It's federal law!

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

As healthcare professionals understand, the risks of serious consequences following vaccination 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 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), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) 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 pneumococcal polysaccharide vaccine, as well as various vaccines used primarily for international travelers. The use of these VISs is recommended but not currently required by federal law.

An alternative VIS—the multi-vaccine VIS—is an option to providing single-vaccine VISs when administering one or more of these routine birth-through-6-month vaccines: DTaP, hepatitis B, Hib, pneumococcal (PCV), polio (IPV), or rotavirus (RV). The multi-vaccine VIS can also be used when giving combination birth-through-6-month vaccines (i.e., Pediarix, Pentacel, or Comvax) or when giving two or more routine birth-through-6-month vaccines together at other pediatric visits (e.g., 12–15 months or 4–6 years).

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.

How to get VISs

All available VISs can be downloaded from the website of the Immunization Action Coalition at www.immunize.org/vis or from 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.

Non-English language versions of VISs are not available from 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 website at www.immunize.org/vis. To find VISs in alternative formats (e.g., audio, web-video), go to: www.immunize.org/vis/vis_audio.asp.

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

Most current versions of VISs

As of May 2009, the most recent versions of the VISs are as follows:

DTaP/DT/DTP	5/17/07	PCV	12/9/08
hepatitis A	3/21/06	PPSV	4/16/09
hepatitis B	7/18/07	polio	1/1/00
Hib	12/16/98	rabies	1/12/06
HPV (H. papillomavirus)	2/2/07	rotavirus	8/28/08
influenza (LAIV)	7/24/08	shingles	9/11/06
influenza (TIV)	7/24/08	Td/Tdap	11/18/08
Japan. enceph.	5/11/05	typhoid	5/19/04
meningococcal	1/28/08	varicella	3/13/08
MMR	3/13/08	yellow fever	11/9/04

Multi-vaccine VIS 9/18/08
(for 6 vaccines given to infants/children: DTaP, IPV, Hib, Hep B, PCV, RV)

"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

Technical content reviewed by the Centers for Disease Control and Prevention, May 2009.

www.immunize.org/catg.d/p2027.pdf • Item #P2027 (5/09)