

# American Academy of Pediatrics

## Reducing Vaccine Liability: Strategies for Pediatricians

### Background Information

The National Childhood Vaccine Injury Act (NCVIA) of 1986 was enacted to respond to public health concerns about vaccines and reduce vaccine liability. Through the NCVIA, the National Vaccine Injury Compensation Program (VICP) was established to maintain an accessible and efficient forum for individuals thought to be injured by childhood vaccines. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims. The VICP covers all vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. New vaccines incorporated into the routine immunization schedule (as recommended by the CDC's Advisory Committee on Immunization Practices) will be automatically included in the Vaccine Injury Table.

Settlements are based on the Vaccine Injury Table, which can be located at: <http://www.hrsa.gov/vaccinecompensation/vaccinetable.html>. This table summarizes medical conditions and the time interval of onset following receipt of a covered vaccine. It was created to justly compensate those injured by vaccines while separating out unrelated claims. The Vaccine Injury Table is continually updated as more information becomes available from research on vaccine side effects.

The NCVIA mandates that all health care professionals report certain adverse events that occur following vaccination. As a result, the Food and Drug Administration and the CDC established the Vaccine Adverse Events Reporting System (VAERS) in 1990. VAERS provides a mechanism for the collection and analysis of adverse events associated with vaccines currently licensed in the United States. Adverse events are defined as health effects that occur after immunization that may or may not be related to the vaccine. While VAERS provides useful information on vaccine safety, the data are somewhat limited. Specifically, judgments about causality (whether the vaccine was truly responsible for an adverse event) cannot be made from VAERS reports because of incomplete information.

Anyone can file a VAERS report including health care professionals, manufacturers, and vaccine recipients or, when appropriate, parents/guardians. VAERS report forms should be used to report adverse events. Pre-addressed postage paid report forms can be obtained by calling 800/822-7967 or through the VAERS Web site.

### Strategies to Reduce Vaccine Liability

#### **Provide Vaccine Information Statements – It's the Law!**

The NCVIA requires physicians to notify all parents and patients of the benefits and risks of vaccines through the use of Vaccine Information Statements (VISs). Despite this, only 62% of pediatricians indicated that they gave out a VIS with each dose of vaccine (Davis TC, et al. Pediatrics. 2001; 107:e17). According to AAP Periodic Survey#48, 6 out of 10 pediatricians report distributing VIS with every dose of each vaccine. About one-fourth do so with the first dose only, 10% sometimes do so, and fewer than 6% say they never distribute VIS.

- VISs must be produced by the CDC and cannot be altered. Pediatricians may add the name, address, etc, of their practice, but substantive changes are not acceptable.
- The relevant VIS must be given prior to administration of every dose of the vaccine (including each dose of a multidose series).
- The VISs should be supplemented with visual presentations or verbal explanations, as appropriate.
- Pediatricians must provide the most current VIS to parents.

For more information on VISs, visit: <http://www.cdc.gov/vaccines/pubs/vis/default.htm>

## Correctly Document Required Vaccine Information

The NCVIA and/or CDC requires physicians to document the:

- Date of vaccine administration
- Vaccine manufacturer
- Vaccine lot number
- Name and business address of the healthcare professional who administered the vaccine
- VIS version date
- Date the VIS was provided to the parent/guardian

The AAP recommends also recording the:

- Site and route of administration
- Vaccine expiration date
- Statement indicating that the VIS was provided and discussed with the parent

Vaccines that are not covered by the VICP do not require VISs to be provided, unless the vaccine is obtained through a CDC contract (ie, VFC program). Any vaccine under CDC contract requires a VIS and documentation regardless of whether it is covered by VICP. The AAP recommends using the VISs and following the same record-keeping practices with all vaccines. Table 1 provides a summary of documentation recommendations.

## Be Informed About Parental Consent Requirements

While obtaining a parental signature on the VIS is optional, it is common practice for pediatricians to request that parents initial each individual VIS. Pediatricians should check with their hospital's office of legal affairs or their state's immunization program manager for current state medical consent laws addressing vaccinations since such laws vary by state.

