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The Role of Trust in the Vaccination Process

The Centers for Disease Control and Prevention (CDC) considers vaccinations, as a group, one of the 10 great public health achievements of the 20th century.¹ In the past century, scientific research led to advances in vaccine development, and many vaccine-preventable diseases have been eradicated from the United States. However, as the number of recommended immunizations increases, so has the rate of non-medical exemptions to school-required vaccinations, and the number of parents deferring vaccinations for homeopathic treatments.² As opponents of immunizations flood the Internet and other media outlets with their views on vaccination safety, providers across the country struggle with the best ways to address parental concern. Recent research helps to shed some light on what factors influence parents who are making the vital decision to immunize their children, and how providers can address their reservations head on.

A study in the journal *Pediatrics* surveyed mothers who were undecided regarding childhood vaccinations and found that trust, or a lack of trust, in a pediatrician or another influential person were pivotal in the decision-making process.³ Surprisingly, an issue that was not a major factor in the decision-making process was medical knowledge regarding vaccines. Very few of the mothers surveyed could name even one vaccine recommended for the two-month visit. Mothers who ultimately decided not to vaccinate their child did so because they viewed their pediatrician as having little time for

them and unwilling to have a scientifically based dialogue with them regarding vaccines. In turn, they perceived their homeopath as willing to do those things and, therefore, trustworthy.

When asked, mothers surveyed stated that qualities of a trustworthy health care provider included: discussing the subject of vaccines in a passionate manner; having a lot of scientific information; spending a long time with the parent; using a "whole person" approach; and behaving in a non-patronizing manner.

Along with trust in their provider, parents who said they would immunize their child said they thought they would do so because it was what most people do and because they had a desire to prevent disease. Parents who considered not immunizing their child cited reasons such as feeling alienated by or unable to trust their pediatrician, having a trusting relationship with an influential homeopath or another person who did not believe in immunizing and fear of harming their child. Non-immunizing parents also believed they could control their child's susceptibility to and outcome of the disease, didn't believe their child could be susceptible to the disease and feared that too many immunizations could be dangerous.

When confronted with parents who are considering not vaccinating their child, the American Academy of Pediatrics suggests providers:

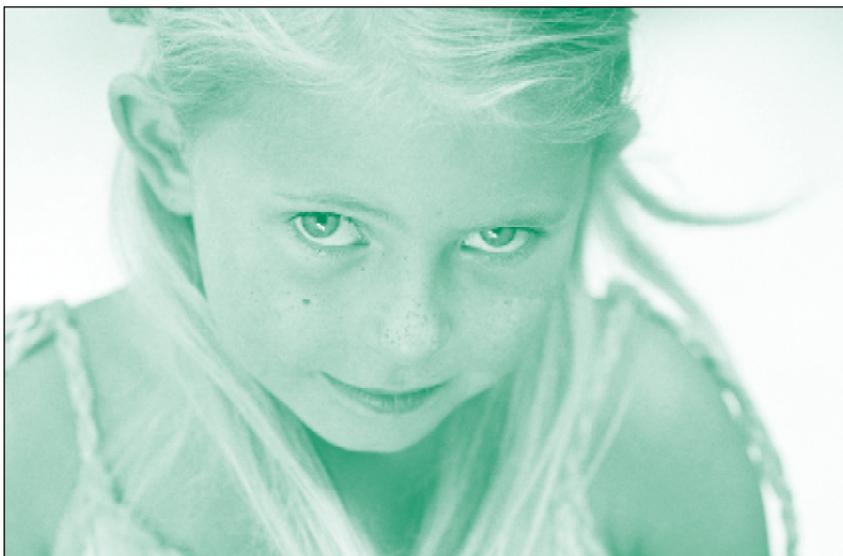
Vaccination Process Continued

- Listen carefully and respectfully to the parents' concerns, recognizing that some parents may not use the same decision criteria as the physician and may weigh evidence very differently than the physician does.
- Share honestly what is and is not known about the risks and benefits of the vaccine in question, attempt to understand the parents' concerns about immunizations and attempt to correct any misperceptions and misinformation.
- Assist parents in understanding the risks of any vaccine should not be considered in isolation but in comparison to the risks of remaining unimmunized.
- Discuss each vaccine separately. The benefits and risks of vaccines differ, and parents who are reluctant to accept the administration of one vaccine may be willing to allow others.
- For all cases in which parents refuse vaccine administration, pediatricians should take advantage of their ongoing relationship with the family and revisit the immunization discussion on each subsequent visit, documenting the discussion in the medical chart. As respect, trust, communication and information build over time, parents may be willing to reconsider previous vaccine refusals.⁴

