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Ohio Department of Health

Vaccinating the Underinsured

In December 2008, Ohio implemented Vaccines for Children (VFC) delegation of authority. This will enable many underinsured Ohio children to be vaccinated in participating local health district clinics through the VFC program.

What is VFC delegation of authority? In the federal VFC entitlement language, federally designated rural health centers (RHCs) and federally qualified health centers (FQHCs) are the safety net of the VFC program, as these are the only facilities designated to serve underinsured children through the VFC program. Although there are a number of RHCs and FQHCs in Ohio, about half of Ohio's counties do not have an RHC or FQHC. RHCs and FQHCs do not have the capacity to immunize all underinsured children through the VFC program. Therefore, many state immunization programs are facilitating a process of allowing RHCs and FQHCs to delegate authority, meaning they deputize local health districts to immunize underinsured children through the VFC program. This is accomplished through an agreement that is signed by an RHC or FQHC and a local health district, which authorizes the local health district to administer VFC vaccine to underinsured children on their behalf.

The Centers for Disease Control and Prevention (CDC) defines the term "underinsured" for the purposes of the VFC program as those children who have health insurance, but coverage does not include vaccines. Children whose health insurance covers only select vaccines or caps the vaccine cost at a certain limit are categorized as underinsured; thus only eligible for VFC program benefits at an RHC or FQHC. Children whose health insurance covers the cost of vaccinations are not eligible for VFC program benefits, even when a claim for the cost of the vaccine and its administration would be denied because the plan's deductible had not been met.

Prior to the implementation of VFC delegation of authority, underinsured children could be vaccinated in local health district clinics in Ohio using vaccine purchased with other state and federal funding sources. Vaccine funding, however, has not increased as the number of recommended vaccines has increased. Therefore, there are several vaccines that cannot be purchased with federal and state funding, which means they are available only to VFC-eligible children. The result was that prior to VFC delegation of authority, underinsured children often could not receive some recommended immunizations such as rotavirus, hepatitis A and HPV vaccines. Now, all VFC-recommended vaccines are more accessible to underinsured children in Ohio.

The Tuscarawas County General Health District (TCGHD), an RHC, agreed to serve as a delegator for the VFC program for interested local health districts in Ohio. When the program was implemented in December 2008, the Ohio Department of Health (ODH) had received

Vaccinating Cont'

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signed agreements for 113 local health districts in Ohio. These 113 local health districts estimate serving nearly 7,000 underinsured Ohio children through VFC delegation of authority. ODH has talked with several additional local health districts that have future plans to participate in delegation of authority.

It is exciting that the partnerships between TCGHD, many local health districts and ODH will enable thousands of additional children to be immunized through the VFC program. To find out if a local health district in your area is vaccinating underinsured children through delegation of authority, please contact the ODH Immunization program at 1-800-282-0546 or call your local health district.

Hib Shortage Continues

In December 2007, a shortage of *Haemophilus influenzae* type b (Hib) vaccine began after Merck & Co., Inc. suspended production of two Hib conjugate vaccines, PedvaxHIB® (monovalent Hib vaccine) and Comvax® (Hib-HepB vaccine). With the suspension of these two vaccines the demand for sanofi pasteur's Hib vaccine, ActHIB®, exceeded the supply. Merck originally projected the return of its Hib vaccines to the US market by the end of 2008; however, later, Merck announced that neither vaccine would return to the market until late 2009. Merck identified the need for additional manufacturing changes as the reason for the delay.

After the initial notice of Hib vaccine shortage, the Centers for Disease Control and Prevention (CDC) recommended that providers defer the booster dose of Hib vaccine, scheduled for 12 – 15 months, for all children except those at increased risk for invasive Hib disease. Children considered to be at increased risk include those with asplenia, sickle cell disease, leukemia, other malignant neoplasms and American Indian and Alaska Native children.

