Training Stressed to Reduce Vaccine Errors

BY ROXANNA GUILFORD-BLAKE

EXPERT ANALYSIS FROM THE NATIONAL IMMUNIZATION CONFERENCE

ATLANTA — The problem of how to reduce vaccine-related errors was raised during the lively question-and-answer session at the conference, which was sponsored by the Centers for Disease Control and Prevention.

The panelists—Dr. Iyabode Akinsanya-Beysolow, Dr. William Atkinson, Dr. Andrew Kroger, and Donna Weaver, R.N., all of the Centers for Disease Control and Prevention's National Center for Immunization and Respiratory Diseases—fielded a variety of vaccine-related questions from the audience.

One audience member reported that, in the last year, the number of vaccine errors she has seen had gone up fourfold, and there is no system to capture them. Without capturing the data, she added, it is difficult to make the case to manufacturers for label changes.

"Point well taken," Dr. Atkinson replied. The Vaccine Adverse Event Reporting System is not built to capture administration errors, he noted. "We just don't have the kind of epidemiologic analysis we'd like to have."

Ms. Weaver emphasized the importance of training and orientation for each new person and each time there is a new vaccine. And after training, she advised, test your office staff to make sure they indeed developed the proper knowledge and skills.

Convincing manufacturers to improve labeling can be helpful, but providers can make important changes in their own offices, she counseled. She cited several simple examples, including carefully labeling diluents and keeping each diluent with the right vaccine.

Educational programs, posters, and other resources are available from the CDC and other organizations to help enhance vaccine safety in the office, she said. In particular, she mentioned California's www.eziz.org.

The other topics discussed included the following:

► **Confusing the diphtheria, tetanus, acellular pertussis (DTaP) vaccine for children and the tetanus, diphtheria, and acellular pertussis (Tdap) vaccine for adolescents and adults.** Practices continue to make this mistake, one audience member reported. Dr. Akinsanya-Beysolow advised storing each vaccine on a different shelf. Label each shelf with the name of the vaccine and the age of the patient "in big, big neon letters."

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She also echoed Ms. Weaver's remarks about the importance of adequate training.

► **More to come on pertussis, Tdap.** The pertussis work group has started meeting again after taking about a year off, Dr. Atkinson reported, and he predicted a flurry of information "emerging from their discussions." Another issue he expects the group to address is the use of Tdap in patients 65 and older.

An audience member asked if the CDC planned to refine its guidance regarding Tdap during pregnancy. It might. ACIP's recommendation to defer the vaccine until after pregnancy is based on data from 1945, Dr. Kroger said.

► **Allaying fears about live attenuated influenza vaccine (LAIV).** An audience member asked about the use of LAIV among health care providers, noting "no one would use it" because of the fears generated by the warning about using it around immunocompromised individuals. Dr. Atkinson explained that warning would be removed, and that it had been "a real distraction." Compounding the concerns, noted an audience member, is that various professional groups issue "countermessages." ■

Disclosures: None of the panelists reported any conflicts of interest.

Prevnar 13™
Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM_{197} Protein)

BRIEF SUMMARY:
These highlights do not include all the information needed to use Prevnar 13™ safely and effectively. Before prescribing, please consult the full Prescribing Information for Prevnar 13™.

INDICATIONS AND USAGE:
Prevnar 13™ is a vaccine approved for use in children 6 weeks through 5 years of age (prior to the 6th birthday). Prevnar 13™ is indicated for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F. Prevnar 13™ is also indicated for the prevention of otitis media caused by *Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F. No otitis media efficacy data are available for serotypes 1, 3, 5, 6A, 7F, and 19A.

