# Influenza School-Located Vaccination (SLV): Information for Planners

## Purpose

To provide information for planning and conducting school-located influenza vaccination clinics.

## Target Audience

Primarily state and local public health department immunization and preparedness staff who are responsible for carrying out influenza vaccination, but also education officials, school nurses, and others who are interested in planning and carrying out such activities.

## Glossary

- ACIP: Advisory Committee on Immunization Practices
- CCV: Commercial Community Vaccinator
- CDC: Centers for Disease Control and Prevention
- CFR: Code of Federal Regulations
- CRA: Countermeasure and Response Administration
- EMAC: Emergency Management Assistance Compact
- FDA: Food and Drug Administration
- FERPA: Family Educational Rights and Privacy Act
- HIPAA: Health Insurance Portability and Accountability Act
- IIS: Immunization Information System
- LAIV: Live Attenuated Influenza Vaccine
- MSF: Medical Services Firm
- NACCHO: National Association of County and City Health Officials
- NEMA: National Emergency Management Association
- PREP Act: Public Readiness and Emergency Preparedness Act
- RBC: Retail-based clinic
- SLV: School-located vaccination
- TIV: Trivalent Inactivated Influenza Vaccine
- UCC: Urgent care clinic
- VAERS: Vaccine Adverse Event Reporting System
- VHP: Volunteer health professionals
- VIS: Vaccine Information Statement
- VPA: Volunteer Protection Act

## Definition

School-located vaccination (SLV):

Vaccination that is:

- Administered on school grounds
- Targets enrolled students and potentially others
- Held before, during, and/or after school hours
- Often involves collaboration between public health departments and public and private schools/school districts

## Background

Recommendations for influenza vaccination have gradually broadened over the last decade. Vaccination of school-aged children has been recommended since 2008. In 2010, the Advisory Committee on Immunization Practices (ACIP) recommended that all people 6 months of age and older receive an influenza vaccine.

Private providers (e.g., pediatricians) are the primary vaccinators of choice for school-aged children. However, children of this age infrequently access health care for preventive, non-acute care, and because vaccinating many children in a short period of time is essential during influenza vaccination season, other vaccination venues may be considered as well (Rand, 2008; Rand, 2007). SLV has been widely discussed as a potentially viable option for vaccinating many school-aged children against influenza in a short period of time.

There are benefits to holding influenza SLV clinics:

- Large numbers of children are found in schools
- Schools are conveniently located throughout communities
- Communities are generally familiar with and trust schools
- School facilities can generally accommodate mass vaccination clinics (e.g., the availability of gymnasiums and auditoriums, ample parking in some locations)
- School nurses, if present, may be available to assist in vaccination activities and may be familiar with the health of individual students
- School staff have access to parental contact information, which could facilitate communications (e.g., for announcing clinic dates, obtaining parental consent for vaccination)
- Others prioritized for vaccination besides enrolled students may request vaccination at vaccination events

There are potential challenges to holding influenza SLV clinics:

- Securing funding or a source of reimbursement to pay staff, purchase vaccine and supplies, and other needs is often challenging
- Locating adequate staff to prepare for and conduct the clinic may be difficult
- Clinics could disrupt educational activities
- Immunization activities may need to be tailored to each school or school district, complicating planning efforts
- Handling and transporting the vaccine to many and varied locations requires considerable planning, equipment, and training
- The date of influenza vaccine availability varies from year to year, complicating planning efforts.

Many schools and public health departments have conducted SLV clinics in the past, for influenza vaccination and other vaccines, but many have not. The information below, as well as the links to guidance developed by other groups (e.g., the National Association of County and City Health Officials [NACCHO] School-located Influenza Immunization School Kit), has been designed primarily to help inexperienced but interested public health departments, schools/school districts, and others conduct successful influenza SLV clinics.

The following information, for the most part, assumes that the public health department will be leading the influenza SLV effort. The information provided focuses on clinics occurring during school hours without parents present because of the many unique challenges associated with that scenario. For planners who are considering the school as a potential venue to offer vaccines primarily to non-students, general guidelines for setting up large-scale vaccination clinics are posted on the CDC influenza website.

## Vaccination Guidelines

The most up to date influenza vaccination recommendations should be followed when implementing influenza SLV clinics. CDC's ACIP provides annual recommendations for the prevention and control of influenza with vaccines. These recommendations can be found on the CDC influenza website.

## Planning for the Vaccination Clinic

In addition to the information provided below about planning for SLV clinics, please also see the more general guidelines for setting up large-scale vaccination clinics posted on the CDC influenza website.

## Vaccine

There are two types of influenza vaccine, the flu shot and the nasal spray. The flu shot is an inactivated vaccine that is given with a needle, usually in the arm and is approved for individuals with chronic medical conditions. The nasal spray vaccine is a live attenuated vaccine that is sprayed in the nostrils. This vaccine is not recommended for everyone, and should not be used for individuals with certain chronic medical conditions. Planners of SLV clinics will need to determine if they plan to offer one or both of these types of influenza vaccine. Additionally, some children less than nine years of age may require two influenza vaccines this year. SLV clinic planners will need to determine if they will schedule clinics to offer second doses of influenza vaccine to these children.

