Know Your Duties Regarding Vaccine Information

Responsibilities for communication, documentation are spelled out for doctors by the AAP and the CDC.

BY SHERRY BOSCHERT
San Francisco Bureau

SAN FRANCISCO — If you're not providing parents a copy of a Vaccine Information Statement every time they accept or reject a child's immunization, you're not meeting your obligations under the National Vaccine Injury Compensation Program and could even be increasing your legal liability, Dr. Kristina Bryant advised.

The no-fault civil litigation system known as the National Vaccine Injury Compensation Program (NVICP) has benefited U.S. physicians since 1988 by reducing injury claims against vaccine manufacturers— and, the American Academy of Pediatrics (AAP) believes, against health care providers in addition, said Dr. Bryant, an assistant professor of pediatrics at the University of Louisville (Ky.).

If an injury that's listed in the program's Vaccine Injury Table occurs within a specified time after immunization, claimants must file for compensation through the NVICP to cover costs for medical care, pain, and suffering before pursuing a civil lawsuit.

The program streamlines reimbursement for claimants, and those claimants who receive awards cannot file a suit.

"We get some benefit from this, and we have responsibilities" for communication and documentation that are spelled out by the AAP and the Centers for Disease Control and Prevention, Dr. Bryant emphasized in speaking at the annual meeting of the AAP.

Discuss the benefits and risks of the vaccine being administered. "We want to make sure we have an open dialogue with our patients" about this, she said.

Note in the chart that you discussed these, she advised.

Give parents the current version of the Vaccine Information Statement each time you administer a covered vaccine. Handing it to them once and then making copies available in exam or waiting rooms during subsequent immunization visits is not enough.

The most current versions can be found at www.immunize.org or at www.cdc.gov/nip/publications/VIS/default.htm.

Document in the patient's chart the date of vaccine administration, the vaccine manufacturer, the vaccine lot number, your name and business address, the date of the Vaccine Information Statement version, and the date you gave parents the statement.

An informal poll of the audience at Dr. Bryant's AAP meeting presentation suggests that perhaps 25% of physicians do not document the version of the statement given to parents, and the date it is given to them.

If a parent refuses a child vaccination, discuss the risk that the child will pose to others and the risk of disease and potential death for the child, and document in the chart that you addressed these topics, Dr. Bryant said.

If a parent refuses a child vaccination, discuss the risk that the child will pose to others and the risk of disease and potential death for the child.

Requirements for obtaining informed consent vary by state, so be familiar with your state's regulations, she added.

Review the risks and benefits of vaccination at each encounter and provide a Vaccine Information Statement. At every refusal, ask the parent to sign the NVICP Refusal to Vaccinate form, which you can find at www.cispimmunize.org.

On the second page of the form, parents attest that they have read the Vaccine Information Statement, have had the opportunity to discuss this with the child's doctor or nurse, and recognize that the child could contract the illness that the vaccine is meant to prevent, and could moreover face consequences such as pneumonia, need for hospitalization, brain damage, meningitis, or death.

Some antivaccine Web sites advise parents to cross out portions of the Refusal to Vaccinate form, or to write comments in the margins about points of disagreement. Some parents even refuse to sign the form.

With the latter, document that you've shown them the form and discussed risks and benefits, and that they refused to sign, Dr. Bryant said.

A physician in the audience said that many pediatricians in his area have gone along with insurance carrier demands that patients who don't want to be vaccinated be asked to leave a physician's practice.

The AAP, however, urges physicians to avoid discharging vaccine refusers if possible, Dr. Bryant noted, while acknowledging that a lack of trust between parent and physician in some situations will lead to discharges.

Dr. Bryant is associated with several companies that make vaccines. She is on the speakers bureaus of Sanofi Pasteur and Abbott Laboratories, and she has received research funds from Merck & Co., MedImmune, Wyeth Pharmaceuticals, and GlaxoSmithKline. ■

Teen Weight, Vaccination Technique Key to Needle Length

BY BRUCE K. DIXON
Chicago Bureau

CHICAGO — For adolescents, body weight and injection technique should guide the choice of needle length during immunizations, according to a poster study presented at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy.