DOSAGE AND ADMINISTRATION:
For intramuscular injection only. Do not inject intravenously, intradermally, or subcutaneously.
Vaccine Schedule for Infants and Toddlers – Prevnar 13™ is to be administered as a 4-dose series at 2, 4, 6, and 12-15 months of age.
Vaccine Schedule for Unvaccinated Children ≥7 Months of Age – For children who are beyond the age of the routine infant schedule and have not received Prevnar® (Pneumococcal 7-valent Conjugate Vaccine [Diphtheria CRM_{197} Protein]) or Prevnar 13™, Prevnar 13™ is to be administered as a 3-dose series beginning at 7-11 months of age; a 2-dose series beginning at 12-23 months of age; and as a single dose at 24 months through 5 years of age (prior to the 6th birthday). The immune responses induced by this catch-up schedule may result in lower antibody concentrations for some serotypes, compared to antibody concentrations following 3 doses of Prevnar 13™ (given at 2, 4, 6, and 12-15 months of age). In children 24 months through 5 years of age, the catch-up schedule may result in lower antibody concentrations for some serotypes, compared to antibody concentrations following 3 doses of Prevnar 13™ (given at 2, 4, and 6 months of age). The clinical relevance of these lower antibody responses is not known.
Prevnar 13™ Vaccine Schedule for Children Previously Vaccinated With Prevnar® (*Streptococcus pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) – Children who have received 1 or more doses of Prevnar® may complete the 4-dose immunization series with Prevnar 13™. Children 15 months through 5 years of age who have received 4 doses of Prevnar® may receive 1 dose of Prevnar 13™ to elicit immune responses to the 6 additional serotypes. This catch-up dose of Prevnar 13™ should be administered with an interval of at least 8 weeks after the fourth dose of Prevnar®. The immune responses induced by this Prevnar 13™ transition schedule may result in lower antibody concentrations for the 6 additional serotypes (types 1, 3, 5, 6A, 7F, and 19A) compared to antibody concentrations following 4 doses of Prevnar 13™ (given at 2, 4, 6, and 12-15 months of age). The clinical relevance of these lower antibody responses is not known.

DOSAGE FORMS AND STRENGTHS:
Prevnar 13™ is a suspension for intramuscular injection available in 0.5-mL single-dose pre-filled syringes.

CONTRAINDICATIONS:
Severe allergic reaction (eg, anaphylaxis) to any component of Prevnar 13™, Prevnar®, or any diphtheria toxoid-containing vaccine.

WARNINGS AND PRECAUTIONS:
Management of Allergic Reactions or Other Adverse Reactions – Before administration of any dose, all precautions should be taken to prevent allergic or any other adverse reactions. This includes a review of the patient's immunization history for possible sensitivity to the vaccine or similar vaccines and for previous vaccination-related adverse reactions in order to determine the existence of any contraindication to immunization with Prevnar 13™ and to allow an assessment of risks and benefits. Epinephrine and other appropriate agents used for the control of immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur following the administration of the vaccine.
Limitations of Vaccine Effectiveness – Prevnar 13™ may not protect all individuals receiving the vaccine. Prevnar 13™ will not protect against *Streptococcus pneumoniae* serotypes that are not in the vaccine or serotypes unrelated to those in the vaccine. It will also not protect against other microorganisms. This vaccine does not treat active infection.
Protection against otitis media is expected to be substantially lower than protection against invasive disease. In addition, because otitis media is caused by many organisms other than the 7 serotypes of *Streptococcus pneumoniae* included in the indication, protection against all causes of otitis media is expected to be lower than for pneumococcal otitis media caused by these 7 vaccine serotypes.
The duration of protection from immunization is not known.
Altered Immunocompetence – Data on the safety and effectiveness of Prevnar 13™ when administered to children in specific groups at higher risk for invasive pneumococcal disease (eg, children with congenital or acquired splenic dysfunction, HIV infection, malignancy, or nephrotic syndrome) are not available.
Children in these groups may have reduced antibody response to active immunization due to impaired immune responsiveness. Vaccination in high-risk groups should be considered on an individual basis.
The use of pneumococcal conjugate vaccine does not replace the use of 23-valent pneumococcal polysaccharide vaccine (PPV23) in children ≥24 months of age with sickle cell disease, asplenia, HIV infection, chronic illness, or who are otherwise immunocompromised.
Premature Infants – Apnea following intramuscular vaccination has been observed in some infants born prematurely. Decisions about when to administer an intramuscular vaccine, including Prevnar 13™, to infants born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination.