Sometimes, a discussion about vaccination can be one of the first opportunities a practitioner has to develop a trusting relationship with parents. By dismissing parents' concerns regarding vaccinations a provider may inadvertently divert their trust to vaccine opponents and perpetuate misconceptions and fears.⁵ However, by addressing concerns directly and truthfully, a provider can increase parents' likelihood to vaccinate and begin building a solid foundation for future communications.

References

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- Recognize that parents may also have concerns about administering multiple vaccines to a child in a single visit. In some cases, taking steps to reduce pain of injection, such as those suggested in the *Red Book*, may be sufficient.
- Explore the possibility that cost is a reason for refusing immunization. For parents whose child does not have adequate preventive care insurance coverage, even the administrative costs and co-payments associated with immunization can pose substantial barriers. In such cases, providers should work with the family to help them obtain appropriate immunizations for the child.

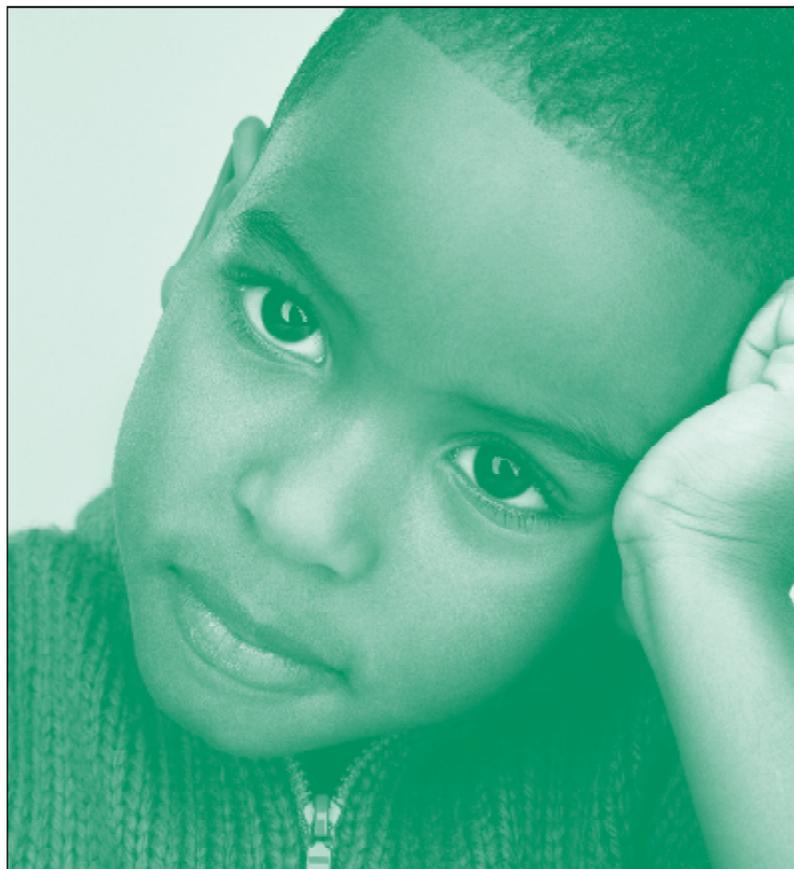
VFC Fraud and Abuse

As the cost of childhood vaccines increases, the Vaccines for Children (VFC) program becomes more vulnerable to fraud and abuse. The cost of fully vaccinating a child through the VFC program has risen to \$1,144.

For the purposes of VFC, fraud and abuse are defined according to Medicaid regulations at 42 CFR § 455.2. Fraud is defined as “an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.” Abuse is defined as “provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, [and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient].”