## Timeline

Developing a timeline for implementation of a SLV clinic will help the program run smoothly and efficiently. Each SLV program is unique with differing resources available which may change the timing of certain events. Sample timelines can be found on NACCHO's School-located Influenza Immunization School Kit . In addition, a generic sample timeline is provided below.

**End of Previous School Year (April/May/June)**
Contact school districts and principals to enlist their support
Identify possible clinic dates
Contact other potential partners

**Summer (June/July/August)**
Develop materials (consent forms, letters and other documents) for parents/guardians
Develop training material for vaccinators and school staff
Begin coordinating clinic staff

**Beginning of School Year (August/September/October)**
Schedule clinics
Disseminate materials to parents/guardians and children
Educate school staff
Order clinic supplies

**Clinic Operations (October/November/December)**
Review consent forms and determine eligibility of students
Report any adverse events

**Post-Clinic (December, January, February)**
Record vaccination in immunization registry

Communicate with childrens' primary healthcare provider
Prepare necessary reports
Send thank-you letters to volunteers

## Influenza SLV Leadership / Initiation

The first step in planning for SLV clinics is to form partnerships between the public health department and education agencies, as well as any other organization(s) that could assist in the SLV clinics. The public health department traditionally has led SLV efforts, but a school/school district or a private organization (e.g., a commercial community vaccinator) also could take primary responsibility. Regardless of who leads or initiates the SLV effort, these partnerships with public health are essential. SLV planners may choose or be required to establish a memorandum of understanding or a similar document, that identifies the roles and responsibilities of each partner (e.g., who will be the main contacts from public health and the school/school district, who will be responsible for collecting parental consent forms and communicating with parents/guardians).

If the public health department initiates the SLV program, the first step should be to contact school district superintendants, but, it is essential to also form partnerships with the school board and to communicate with and gain support of school principals, who ultimately oversee all activities within their school. Support of SLV clinics by school principals can help make program implementation easier and also increase student participation (Wilson, 2001). Where principals have the authority to make decisions on conducting/participating in SLV clinics autonomously, the reverse order of communication should be applied. It is recommended that principals be contacted toward the end of the school year prior to the year of the SLV clinic. When this is not possible, principals should be contacted about holding an SLV clinic in their school as early in the planning process as possible. A template letter to principals is provided.

## Population(s) Identified for Vaccination

Planners will need to identify which population(s) will be offered the opportunity to be vaccinated. The information contained in this document focuses on vaccination of enrolled students. Although most enrolled students will be school-aged (5-18 years), planners should be aware that some schools include students who are older than age 18 or younger than age 5.

Planners may also decide to include the following populations, for example:

- Students attending nearby schools other than the school where the SLV clinic will take place
- Home-schooled children and/or school-aged children who are not enrolled in school for other reasons
- School staff
- Students' siblings and other family members
- Other members of the community

Many factors will affect the decision to include persons other than students of the school where the SLV clinic will be held, including vaccine supply or which populations would most benefit from vaccination according to local influenza epidemiology.

## When to Hold SLV Clinics

Planners will also need to decide whether to hold SLV clinics before, during, and/or after school hours. Below are some benefits and challenges to consider when making decisions on when to hold SLV clinics.

## SLV during school hours

### Benefits

- Parents/guardians do not need to take time off work because their children can be vaccinated without them being present.

- Children are present in large numbers.
- Vaccinations can be conveniently provided to school staff, if desired and appropriate.
- Because parental consent is obtained prior to the clinic, there is some lead time during which planning for adequate staffing, vaccine, and medical supplies can take place.

### Challenges

- Parental consent to vaccinate children must be obtained ahead of time; coordination will be required to send consent forms to parents/guardians and allow time for them to be returned to school officials.
- Some parents/guardians may not consent to vaccination of their children without being present (but parents/guardians entering the school during the SLV clinic could be logistically problematic).
- Disruption of class time may be unacceptable to parents, students, and school administrators

### SLV before/after school hours

### Benefits

- Parental consent to vaccinate children can be obtained at the time of service, avoiding the challenges of getting consent forms to, and back from, parents/guardians.
- Clinics could be held in one or several centrally-located schools instead of every school, which may be cost-saving and more feasible for planners and those who conduct the clinic.
- Persons other than school-aged children can be vaccinated, if desired, appropriate, and logistically feasible.

### Challenges

- Extending school hours may require overtime for vaccinators and school staff, incurring additional expenses.
- Parents/guardians may find it difficult to bring the child to clinics held in the evenings or on the weekends.

In addition, regardless of whether an influenza SLV clinic is held during or before or after school hours, school officials may need to consult with local union representatives if holding such a clinic has an impact on staff members' rights under a collective bargaining agreement.

### Planning for Adequate Staff

Implementing SLV clinics may require staffing capacity that exceeds that of the local public health department (There are several tools available on CDC's website for planning adequate staff). Because of this, planners should consider recruiting additional staff, both medical and non-medical.

Potential roles and duties for additional, non-public health department staff could include the following (Note: licensure/liability issues are discussed below under "Legal Issues"):

Non-medical, non-public health department staff:

- Assembling, distributing, and collecting vaccine information, consent forms, and other materials
- Communicating with parents/guardians (e.g., to encourage return of consent forms if consent is required prior to the clinic day)
- Assisting with the promotion of the clinics (e.g., placing posters, posting information on school website, communicating with local radio/television/newspaper)
- Assisting with clinic flow and escorting students to and from the vaccination site
- Verifying the identity of each child to be vaccinated to ensure that parental consent was given
- Assisting with the transportation of vaccine and other materials to and from clinic sites
- Providing security
- Tracking and entering vaccination information into immunization registries or other databases.

