have each school administrator establish the school point-of-contact (POC) for the project leader for that school. This POC was responsible for conveying a plan in advance to the teachers. The plan included escorting the children to and from the clinic efficiently. Some schools had the POC and a volunteer cue the next classroom to be vaccinated toward the vaccination clinic. This occurred in person at the classroom door, or by using 2-way radios or the public address system—both worked well. By defining the flow and order of classrooms in advance, it was easier to keep track of the number of children remaining to be vaccinated. This in turn allowed the vaccine/supply team leader to regulate the amount of vaccine that needed to be thawed, thereby potentially reducing vaccine wastage, as described later in this article.

PREPARING THE SCHOOL

Planning a proper site within the school is important because space needs to be sufficient to maintain an acceptable flow of students through the clinic. School gymnasiums, cafeterias, and libraries are excellent areas for these clinics. The clinics should be scheduled to begin as early as possible in the morning because schools have different dismissal times and some kindergarten classes are only half-day programs.

Ideally, parents should be given the opportunity to choose which formulation their child should receive, either LAIV or trivalent influenza vaccine (TIV), as available. TIV may not be available at the SLV clinic, although it could be available at a different time or site (eg, school nursing station or the local health department). As an alternative to LAIV, KCHD offered free TIV to students at all their health department locations.

STAFFING

In a large operation such as this, it is important to carefully conceive and execute a workable staffing plan. We created the following staffing plan and applied it to all vaccination clinics. A central manager, the most senior member of the team, was charged with coordinating staffing, ensuring that the appropriate type and level of staff were provided for each clinic, and tracking staffing hours of paid employees.

KCHD developed 3 operating guidelines to help determine the optimal staffing model. The first operating guideline was the establishment of a clinic duration that would minimize disruption of the normal school day. We determined the number and type of staff to fit this objective in the following manner. The students in the Phase 1 clinic received their first and often only dose of LAIV there. Because of this, these clinics would have the greatest number of students to vaccinate. As a priority, we established that each Phase 1 clinic should last no longer than 3 hours. Phase 2 clinics delivered a second dose to children younger than 9 years of age who had never received a dose before, or during the prior year season had received only 1 dose. Phase 2 clinics should last no longer than 1 hour. We estimated that each vaccinator should be able to vaccinate between 40 and 50 students per hour, provided that the students were properly queued. This estimate was based on local data from hepatitis A vaccines administered during a hepatitis A outbreak. Therefore, 5 vaccinators at a school should be able to vaccinate a total of 200 to 250 students per hour. Time measurements of clinics indicated that Phase 1 clinics typically lasted 90 to 120 minutes, whereas Phase 2 clinics were completed in 30 to 45 minutes. At our most efficient clinics, we achieved a vaccination rate of more than 60 students per vaccinator per hour.

The second operating guideline for staffing was to ensure that the clinic
had adequate support personnel on-site. The clinic leader needed to be well trained to coordinate activities and maintain good patient flow. One support person was needed for every 2 vaccinators. KCHD nonmedical public health support staff served this function, but lay volunteers, contractors, or school employees could provide good vaccine management and student flow if provided with the necessary training.

The third operating guideline was to maintain accountability of all personnel at all times during the clinic. To achieve this, we created and printed a roster of all clinic staff and their roles before each clinic began. The roster contained a “presence log” that tracked personnel and their clinic hours. This was reviewed periodically to establish the optimal number of staff hours needed to operate the clinics. For the children’s personal safety, team leaders ensured that all staff participating in the vaccination clinics had been vetted by either KCHD or the school in advance. Team leaders also ensured that all nonschool staff left the school grounds promptly after the clinic ended.

KCHD considered several staffing approaches in developing a sustainable model. In each case, KCHD was the lead agency responsible for planning, and provided the clinic leadership for both phases. The eventual model used involved KCHD staff nurses and support personnel, plus contract staff. These staff were supplemented with volunteers who served mainly in supporting roles. The role of the school nurses was vital in advocating for the program and their role. The project and their role. This was conducted well before the first clinic was held, and instructed personnel in using the vaccination administration protocol and in practicing sound vaccination technique. They needed special instruction on how to administer the intranasal formulation of the vaccine, and quickly and efficiently evaluate a consent form just before vaccinating a child. Additionally, a brief just-in-time (JIT) training session was held immediately before the start of each clinic. This was helpful and allowed workers and volunteers to meet each other, review their role, receive key messages, review the protocol and understand the need for strict adherence to it, address issues concerning the cold chain, learn new information, discuss successes and problems noted in previous clinics, and get their questions answered. We allocated 30 minutes to set up the clinic and conduct each JIT session.

