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If you would like to suggest future topics or articles please contact the ImmuneNews Editor at (614) 466-4643.



Ohio Department of Health

Ask the Expert

What are the new school immunization requirement changes?

The Director's Journal Entry that details the immunizations required for school enrollment in Ohio has been revised to more closely reflect recommendations of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). These changes for the 2010-2011 school year include:

1. The requirement of a second dose of Varicella for entering kindergarteners.
2. The requirement that a dose of polio be administered on or after the 4th birthday for entering kindergarteners.
3. The requirement of a Td/Tdap dose for entering 7th graders.

These requirements are all progressive, meaning after the 2011-2012 school year, all entering kindergartners and all 1st graders (whether retained, transferred or newly entering) will need to meet the first and second requirements, and 7th and 8th graders will need to meet the third requirement. The Director's Journal has been updated and may be found at: <http://www.odh.ohio.gov/ASSETS/DDFE6F33D17E491A8487092FFC24406E/djourn10.pdf>



VARICELLA

This requirement assures that all children entering kindergarten have a second dose of varicella. The first dose of varicella vaccine must be administered on or after the 1st birthday and must be given at same time or at least 28 days after receiving other live virus vaccines such as MMR.

POLIO

This requirement assures that the the final dose of polio vaccine is administered on or after the child's 4th birthday, regardless of the number of previous doses. The Advisory Committee on Immunization Practices (ACIP) and American Academy of Pediatrics (AAP) guidelines, indicate that at least three doses of polio are needed if all IPV is used and, the last dose must be given on or after age 4. Most children will receive four doses due to combination vaccines. There are several examples provided below to help guide you:

Expert Cont'

from P.1

1. Child presents with no doses of IPV: child needs at least three doses for kindergarten entry; the last dose must be after age 4, and the minimum vaccine schedule should be: now, 4 weeks, 6 months.
2. Child presents with 1 dose of IPV: child needs at least two doses for kindergarten entry; the last dose must be after age 4, and the vaccine spacing should be: now, 6 months.
3. Child presents with 2 doses of IPV; child needs at least one dose for kindergarten entry; the last dose must be after age 4, and the 3rd dose should be 6 months from the 2nd.
4. Child presents with 3 doses of IPV: if the 3rd dose was given prior to age 4, then one additional dose is required. The 4th dose should be given at least 6 months from the 3rd dose. If the 3rd dose was after age 4, then the child meets the minimum requirement for entry. No further doses are required for entry into kindergarten.
5. Child presents with 4 doses of IPV; if the 4th dose was given prior to age 4, then a 5th dose is required for entry. If the 4th dose was given after age 4, then the child meets the requirement for entry and no further doses are required.
6. Child presents with 5 doses of IPV; if the 5th dose was given prior to age 4, then a final dose is required for school entry. If the 5th dose was given after age 4, then the child meets the requirement for entry and no further doses are required.

Tdap/Td

This requirement provides a booster dose to protect adolescents against pertussis. Many states, including Ohio, experience ongoing outbreaks of pertussis. There are numerous boosters/vaccines recommended for adolescent age children, but many adolescents do not receive these vaccines. A Td can be substituted for Tdap if: 1) the child has an allergy to pertussis vaccine; 2) the child previously received a dose of Td between 7-10 years of age; or 3) the child could not receive Tdap because it was not readily available.

If an adolescent received a Td, ODH encourages all health care providers to educate caregivers on the importance of receiving a booster of Tdap when the next booster is due. ACIP does not define an absolute minimum amount of time between a dose of Td and Tdap, but a recommended 5-year interval is encouraged due to possibility of adverse local reactions. The ACIP indicates that the benefits of protection against pertussis must outweigh the risk of local adverse reactions if 5 years have not elapsed.

For more information please call the ODH Immunization line at 800-282-0546.

Vaccine Information Statements



Vaccine Information Statements (VISs) are brief, one page information sheets drafted by the Centers for Disease Control and Prevention (CDC) that outline the benefits and risks associated with a certain vaccine.

Federal law states that all patients, or their parents/ guardians be given a copy of the proper VIS whenever a vaccine is given. This law applies to both public and private sector providers, and is the result of the National Childhood Vaccine Injury Act of 1986. The following VISs must be given out at the time of vaccination: DTaP, Td/Tdap, Hepatitis A, Hepatitis B, Hib, HPV, Influenza, Meningococcal, MMR, Pneumococcal Conjugate, Polio, Rotavirus and Varicella. Additionally, it is recommended that VISs also be given for these vaccines: Anthrax, Japanese Encephalitis, Pneumococcal Polysaccharide, Rabies, Shingles, Smallpox, Typhoid, and Yellow Fever.