Medical, non-public health department staff, depending on licensure and training:

- Preparing and/or administering vaccines
- Ensuring that vaccination medical screening eligibility has been met
- Evaluating children for illness when they present to the clinic for vaccination

## Potential Sources of Non-public Health Department Staff and Ideas for Recruitment

### School Staff

School staff, including school nurses, teachers and teachers' assistants, security and maintenance personnel, and other staff, can contribute greatly to the success of a SLV clinic. These staff members are familiar with the students, the school facilities, and the administrative structure of the school. School nurses and teachers may be familiar with students' personalities, pre-existing health conditions, and their parents/guardians. School nurses, who are present in many, but not all, U.S. elementary and secondary schools, can play a critical role in SLV clinics by answering questions from parents and educating school staff about influenza, the consent process, and the SLV clinic. School nurses can also serve as the liaison between the public health department and the school community.

Although school nurses and other staff are likely to be willing to provide assistance, competing priorities and other school responsibilities may serve to limit their involvement. Roles and responsibilities, and the degree to which school staff are involved in the SLV clinic will vary from school to school and should be determined and defined by partners in advance of the clinic. In many cases, school administrators may determine the roles their staff will play. School officials are encouraged to review collective bargaining agreements (CBAs) with school staff prior to making decisions on how staff are to be utilized.

For each participating school, a liaison or point of contact should be identified through which planning communications should be directed. Identifying such a person has been recognized as a key to the successful implementation of SLV programs (see: NACCHO School-located Influenza Immunization School Kit). Regardless of the degree of school staff involvement, the SLV clinic should be viewed as a partnership between staff from public health and the school/school districts, in addition to any other organizations that participate.

The following lists activities for which school and partner organization staff may wish to take responsibility.

- Advertising the SLV clinic, perhaps using materials supplied by the public health department.
- Distributing to parents/guardians (e.g., via students, direct mailings, internet sites, or by other means) informational materials and parental consent forms authorizing their child to be vaccinated, subsequently collecting and tracking the return of consent forms, and following up on students who have not submitted consent forms. These activities may be coordinated by school nurses or by teachers (e.g., for their homeroom class).
- Screening returned consent forms for completeness and ensuring that medical eligibility for vaccination has been verified.
- Identifying a location within the school where informational meetings, training, and the SLV clinic will take place; working with public health staff to establish clinic times/dates.
- On scheduled clinic days, escorting students to and from classrooms to the clinic, verifying the identity of the student to be vaccinated, and ensuring that parental consent has been properly given prior to vaccination.
- Communicating vaccination information to the vaccinee's primary health care provider.
- Alerting the vaccinee and his/her parent/guardian of plans for the administration of the second dose.

It also is important that school staff members are able to answer questions from parents or others about the SLV clinic or direct questions to the appropriate staff member(s). School districts and schools should consider identifying a single spokesperson and also provide information on their websites, to the extent feasible. Questions may be directed to the school superintendent's office, school board members, school

nurses, teachers, school secretaries, or others; however, all school staff should be appropriately educated about influenza and the SLV clinics and know where to direct more complex questions.

## Contractual Staff

Temporary employment agencies may be a resource to hire both medical and non-medical staff to assist with SLV clinics.

Other potential staffing sources include private, for-profit organizations, collectively known as commercial community vaccinators (CCV). In addition to supplying temporary staff, CCV also can be hired to plan and conduct SLV clinics. Many of these organizations are experienced in operating influenza vaccination clinics for children and adults. Some have partnered with schools to conduct SLV clinics or worked with local public health departments in partnership with schools. Planners interested in staffing SLV clinics using a commercial group can refer to the following document that defines the different categories of CCVs.

## Volunteers

Volunteers can serve as an excellent source of SLV clinic staff and may even be considered an essential component of an SLV program, depending on the number of SLV clinics planned within a local jurisdiction. Volunteers can fill many roles in SLV clinics, both non-medical and medical.

For example:

### Non-medical Volunteers

Parents of school children could be helpful in conducting the SLV clinic. Other groups to consider are fraternal and service organizations, large local employers, area faith groups, medical service organizations, and students from local colleges and professional schools. Law enforcement, hospitals, and for-profit organizations (e.g., local health insurance companies) also may provide staff.

Students of the school or school district where the SLV clinic will take place are another potential source of volunteers. In addition to providing a positive experience for the student volunteers, peer involvement may increase student participation in the program considerably.

### Medical Volunteers

For medical staffing needs, planners may consider contacting area colleges that grant degrees in health care-related fields, such as medicine, nursing, dentistry, and pharmacy, to recruit staff, students, or alumni willing to provide assistance with SLV clinics. Planners may also consider soliciting assistance from retired health care professionals. Medical Reserve Corps have also been a source of experienced, credentialed volunteers for many programs.