Along with the deferral recommendation, the CDC limited the number of Hib doses that each state was allotted for the Vaccines for Children (VFC) program. So while sanofi pasteur stated it had sufficient Hib doses to cover a three-dose series, Ohio's allotment of ActHIB® at times only allowed some

VFC providers enough ActHIB® to administer the first two doses. Ohio's VFC providers are also waiting up to 11 weeks for their ActHIB orders to be filled.

The Ohio Department of Health's (ODH) Immunization program is encouraging providers to track children who had a deferred dose of Hib to facilitate a recall once the shortage has ended.

The extended shortage of Hib vaccine heightens the importance of Hib surveillance. *Haemophilus influenzae* (*H. influenzae*) is a class B (1) disease that must be reported to public health by the end of the next business day after the existence of a case, a suspected case or a positive laboratory result is known. Serotyping should be conducted on all isolates of children less than 5 years to determine if the disease was caused by *H. influenzae* type B. For additional information regarding *H. influenzae*, refer to the Infectious Disease Control Manual on the ODH Web site www.odh.ohio.gov.



VFC Vaccine Wastage Policy

Protecting Federal Tax Dollars

The Ohio Vaccines for Children (VFC) program now has a vaccine-wastage policy. Accountability for vaccine has become an essential requirement of the Ohio Department of Health (ODH) Immunization program and the VFC program. Vaccine is extremely costly and the Centers for Disease Control and Prevention (CDC) is requiring state VFC programs to take steps to account for the usage of VFC vaccine and reduce waste. Periodic vaccine shortages further illustrate the need to ensure doses are not wasted. As a result, ODH has adopted a vaccine-wastage policy and incorporated new language regarding this policy into the VFC Provider Enrollment Agreement for 2009.

For the purposes of the VFC vaccine-wastage policy, wasted vaccine is vaccine that is deemed as nonviable due to expiration, improper storage or erroneous discarding. The costs associated with wasted vaccine can be extensive. The cost to fully vaccinate a child through the VFC program has risen to more than \$1,000. The CDC allocates approximately \$80 million each year to vaccinate VFC-eligible children in Ohio. In light of this, working to conserve public vaccine dollars by minimizing wastage of vaccine is critical.



Additionally, there is concern that children who are immunized with wasted (nonviable) vaccine may not be adequately protected from vaccine-preventable diseases.

In the CDC's Feb. 8, 2002, *Morbidity and Mortality Weekly Report*, the Advisory Committee on Immunization Practices said, "Failure to adhere to recommended specifications for storage and handling of immunobiologics can reduce potency, resulting in an inadequate immune response in the recipient... If mishandled or expired vaccines are administered inadvertently, they should not be counted as valid doses and should be repeated, unless serologic testing indicates a response to the vaccine." So, in addition to costs associated with replacing nonviable vaccine, there are often costs associated with the need to revaccinate patients who were administered nonviable vaccine.

"Failure to adhere to recommended specifications for storage and handling of immunobiologics can reduce potency"

The VFC Provider Enrollment Agreement has always included a statement indicating the participating VFC provider agrees to comply with the requirements for ordering, vaccine accountability and vaccine management and understands that the responsibility for proper storage and handling of vaccine begins when delivery of the vaccine is accepted. Additionally, participating providers have, for years, agreed to document temperatures in the refrigerator and freezer at least twice each day and to store and handle the vaccine appropriately (see item No. 8 in the VFC Provider Enrollment Agreement). Beginning in 2009, a new item No. 9 was added to the Provider Enrollment Agreement that states, "I will cooperate with ODH to recall patients for revaccination if vaccine administered was nonviable or administered incorrectly. I will be required to replace wasted vaccine dose-for-dose, at my own expense."

Wastage Cont'

from P.3

The complete policy was mailed to all VFC providers in January. The most important message is that ODH Immunization program staff plan to continue to work with providers to ensure that vaccine wastage is minimized and children are immunized with viable vaccine, through strategies such as managing inventory and maintaining proper vaccine storage. Your immunization consultant can assist you in protecting vaccine by providing resources such as vaccine temperature recording logs and calibrated thermometers. Please contact your ODH immunization consultant directly or call the ODH Immunization program at 1-800-282-0546 with any questions regarding vaccine management, storage or wastage.