Obtaining current VISs and providing them to patients is easier than ever before. With concerns

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Statements Cont'

from P.2

about conserving resources, many offices have found inventive ways to comply with the law and reduce wasted paper. Offices may choose to offer the VISs to patients in the following ways:

- ⦿ Offer the patient a printed copy of the appropriate VIS to read during their appointment, as well as a copy to take home with them.
- ⦿ Offer the patient a copy of the appropriate VIS to review before the visit. The provider may give patients a printed copy at prior visits or give instructions on how to obtain the VISs on the internet.
- ⦿ The provider may offer the patient a permanent copy to read during the visit or the patient may be directed to an office computer to review the VIS online.
- ⦿ Encourage patients to take a copy of the VIS home with them to review, as it may be helpful in the event of an adverse event or identifying the correct schedule for the vaccine.
- ⦿ The VIS may be enhanced by discussion, videos, with additional supporting documentation, or in any other way the provider sees fit to convey the information contained on the VIS*.

**Please note providers are not permitted to change the VIS or produce their own VISs in place of the CDC's documents.*

It is important to note that VISs are not informed consent sheets, and to that end, there is no Ohio law that requires an informed consent form be collected from the patient or guardian. Once the VIS is given to the patient or guardian, the provider must record the following information on the patient's vaccine record:

- ⦿ Edition date of the VIS; this is typically found in a bottom corner of either the front or the back of the sheet.
- ⦿ Date the VIS is being provided to the patient.
- ⦿ Name, office address, and title of the person administering the vaccine.
- ⦿ Date the vaccine is administered.
- ⦿ Name of vaccine manufacturer.
- ⦿ Vaccine lot number.

VISs are updated only when necessary, for example when ACIP recommendations change. It is important to check VIS dates regularly. You can find the most updated versions on www.cdc.gov/vaccines or www.immunize.org/vis. You can order hard copies at www.cdc.gov/vaccines/pubs. VISs may be obtained in over 30 different languages. The CDC contact center can be reached at **1-800-CDC-INFO**, and the ODH Immunization program is at **1-800-282-0546** if you would like further information about Vaccine Information Statements.

The Statewide Immunization Information System, ImpactSIIS 2.0, is here!



Public and private providers throughout Ohio use ImpactSIIS to retrieve immunization records, manage vaccine inventory, administration, and a host of additional functions. Providers recognize ImpactSIIS to be more than just a repository of immunization data. The talents of Ohio providers and their continued usage are recognized as a key ingredient to making our state the third ranked state in the nation for immunization rates. The Ohio Department of Health (ODH) has successfully developed and implemented a more robust, streamlined and stable application to help in daily vaccine tracking.

ImpactSIIS will provide shared comprehensive immunization records, timely news, information, inventory management, automated reminder/recall notifications, daycare/camp forms, and lead test results

Improvements to the current system include:

- ⊙ Improved patient search engine using “fuzzy search” technology.
- ⊙ Segregation of vaccine inventory reconciliation and VFC accountability.
- ⊙ Streamlined approach to inventory transaction entry.
- ⊙ Faster and more stable VFC accountability utilizing ‘save as you go’ technology.
- ⊙ Practice specific patient identifiers.
- ⊙ Updated vaccine schedule algorithms.
- ⊙ Streamlined historical shot data entry.
- ⊙ Portable reports with the ability to export directly to MS Excel.
- ⊙ Removal of third party software dependencies, elimination of JAVA compatibility and caching issues.
- ⊙ Freedom to choose your internet browser.
- ⊙ Improved patient de-duplication.

Along with the above list of improvements, the system will continue to provide shared comprehensive immunization records, timely news, information, inventory management, automated reminder/recall notifications, daycare/camp forms, and lead test results.

Recorded webinar trainings are available for viewing. The webinar sessions can be accessed via the ImpactSIIS Resource Center Help Link in the upper right portion of the ImpactSIIS homepage. Providers can use the following link, <http://64.56.35.228/OHIOMarketing/impactNews.asp>, to access the Resource Center. The Resource Center has a plethora of information including issues currently being resolved, issues that have been fixed, tips and tricks, helpful resources, and frequently asked questions. In addition, providers can request onsite training and enrollment, receive SSO conversion instructions, and even get the weather. All users are encouraged to visit the resource center.

As always, personalized support from ImpactSIIS regional trainers is available upon request. Please call **1-866-349-0002** for questions and support.

Prefilling Syringes

Prefilling syringes is a practice that is strongly discouraged by the National Center for Immunization and Respiratory Diseases (NCIRD), the Center for Disease Control and Prevention (CDC), as well as the Ohio State Board of Pharmacy. This practice is advised against for several reasons, including concerns about administration errors, storage and handling.