### Challenges of Using Non-public Health Department Staff in SLV Clinics

Challenges of using non-public health department staff in SLV clinics include:

- All SLV clinic staff and volunteers will need to be trained to perform their duties. Working with children is a specific skill which some medical staff may not possess.
- Although not specific to vaccinating children, planners might find the immunization encounters information in the following CDC websites helpful for training purposes: http://www.cdc.gov/vaccines/ed/courses.htm , and www.cdc.gov/vaccines/ed/encounter08/imencounter-resources.htm
- Schools may require background checks for SLV clinic staff who will be present on school property. Many staff may have already undergone background checks conducted through their organizations. For those who require background checks, the process may be quite lengthy and will vary locally.
- Planners may consider making plans to enable replacement of volunteer staff who are not available at the last minute, especially during local outbreaks of influenza.

## SLV Clinic Promotion and Education

Education of students and parents, as well as school staff, may contribute to the success of SLV programs (Wilson, 2001; Guajardo, 2002).

### Students

Students may be more likely to participate in a SLV program when they thoroughly understand the benefits and risks of vaccination. Classroom-based instruction and school-wide assemblies have been effective in educating students prior to immunization (Wilson, 2000; Boyer-Chuanroong, 1997; Woodruff, 1996). For schools willing to include classroom-based instruction as an element of their vaccination program, planners may consider providing teachers and school nurses with ideas for lesson plans (Goldstein, 2001). This represents an ideal opportunity to emphasize the importance of influenza vaccination as well as hygienic measures that can reduce transmission of influenza virus and other common causes of illness in children.

### Parents/Guardians

Of course, because parents/guardians must provide consent for children to be vaccinated, parent education also is important. Information about the SLV clinic should be disseminated as early in the school year as possible, especially if advanced consent has been determined to be feasible (Note: advanced consent issues are discussed below under "Timing and Procedures on Obtaining Consent"). Consent forms and other SLV informational materials can be sent home with other school documents distributed to parents at the beginning of the school year. A variety of methods, including public service announcements, radio campaigns, bulletins, and announcements on school websites, have been used to promote vaccination programs to parents/guardians (see: NACCHO School-located Influenza Immunization School Kit). Messages may also emphasize the importance of influenza vaccination and other means to prevent the spread of influenza and other illnesses. Depending on the availability of resources, public health departments may establish a telephone line or provide a website or email address parents could use to access information and ask questions in the weeks before, during, and after the vaccination program (Carpenter, 2007).

### Teachers and Other Staff

In past SLV clinics, teacher support and participation has been perceived to be linked to the success of SLV programs, and students have reported that teacher influence was an important factor in returning consent forms (Tung, 2005; Unti, 1997). As mentioned in the "Planning for Adequate Staff" section, it is important that school staff are educated about the vaccination program. Educated school staff are able to answer questions from parents and others about the program, and are more likely to emphasize the importance of vaccination and provide vaccination-related lessons to students (Tung, 2005; Boyer-Chuanroong, 1997). After-school teacher workshops have been used as a method of educating school staff (Boyer-Chuanroong, 1997; Unti, 1997; Goldstein, 2001).

## Frequently Asked Questions

A frequently asked question (FAQ) fact sheet is a useful tool to educate parents, teachers, school staff, and other community members about the specifics of the SLV clinic, as well as influenza in general. FAQ fact sheets can be included with other information being disseminated about the SLV clinic. These FAQ can also be added to health department, department of education, and school websites. Frequently asked questions about influenza and the influenza vaccine can be found on CDC's influenza website. A list of possible FAQ about the specifics of the SLV are listed below, but are not meant to be inclusive. FAQs will differ by SLV program.

- Why are school children being offered influenza vaccine at the school?
- When will the vaccine be given?
- Can our entire family get the vaccine at the school?
- What do I have to do to make sure my child gets the vaccine?

- What if my child is absent when the vaccine is given?
- Who will give the vaccine to my child?

## Informing and Enlisting the Support of Health Care Providers

In the U.S., children are vaccinated primarily in their pediatrician's or family doctor's office (Groom, 2007). Because the idea of vaccinating children at school may be unfamiliar to some parents/guardians, there may be reluctance to consent to influenza vaccination at school. Parents/guardians may seek the advice of others, including their child's health care provider (Woodruff, 1996). For this reason, the success of SLV programs also will be enhanced by enlisting the support of local health care providers, especially pediatricians, family practitioners, obstetrician/gynecologists (since they often serve as primary care providers for adolescent girls), and community health clinics. Partnerships with organizations such as the American Association of Pediatricians and the American Academy of Family Physicians may also add to the success of the SLV program and assist in gaining support from local physicians. Attached is a template letter to providers. Having mechanisms in place to disseminate vaccination information to healthcare providers will also help gain backing from local health care providers.

Hopefully, most providers will be supportive of the SLV clinics, but some may be concerned about vaccinations occurring outside of their offices, especially with regard to keeping their patient records up-to-date and having adequate information in case a patient seeks care for a possible vaccine-related adverse event. The need to conduct SLV programs to ensure children are vaccinated in a timely manner can be explained given the likelihood that providers will be busy treating ill patients. Keeping providers informed about planned SLV clinics also will help them estimate how much influenza vaccine they will need to order for their own patients.