The VFC program at the Ohio Department of Health strives to work with VFC providers to protect VFC vaccine and prevent fraud and abuse. Building an awareness of situations that may be viewed as fraud and abuse is an important step in preventing fraud. Some examples of potential fraud and abuse include:

- Providing VFC vaccine to non-VFC-eligible children.
- Selling or otherwise misdirecting VFC vaccine.
- Billing a patient or third party for VFC vaccine.
- Charging more than the established maximum regional charge for the administration of a VFC vaccine (\$14.67 in Ohio).
- Not providing VFC-eligible children VFC vaccine due to parents’ inability to pay for the administration fee.
- Failing to screen patients for VFC eligibility.
- Failing to maintain VFC records (e.g., accountability sheets).
- Failing to fully account for VFC vaccine.
- Failing to properly store and handle VFC vaccine.
- Wasting of VFC vaccines.



VFC immunization consultants are available to assist provider offices with a variety of issues (e.g., developing vaccine management plans, developing a procedure to screen patients for VFC eligibility) and can help your office prevent VFC abuse. Please contact your VFC immunization consultant at 1-800-282-0546 to request assistance in these areas. Suspected cases of VFC fraud and abuse may be reported to the VFC coordinator, also at 1-800-282-0546. Please help us to protect our federal tax dollars.

ProQuad® Shortage

In February 2007, the Centers for Disease Control and Prevention (CDC) received notice from Merck & Co., Inc., that it has lower amounts of varicella-zoster virus (VZV) than expected from recently manufactured VZV-containing bulk vaccine. Merck is the only United States supplier of VZV-containing vaccine, including

varicella vaccine (Varivax®); combined measles, mumps, rubella, and varicella (MMR-V) vaccine (ProQuad®); and zoster vaccine (Zostavax®). VZV-containing vaccines currently on the market are not affected by the lower virus yield; however, to conserve existing bulk vaccine with adequate VZV potency, Merck prioritized production of VZV-containing vaccines.

At this time, Merck has opted to prioritize continued production of varicella and zoster vaccines over production of MMR-V vaccine. Supplies of separate MMR and varicella vaccines are expected to be adequate to fulfill the immunization need. The U.S. varicella vaccine supply is expected to be adequate to fully implement the 2007 recommended immunization schedule, including the routine two-dose schedule for children 12-15 months and 4-6 years.

As of June 2007, the supply of MMR-V has been depleted. More information regarding this issue and other vaccine shortages can be found at <http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm>.



2006 Providers Satisfaction Survey Results

In 2006, the ODH Immunization program sent out a Provider Satisfaction Survey to all VFC providers and local health departments. Eighty-five of the 88 counties were represented with at least one returned survey, for a total of 86 health department and 480 private VFC providers responding.

Survey results showed 94 percent of private providers and 81 percent of health departments agreed or strongly agreed to being satisfied with the overall immunization program. Ninety-three percent of providers and 89 percent of the health departments felt the VFC program keeps them up to date regarding changes and requirements. Ninety-three percent of providers and 92 percent of health departments also agreed or strongly agreed that vaccines are delivered within a reasonable

amount of time. Eighty-one percent of providers who stated they had received a site visit within two years of the survey reported they thought it was beneficial, with 71 percent confirming that recommendations for the site visit led to changes in office practice.

When asked, "What do you like best about the VFC program?," 29 percent of the 248 providers and 36 percent of the 42 health departments who answered stated, "Helping children in need." When asked, "What would you change about the VFC program?," 15 percent of the 161 providers who answered stated, "Flexibility in ordering vaccines," while 36 percent of the 42 health departments who responded stated, "Change or lessen eligibility requirements." Thank you to all of the providers who responded to this survey.

New Rotavirus Safety Data

The Centers for Disease Control and Prevention released new safety data in its *Morbidity and Mortality Weekly Report* on RotaTeq,® the recently released rotavirus vaccine. The data show there is no current evidence of an association between the vaccine and intussusception. Intussusception, a form of bowel obstruction, occurs spontaneously in the absence of vaccination. There are a



number of intussusception cases that occur every year in children in the age group recommended for RotaTeq® (6-32 weeks of age) and are not related to the vaccine.