Clinics ran most efficiently if a vaccination protocol was established in advance and used to manage each step. Adherence to this protocol was important because of the sheer number of children who needed to be vaccinated in a very short period. For the most part, this precluded any special considerations for any individual child, which might have invited deviation from the protocol.

Consent forms were reviewed 3 times for each child for completeness and accuracy. The first review occurred when the signed consent form was initially sent back by the parent to the school. That review identified by protocol any incomplete areas as well as any children with known contraindications to LAIV. In such cases, staff called the parent (or guardian) well before the clinic day to provide any missing data, determine VFC eligibility, or identify any contraindications for that child. The second review occurred on the day of the clinic by a person dedicated to checking each consent form as the children entered the clinic. Finally, the vaccinator reviewed each consent form just before vaccination.

**GENERAL SUPPLIES**

We developed and used a well-defined supply list for all clinics to prevent confusion, omissions, and delays at the school clinic. The vaccine/supply planning leader was responsible for updating and maintaining the supply list and ordering supplies. The leader prepared the necessary clinic supplies the day before the clinic was held. Some of the standard supplies taken to each school clinic were extra consent forms (to manage any last-minute decision by parents), vaccine information sheets, tissues, and stickers for students after vaccination. Clinic supplies for a 400- to 500-person clinic could fit into a small box approximately 12 x 12 x 18 inches (1.5 cubic feet). Small biohazard containers were also included to enable the LAIV spray applicator, a biohazard, to be discarded appropriately. Tissues could be discarded in ordinary waste baskets. Once used, a biohazard container had to be completely closed during transport. Each clinic was prepared for a possible anaphylactic emergency, with diphenhydramine, epinephrine, and other supplies immediately available on-site if needed.

**VACCINE MANAGEMENT**

Maintaining the vaccine cold chain in this environment was sometimes a challenge. According to the LAIV manufacturer’s instructions, the formulation of LAIV used during the earlier seasons needed to be stored frozen and maintained at −15°C (5°F). This was relatively easy to accomplish with dry ice, which is solid below −78.5°C (−109.3°F). Once the frozen formulation was thawed, it needed to be used within 72 hours or else discarded. The
current LAIV formulation requires only refrigeration, however, which imposes different constraints. It must be kept between 2°C and 8°C (35°F–46°F), which, over the course of a 3-hour clinic, is difficult to maintain in a school setting using only coolers and ice packs. Any vaccine stored or held above 8°C (46°F) must be used within 8 hours or else discarded (MedImmune, Inc data on file). This commonly prevented batches of vaccine left in coolers but not used at a clinic (and therefore likely to be warmer than 8°C, or 46°F at the end of a clinic) from being used the next day.

KCHD developed several strategies to reduce the amount of wasted vaccine. First, by 10:00 AM the day before each clinic was held, that school was required to contact the health department with the number of consent forms collected. This required amount was increased by 20% to adjust for any late returns of consent forms. This algorithm was designed to reduce the possibility of needing to make additional trips back to the health department during clinic hours to obtain more vaccine. The algorithm was very successful. During these 3 seasons, KCHD had only 5 occasions when additional vaccine beyond that expected to be used had to be transported from the health department to a clinic during a session.

Second, each clinic had a designated vaccine/supply leader who was responsible for checking, documenting, and adjusting vaccine temperature (by adding or removing ice packs) every 20 minutes during clinic operations. The leader was in charge of periodically transferring vaccine from the larger, more-temperature-stable vaccine transport coolers to the less-temperature-stable tabletop coolers located at each station.

Third, vaccine designated for use that half-day was picked up from KCHD just before the clinic began and returned immediately after the clinic ended. Teams were not permitted to take vaccine from KCHD in the morning to cover their afternoon clinic. Returned vaccine was then targeted for use either that day in a health department clinic or at a school clinic that afternoon or the next morning. Any returned vaccine stored or held above 8°C (46°F) was used that day or sent to another clinic for use whenever possible, but within the authorized 8-hour limit. Any such out-of-range not used that day was discarded according to protocol. Only 231 doses were discarded in the 2007 to 2008 season and 274 doses in the 2008 to 2009 season.