Eight City Immunization Survey

During the period 1989-91, the United States experienced a dramatic increase of measles disease, with over 51,000 cases and 123 deaths. The “measles resurgence,” as the increase was subsequently named, was unlike others in that children less than 5 years of age made up the most affected group (45 percent of cases). Many of the cases occurred among children living in large cities, including Chicago and Los Angeles. Immunization surveys among preschool-age children in these cities indicated that as few as 50 percent had received measles vaccine by their 2nd birthday, and that black and Hispanic children were less likely to have been vaccinated than white children.

In 1991, the Centers for Disease Control and Prevention performed a study in a number of large cities, including Cleveland, to ascertain the level of age-appropriate vaccine coverage for the series of four DTP, three polio and one MMR (4:3:1) vaccines. The survey was a school-based retrospective in 35 randomly selected schools, with 25 randomly selected students chosen in each school. The results indicated only a one-third of preschool children were fully vaccinated by age 2.

In an effort to determine preschool coverage in Ohio's other large cities ODH undertook surveys in seven additional cities (Akron, Canton, Cincinnati, Columbus, Dayton, Toledo and Youngstown). Also, in an effort to identify

areas with low series coverage, and to target federal Immunization Action Plan (IAP) dollars to areas of need, ODH also chose to survey schools in affluent suburban areas of the eight largest cities, and three rural counties (Defiance, Jackson and Seneca). This initial Eight City Survey took place in 1992, and repeated every four years. The last survey was conducted in 2008 and continues to use the 4:3:1 series.

During the period 1992-2008, coverage in the cities increased an average of 31 percent.

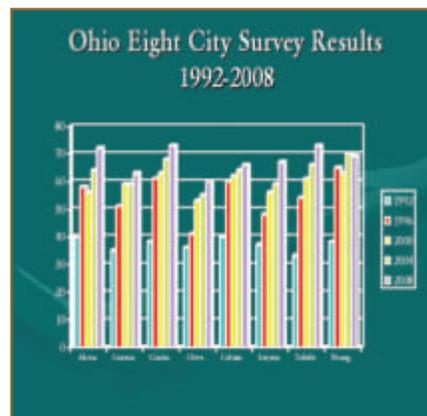
During the same period, coverage increased 33 percent and 30 percent in the suburbs and

rural counties, respectively.

The largest increase from one survey to the next occurred between 1992 and 1996. Coverage since then has increased only slightly or remained essentially unchanged.

While suburban children continue to have higher coverage than children

in cities and rural areas, no location has yet to achieve the 90 percent coverage level set by Healthy People 2010. In addition, disparities in coverage continue to exist between children living in Ohio's large cities, rural areas and affluent suburbs. This continues despite the existence of programs such as Vaccines for Children (VFC), which makes vaccines an entitlement for approximately 50 percent of infants in the state. Ohio's public and private immunization providers should continue to collaborate to improve immunization rates among Ohio's preschool children.



Ohio Statewide Immunization Conference

Embracing Change and Moving Forward

On Sept. 16-17, 2008, the Statewide Immunization Conference – Embracing Change and Moving Forward was held at the Crown Plaza hotel in north Columbus. Nearly 360 health professionals from around the state attended the two-day event. Attendees included local health department nurses, private provider nurses, physicians, academicians and school nurses. The event featured world-renowned plenary speakers

with expertise in the field of immunizations and infectious diseases. During the two-day conference, breakout sessions flanked the plenary sessions and provided information on a variety of immunization related topics such as Ohio’s statewide immunization registry, ImpactSIIS, Ohio’s Timely Immunization Schedule (OTIS), immunization coding and global immunizations.

The conference was not only an opportunity to hear from national and state experts but also a chance for local professionals to discuss their own experiences in hopes of learning from each other.

