

## Vaccine Information Statements

**IMPORTANT:** By Federal law, all vaccine providers must give patients, or their parents or legal representatives, the appropriate Vaccine Information Statement (VIS) whenever a vaccination is given.

Basic Information about Vaccine Information

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### What is a Vaccine Information Statement?

A Vaccine Information Statement (VIS) is a one-page (two-sided) information sheet, produced by CDC. VISs inform vaccine recipients — or their parents or legal representatives — about the benefits and risks of a vaccine. The law requires that VISs be given out whenever certain vaccinations are given.

### Who must give out VISs?

All provider of vaccines, both public and private sector.

### Why must VISs be used?

It is a requirement of the National Childhood Vaccine Injury Act of 1986. Their purpose is to inform vaccine recipients, or parents of children getting vaccines, about the benefits and risks of vaccines.

### When must VISs be given out?

They must be given out at the time of each vaccination — prior to administration of the vaccine.

### Which VISs must I use?

A VIS must be provided for any vaccine that is covered by the Vaccine Injury Compensation Program (i.e., appears on the Vaccine Injury Table). As of June 2009, VISs that must be used are: DTaP, Td, MMR, Polio, Hepatitis A, Hepatitis B, Hib, Varicella, Influenza, and Pneumococcal Conjugate.

Other VISs that are available are Pneumococcal Polysaccharide, Meningococcal\*, Tdap\*, Rabies, Rotavirus\*, HPV\*, Shingles, Yellow Fever, Typhoid, Japanese Encephalitis, Anthrax, and Smallpox. Their use is not required by the National Childhood Injury Act, but is strongly encouraged – and they must be used when giving vaccines purchased through a CDC contract.

\*Rotavirus Tdap, HPV, and meningococcal vaccines are covered by the Vaccine Injury Compensation Program, but the VISs for these recently-licensed, or recently-covered vaccines have not yet been published in "final" (i.e., non-interim) versions.

### Provider Responsibilities

Today there are more ways to obtain VISs electronically than there have been in the past, and providers have found innovative ways to comply with the VIS law while conserving paper . . . all of which have led to confusion about exactly what a provider's responsibilities are regarding use of VISs.

The legal mandate, as stated in the National Childhood Vaccine Injury Act, is that providers must:

- give the appropriate VIS to the recipient or to the recipient's parent or legal representative with each dose of vaccine,
- give it prior to administration of the vaccine,
- give it each time the vaccine is given (not just with the first dose), and
- record certain information in the patient's permanent medical record.

Within the context of this mandate, and given the variety of ways a VIS can now be offered, note the following instructions:

1. Always offer the patient or parent a copy of the appropriate VIS to read *during the immunization visit*, and a copy (either paper or electronic) to take home. Always offer the patient an opportunity to ask questions. *[Note: When a combination vaccine is administered for which there is not a consolidated VIS, give the patient the individual VISs for each component.]*
2. It is acceptable to make a VIS available to be read *before* the immunization visit (e.g., by giving the patient or parent a copy to take home during a prior visit, or telling them how to download or view a copy from the internet). We encourage this when possible. These patients must still be offered a copy to read during the immunization visit, as a reminder, and a copy to take home.
3. The patient may be offered a permanent (e.g., laminated) copy of the VIS to read during the immunization visit (instead of their own paper copy), or may be directed to the appropriate VIS on an office computer. *[Note: Check the CDC's VIS website periodically to ensure that the office copies you are using are the current editions.]*
4. Always encourage the patient to take a copy of each appropriate VIS home when they leave the office. This is because some information (e.g., the routine schedule, or how to recognize or report an adverse event) can be useful later. Offer the patient a paper copy, or if they prefer to download the VIS onto a mobile device, direct them to CDC's patient download webpage (<http://www.cdc.gov/vaccines/pubs/vis/vis-downloads.htm>) during the visit.
5. As needed, supplement VISs orally, with videotapes, with additional printed material, or in any other way that will help recipients understand the disease and vaccine.
6. Record the required information on the patient's medical record or on a permanent office log (the record should be both permanent and accessible):
  - The edition date of the VIS (found on the back in either the left or right bottom corner). *[Note: When multiple VISs are given for a combination vaccine, record the individual edition dates.]*
  - The date the VIS is provided (i.e., the date of the visit when the vaccine is administered).
  - The name, address (office address) and title of the person who administers the vaccine.
  - The date the vaccine is administered.
  - The vaccine manufacturer and lot number.

