

Q & A about Vaccine Information Statements

Q What is a Vaccine Information Statement (VIS)?

A A VIS is a two-sided information sheet, produced by the Centers for Disease Control & Prevention (CDC), informing vaccine recipients (or their parents or legal representatives) of the benefits and risks of a vaccine.

Q What Vaccine Information Statements (VISs) must be used?

A *The National Childhood Vaccine Injury Act (NCVIA)* of 1986 requires all health care providers in the United States who administer any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, hepatitis A, *haemophilus influenzae* type b (Hib), human papillomavirus (HPV4), influenza, pneumococcal conjugate, pneumococcal polysaccharide, meningococcal, rotavirus, or varicella antigen to provide a copy of the relevant VIS to either the adult vaccinee or, in the case of a minor, to the parent or legal representative of the child. The VIS must be given prior to administration of the vaccine.

Q What VISs are currently available and what is the most recent date on the VISs as of August 09, 2011?

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| ⇒ DTP/DTaP (5/17/07) | ⇒ Hepatitis A (3/21/06) |
| ⇒ Hepatitis B (7/18/07) | ⇒ Hib (12/16/98) |
| ⇒ HPV2 (Cervarix) (5/3/11) | ⇒ HPV4 (Gardasil) (5/3/11) |
| ⇒ Influenza TIV and LAIV (7/26/11) | ⇒ Meningococcal (1/28/08) |
| ⇒ MMR (3/13/08) | ⇒ MMRV (5/21/10) |
| ⇒ Multi-vaccine* (9/18/08) | ⇒ Pneumococcal Polysaccharide (10/6/09) |
| ⇒ Pneumococcal Conjugate (4/16/10) | ⇒ Polio (1/1/00) |
| ⇒ Rotavirus (12/6/10) | ⇒ Td/Tdap (11/18/08) |
| ⇒ Varicella (chickenpox) (3/13/08) | |

* Multi-vaccine VIS

This VIS may be used in place of individual VISs whenever routine birth through 6-month vaccines (DTaP, IPV, Hib, Hepatitis B, PCV7, and Rotavirus) are administered at the same visit – including combination vaccines (e.g., Pediarix or Comvax) containing those components. When using this VIS, please check the boxes on the first page indicating which antigens are being administered. Note that this VIS is 4 pages (2 pages front & back), instead of the usual 2. Use of the Multi-vaccine VIS is optional. The individual VISs for these vaccines may still be used.

Q Who must use Vaccine Information Statements?

A All public and private providers who administer the vaccines covered by the *NCVIA* are required to use VISs. In 1994, an amendment to the act deleted the language that allowed providers who buy their own vaccine the flexibility to develop their own materials.

Q Are immunization projects permitted to add state or local health department identification to the VISs?

A Yes, in Michigan, the Michigan Department of Community Health (MDCH) has added language about the Michigan Care Improvement Registry (MCIR) to each VIS. This language informs parents or legal representatives about the registry and lets them know that they may choose not to have their children's immunization history data entered into the registry. This language is found at the bottom of the page of each VIS distributed by MDCH. Providers should only use VISs that include the MCIR language.

Q How are VISs distributed?

A Vaccine Information Statements for routine vaccines are available in the quantities you need from your local health department. You may also download camera-ready copies from the MDCH website by going to www.michigan.gov/immunize and clicking on the **Vaccine Information Statements (VIS)** link.

Q Are VISs considered to be "informed consent?"

A The VISs were written to fulfill the information requirements of the amendment to the *NCVIA*. They are not designated informed consent documents. However, they provide enough information that anyone reading them should be adequately informed because the materials cover both benefits and risks associated with vaccinations.

NOTE: All health care providers are required to provide VISs whenever vaccines are given.

Q What are the record-keeping requirements regarding VISs?

A Health care providers are not required to obtain the signature of the patient, parent, or legal representative acknowledging receipt of the VIS. 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* requires that health care providers note the following information in the patient's permanent medical record:

1. the date the vaccine was administered;
2. the manufacturer and lot number of the vaccine; and
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.)

- Q What does "legal representative" mean?
- A A "legal representative" is a parent or an adult designated by the parent (or by the courts, if the child is no longer in the custody of the parent) to consent to the immunization of a minor.
- Q Must a VIS be given out every time a vaccine is administered?
- A Yes, a VIS must be given out prior to each 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).
- Q 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?
- A The provider should encourage the person getting the shot or their representative to actually take the VIS home, because the VIS includes 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).
- Q What about patients or parents who are unable to read the VIS?
- A It is the spirit of the law that providers give their patients certain information about vaccines. If patients are unable to read the VIS, it is up to the provider to ensure that they have that information, either by reading or paraphrasing the VIS to them, and confirming that they understand.
- Q Are the VISs available in languages other than English?
- A There are currently no "official" CDC translations of the VISs. Several states have done translations, and sharing of translations among states is encouraged. Projects or providers may translate the VIS into other languages. These do not have to be approved by CDC. Currently in Michigan, VISs are available in the following languages: Albanian, Amharic, Arabic, Armenian, Bosnian, Burmese, Cambodian, Chinese, Croatian, Farsi, French, German, Haitian Creole, Hindi, Hmong, Ilokano, Italian, Japanese, Karen, Korean, Laotian, Marshallese, Nepali, Polish, Portuguese, Punjabi, Romanian, Russian, Samoan, Serbo-Croatian, Somali, Spanish, Tagalog, Thai, Turkish, Urdu, Vietnamese, and Yiddish. To receive a foreign language VIS, call the Division of Immunization at 1-517-335-8159.