- Parental consent for immunization is standard practice in 43 states
- Thirty-four states require separate consent for each injection when more than one injection is required to complete a vaccination series

## Address and Document Parental Refusal to Vaccinate

There are many reasons why parents refuse to vaccinate their children. Most commonly, parents are not aware or may have no memory of the seriousness of the diseases that vaccines prevent. Therefore, their concern frequently shifts from the risk of disease to the risk of vaccines. The proliferation of an increasingly vocal anti-vaccine movement, which produces a wealth of unreliable, emotionally charged information that is easily accessible to parents has also increased concern about vaccine safety.

Another reason parents may refuse to vaccinate relates to vaccine mandates for school entry. Parents may feel that their right to make decisions for their children is taken away. An ongoing debate regarding the duty of society to protect healthy children versus the right of families to make decisions has caused efforts in more than a dozen states to rescind vaccine mandates or provide philosophical exemptions (AAP Committee on Medical Liability, 2004).

If a parent refuses a recommended vaccine and their child later develops a disease, the issue of professional liability can arise. Therefore, documentation of a parental refusal is essential. Documentation should indicate that:

- The parent was informed of why the vaccine is recommended
- The parent was informed of the risks and benefits of vaccination
- The parent was informed of the possible consequences of not vaccinating
- Patient educational materials were provided

The AAP Refusal to Vaccinate Form, which should not be considered a legal document without advice from a lawyer, may be used as a template for documentation of parental refusal.

The form can be revised based on the needs of individual practices.



AAP Committee on Medical Liability “Medical Liability for Pediatricians”

[https://www.nfaap.org/netforum/eweb/dynamicpage.aspx?site=nf.aap.org&webcode=aapbks\\_homepage](https://www.nfaap.org/netforum/eweb/dynamicpage.aspx?site=nf.aap.org&webcode=aapbks_homepage)

AAP Committee on Medical Liability and Risk Management

<http://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/Pages/Committee-on-Medical-Liability-and-Risk-Management.aspx>

AAP Childhood Immunization Support Program (CISP) Vaccine Liability

<http://www2.aap.org/immunization/pediatricians/liability.html>

Vaccine Injury Compensation Program

<http://www.hrsa.gov/vaccinecompensation/>

Vaccine Injury Table

<http://www.hrsa.gov/vaccinecompensation/vaccinetable.html>

Vaccine Adverse Events Reporting System

<http://vaers.hhs.gov/index>

CDC Vaccine Information Statements Fact Sheet

<http://www.cdc.gov/vaccines/hcp/vis/index.html>

Immunization Action Coalition. Vaccine Information Statements (VISs) in over 30 languages

[www.immunize.org/vis/index.htm#index](http://www.immunize.org/vis/index.htm#index)

AAP CISP. Improve Vaccine Liability Protection: The 4 D’s Fact Sheet

<http://www2.aap.org/immunization/pediatricians/pdf/ImproveVaccineLiabilityProtection.pdf>

AAP Refusal to Vaccinate Form.

<http://www2.aap.org/immunization/pediatricians/refusaltovaccinate.html>

AAP Committee on Bioethics Policy Statement: Responding to Parental Refusals of Immunization of Children.

<http://pediatrics.aappublications.org/content/115/5/1428.full.pdf+html?sid=ef2ac253-8e6a-4ffd-8292-b6efc5f329ee>

AAP Coding Resources for Parental Refusal to Vaccinate

<http://www2.aap.org/immunization/pediatricians/pdf/VaccinationNotCarriedOutVCodes.pdf>

### Table 1. Guidance for Use of Vaccine Information Statements

(Source: AAP Committee on Medical Liability. Medical Liability for Pediatricians, 6<sup>th</sup> Edition. 2004)

| Distribution  | Documentation in the Patient’s Medical Record   |
|---|---|
| Must be provided each time a National Vaccine Injury Compensation Program (VICP)-covered vaccine is administered* | Vaccine manufacturer, lot number, and date of administration*   |
| Given to parent, legal guardian, or patient (non-minor) to keep*  | Name and business address of the physician administering the vaccine*                                     |
| Must be the current version†  | Vaccine Information Statement version date and date it is provided†                                       |
| Can provide (not substitute) other written or audio-visual materials as necessary‡                                | Site (eg, deltoid area), route of administration (eg, intramuscular), and expiration date of the vaccine‡ |

\*Required under the National Childhood Vaccine Injury Act.

†Required under Centers for Disease Control and Prevention instructions implementing the National Childhood Vaccine Injury Act.

‡Recommended by the American Academy of Pediatrics.