## Preparing Forms and Letters to Provide to Parents / Guardians

The following are suggestions on the development of materials that should be delivered – via the child, mail, and/or email - to parents/guardians to inform them of the planned SLV clinic and solicit their permission to vaccinate their child. Each of the following materials should be translated and available in various languages, as locally appropriate.

### Letter to parents/guardians:

Among materials provided to parents/guardians should be a letter announcing that influenza SLV clinics will be offered at their child's school. Typically, this letter is sent out as a cover letter to accompany other materials, including the consent form, information about the vaccine, and when the SLV clinics are scheduled to occur. Such a letter also could be sent well in advance of the planned SLV date, perhaps even before vaccine is available in the area.

The letter to parents/guardians should include:

1. an explanation about why influenza vaccination is recommended for their children,
2. an announcement that influenza vaccine will be offered at the school, along with the clinic date(s) for both doses (if a second-dose clinic is planned and dates are possible to determine),
3. a request for parental consent, and
4. contact information in case parents/guardians have questions or concerns.

## Parental Consent Forms

The requirement to seek parental consent prior to vaccination, and the exact format and elements that must be included on a standard consent form, generally are not governed by federal law or regulation. Instead, requirements for informed consent are legislated or regulated by each state or jurisdiction, including the circumstances under which minors can consent to their own medical treatment. If planning on obtaining advanced consent, planners should discuss this approach with state and local legal advisors before deciding to implement it. Planners also should consider whether state/local law would require separate consents for administration of each dose of a two dose vaccine series.

Attached are three templates that SLV program planners may use as starting points for developing consent forms in accordance with applicable state and local laws and requirements. These template consent forms can be modified to conform to state and local requirements. As some influenza SLV programs do not offer second doses of influenza vaccine, these consent forms were developed for programs administering only one influenza vaccine to students. If a second dose of influenza vaccine will be offered, additional information about influenza vaccination histories may need to be collected.

While consent to be vaccinated is generally not regulated by federal law, federal law (as well as state law) may regulate the vaccinator's use or disclosure of individually identifiable health information regarding the child.

The first template consent form is designed for the injectable formulation of the vaccine, the second template consent form is designed for the intranasal formulation of the vaccine, and the third form is designed for both the injectable and the intranasal formulations. The choice of which consent form(s) to distribute to parents/guardians will depend on which vaccine formulation (live-attenuated intranasal vaccine [LAIV], inactivated injectable vaccine, or both) will be offered at the SLV clinic.

See the Template Consent Forms:

- Template Consent Form for Use With Intramuscular, Injectable Formulation of Vaccine
- Template Consent Form for Use with Live, Attenuated, Intranasal Formulation of Vaccine
- Template Consent Form for Use With Both the Intramuscular, Injectable Formulation and Live Attenuated, Intranasal Formulation of Vaccine

Below are notes about each section on the template consent forms:

**Section 1**

Information about child to receive vaccine: This section includes suggestions for collecting personal and demographic information.

**Section 2**

Screening for vaccine eligibility: This section includes standard vaccination eligibility screening questions for either the injectable or both injectable and intranasal formulations of the vaccine.

**Section 3**

Consent: This section includes a statement and signature line for parents/guardians to consent to or decline vaccination on behalf of their child. Also, planners may consider including an option for parents/guardians to select the type of vaccine (e.g., intranasal, injectable, or no preference) they prefer be given to their child with a statement that the preference will be honored depending on vaccine availability and the child’s eligibility. Note that state laws vary regarding whether one parental signature will suffice for both doses.

**Section 4**

Vaccination record: This section includes suggestions for collecting information regarding the vaccine and its administration.

SLV program planners may also want to include a section for consent or authorization for disclosures of certain vaccination, medical, personal, and/or demographic information. Student information contained in the vaccine consent form may be protected by state or federal privacy laws or regulations. Requesting such authorization may be recommended or necessary, depending on local needs and/or laws such as the Family Educational Rights and Privacy Act (FERPA) or the Health Insurance Portability and Accountability Act (HIPAA).

The following are examples of authorizations that could be sought by SLV program planners including a statement with a request for a parental signature on the consent form:

- The release of information to public health authorities (e.g., for entry into an immunization registry for influenza reporting requirements)

- The release of information to the child's health care provider (e.g., for inclusion in the child's health care record)

The entity conducting the vaccination program is responsible for only using and disclosing a child's health information consistent with applicable laws. For example, the entity should know whether it is subject to the HIPAA Privacy Rule, which only applies to certain health care providers, to health plans and to health care clearinghouses, to FERPA, which only applies to educational agency or institutions receiving Department of Education funding, and/or to other Federal or state laws.

Entities subject to the HIPAA Privacy Rule may use or disclose a minor's health information with the signed authorization of the parent or a guardian with authority to make health care decisions for the child using a form that meets HIPAA requirements or without such authorization for treatment purposes and certain public health and other purposes. (Note: FERPA and HIPAA issues are discussed below under "Legal Issues").

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### Timing and Procedures on Obtaining Consent

State and local planners may consider distributing consent forms to parents in advance of influenza vaccine availability. The benefits of such a procedure, if determined to be legally viable and feasible in the jurisdiction that will be offering influenza SLV clinics, are that vaccine may be expeditiously given to consented children as soon as it is received by the vaccinator, and planners may be better able to plan for adequate staff, vaccine, and supplies.