ADVERSE REACTIONS:
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. As with any vaccine, there is the possibility that broad use of Prevnar 13™ could reveal adverse reactions not observed in clinical trials.
Serious Adverse Events in All Infant and Toddler Clinical Studies – Serious adverse events were collected throughout the study period for all 13 clinical trials. This reporting period is longer than the 30-day post-vaccination period used in some vaccine trials. The longer reporting may have resulted in serious adverse events being reported in a higher percentage of subjects than for other vaccines. Serious adverse events reported following vaccination in infants and toddlers occurred in 8.2% among Prevnar 13™ recipients and 7.2% among Prevnar® recipients.
The most commonly reported serious adverse events were in the "Infections and infestations" system organ class, including bronchiolitis (0.9%, 1.1%), gastroenteritis (0.9%, 0.9%), and pneumonia (0.9%, 0.5%) for Prevnar 13™ and Prevnar®, respectively.
There were 3 (0.063%) deaths among Prevnar 13™ recipients and 1 (0.036%) death in Prevnar® recipients, all as a result of Sudden Infant Death Syndrome (SIDS). These SIDS rates are consistent with published age-specific background rates of SIDS from the year 2000.
There was 1 hypotonic-hyporesponsive episode adverse reaction reported (0.015%).
Solicited Adverse Reactions in the 3 US Infant and Toddler Studies – The most commonly reported solicited adverse reactions (≥20%) in US clinical trials with Prevnar 13™ were redness, swelling and tenderness at the injection site, fever, decreased appetite, irritability, increased sleep, and decreased sleep.
Unsolicited Adverse Reactions in the 3 US Infant and Toddler Safety Studies – The following were determined to be adverse drug reactions based on experience with Prevnar 13™ in clinical trials:
Reactions occurring in greater than 1% of infants and toddlers: diarrhea, vomiting, and rash.
Reactions occurring in less than 1% of infants and toddlers: crying, hypersensitivity reaction (including face edema, dyspnea, and bronchospasm), seizures (including febrile seizures), and urticaria or urticaria-like rash.

DRUG INTERACTIONS:
Concomitant Immunizations – In clinical trials, Prevnar 13™ was administered concomitantly with the following US licensed vaccines: Pediarix [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant), and Inactivated Poliovirus Vaccine Combined] (DTaP-HBV-IPV) and ActHIB [*Haemophilus* b Conjugate Vaccine (Tetanus Toxoid Conjugate)] (PRP-T) for the first 3 doses and with PedvaxHIB [*Haemophilus* b Conjugate Vaccine (Meningococcal Protein Conjugate)] (PRP-OMP), M-M-R II [Measles, Mumps, Rubella Virus Vaccine Live] (MMR), and Varivax [Varicella Virus Vaccine Live], or ProQuad [Measles, Mumps, Rubella, and Varicella Virus Vaccine Live] (MMRV) and VAQTA [Hepatitis A vaccine, Inactivated] (HepA) for dose 4.
When Prevnar 13™ is administered at the same time as another injectable vaccine(s), the vaccines should always be administered with different syringes and given at different injection sites.
Do not mix Prevnar 13™ with other vaccines/products in the same syringe.
Immunosuppressive Therapies – Children with impaired immune responsiveness due to the use of immunosuppressive therapy (including irradiation, corticosteroids, antimetabolites, alkylating agents, and cytotoxic agents) may not respond optimally to active immunization.

USE IN SPECIFIC POPULATIONS:
Pregnancy
Pregnancy Category C – Animal reproduction studies have not been conducted with Prevnar 13™. It is also not known whether Prevnar 13™ can cause fetal harm when administered to a pregnant woman or whether it can affect reproductive capacity.
Pediatric Use – Safety and effectiveness of Prevnar 13™ in children below the age of 6 weeks or on or after the 6th birthday have not been established. Prevnar 13™ is not approved for use in children in these age groups. Immune responses elicited by Prevnar 13™ among infants born prematurely have not been specifically studied.
Geriatric Use – The safety and effectiveness of Prevnar 13™ in geriatric populations have not been established. Prevnar 13™ is not to be used as a substitute for 23-valent pneumococcal polysaccharide vaccine (PPV23) in geriatric populations.

OVERDOSAGE:
Overdose with Prevnar 13™ is unlikely due to its presentation as a pre-filled syringe. However, there have been reports of overdose with Prevnar 13™ defined as subsequent doses administered closer than recommended to the previous dose. In general, adverse events reported with overdose are consistent with those which have been reported with doses given in the recommended schedules of Prevnar 13™.

NONCLINICAL TOXICOLOGY:
Carcinogenesis, Mutagenesis, Impairment of Fertility – Prevnar 13™ has not been evaluated for any carcinogenic or mutagenic potential, or impairment of fertility.

HOW SUPPLIED/STORAGE AND HANDLING:
Pre-filled syringe, 1 dose (10 per package) – NDC 0005-1971-02.
Store refrigerated at +2ºC to +8ºC (36ºF to 46ºF).
The tip cap and rubber plunger of the pre-filled syringe do not contain latex.
Do not freeze. Discard if the vaccine has been frozen.

This product's label may have been updated. For current package insert and further product information, please visit www.wyethhcp.com or call our medical communications department toll-free at 1-800-934-5556.

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