**TEAM COMMUNICATION**

During the clinic, having fast, easy, dependable communication among the clinic leader, staff, and project leader was essential. We depended on cell phone communication, as well as team leader sheets unique to each vaccination clinic. These included contact information for key project team members, the number of students at the school, the estimated number of students to be vaccinated based on consent forms returned, the number of vaccine doses delivered to the clinic, and the contact information for clinic staff members working in the clinic that day. This tool greatly facilitated resource management at each clinic. Furthermore, for each clinic, the team leader was given a cell phone with preprogrammed numbers of key personnel, including the project leader and medical advisor. Important contact numbers also were printed on the team leader sheets and on laminated cards attached to name badges. Cell phones allowed the team leaders to ask the medical advisor or project lead questions about a protocol, vaccine supply issue, or a specific medical question about a child. The project medical advisor was available on-call during clinic hours for consultation when team members encountered medical issues they could not settle. On such occasions, albeit rare, the team leader would pull that child out of the clinic flow, consult the medical advisor, and take appropriate action to either vaccinate the student or declare the student ineligible. The team leader would also write a note to the student’s parents explaining the situation.

Constant interchange of information was most likely to occur if (1) team leader sheets and cell phones were used; (2) a JIT session was held before the clinic began; and (3) face-to-face communication occurred at the supply distribution point, namely, the health department. At the JIT sessions, team leaders passed out yellow mesh vests to all team members and orange mesh vests to the team leader and the staff leadership. These colored vests were an excellent communication tool for clinic staff, students, and school staff.

Potential problems and changes to the protocol did occur throughout the month the clinics were held. These issues were discussed each morning in a meeting of the project lead and clinic team leaders. Problems observed during the more recent clinics were discussed and changes implemented as needed at that time. For example, after the first 2 days of clinics in 2005, we noticed that too many doses of vaccine were warming beyond the allowable temperature range, causing excess wastage. After conducting a quick continuous quality improvement cycle, it was determined that, against protocol, staff were placing too much vaccine into tabletop coolers because they thought the fast pace of the clinic did not allow enough time for thawing. Also, the vaccine/supply lead was not keeping track of the number of classes yet to be vaccinated. Accordingly, on the third morning of the clinics, we provided further education to vaccinators about proper thawing of the vaccine,
and assured them that patient flow would not be interrupted if they adhered to the protocol. We instituted tighter controls on placing vaccine in tabletop coolers, and made sure that the team leader informed the vaccine supply leader when only 3 to 5 classrooms remained. These actions reduced the number of out-of-temperature-bound doses from 50 to 150 doses per clinic returned to KCHD to fewer than 20 doses per clinic.

DATA MANAGEMENT

Data requirements need to be identified early in the planning process and appropriate forms designed to capture the necessary information. These consent forms, when fully and properly completed, provided the information we needed to identify those ineligible for vaccination. Data requested from the parent/guardian on the consent form included demographic information, insurance information, contact information, medical screening questions, and a parent/guardian signature line. Information from the consent form or a registry was used to verify a child's eligibility for the VFC program. The same form was used during the clinic to record the vaccine lot number, expiration date, and provider signature. Certain data from the consent form and clinic record were entered into a state immunization registry (immunization information system), especially demographic and insurance data, vaccine lot number, and date of vaccine administration.

A data entry team (in our case, KCHD clerical and immunization project staff) was needed to efficiently enter consent form data into the local electronic database (Immunization Information System) after each clinic was completed. A KCHD goal was to enter Phase 1 data within 2 weeks after the last such clinic took place. Consent form data were used to identify formerly vaccine-naïve children and to create notification letters to send parents indicating their child's need for a second dose, when appropriate. Data entry was a daunting task because there were ~15 000 consent forms needing to be entered each year for just kindergarten through fifth grade.

Because of the large volume of vaccine used each year (27 000–36 000 doses), KCHD needed a well-developed vaccine accountability system. We tracked all vaccine from storage at KCHD to the main school distribution site to each clinic station. By doing so, the project leader could identify and thus understand patterns of use by schools and clinic teams. The clinic team leader was responsible for recording how many doses of vaccine were used, returned, or wasted. This allowed the project leader to request and distribute only the amount of vaccine needed, thereby reducing potential vaccine wastage.

COSTS AND SUSTAINABILITY

The KCHD school immunization program had several sources of support, including especially corporate support in the early years. In the 2005 to 2006 influenza season, MedImmune, Inc (Gaithersburg, MD) provided all LAIV needed free of charge plus a $10 000 grant to purchase supplies. In the 2006 to 2007 season, MedImmune, Inc provided free of charge all the LAIV needed, for 1 year only. In addition, in 2006 MedImmune, Inc provided a $1.7 million grant to KCHD. These funds were sufficient to hire personnel and purchase vaccine (both LAIV and TIV were provided for adults) needed for 4 consecutive seasons, ending in 2009 to 2010.

