

New York Medical Practices Face Patient Safety Risks with Vaccinations

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As the U.S. and New York State deal with one of the worst outbreaks of measles in years, New York Governor Andrew Cuomo recently [signed legislation](#) into law that ended religious exemptions for vaccines. Now more than ever, it is important to take time to assess the vaccine administration protocol in your practice. Although vaccinations are a routine procedure, physicians and staff should remain vigilant about patient safety considerations.

As with any medical intervention, the risks, benefits, and alternatives of the vaccination must be discussed and documented in the medical record, as well as ensuring that safety protocols are followed.

Could This Happen in Your Office?

The Doctors Company performed a closed claims analysis of vaccine-related events in the medical office setting. Could similar situations occur in your office?

- **Missed vaccination:** A 4.5-month-old male infant received the pneumococcal conjugate vaccine (PCV) Prevnar 7, which provided protection against seven serotypes of pneumococcus. The following year, the FDA approved the use of Prevnar 13, which provided protection against an additional six serotypes of the disease. The American Academy of Pediatrics recommended that those vaccinated with Prevnar 7 also receive Prevnar 13. The physician did not update recommended immunization protocols in her office, and even though the child returned for three additional well visits, the child never received Prevnar 13. At age 39 months, the child developed serotype 6A pneumococcal meningitis, which resulted in left hemiparesis, seizures, and vision and hearing impairment. This disease could have been prevented if the child had received Prevnar 13.
- **Dental injury:** A 13-year-old female received a Gardasil vaccine. Even though her mother was monitoring her in the exam room, the patient fainted and fell off the exam table, resulting in a tooth avulsion, another tooth luxation, a fractured wrist, and a laceration to her hand.
- **Injection site reaction:** A 35-year-old female complained of redness and swelling at the injection site for a flu vaccine, interfering with her ability to perform her job over the course of several months and resulting in several weeks of physical therapy. No

informed consent was obtained. She stated she would never have had the injection had she known of the potential complications.

- **Vaccination overdose:** A 41-year-old female with a history of ankylosing spondylitis requested a pneumovax vaccination. No informed consent was obtained. The patient was queried regarding whether she had previously received pneumovax, which the patient denied. Actual vaccination status was never verified by the physician; however, the patient had received the vaccine two years earlier. The patient developed inflammatory response syndrome, including the amputation of a toe, which was alleged to have resulted from administering the vaccine without checking her immunization history and because the vaccine was not indicated for patients younger than 65 years old.

Take These Steps for Safety

To help avoid these types of issues:

- Ensure that immunization tracking is up to date and well documented in the medical record so that patients remain on schedule. Obtain copies of vaccination records from previous providers or state registries. Create easy-to-read office forms for documenting administration.
- Screen patients for contraindications and precautions to administering any vaccine to prevent adverse events following vaccinations. [Reference the CDC guidelines.](#)
- Educate patients and parents regarding vaccination schedules.
- Designate a staff member to monitor for revisions/new recommendations of FDA/CDC [vaccination schedules](#). Ensure that new vaccination schedules are incorporated with office procedures and are included on office vaccination forms.
- Provide accurate information to patients. Conduct and document a thorough informed consent discussion; use [Vaccine Information Statements](#) *prior* to vaccine administration. Include information on the consequence of diseases contracted as a result of non-vaccination. Since parental immunization attitudes vary, be knowledgeable and prepared to address concerns utilizing appropriate communication methods. Use [this resource from the American Academy of Pediatrics](#) to assist with addressing vaccine-hesitant parents.
- Obtain patient or parent signatures on an informed consent form that includes potential side effects and complications. In the case of parents who have disagreed previously on vaccination, consider requesting both signatures on a vaccination consent. In the case of pediatric patients of divorce where sole physical custody is involved, the custodial parent or guardian should provide documentation to show authorization to sign a consent.

Document the discussion in the progress notes when the immunization is refused.

Consider using the [Refusal to Vaccinate form from the American Academy of Pediatrics](#) or The Doctors Company's [sample informed refusal form](#).

- Check [state laws](#) regarding exemptions, and educate patients. Be aware that religious and philosophical exemptions vary by state.
- Monitor patients closely post-administration for anaphylaxis, vasovagal response, and reaction at the injection site. Document any reactions, suspected side effects, and complications in the medical record.
- Educate staff and conduct skills verification on accepted procedures, new standards, and risk prevention methods. Document these efforts in administrative training files.
- Store and handle vaccinations in accordance with Vaccines for Children/[CDC guidelines](#). Monitor these practices with staff—don't just assume they are being followed correctly.
- Follow basic medication administration safety protocols for vaccine administration. Be aware of the most common vaccine-related errors by reviewing “Confusion Abounds! 2-Year Summary of the ISMP National Vaccine Errors Reporting Program” [Part I](#) and [Part II](#).
- Should an error in vaccine administration occur, conduct a disclosure discussion with the patient/parent utilizing The Doctors Company's [Disclosure Resources](#). Conduct a Root Cause Analysis with your staff to determine why an error occurred and to prevent reoccurrence in the future by adjusting office procedures and providing staff training, as needed.
- Be responsive to patients who express concerns about reactions from their vaccines. Document these discussions in the medical record.
- Report errors or hazards (anonymously) to the [ISMP National Vaccine Errors Reporting Program](#).

What to Do When a Patient Declines Vaccines

It is a physician's obligation to talk with all patients (or their guardians) about what could happen if they decline vaccination. This discussion should include these points:

- In New York State, children might be excluded from school if they are not vaccinated in accordance with [new vaccination laws](#).
- Not vaccinating can result in disease or even death.
- Unvaccinated children and adults pose a threat to the population of people unable to receive vaccinations due to age or due to weakened immune systems, such as those

with leukemia, who rely on the general public being vaccinated to reduce their risk of exposure.

- Social implications may include exclusion and quarantine. If there is an outbreak in a community, parents may be asked to remove their unvaccinated child from organized events and activities due to the threat of transmission.
- Females of childbearing age who are unvaccinated and who become pregnant are vulnerable to diseases such as rubella, which can cause congenital rubella syndrome with congenital fetal anomalies.

Parents should be reminded to alert medical personnel of their child's immunization status each time the child seeks healthcare should distinctive care be required.

Healthcare providers can help raise awareness of the benefits of immunizations. [Use CDC materials](#) to:

- Encourage parents of young children to get immunizations by age two.
- Help parents make sure older children have received vaccinations by the time they return to school.
- Remind college students to get vaccinations before moving into dormitories.
- Educate adults, including healthcare workers, about vaccines and boosters they may need.
- Inform pregnant women about getting vaccinated to protect newborns from disease such as whooping cough.

The guidelines suggested here are not rules, do not constitute legal advice, and do not ensure a successful outcome. The ultimate decision regarding the appropriateness of any treatment must be made by each healthcare provider considering the circumstances of the individual situation and in accordance with the laws of the jurisdiction in which the care is rendered.