

**APPENDIX E
Vaccine Information Statements**

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Appendix E

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 and shingles 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 vaccines (e.g., Pediarix, Pentacel, Comvax) or when giving two or more routine vaccines at other pediatric visits (e.g., 12–15 months, 4–6 years).

It is also acceptable to have the patient read the VISs on an office computer or in a more permanent (e.g., laminated) format during the office visit. If this option is chosen, the patient must be given the option to take a paper copy with them.

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.

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

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_sources.asp.

Most current versions of VISs

As of December 2010, the most recent versions of the VISs are as follows:

DTaP/DT/DTP.....	5/17/07	MMR.....	3/13/08
Hepatitis A	3/21/06	MMRV	5/21/10
Hepatitis B	7/18/07	PCV7	12/9/08
Hib	12/16/98	PCV13	4/16/10
HPV (H. papillomavirus).....		PPSV	10/6/09
Cervarix.....	3/30/10	Polio	1/1/00
Gardasil.....	3/30/10	Rabies	10/6/09
Influenza (inactive)...	8/10/10	Rotavirus	12/6/10
Influenza (live).....	8/10/10	Shingles	10/6/09
Japanese encephalitis.....		Td/Tdap	11/18/08
JE-VAX.....	3/1/10	Typhoid	5/19/04
JE-Ixiaro.....	3/1/10	Varicella	3/13/08
Meningococcal.....	1/28/08	Yellow fever	11/9/04

Multi-vaccine VIS9/18/08
(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**

Instructions for the Use of Vaccine Information Statements

Required Use

1. Provide a Vaccine Information Statement (VIS) when a vaccination is given.

As required under the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), all health care providers in the United States who administer, to any child or adult, any of the following vaccines – diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), trivalent influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) – shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- to the parent or legal representative* of any child to whom the provider intends to administer such vaccine, or
- to any adult† to whom the provider intends to administer such vaccine.

If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines.

VISs should be supplemented with visual presentations or oral explanations as appropriate.

*"Legal representative" is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor child or incompetent adult.

†In the case of an incompetent adult, relevant VISs shall be provided to the individual's legal representative. If the incompetent adult is living in a long-term care facility, all relevant VISs may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each vaccination.

2. Record information for each VIS provided.

Health care providers shall make a notation in each patient's permanent medical record at the time vaccine information materials are provided, indicating:

- (1) the edition date of the Vaccine Information Statement distributed, and
- (2) the date the VIS was provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. §300aa-25 that all health care providers administering these vaccines must record in the patient's permanent medical record (or in a permanent office log):

- (3) the name, address and title of the individual who administers the vaccine,
- (4) the date of administration, and
- (5) the vaccine manufacturer and lot number of the vaccine used.

Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State laws.

Availability of Copies

Copies are available in English and many other languages from CDC's website at www.cdc.gov/vaccines/pubs/vis. Single camera-ready copies may also be available from State health departments.

Current VIS Editions

DTaP/DT: 5/17/07	Meningococcal: 1/28/08†
Hib: 12/16/98	Pneumococcal (PCV7): 12/9/08†
Hepatitis A: 3/21/06	Pneumococcal (PCV13): 4/16/10†
Hepatitis B: 7/18/07†	Polio: 1/1/00
HPV (Cervarix): 3/30/10†	Rotavirus: 5/14/10†
HPV (Gardasil): 3/30/10†	Tdap/Td: 11/18/08†
Influenza (inactivated): 8/10/10†	Varicella: 3/13/08†
Influenza (live): 8/10/10†	Multi-Vaccine*: 9/18/08†
MMR: 3/13/08†	
MMRV: 5/21/10†	

*An optional alternative when two or more routine childhood vaccines (i.e., DTaP, hepatitis B, Hib, pneumococcal, polio, or rotavirus) are administered at the same visit.

†Interim

Reference 42 U.S.C. §300aa-26
August 10, 2010



Where to Get Vaccine Information Statements

1. **The Internet.** All current VISs are available on the internet from two websites:
 - CDC (www.cdc.gov/vaccines/pubs/vis/default.htm)
 - The Immunization Action Coalition (www.immunize.org/vis/)
 VISs from these sites can be downloaded as pdf files and printed.

2. **CDC's Immunization Works CD.** This CD contains pdf files for all VIS (current as of the date the CD was issued). *Immunization Works* is usually available at CDC's immunization booth at conferences or can be ordered through CDC's online publications order form at https://www2a.cdc.gov/nchstp_od/PIWeb/niporderform.asp.

3. **State Health Departments.** CDC sends each state health department's immunization program camera-ready copies when a new VIS is published. The programs, in turn, can provide copies to providers within the state.

Audio files for most VISs can be downloaded from CDC's VIS webpage.