### **Providers May Also**

- Add a practice's name, address, or phone number to an existing VIS. If the publication date is cut off during downloading, add the date.
- Have a recipient or their parent or legal representative sign a separate "informed consent" form if it is required by your state. There is no Federal requirement for written informed consent for vaccinations, and VISs are not informed consent forms, but some states have such requirements.

### **Providers Should Not**

- Change a VIS or make your own VIS. The law requires providers to use those developed by CDC.

### **Types of VISs and When to Use Them**

Vaccine Information Statements are mandated by the National Childhood Vaccine Injury Act (NCVIA), and must be used for all vaccines that are covered by this law.

### **Vaccines Covered by the National Childhood Vaccine Injury Act**

VISs for vaccines covered by the NCVIA (as of June 2009), and the dates they were issued, are:

- DTaP (includes DT): 5/17/07
- Td/Tdap: 11/18/08 (Interim)
- Hib: 12/16/98
- Hepatitis A: 3/21/06
- Hepatitis B: 7/18/07 (Interim)
- Human Papillomavirus (HPV): 2/2/07 (Interim)
- Inactivated Influenza: 7/24/08 (Updated annually)
- Live, Intranasal Influenza: 7/24/08 (Updated annually)

- MMR:3/13/08 (Interim)
- Meningococcal: 1/28/08 (Interim)
- Pneumococcal Conjugate: 12/9/08 (Interim)
- Polio: 1/1/00
- Rotavirus: 8/28/08 (Interim)
- Varicella: 3/13/08 (Interim)
- Multi-Vaccine VIS: 9/18/08 (Interim) May be used for any combination of DTaP, polio, hepatitis B, rotavirus, PCV, and Hib.

Note: When giving combination vaccines for which no separate VIS exists (e.g., DTP/Hib, Hib/Hepatitis B) give out all relevant VIS's.

**These VISs must always be used\***. Every time one of these vaccines is given — regardless of what combination it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — regardless of the age of the recipient — the appropriate VIS must be given out at the time of the vaccination. (\*Because "final" VISs have not yet been issued for rotavirus, HPV, Tdap, and meningococcal vaccines, their use is technically not mandated by the NCVIA, but it is strongly encouraged.)

### **Vaccines NOT Covered by the National Childhood Vaccine Injury Act**

VISs also exist for vaccines not covered by the NCVIA. We encourage their use whenever the vaccine is given, but they must be used when the vaccine was purchased under CDC contract. The legal basis for this is not the NCVIA, but a "Duty to Warn" clause in CDC's vaccine contracts.

These VISs are identical to those for the NCVIA vaccines, except they do not bear a reference to the law (42 U.S.C. § 300aa-26) and do not contain information about the National Vaccine Injury Compensation Program.

VISs for vaccines not covered by the NCVIA (as of June 2009), and the dates they were issued, are:

- Anthrax: 4/24/03
- Japanese Encephalitis: 5/11/05
- Pneumococcal Polysaccharide: 4/16/09
- Rabies: 1/12/06
- Shingles: 9/11/06 (Interim)
- Smallpox: 1/16/03
- Typhoid: 5/19/04
- Yellow Fever: 11/9/04

VISs were once available for these vaccines that are no longer used in the U.S.:

- Rotavirus (discontinued vaccine used in 1998-99)
- Lyme Disease

### **How to get Vaccine Information Statements**

- **The Internet.** All current VISs are available on the internet at two websites — the CDC's Vaccines & Immunizations site ([www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)) and the Immunization Action Coalition ([www.immunize.org/vis/](http://www.immunize.org/vis/))(exit). VISs from these sites can be downloaded as pdf files and printed. You can also order single hard copies of the VISs using NIP's Online Order Form (at [www.cdc.gov/vaccines/pubs](http://www.cdc.gov/vaccines/pubs)).
- **State Health Department.** CDC sends each state health department's immunization program camera-ready copies when a new VIS is published. The immunization program in turn provides copies to providers within the state.
- **CDC Contact Center** (immunization information). Call 1-800-CDC-INFO (or 1-800-232-4636) English and Español.

- A set of **7 videotapes** of VISs (MMR, DTP, Polio, Hepatitis B, Hib, Varicella, and Pneumococcal Conjugate) is available in English and Spanish from Michigan State University Extension. Tapes run approximately 5-9 minutes each, and a set costs \$25. For information, call (517) 432-8204.

## Translations

VISs have been translated into 30 languages by the California and Minnesota immunization programs.

Arabic	German	Marshallese	Somali
Armenian	Haitian Creole	Polish	Spanish
Bosnian	Hindi	Portugese	Tagalog
Cambodian	Hmong	Punjabi	Thai
Chinese	Ilokano	Romanian	Turkish
Croatian	Japanese	Russian	Vietnamese
Farsi	Korean	Samoan	
French	Laotian	Serbo-Croatian	

Translations can be found on the Immunization Action Coalition's website ([www.immunize.org/vis](http://www.immunize.org/vis))(exit).

## Frequently Asked Questions

### Are VISs "informed consent" forms?

No. People sometimes use the term "informed consent" loosely when referring to VISs. But even when vaccine information materials had tear-off sheets for parents to sign, they were not technically informed consent forms. The signature was simply to confirm that the "Duty to Warn" clause in the vaccine contract was being fulfilled.

There is no Federal requirement for informed consent. VISs are written to fulfill the information requirements of the NCVIA. But because they cover both benefits and risks associated with vaccinations, they provide enough information that anyone reading them should be adequately informed. Some states have informed consent laws, covering either procedural requirements (e.g., whether consent may be oral or must be written) or substantive requirements (e.g., types of information required). Check your state medical consent law to determine if there are any specific informed consent requirements relating to immunization. VISs can be used for informed consent as long as they conform to the appropriate state laws.

### Should the VISs be used for adults getting vaccines as well as for children?

Yes. Under the National Childhood Vaccine Injury Act, anyone receiving a covered vaccine should be given the appropriate VIS. VISs are worded so they may be used by adults as well as children. An exception is the DTaP VIS, since DTaP is not licensed for adults. There are separate VISs for adult Td and Tdap vaccines. Apart from legal requirements, it is good practice to give the appropriate VIS every time a vaccine is administered, to anyone of any age.

### The law states that vaccine information materials be given to a child's legal representatives. How is "legal representative" defined?

A "legal representative" is a parent or other individual who is qualified under state law to consent to the immunization of a minor. There is not an overriding Federal definition.

### Must the patient, parent, or legal representative physically take away a copy of each VIS, or can we simply let them read a copy and make sure they understand it?

Ideally the person getting the shot, or their representative, should actually take each VIS home. They contain information that may be needed later (e.g., the recommended vaccine schedule, information about what to do in the case of an adverse reaction). Patients may choose not to take the VIS, but the provider should offer them the opportunity to do so.

## **When do providers have to start using a new VIS?**

The date for a new VISs required use is announced when the final draft is published in the Federal Register. Ideally, providers will begin using a new VIS immediately, particularly if the vaccine's contraindications or adverse event profile have changed significantly since the previous version.

## **How should we comply with the law for patients who cannot read the VISs (e.g., those 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 that information. VISs can be read to these patients, or videotapes can be used as supplements. At least one CD-ROM is being produced on which users can hear the VIS's read. The VISs available on CDC's website are compatible with screen reader devices.