To provide parents/guardians with information on which to base their consent decision, parents/guardians could be given Influenza Vaccine Information Statements (VIS), which describes the best current understanding of the expected risks and benefits of the influenza vaccines (see VIS for the inactivated, injectable formulation of the vaccine and VIS for the live, attenuated intranasal formulation of the vaccine). Along with a cover letter (see Template Letters Seeking Advanced Consent for Vaccination and Template to Alert Parents to Upcoming Planned Clinics). To document their consent decision, parents would also need be given an appropriate consent form to complete and return to the school (see Template Consent Form for Use With Intramuscular, Injectable Formulation of Vaccine, Template Consent Form for Use with Live, Attenuated, Intranasal Formulation of Vaccine, and Template Consent Form for Use With Both the Intramuscular, Injectable Formulation and Live Attenuated, Intranasal Formulation of Vaccine).

If parental consent for vaccination is obtained substantially in advance of the time that the vaccine is to be administered to the child, a mechanism must be provided for the parent/guardian to withdraw consent prior to the time of vaccination, if desired. A mechanism should also be provided for a parent/guardian who initially declines to give consent for his/her child to be vaccinated to subsequently change that election and give consent for the child to be vaccinated. Additionally, if it is anticipated that LAIV will be offered, plans should be in place to confirm that the child has not received another live vaccine (e.g., varicella or measles, mumps, rubella [MMR] vaccines) within four weeks of the SLV clinic.

If planners decide to pursue consent substantially in advance of the time that the vaccine is to be administered to the child , as described above, an informational packet also could be sent slightly in advance of the clinic (e.g., two or three weeks in advance). This procedure could serve to announce or remind parents of the clinic date, provide an official VIS form for those who have not received one, and remind parents/guardians of mechanisms to change their consent status.

Planners should discuss this approach with state and local legal advisors before deciding to implement it. Planners also should consider whether state/local law would require separate consents for administration of each of a two dose vaccine series.

Important information about the use of the template consent form is provided above. Please also refer to the section below on "Legal issues" for important information on liability, licensing, FERPA, and HIPAA.

## Vaccine Information Statements

Vaccine Information Statements (VISs) are information sheets produced by the CDC that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. They also include information about indications and eligibility for each vaccine. An appropriate VIS (depending on which formulation of influenza vaccine is being offered–intranasal or injectable) should be included among materials provided to parents/guardians before and after vaccine administration.

## Maximizing Participation in the SLV Program

A variety of strategies for maximizing participation in SLV programs have been successfully implemented in past SLV programs. These strategies are summarized below.

## Consent Form Dissemination, Collection, and Follow-Up

Consent forms and other SLV informational materials can be provided to parents/guardians using a variety of methods. For example, the materials can be sent home with students after having been distributed in class, sent to parents/guardians via US mail along with registration materials at the beginning of the school year, provided at registration or other school events, or posted on-line. Sending information packets home with students is common and appears to be effective relative to sending the information home via US mail (IZ Xtreme; El Amin, 2009). Schools also should consider making consent forms available on-line, either through the school website (if available) or via email (schools and/or parent organizations may have pre-established list serves for students' families) (Boyer-Chu, 2008; NACCHO School-located Influenza Immunization School Kit). Additionally, high schools might want to make consent forms available on-site for eligible students who do not require parental consent (e.g., students aged 18 years or older) (NACCHO School-located Influenza Immunization School Kit).

Limited data suggest that return rates are higher when teachers (rather than nurses or other school staff) are responsible for collecting consent forms (Tung, 2005). To facilitate follow-up, schools may consider setting an absolute deadline for return of consent forms (Wilson, 2001).

If resources are available, school staff should attempt to follow up with students who do not initially return the forms (Boyer-Chuanroong, 1997). For this reason, consent forms should include an option for the parent/guardian declining vaccination so that school staff can easily identify students who have not returned consent forms and distinguish them from students whose parents/guardians declined vaccination. Also, including a "decline" option allows incentives (see below) to be based on the total number of forms returned, regardless of whether parents/guardians consented to or declined vaccination.

### Incentives

Student incentives can motivate students to return completed parental consent forms (Boyer-Chuanroong, 1997). Individual incentives for students who return completed consent forms or peer or group incentives for classes with a high proportion of students who returned completed consent (e.g., increased class recess time), may be considered (Boyer-Chuanroong, 1997; Uniti, 1997; Guajardo, 2008; Wilson, 2001; NACCHO School-located Influenza Immunization School Kit.)

A randomized controlled study of different types of incentives found that peer or group incentives were more effective than individual incentives (Unti, 1997). To reduce or eliminate costs associated with providing student incentives, schools may consider approaching local merchants or community organizations for non-food-related donations, coupons, or gift certificates (Boyer-Chu, 2008).

Because teacher support has been identified as an important factor for maximizing participation in SLV programs (Tung, 2005; Goldstein 2001), when resources are available, teachers who actively participate in the vaccination program could be provided with appropriate incentives (Boyer-Chuanroong, 1997; Goldstein, 2001; Cassidy, 1998). A simple note expressing appreciation may also be an effective reward

(Boyer-Chuanroong, 1997). In addition, it may be necessary to consult with local union representatives if an incentive system has an impact on staff members' rights under a collective bargaining agreement.