For the 2009 to 2010 school vaccination program, KCHD projected a total outlay of $316 500 for personnel (61%), vaccine (36%), and miscellaneous costs and supplies (3%) needed to vaccinate 34 000 students. These funds were provided entirely by residual funds from the 2006 corporate grant from MedImmune, Inc. and other donations. These projected budget figures do not include $419 000 for the procurement of vaccine through the federal VFC program. Approximately 94% of the personnel costs above are for non-KCHD employees. A full economic account is beyond the scope of this article.

For 2009–2010 season, some roles and responsibilities were shifted. Whereas in previous years public and private school nurses reviewed consent forms for completeness and accuracy, they commented that this duty took too much time away from their primary duties. Accordingly, paid school coordinators will now have primary responsibility for that function. The school nurses will continue to administer vaccine to students as their time permits, and will serve as consultants to school program coordinators, faculty, and parents as needed. Whether they serve in an operational or consultant role, school nurses are particularly helpful in making the program a success.

Most local programs require some funds to sustain it year after year, particularly to pay for vaccine and personnel that are not provided in-kind. We recommend that funding be sought from multiple sources to enhance the likelihood that the program can continue every year even if 1 donor ceases to provide funds 1 year. For many communities, the largest source of influenza vaccine doses is their state immunization program, which has access to the federal VFC program to purchase vaccine for a large number of their children.1 Third-party billing for vaccine and its administration could be a useful solution, and pilot studies to explore this possibility are now under way.

The school system can provide in-kind help through its staff, but is not likely
to have funds to directly support this project. At least in theory, local hospitals, medical societies, and other community groups might be able to contribute funds or in-kind support, including volunteer time, staff, or funds to purchase vaccine or offset administrative costs. Large employer organizations are another potential source of financial support for such initiatives. Many employers recognize the likelihood that their employee absentee rates will be lower when the employee's young children remain healthy, as a child's illness may keep a worker off the job for several days. In addition, the direct medical costs of ill employees may be reduced, a matter of particular value to self-insured employers.

Although grant funding may be locally available, most grant processes require a long lead time and at least some grant-writing experience. In the past few years, pharmaceutical companies have provided small grant amounts to help offset vaccine or administrative costs of the project. Other companies that provide supplies (other than vaccine) for such clinics may be willing to support the project if a link can be made with one of their products.

Many companies, schools, and city/county governments will provide staff in-kind to defray program costs. These organizations, which may have access to some grant and discretionary funds, base their funding decisions on the nature of the program and the group it serves. Local merchants might provide printing to offset the administrative costs of the project, or small giveaways to be used as incentives to return the signed consent forms to school.

Parent-teacher associations and booster organizations can help fund the project or help seek outside funding for it. Because these groups conduct fund-raising for other school programs throughout the year, they are familiar with potential sources of support in the community and may be able to leverage existing local relationships to obtain small donations. In addition, many parent-teacher associations or booster club members are also business and community leaders whose children attend schools where the vaccination clinics will be held.

CONCLUSIONS

Conducting school-located mass immunization clinics for seasonal influenza is a viable option to providing vaccinations in a physician's office or at the health department. Such a program allows rapid, efficient, and safe vaccination of large numbers of students in a short time with minimal interruptions to the educational activities of the schools. Over a 3-year period, KCHD used similar processes, albeit with different staffing models each year, to conduct the vaccination clinics. Modifications were made to these processes continuously as lessons were learned. Some issues need to be addressed on a national level, especially funding and availability of vaccine, even though these programs are a local endeavor achieved through community efforts. The most important aspects of these programs continue to be the twin goals of vaccinating as many children as possible to reduce the occurrence and therefore health risk of influenza in students, as well as interrupting its spread and burden of disease in the community.

ACKNOWLEDGMENTS

We thank the many public health workers, nurses, and physicians who helped us develop and deliver this program over these years. MedImmune, Inc (Gaithersburg, MD) provided vaccine and funds indicated in the text. We appreciate the extensive editorial input provided by Richard Schieber, MD, MPH, throughout the writing of this manuscript.

REFERENCES


Promising Practices for School-located Vaccination Clinics—- Part II: Clinic Operations and Program Sustainability
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Pediatrics 2012;129;S81
DOI: 10.1542/peds.2011-0737G
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