Once a vaccine is drawn up, it is difficult to identify the type of vaccine contained within the syringe. The medication administration guidelines attempt to address this issue by stating only the individual who is administering the vaccine should prepare the medication. If there is an event in which some doses may be drawn up (for example, a large flu clinic) it is essential that the vaccines that have been drawn into the syringe are appropriately labeled. This may be done by utilizing a color coded label system, preprinted labels, marking the tray that the vaccine is being kept on or keeping syringes with the appropriate vial.

Another problem that may be created by prefilling syringes is vaccine wastage. The act of prefilling syringes may lead to storage issues in inappropriate conditions that might compromise vaccine effectiveness. Similarly, since there is no data available regarding the stability of vaccines that have been prefilled, it is possible that vaccine potency may be reduced as a result of this practice.

Most syringes are intended for immediate use after filling as opposed to vaccine storage, as a result there may be the risk of bacterial contamination and growth should these syringes be used as storage units. Syringes that are not prefilled in single-dose vials from the manufacturer do not contain the bacteriostatic components necessary for safe storage. Please note that MMR, varicella, and zoster vaccines should NEVER be reconstituted and drawn up before needed. These vaccines are live virus vaccines and are unstable. They will begin to weaken as soon as they are reconstituted with diluents.

For mass vaccination clinics, such as flu clinics, staff may be able to prefill a limited amount of vaccine in order to facilitate efficiency. It is important that several practices are followed if the clinic chooses to use predrawn vaccine. First, only one type of vaccine should be used. If additional formulations are needed, please allow for administration stations to be set up for each type of vaccine used. Second, the vaccine should only be drawn up once the clinic site is set up. Do not draw up vaccine prior to arriving at a clinic site. Third, only transport vaccine in the packaging in which it was received. Fourth, always maintain the cold chain; most vaccine must be stored at 35° to 46°F (2° to 8°C) in a refrigerator or an appropriate vaccine transport container. Additionally, each worker at the clinic may draw up a small amount of doses to meet the initial demands of the clinic. It is important to observe patient flow in order to avoid drawing up too many doses, which may then be wasted. Finally, once the clinic day has ended all remaining vaccine that has been predrawn MUST be discarded— under no circumstances may it be used on any other day.

By complying with the expectation to draw only vaccine that is needed, utilizing prefilled syringes from the manufacturers when possible, and following the guidelines listed above; clinics can be sure they are taking appropriate steps to ensure both patient safety and quality control of the vaccine.



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HPV Vaccine Updates

In October, 2009, the Food and Drug Administration (FDA) approved the quadrivalent human papillomavirus (HPV) vaccine (HPV4; Gardasil, manufactured by Merck) for use in males aged 9 through 26 years for prevention of genital warts caused by HPV types 6 and 11. HPV4 provides protection against HPV types 6, 11, 16 and 18; types 6 and 11 cause about 90 percent of all cases of genital warts and nearly all cases of recurring respiratory papillomatosis. In addition, types 16 and 18 are known to cause cervical, vaginal, penile and other anogenital cancers. In response to the FDA's approval, the CDC's Advisory Committee on Immunization Practices (ACIP) issued provisional approval of the use of HPV4 vaccine for males, as well.

The ACIP continues to recommend the use of HPV vaccines for females 9 through 26 years of age for the prevention of precancers and cancers associated with types 16 and 18, as well as for genital warts associated with types 6 and 11. There are approximately 340,000 new cases of genital warts diagnosed in the United States each year. Incidence is highest in females 20-24 years of age and males 25-29 years of age and results in an estimated economic burden in excess of \$220 million each year.

Cervarix, a bivalent human papillomavirus (HPV2) vaccine, manufactured by GlaxoSmithKline, was approved by the FDA for administration to females aged 10 through 25 years for prevention of precancers and cancers caused by HPV types 16 and 18 effective October 2009. Following this approval, the ACIP issued a recommendation to begin using Cervarix.

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Ohio Billables Project

The Ohio Department of Health was selected as one of fourteen recipients nationwide to receive American Recovery and Reinvestment Act (ARRA) funding to work on a billables project. The billables project will explore the feasibility of all local health departments (LHDs) in Ohio participating in third party billing for vaccine services. The goal of the project is to create an action plan LHDs can implement to bill private insurance for immunization services rendered to privately insured patients.