Alvin D. Jackson, M.D., director of the Ohio Department of Health (ODH), kicked off the first day of the conference with the presentation of AFIX and ImpactSIIS awards to providers, both public and private, from around the state for their achievements in immunizations. Immediately following the awards presentation, Katalin Koranyi, M.D., of Nationwide Children’s Hospital presented information regarding the incidence of pertussis in Ohio as well as changes in vaccine recommendations. Koranyi stressed the key to controlling and decreasing pertussis disease is to improve immunization coverage rates in both children and adolescents, improving testing, surveillance and reporting.

Next on the agenda was Dr. Andrew Kroger of the Centers for Disease Control and Prevention, National Center for Infectious Respiratory Diseases. Kroger spoke about adolescent vaccines and discussed why immunizations are a significant component of adolescent health care. A childhood immunization update was the third plenary given by Dr. Michael Brady.

The first day ended with a round of breakout sessions that include a presentation of OTIS. ODH in conjunction with the Ohio Chapter of the American Academy of Pediatrics, designed OTIS to



Survey Cont'

from P.4

Immunization rates can continue to improve if providers: 1) re-examine their immunization procedures, 2) identify and reduce “missed opportunities” to immunize, 3) develop or improve their immunization recall/reminder systems to notify parents/guardians when their children are due for shot(s), and 4) measure the effectiveness of their immunization practices by conducting appropriate and periodic coverage assessments. The Statewide Immunization Information System (SIIS), ImpactSIIS, is an immunization registry that helps to accomplish the above items. ImpactSIIS is available to any interested health care provider, at no cost.

Information on ImpactSIIS is available through the ODH Immunization program at 1-800-282-05446 or <https://www.impactsiis.org>.

Conference Cont'

from P.5

improve immunization rates in any practice. OTIS promotes giving children combination vaccines and all vaccines at the earliest opportunity, both of which have been shown to improve immunization rates.

The second day of the conference began with nationally renowned physician, Dr. Paul Offit, chief of Infectious Diseases and the director of the Vaccine Education Center at the Children's Hospital of Philadelphia. Offit spoke about the challenges facing immunization providers and provided guidance on how providers can approach parents that are reluctant to vaccinate their children. A copy of Offit's book "Autism's False Prophets" was provided to each attendee. After Offit's presentation, there was a final round of breakout sessions. Rounding out the second day was the fifth and final plenary, Vaccine Finance. This plenary had a panel comprised of topic experts: Dr. Grace Lee from Harvard Medical School; Amy Rae Bashforth, Immunization program manager at ODH; Shannon Ginther, J.D., Chief of Government Affairs at ODH; and Sherry Robison, office manager at Olentangy Pediatrics. This presentation provided the audience with a look at how vaccines are funded from many different perspectives, both nationally and statewide.

Overall, the conference posed a great opportunity for public health professionals from around the state to gather and exchange information with each other as well as field experts. The conference was well-attended and according to the evaluations, the content was greatly appreciated by many attendees.

Conference Award Winners

The AFIX Project for Ohio is a continuous quality-improvement program for practices to assess and improve the immunization rates of their 2-year-olds. AFIX is a free service provided by the ODH Immunization program and participating local health districts. For more information or to request an AFIX visit, contact the ODH Immunization program at (614) 466-4643 or (800) 282-0546.

AFIX Awards were based on the 4 DTaP, 3 Polio, 1 MMR, 3 HIB, 3 Hepatitis B and 1 Varicella (4:3:1:3:3:1) series. The awards were presented based on 2007 rates.

AFIX 90 percent Club Award

Awarded to those practices who achieve immunization rates of 90 percent or higher by 24 months of age.