"We looked at the performance of a 5/8-inch vs. a 1-inch needle—using both pinching and flattening of the injection site—in relation to the recipient's body weight," said Dr. Michael Koster.

Using a needle that is too short may result in reduced immunogenicity and more adverse reactions to vaccines that are intended for intramuscular injection, whereas using a needle that is too long may strike bone and injure underlying neurovascular structures, Dr. Koster said in an interview.

With use of the pinching technique on adolescents weighing 88-155 pounds, a 1-inch needle is appropriate.

For those weighing less than 88 pounds, the shorter needle is best, said Dr. Koster, who conducted the study at Schneider Children's Hospital at North Shore in Manhasset, N.Y.

With use of the muscle-flattening technique, the longer needle likewise is recommended when body weight is 88-155 pounds, and the 5/8-inch needle is appropriate for adolescents weighing less than 88 pounds, said Dr. Koster, who is now a pediatric infectious disease fellow at Hasbro Children's Hospital in Providence, R.I.

The investigation included 141 participants. They were aged 11-15 years, with 87% of them aged 12-13 years.

Of the total, 28% of the participants weighed less than 88 pounds, while about 20% weighed more than 132 pounds.

The investigators recorded the adolescents' height, weight, and arm circumference, and conducted upper-arm ultrasonography during both muscle pinching and skin flattening of the participants' nondominant arms.

These ultrasound measurements were duplicated by a second investigator and averaged for analysis.

"When injecting someone [while using] the pinching technique, you increase muscle and subcutaneous tissue layers, in which case you'll want a little longer needle. When flattening, typically using the forefinger and thumb, you can go up to [a weight of] about 50 kilos [110 pounds] and be safe in terms of getting the vaccine into the muscle without striking bone," Dr. Koster said at the meeting, which was sponsored by the American Society for Microbiology.

Independent of technique, a 5/8-inch needle is appropriate to use on subjects less than 88 pounds.

DR. KOSTER

As a general rule, with the pinching technique, a 1-inch needle is appropriate most of the time, and the shorter needle is appropriate only for patients who weigh less than 88 pounds.

With the flattening technique, the shorter length is appropriate only three-quarters of the time and only on patients weighing less than 110 pounds.

"Independent of technique, it would be appropriate to use a 5/8-inch needle on subjects less than 88 pounds," he said.

Although females had a larger subcutaneous layer than did males of the same body weight, the difference did not result in the use of a different needle length, Dr. Koster said.

He added that body weight was a better predictor of required needle size than was arm circumference.

The American Academy of Pediatrics Red Book makes needle length recommendations for adolescents only in terms of body weight and sex.

For example, both sizes of needles are recommended for girls and boys who weigh less than 132 pounds. The 1-inch needle is recommended for girls who weigh 132-198 pounds and boys who weigh 132-260 pounds.

The AAP recommends an even longer (1½-inch) needle for females over 198 pounds and males over 260 pounds. Only 2 of the 141 subjects were that heavy, and the data on these two still are being analyzed.

Data from previous studies have suggested that obese adolescents who are immunized with 1-inch needles develop lower hepatitis B virus (HBV) vaccine titer levels, compared with those vaccinated with 1½-inch needles, and this seemed to have been borne out by findings in a limited study of 24 obese subjects aged 14-24 years (J. Adol. Health 2006;38:101).

In that study, after randomization to 1-inch and 1½-inch needle groups, subjects (girls over 198 pounds and boys over 265 pounds) were given an HBV vaccination using a 0-, 1-, and 4-month schedule.

HBV surface antibody was obtained 2 months after the third vaccination, and data showed that the final titer levels in the 1½-inch needle group were statistically higher to a significant degree than those in the 1-inch needle group.

"I hope that adjustments are made in the 2009 Red Book to reflect our finding that optimal needle length is influenced by intramuscular injection technique," Dr. Koster said.

He added that there is heightened need for these data because several vaccines—including Tdap (tetanus, diphtheria, and pertussis), meningococcal conjugate vaccine, and human papillomavirus vaccine—recently have been licensed and recommended for all adolescents in the United States. ■