Between Feb. 1, 2006, and Feb. 15, 2007, 35 confirmed cases of intussusception were reported to the Vaccine Adverse Event Reporting System (VAERS). Of the 35 reports, 17 cases occurred within 21 days following RotaTeq® vaccination, considerably fewer than the 52 intussusception cases expected to occur naturally among infants without vaccination. As with any newly licensed vaccine, the CDC is closely monitoring VAERS reports associated with the rotavirus vaccine.

The CDC recommends routine rotavirus vaccination of U.S. infants to protect against rotavirus disease. A recent study published in the April 2007 edition of the journal *Pediatrics* estimates routine rotavirus vaccination could prevent 13 deaths, 44,000 hospitalizations, 137,000 emergency department visits, 256,000 office visits and 1.1 million episodes of rotavirus that require home care each year.

For more information on VAERS or to report a vaccine adverse event, go to <http://www.vaers.hhs.gov>. For more information on rotavirus safety data, go to <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5610a3.htm>.

VFC Reminders

- All Vaccines for Children (VFC) providers must ship all Ohio Department of Health (ODH)-supplied expired and wasted vaccines back to ODH. Expired or wasted vaccines may be sent back to ODH through the method you find cheapest and most convenient. However, please package the contents in a way that is appropriate for biologicals and will prevent breakage. The package must be clearly marked "biologicals" or "expired vaccines" on the outside. The Vaccine Transfer Form(s) should be included with all return vaccines. The address to use for returning vaccines is as follows:

Ohio Department of Health
Immunization Program
900 Freeway Dr. N., Bldg. #8
Columbus, Ohio 43229
- 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. These include Hepatitis A, rotavirus and Human Papillomavirus (HPV) vaccines. This will enable us to keep children in their medical homes and reduce barriers to receiving all the recommended childhood immunizations. Please ensure you are ordering all VFC vaccines when you place your next quarterly order.
- ODH sends influenza vaccine ordering information to all VFC providers in June. Please remember that orders are due every year on Aug. 1. Contact the warehouse or your immunization consultant if you haven't received your ordering information.

Changes in Vaccine Shipping

In 2008, the Ohio Department of Health (ODH) will begin shipping Vaccines for Children (VFC) vaccine through a federally funded centralized distributor as part of the Centers for Disease Control and Prevention's (CDC) Vaccine Management Business Improvement Project (VMBIP). VMBIP represents the efforts of the CDC to improve current vaccine management processes at the federal, state and local levels. The goals for the project are to identify opportunities and develop solutions toward improving efficiency, accountability and the nation's ability to respond to public health crises.

The ODH Immunization program began the transition to centralized distribution through VMBIP on March 12, 2007, through a conference call led by the CDC. Ohio's estimated transition to centralized shipping is Feb. 25, 2008. Under the new system, the ODH Immunization program will continue to monitor provider profile numbers, monthly accountability reports from public providers and process quarterly vaccine orders from VFC providers, while packing and shipping of vaccines will be handled through the CDC contractor. More information regarding VMBIP and changes in vaccine shipping will be made available in the upcoming months.

Save the Date

The Consortium for Healthy and Immunized Communities (CHIC) will be holding the Seventh Annual Immunization Conference: "Vaccinations B-Z" on Friday, Oct. 12, 2007, at the Ritz Carlton in Cleveland. Additional information regarding the conference can be found by calling (216) 201-2001 x1310 or on the CHIC Web site <http://www.chicohio.com>.



Ask the Expert — Questions & Answers

Q Was there a recent change in the recommendation on who should receive two doses of influenza vaccine?

A Yes, the Advisory Committee on Immunization Practices now recommends children 6 months through 8 years who received only one dose of influenza vaccine in their first season should receive two doses of influenza vaccine in their second season. The prior recommendation was these children needed only one dose in their second season. The second dose may even be given late into the influenza season because influenza may be circulating until April or May.

Q If I have a VFC-eligible female patient who will turn 19 before she can finish her HPV series, may I finish the series with VFC vaccines after her birthday? If not, should I even start the series?

A All VFC-eligible children (18 or younger) should be given any vaccine that is age appropriate for them. However, once the child is no longer VFC eligible, they should no longer receive VFC vaccine. In this case, the patient should receive as many doses of HPV as possible before her 19th birthday; she is not eligible for VFC vaccine after her birthday.