As mentioned above, if planners decide to use incentives, they should be based on the number of consent forms returned complete, regardless of whether parents consented to or declined vaccination. Thus, in order to use incentives, consent forms must include an option for parents to either consent to or decline vaccination (see parental consent form discussion and templates in the section on "Preparing Forms and Letters to Provide to Parents/Guardians").

## SLV Clinic Day Logistics

Published guidelines for setting up large-scale vaccination clinics can be found on CDC's influenza website. These guidelines were not developed specifically for influenza SLV clinics. However, most of the suggested approaches are relevant, especially to SLV clinics held during non-school hours. Additional considerations apply to SLV clinics held during school hours.

These challenges, along with tips and examples of how to manage them, are outlined below:

### For SLV clinics held during school hours:

- Rules on who may be present in the school building during school hours may vary. Communicate well in advance about these issues and plan accordingly. Additional security staff to monitor safety and help with traffic flow may be necessary.
- Since parents/guardians may not be present when students are vaccinated, processes need to be in place to ensure that only children for whom parental consent was obtained are vaccinated. This process of confirming the identity of children is easiest if school staff (e.g., teachers and school nurses) are overseeing the process.
    - Placing labels and/or name tags on children (usually younger students) can help reduce the risk of immunizing the wrong students (NACCHO School-located Influenza Immunization School Kit), although monitoring is suggested as these identifiers can be exchanged by children.
    - Asking multiple questions in addition to the child's name (e.g., parent/guardian names, street address) may be helpful.
- If both types of influenza vaccine are being offered at the SLV clinic, a mechanism needs to be in place that ensures children get the appropriate vaccine. This can be done by color coding the consent forms for each type of vaccine or making sure vaccinators are assigned to administer only one type of vaccine.
- Processes need to be in place for orderly vaccination of children. Staff will be needed to escort students to and from the clinic site.
    - Often, children are escorted classroom by classroom. For older students who change classrooms throughout the day, it may be helpful to focus on one particular class that is attended at some point by most or all students (e.g., Language Arts/English)
- Despite some parents/guardians providing consent for their child to be vaccinated, it may not be possible to vaccinate the child on clinic day for reasons such as illness, child refusal, or discovering a contraindication. In this case, it is essential that parents/guardians are informed that the child was not actually vaccinated. This could be accomplished by returning a form to parents/guardians via the child or via U.S. mail, sending the parent an email message, and/or calling the parent on the telephone. It may be helpful to designate one SLV clinic staff member to be in charge of this important task.

## Materials to Send Home with Students Post-Vaccination:

An appropriate VIS (depending on which formulation of influenza vaccine is being offered–intranasal or injectable) should be provided to parents/guardians after vaccine administration. Planners may also wish to consider distributing influenza vaccination record cards to vaccinees (e.g., to parents via vaccinated

children). Information can be recorded on these cards about the vaccine provider, lot number, manufacturer, etc., which can be shared with the vaccinee's primary health care provider. Information can also be recorded on the card about the potential need for a second dose and what to do in case of a possible adverse event.

## Administering Vaccine and Preventing, Managing, and Reporting Possible Vaccine-related Adverse Events

Please consult the following links for publications that provide guidance on administering vaccine and preventing/managing adverse events, including syncope, which is most common in adolescents: (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm and http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5717a2.htm).

Health care providers and parents are encouraged to report clinically significant adverse events after influenza vaccine or any vaccine to the Vaccine Adverse Event Reporting System (VAERS).

A report should be submitted even if the reporter is not certain that the vaccine caused the event. Reports may be filed securely online, by mail, or by fax.

## Vaccine Storage and Handling

Please consult the following links for information on vaccine storage and handling: http://www.usamma.army.mil/cold_chain_management.cfm, and http://www.usamma.army.mil/assets/docs/CCM%20Brief.pdf

## Recording, Reporting, and Tracking Vaccination Information

States may use their state immunization information system (IIS), or "immunization registries," to collect information on influenza vaccine administration. Reporting to the IIS is not a federal mandate, but may be required under state law. These systems may be an effective method to consider when electronically transmitting data to a public health department or creating a general data file to be kept by the vaccinator in case of a possible vaccine-related adverse event. Some IIS can produce a vaccination history which can be provided to the parent/guardian and subsequently shared with the child's health care provider. Providers may also be able to access the IIS directly to determine if their patient received influenza vaccine.

SLV clinic planners should consider mechanisms for dissemination of vaccination information to the medical home of participating students. This can be done by requesting the student's pediatrician's information on consent forms or other documents. The physician listed can then be sent information regarding their patient's vaccination once the SLV clinic has occurred.

Planners may also wish to consider distributing influenza vaccination record cards to vaccinees (e.g., to parents via vaccinated children). Information can be recorded on these cards about the vaccine provider, lot number, manufacturer, etc., which can be shared with the vaccinee's primary health care provider. Information can also be recorded on the card about when the second dose is needed and what to do in case of a possible adverse event.

## Legal Issues

States should consult their legal counsel for advice concerning the applicability of legal immunity, licensure, and privacy laws that may exist with respect to persons involved in vaccination programs. The paragraphs below provide general summaries of some relevant legal authorities, but the list is not intended to be exhaustive.

