It's federal law!

You must give your patients current Vaccine Information Statements (VISs)

A vaccine complication *in Florida highlights the importance of distributing the most recent VISs to your patients. In 1997, a 3-month-old boy developed vaccine-associated paralytic poliomyelitis (VAPP) following a first dose of OPV. The boy's parents reported that their physician furnished them with the 1994 polio VIS at the time of vaccination. The polio VIS had been revised in 1997 to reflect the ACIP preference for sequential use of inactivated polio vaccine (IPV), making the 1994 polio statement that was given to the parent outdated.*

Note: *the most current polio VIS carries the date of 1/1/00.*

To obtain a complete set of current VISs in more than 30 languages, visit IAC's website at www.immunize.org/vis

This article was originally written by Neal A. Halsey, MD, director, Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health and was updated by the Immunization Action Coalition in September 2007.

As healthcare professionals understand, the risks of serious consequences following vaccines are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against. Most adverse reactions from vaccines are mild and self-limited. Serious complications such as the one in the Florida case are rare, but they can have a devastating effect on the recipient, family members, and the providers involved with the care of the patient. We must continue the efforts to make vaccines as safe as possible.

Equally important is the need to furnish vaccine recipients (or the parents/legal representatives of minors) with objective information on vaccine safety and the diseases that the vaccines protect against so that they are actively involved in making decisions affecting their health or the health of their children. When people are not informed about vaccine adverse events, even common, mild events, they can lose their trust in healthcare providers and vaccines. Vaccine Information Statements (VISs) provide a standardized way to present objective information about vaccine benefits and adverse events.

What are VISs?

VISs are developed by the staff of the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccine recipient or the minor child's parent or legal representative about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers who should answer questions and address concerns that the recipient or the parent/legal representative may have.

Use of the VIS is mandatory!

Before a healthcare provider vaccinates a child or an adult with a dose of any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), influenza, or pneumococcal conjugate vaccine, the provider is required by the National Childhood Vaccine Injury Act (NCVIA) to provide a copy of the VIS to either the adult recipient or to the child's parent/legal representative.

VISs are also available for human papillomavirus (HPV), meningococcal, pneumococcal polysaccharide, and rotavirus, as well as various vaccines used primarily for international travelers. The use of these VISs is recommended but not currently required by federal law. (Editor's note: Use of VISs for HPV, meningococcal, and rotavirus vaccines will become mandatory at a later date.)

State or local health departments or individual providers may place the clinic name on the VISs, but any other changes must be approved by the director of CDC's National Center for Immunization and Respiratory Diseases.

What to do with VISs

Some of the legal requirements concerning the use of VISs are as follows:

1. Before an NCVIA-covered vaccine is administered to anyone (this includes adults!), you must give the patient or the parent/legal representative a copy of the most current VIS available for that vaccine. Make sure you give your patient time to read the VIS prior to the administration of the vaccine.
2. You must record in your patient's chart the date the VIS was given.
3. You must also record on the patient's chart the publication date of the VIS, which appears on the bottom of the VIS. As the Florida case above illustrates, it is imperative that you have the most current VIS.

Most current versions of VISs

As of September 2007, the most recent versions of the VISs are as follows:

DTaP/DT/DTP 5/17/07	PCV 9/30/02
hepatitis A 3/21/06	PPV 7/29/97
hepatitis B 7/18/07	polio 1/1/00
HPV (H. papillomavirus) 2/2/07	rabies 1/12/06
Hib 12/16/98	rotavirus 4/12/06
influenza (LAIV) ... 7/16/07	shingles 9/11/06
influenza (TIV) 7/16/07	Td 6/10/94
Japan. enceph. ... 5/11/05	Tdap 7/12/06
meningococcal 8/16/07	typhoid 5/19/04
MMR 1/15/03	varicella 1/10/07
yellow fever 11/9/04	

How to get VISs

VISs can be downloaded from the Immunization Action Coalition's website at www.immunize.org/vis or CDC's website at www.cdc.gov/vaccines/pubs/vis/default.htm. Ready-to-copy versions may also be available from your state or local health department.

Foreign language versions of VISs are not officially available from the CDC; however, several state health departments have arranged for their translations. These versions do not require CDC approval. You can find VISs in more than 30 languages on the Immunization Action Coalition's website at www.immunize.org/vis.

"We have an obligation to provide patients and/or parents with information that includes both the benefits and the risks of vaccines. This can be done with the Vaccine Information Statements that healthcare providers are required by law to provide prior to the administration of vaccines."

Walter A. Orenstein, MD, past director, National Immunization Program, CDC

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