Currently, Ohio is two-tiered for three vaccines: Hepatitis A, HPV, and Rotavirus. In the two-tiered system, children who are not eligible for the Vaccines for Children program are unable to receive certain ODH-supplied vaccines free of charge at LHDs. This system results from reduced state funding coupled with increases in both vaccine cost and the total number of recommended vaccines. The two-tiered system limits access to vaccines for privately insured children whose families cannot



afford to receive vaccine through their primary care provider due to high co-pays or deductibles. A statewide billing system will potentially decrease the need to maintain Ohio's two-tiered system for publicly purchased vaccines, and improve low-cost vaccine availability.

The first step of the project is data collection. This summer 13 college interns were hired to administer a survey to patients utilizing immunization services at all LHD immunization clinics. Ultimately, the survey will help to determine the proportion of patients utilizing immunization services who are privately insured. Information collected from this survey along with information gathered from LHDs regarding billing capacity will be utilized in a cost benefit analysis. If it is found that implementing a statewide billing system would be cost beneficial, future steps include negotiating contracts with insurance companies, developing a process to successfully bill these companies and implementing the billing system in LHDs. In addition, a billables stakeholder group has been formed to hold discussions, make vital decisions, and assist in the progress of the project. This group is composed of representatives from key groups including: LHDs, Medicaid, and private insurance companies. The group will be instrumental in guiding the future steps of the billables project and in formulating the required action plan.

The billables project serves as a means to improve reimbursement in the public sector. If private insurance companies provide coverage for vaccines given to their plan patients by LHDs, requiring reimbursement will provide additional revenue by which the state will be able to offer an increased number of vaccines to children. Ultimately, this means more vaccine will be available to protect more children against vaccine preventable diseases.

Vaccine Storage and Handling

Proper storage and handling of vaccines is essential to protecting patients from vaccine preventable disease.

Vaccines that are not stored correctly cannot be considered viable or reliable products. Vaccine that is stored improperly and administered to children or adults will result in an inadequate immune response. Storage and handling is also important in order to prevent the wastage of increasingly expensive vaccines. Immediately upon arrival, vaccines should be placed in either the refrigerator or freezer according to manufacturer instructions. Refrigerator temperatures are to be maintained at 35-46 degrees Fahrenheit or 2-8 degrees Celsius while freezer temperatures must not be above 5 degrees Fahrenheit or -15 degrees Celsius.

Vaccines need to be stored in the center of the shelves away from vents to allow continuous air circulation. Vaccine should not be placed in doors or drawers, such as vegetable bins or on the floor of the refrigerator. Do not place vials directly on glass shelves. Large bottles of water in the refrigerator and ice packs in the freezer help maintain stable cold temperatures in case of a power failure or frequently opening doors. Food and beverages should not be stored along with vaccine. Keep vaccine vials in their boxes with the earliest expiration dates in front to be sure those are used first. Be sure to never use outdated vaccines. New in 2010, the Centers for Disease Control and Prevention (CDC) is requiring all Vaccines for Children (VFC) providers to eliminate the use of dorm-style refrigerators as long term storage units for VFC supplied vaccine. Dorm-style refrigerators may be used to store a clinic's single day supply of refrigerated vaccine if vaccines are returned to the main refrigerator at the end of the day. (The freezer compartments of these units are not acceptable for temporary storage of varicella).

The CDC defines a dorm-style refrigerator as a small combination refrigerator/freezer unit outfitted with one external door, an evaporator plate (cooling coil) which is usually located inside an ice-maker compartment (freezer) within the refrigerator, and is void of a temperature alarm device. A dorm-style refrigerator's temperature control sensor reacts to the temperature of the evaporator rather than the general air in the storage compartment. When the compressor is on, the evaporator cools to lower the temperature in the refrigerator, in most cases to below 0 degrees Celsius. Storage of VFC vaccines in refrigerators that are designed for use in small household spaces such as dorm rooms are never acceptable for permanent storage of VFC vaccines. Permanent storage of the vaccine supply is to be maintained in the unit 24 hours a day/7 days a week.

On February 3, 2010, the Ohio Department of Health (ODH) notified all VFC providers about the transition away from the use of dorm-style refrigerators. It is essential that vaccines be stored appropriately in an attempt to decrease the opportunity for vaccine loss due to unacceptable storage conditions. ODH has been working with VFC providers to help transition away from these units. Effective July 1, 2010 any provider not in compliance with this directive may be suspended from the VFC Program until acceptable storage units are in place. ODH will continue to work with providers to verify this transition has occurred.

For more information please contact your ODH consultant or refer to one of the following CDC websites:

<http://www.cdc.gov/vaccines/programs/vfc/projects/faqs-doc.htm>

<http://cdc.confex.com/cdc/nic2010/webprogram/Session10707.html>



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