Ashtabula Clinic Pediatrics, *Jefferson*
Crosswoods Pediatrics, *Westerville*
Harrison Pediatrics, Inc., *Harrison*
Craig Johnson, M.D., *Middletown*
Medina Pediatrics, Inc., *Medina*
North Coast Pediatrics, Inc., *Fairview Park*
Pediatric & Adolescent Health: Dr. Dieter Sumerauer,
Middleburg Heights
Queen City Physicians, *Cincinnati*
Sharon Family Physicians, Inc., *Sharon Center*
West Chester Pediatrics, *West Chester*
West Side Pediatrics, Inc., *Cincinnati*

AFIX Improvement Award

Awarded for outstanding improvement in immunization rates

to practices in the state with at least a 25 percent margin of increase in rates between 2005 and 2007.

Caro Pediatric Center, *Dayton*

Landon Lakes Pediatrics, *Mason*

Maumee Bay Pediatrics, *Oregon*

Pediatric Care, Inc., *West Chester*

PrimeHealth Pediatrics, *Mentor*

ImpactSIIS Awards

Pioneer Award: Cincinnati Children's Hospital Medical Center received this award for working diligently with the Immunization program to validate the ImpactSIIS algorithm and providing valuable feedback. This organization blazed the trail by being the first hospital to incorporate ImpactSIIS into the workflow of the Primary Care Unit within Cincinnati Children's Hospital Medical Center, using the system interactively to manage vaccine, determine shots for patients and use the reminder/recall system. This organization has also helped to recruit new users in the Hamilton County area.



Step Forward Award: The Ohio State University and Nationwide Children's Hospital were the recipients of this award for stepping forward to apply innovative 21st century information technology strategies. These techniques include integrating their electronic medical records with national standards including health level 7 standards with ImpactSIIS. They lead the field by moving the bar higher in providing efficient exchange of information, integration and collaboration.

Complete Records Award: The recipients of this award are recognized for having the highest percent of patients 24 to 35 months of age with complete immunization records on file indicating the child is fully immunized.

Harrison Pediatrics

Primary Care Physicians

Dr. Sasha Narang

Difference Maker Award: The recipients of this award are at the forefront of identifying and developing opportunities through public-private partnerships to integrate ImpactSIIS into all medical practices. These providers have the highest urban saturation level for children 0-6 years of age with two or more immunization records.

Toledo Lucas County Health Department

ProMedica Physicians Group
Paramount, Inc.

Henry County Health Department

Integration Award: The Northeast Ohio Neighborhood Health Services received this award for combining exceptional work flow design, office culture sensitivity and work flow efficiency

through the successful implementation of ImpactSIIS. This award acknowledges the extra time and effort it takes to successfully integrate information technology, immunizations and office work flow.

Vaccines on the Horizon ...

The development of new and improved vaccines is a continuous and ever-evolving process as medical and scientific technology advances. Manufacturers are constantly trying to develop vaccines that meet the challenges posed by the global face of vaccine-preventable diseases. Their efforts included the development of not only the many combination vaccines that reduce the number of injections children receive, thus helping to ensure full immunization coverage, but also vaccines for diseases that continue to cause a significant burden of morbidity and mortality worldwide. Some vaccines that are either in the final stages of development or have already applied for FDA licensure are:

- 10 valent pneumococcal conjugant (with 19A strain)
- 13 valent pneumococcal conjugant (with 19A strain)
- Bivalent HPV vaccine
- Herpes Simplex Virus vaccine
- New Japanese Encephalitis vaccine
- New meningococcal vaccine

In addition, there continues to be great optimism that in the near future effective vaccines will be available for devastating diseases such as HIV, malaria and tuberculosis.

Ask the Expert:

Q: I recently stopped ordering rotavirus and HPV for my private-pay patients due to insurance reimbursement rates. Do I still have to order these vaccines through Vaccines for Children (VFC)?

A: Yes, the VFC program is a federal entitlement that allows eligible children to receive all VFC vaccines, as recommended by the Advisory Committee on Immunization Practices (ACIP) in VFC resolutions. Therefore, one of the requirements of providers participating in the VFC program is to order and make available all VFC vaccines for VFC-eligible children. This will enable providers to keep children in their medical homes and reduce barriers to receiving all the recommended childhood immunizations.

If you have a change in staff responsible for VFC vaccines notify your ODH VFC consultant.