## **Why are the dates on some of the VISs so old? Are they obsolete? Why can't they be updated every year?**

VISs are updated only when they need to be. For instance, a VIS would be updated if there were a change in ACIP recommendations that affects the vaccine's adverse event profile, indications, or contraindications. It's true that some people might be concerned that a VIS that is several years old might be outdated. On the other hand, knowing that VISs posted on the NIP website will always be the current versions should help alleviate that concern. Annually changing the dates on VISs that haven't changed otherwise could be confusing too, because there would be multiple VISs in circulation that were identical but would have different dates.

## **Sometimes a VIS will contain a recommendation that is at odds with the manufacturer's package insert. Why?**

VISs are based on the ACIP's recommendations, which occasionally differ from those made by the manufacturer. These differences may involve adverse events. Package inserts generally tend to include all adverse events that were temporally associated with a vaccine during clinical trials, whereas ACIP tends to recognize only those likely to be causally linked to the vaccine.

## **What is the reading level of VISs?**

Defining the readability of a VIS by a traditional "grade level" measure can be difficult and misleading. Two of the criteria used by standard readability formulas are word length and sentence length. Word length is not necessarily a reliable measure of readability, as there are multi-syllable words that are widely understood (e.g., "individual") and short words that are not (e.g., "spiv"). VISs are often unavoidably saddled with long words ("*Haemophilus influenzae*" for instance, or "vaccination" or "compensation" or "polysaccharide") which drive the reading level up. Sentence length can be a problem with VISs because they incorporate bulleted lists, which may be read as very long sentences (no period), while they are actually quite easy to understand.

Applying a Fletch-Kincaid test to a VIS usually reveals about a 10th grade reading level, but this should be taken with the caveats in the preceding paragraph.

In what may be a more useful measure of readability, several VISs were the subject of a series of focus groups among low-literacy parents in a variety of racial and ethnic groups (some not native English speakers) in 1998, and the participants overwhelmingly rated them easy to read and understand.

## **How should we distribute VISs when the parent or legal representative of a minor is not present at the time the vaccination is given, for example during a school-based adolescent vaccination program?**

CDC's legal advisors have proposed two alternatives for this situation:

1. Consent Prior to Administration of Each Dose of a Series. With this alternative the VIS must be mailed or sent home with the student around the time of administration of each dose. Only those

children for whom a signed consent is returned may be vaccinated. The program must place the signed consent in the patient's medical record.

2. **Single Signature for Series.** This alternative is permissible only in those States where a single consent to an entire vaccination series is allowed under State law and in those schools where such a policy would be acceptable. The first dose of vaccine may be administered only after the parent or legal representative receives a copy of the VIS and signs and returns a statement that a) acknowledges receipt of the VIS and provides permission for their child to be vaccinated with the complete series of the vaccine (if possible, list the approximate dates of future doses); and b) acknowledges their acceptance of the following process regarding administration of additional doses:
  - prior to administration of each dose following the initial dose, a copy of the VIS will be mailed to the parent (or legal representative) who signs the original consent at the address they provide on this statement, or the VIS will be sent home with the student; and
  - the vaccine information statements for the additional doses will be accompanied by a statement notifying the parent that, based on their earlier permission, the next dose will be administered to their child (state the date), unless the parent returns a portion of this statement by mail to an address provided, to arrive prior to the intended vaccination date, in which the parent withdraws permission for the child to receive the remaining dose.

The program must maintain the original consent signature and any additional dose veto statements in the patient's medical record. A record must be kept of the dates prior to additional doses that the VIS was mailed, or sent home with the adolescent.

Prior to administration of each additional dose, the provider should ask the adolescent whether he/she experienced any significant adverse events following receipt of earlier doses. If yes, the provider should consider consulting the parent or delaying the vaccination. The adolescent's response to questions about adverse reactions to previous doses should be kept in the medical record.