## National Vaccine Injury Compensation Program (VICP)

Qualified persons who administer seasonal influenza vaccines are afforded the liability protections of the National Childhood Vaccine Injury Act of 1986, as amended, because trivalent influenza vaccines are covered under the National Vaccine Injury Compensation Program (VICP). The VICP was established to compensate individuals suffering adverse events found to result from covered vaccines. More information about the VICP can be found at http://www.hrsa.gov/vaccinecompensation/. Specific information regarding the vaccine liability protections afforded to vaccine administrators can be found here.

## State and Local Government Immunity

Officials of state and local governments may also have "official" or "governmental" immunity under state legislation, municipal ordinances, or as otherwise provided for by common law. These laws may differ depending upon the level of government, the nature of the official function, the presence or absence of malice, and the degree of alleged negligence. In some instances, however, this immunity may only be provided to public officers while exposing their government employers to at least limited liability. Officials may wish to contact State and local legal advisors on these matters.

## Family Educational Rights and Privacy Act (FERPA)

FERPA is the federal law, administered by the U.S. Department of Education, which protects the privacy of student education records, including health records, maintained by educational agencies and institutions. The law applies to all educational agencies and institutions that receive funds under a program administered by the U.S. Department of Education. FERPA generally prohibits the disclosure, without prior written consent, of education records or personally identifiable information (PII) from education records to outside entities, although there are a number of exceptions to the requirement of prior written consent. (see: http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html).

The applicability of FERPA will vary based on who is conducting the school-located vaccination clinic as follows:

- If a public health department, or an entity acting on its behalf (e.g., a commercial community vaccinator with whom the public health department developed a contract), conducts the clinic and maintains the student's records, FERPA does not apply to the vaccination records because they are maintained by the public health department.
- If a school, school district, or an entity acting on its behalf (e.g., a commercial community vaccinator with whom the school or district developed a contract) conducts the clinic and maintains the student's records, FERPA applies to the vaccination records because they are maintained by the school or school district.
- If an entity, other than the public health department or the school/school district, conducts the clinic (e.g., a commercial community vaccinator not under a contract with the school or the public health department) and maintains the student's records, then FERPA does not apply to the vaccination records because they are not maintained by an educational institution or agency or a party acting for an educational institution or agency.

Under the FERPA regulations at 34 Code of Federal Regulations (C.F.R.) Part 99, many disclosures of PII from education records of students require signed and dated parental consent. However, when a student turns 18 years of age or attends an institution of postsecondary education, the signed and dated consent must be obtained from the student. 34 C.F.R .99.3 (definition of "Eligible student") and 99.5. The FERPA regulations provide that the prior written consent must specify the records to be disclosed, the purpose of the disclosure, and the party or class of parties to whom the disclosure may be made. 34 C.F.R. 99.30. For example, in the absence of a health or safety emergency, signed and dated consent is generally needed for a school to release PII from education records to public health authorities (e.g., for entry into an immunization registry) or to the child's health care provider (e.g., for inclusion in the child's health care record).

Certain disclosures may be made without prior written consent. 34 C.F.R. 99.31. For example, a disclosure may be made without prior written consent to other school officials within the educational agency or institution whom the agency or institution has determined to have legitimate educational interests (e.g., school officials may be informed that a student has the influenza virus and has been advised to stay at home; the disclosure is needed so that school officials can monitor whether that student nevertheless attends school or a school-related activity). 34 C.F.R. 99.31(a)(1). Additional information regarding disclosures in a health or safety emergency may be found at 34 CFR 99.31(a)(10) and 99.36.

## Health Insurance Portability and Accountability Act (HIPAA)

The HIPAA Privacy Rule provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes. The HIPAA Privacy Rule requires covered entities to protect individuals' health records and other identifiable health information by requiring appropriate safeguards to protect privacy, and setting limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.

In most cases, the HIPAA Privacy Rule does not apply to elementary or secondary schools because the schools either: (1) are not HIPAA covered entities; or (2) are HIPAA covered entities, but maintain health information on students only in records that are by definition "education records" under FERPA and, therefore, are not subject to the HIPAA Privacy Rule. If a person or entity acting on behalf of a school subject to FERPA, such as a school nurse that provides services to students under contract with or otherwise under the direct control of the school, maintains student health records, these records are education records under FERPA, just as they would be if the school maintained the records directly.

More information about HIPAA can be found at http://www.hhs.gov/ocr/privacy/ Joint Guidance on the Application of the Family Educational Rights and Privacy Act (FERPA) And the Health Insurance Portability and Accountability Act of 1996 (HIPAA) To Student Health Records can be found at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/hipaaferpajointguide.pdf

## Tools and Helpful Links

- CDC's Resources for Child Care Programs, Schools, Colleges, and Universities
- CDC's Division of Adolescent and School Health

Note; The following are non-governmental examples of useful websites. There are many others that may be find useful.

- National Association of County and City Health Officials' "School-Located Influenza Immunization School Kit"
- National Association of State Boards of Education publication, "How Schools Work and How to Work with Schools"
- National Association of School Nurses, Don't get sidelined by the flu: Influenza prevention and treatment education program

## Reference

Note; There are many others articles on influenza SLV clinics that may also be useful.


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