

Q&A: Vaccine Information Statements

1. What Vaccine Information Statements (VISs) must be used?

The relevant VIS must be provided to the vaccinee (or to the parent or legal representative) for *any vaccine covered by the National Childhood Vaccine Injury Act (NCVIA)*. As of January 2002, these VISs are: **DTaP, Td, MMR, Polio, Hepatitis B, *Haemophilus influenzae* type b (Hib), Varicella, and Pneumococcal conjugate vaccine**. Rotavirus is also covered by the NCVIA, but the vaccine is not in use.

Use of VISs for vaccines not covered by the NCVIA is strongly encouraged. Other VISs that are available are **Hepatitis A, Influenza, Pneumococcal polysaccharide, Lyme disease, Anthrax, Meningococcal, and Smallpox**.

2. What is the difference between VISs, Important Information Statements (IIS's), and Vaccine Information Materials (VIM's)?

Technically, the law designates statements describing vaccines covered by the NCVIA as Vaccine Information Statements. Important Information Statement is a term that was used for these statements in the past, and is still sometimes used to describe statements for vaccines not covered by NCVIA (e.g., hepatitis A, influenza). From 1991 to 1994 multi-page "Vaccine Information Pamphlets" (VIP's) were used for MMR, DTP, Td, and Polio. Vaccine Information Materials is a generic term that has been used to describe any of these statements. For convenience sake, we now use the term VIS for *all* current information statements.

3. How can I tell if the VISs I am using are the most up-to-date versions?

Check the NIP's website at <http://www.cdc.gov/nip/publications/VIS/>. The VISs posted there will be current.

4. Can providers develop their own vaccine information materials?

All public and private providers who administer the vaccines covered by the NCVIA are required to use the CDC-developed VISs. In 1994, an amendment to the act deleted the language that allowed providers to substitute their own materials for the VISs. However, providers may still *supplement* the VISs with materials of their own.

5. May immunization projects add state or local health department identification to the VISs?

Yes. But any other addition to these documents or variations from their language or format must have the prior written approval of the Director of CDC's National Immunization Program.

6. How are VISs distributed?

Camera-ready copies and explanatory information are sent to all Immunization Projects. The Immunization Projects are responsible for printing and distributing VISs to their public health clinics. They will also be asked to print and distribute single camera-ready copies to all providers who administer vaccine in their state or metro area. Funds have been included in the Immunization Project grants for printing and distribution of the VISs. Some private provider organizations also print and sell copies of the VISs.

The VISs are also available on the internet (see "Where can I get the VISs," below). These are identical to the printed VISs, and may be downloaded and printed out by Immunization Projects or providers and used as camera-ready copy.

7. Must VISs be used for adults as well as for children?

Yes. Under the NCVIA, anyone receiving a covered vaccine should be given the appropriate VIS.

8. Are VISs "informed consent" forms?

No. Informed consent requirements are determined by state law. The VISs were written to fulfill the information requirements of the NCVIA, and are not informed consent documents. However, because the materials cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed.

Nevertheless, you should consult your state law to determine if there are any specific "informed consent" requirements relating to immunization. The requirements could include *procedural* requirements (e.g., whether informed consent is required prior to vaccination, whether it may be oral or must be in writing, whether state law requires a signature prior to vaccination) or *substantive* requirements (e.g., the types of information the state would require to be included in any informed consent).

NOTE: VISs must still be used, even if state law requires use of other informed consent materials.

9. What are the recordkeeping requirements regarding VISs?

Health care providers are **not** required to obtain the signature of the patient, parent or legal representative acknowledging receipt of the VISs. However, to document that the VIS was given, health care providers must note in each patient's permanent medical record at the time a VIS is provided: (1) the date printed on the VIS and (2) the date the VIS is given to the vaccine recipient, or the parent or legal representative.

In addition, the NCVIA still requires that health care providers note in the patient's permanent medical record:

- (1) the date of administration of the vaccine
- (2) the manufacturer and lot number of the vaccine
- (3) the name and address of the health care provider administering the vaccine (This should be the address where the record is kept. If immunizations are given in a shopping mall, for example, the address would be the clinic where the permanent record will reside.)

10. What does "legal representative" mean?

A "legal representative" is a parent or other individual who is qualified *under state law* to consent to the immunization of a minor.

11. Must a VIS be given out every time a vaccine is administered?

Yes. A VIS must be given out with every vaccination, including each dose of a multi-dose series. This is done for several reasons. The statement might have been updated between visits, or the health status of the child could have changed (*e.g.*, he or she may have an evolving neurological disorder).

12. Must the patient, parent, or legal representative physically take away a copy of each VIS, or is it acceptable to simply let them read a copy and ensure that they understand it?

It is desirable for the person getting the shot or their representative to actually take the VISs home, because they include information that may be needed later (*e.g.*, the recommended schedule for the vaccines, information concerning what to look for and do after the vaccination, and what to do if there is a serious reaction). Even if some patients may elect not to take the VISs home, the provider should offer them the opportunity to do so.

13. How should we comply with the law for patients who are illiterate or blind?

The NCVIA requires providers to supplement the VISs with “visual presentations” or oral “explanations” as needed. If patients are unable to read the VISs, it is up to the provider to ensure that they have the information. VISs can be read to these patients, or videotapes (or other media) can be used as supplements.

14. Are the VISs available in languages other than English?

There are currently no “official” CDC translations of the VISs. Several states have translated them, however, and sharing of translations among states is encouraged. Projects or providers may translate the VISs into other languages. These do not have to be approved by CDC. (See “Where can I get the VISs,” below.)

Translations currently exist on the web in Arabic, Armenian, Cambodian, Chinese, Croatian (Serbian), Farsi, French, German, Haitian Creole, Hmong, Japanese, Korean, Laotian, Portugese, Punjabi, Romanian, Russian, Samoan, Serbo-Croatian, Somali, Spanish, Tagalog, Thai, Turkish & Vietnamese.