Text versions of VISs can also be accessed from CDC's VIS webpage. These files are compatible with screen-reader devices for use by the vision-impaired.

Translations of many VISs are available in more than 30 languages from the Immunization Action Coalition's website (www.immunize.org/vis/index.htm). Languages available include:

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

Vaccine Information Statements: Frequently Asked Questions

Are VISs "informed consent" forms?

No. People sometimes use the term "informed consent" loosely when referring to VISs.

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. 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 each VIS should be taken 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 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. VISs can be read to illiterate or blind 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. VISs posted on the NIP website are always be the current versions. Annually changing the dates on VISs that haven't changed otherwise could be confusing, 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 shown to be causally linked to the vaccine.

What is the reading level of VISs?

We discourage defining a VIS's readability by using traditional "grade level" measures, which can be misleading.

Applying a Fletch-Kincaid test to a VIS usually reveals about a 10th grade reading level. 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. Additional testing was done in 2010, also with positive results.

Appendix E

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:

- **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.
- **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.

Questions concerning the Pediatric Multi-Vaccine VIS:**May the existing, single-vaccine VISs still be used?**

Yes. The Multi-Vaccine VIS is an optional alternative to existing VISs. Providers wishing to continue using the individual VISs may do so. These will continue to be updated when recommendations change.

May the Multi-Vaccine VIS be used with combination vaccines, such as Pediarix or Comvax?

Yes. Just check the appropriate boxes on the first page as you would if you were administering the individual vaccines.

When we record the edition date of the VISs on the patient's medical record, do we record the date on the Multi-Vaccine VIS or the dates on the individual VISs?

Record the date of the Multi-Vaccine VIS for each vaccine given. If there is ever a question, this will make it clear that this VIS was used, and not the individual VISs.

Can the Multi-Vaccine VIS be used for children older than 6 months, or for adolescents or adults getting any of these vaccines?

It may be used for older children getting two or more of these vaccines during the same visit (e.g., a 12-month old getting Hib and PCV or a 4-year old getting DTaP and IPV). It should not be used for adolescents or adults.

Can the Multi-Vaccine VIS be used for catch-up doses?

Yes, as long as the doses are given to children as part of the primary series or routine pediatric boosters.

If a single-vaccine VIS is updated before the Multi-Vaccine VIS, may the multi continue to be used for that vaccine?

Sometimes there can be delays in updating a VIS. If an individual VIS for a vaccine covered on the multi gets updated before the multi does, the multi may still be used. You may give the patient the new single VIS at the same time, or explain verbally or with other written materials any changes. This is most important if the changes involve contraindications or adverse events; *in these cases be certain the patient gets up-to-date information*. It is less important if the update reflects other changes, such as changes in the routine schedule.

CDC's Vaccine Information Statement Webpage <http://www.cdc.gov/vaccines/pubs/vis/default.htm>

Vaccines: Pubs/VIS/main page - Windows Internet Explorer provided by ITSO

http://www.cdc.gov/vaccines/pubs/vis/default.htm

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- Basics and Common Questions
- Vaccination Records
- Vaccine Safety and Adverse Events
- For Travelers
- For Specific Groups of People
- Campaign Materials

Additional Resources

- Publications
 - Vaccine Information Statements (VIS)
 - Textbooks, Manuals and Guidelines
 - Fliers and Brochures
 - Posters
 - Videos, Broadcasts, Webcasts, PSAs and Podcasts
 - Recommendations and Reports
 - Stickers, Buttons, CDs, etc.
 - More Sources of Publications

Publications:

Vaccine Information Statements

At a glance: _____

Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Federal law requires that VISs be handed out whenever (before each dose) certain vaccinations are given.

Downloadable VISs :

- Multiple Vaccines (DTaP, IPV, Hib, PCV, Hepatitis B, and Rotavirus)
- Anthrax | DTaP | Hepatitis | Hib | Influenza UPDATED | HPV | JE | MMR | MMRV
- Meningococcal | PCV13 and PCV7 | PPSV23 | Polio | Rabies
- Rotavirus UPDATED | Shingles | Smallpox | Td/Tdap | Typhoid | Varicella | Yellow Fever

VIS News Information about new, existing, and upcoming VISs (last updated 12/14/10)

UPDATED

- Mandatory Instructions for Use of the Vaccine Information Statements
- Q&A - VIS Facts (Updated 12/7/10)
- Important VIS Information
- Do NOT delay vaccination because of absence of VIS
- Download VIS to Patient's Mobile Device

Downloadable VISs

Get Email Updates

Callouts:

- Jump to any VIS.
- Learn about new VISs, upcoming VISs, other items of interest.
- Download VIS Instructions
- Get on mailing list for VIS updates.

Vaccines: Pubs/VIS/main page - Windows Internet Explorer provided by ITSO

http://www.cdc.gov/vaccines/pubs/vis/default.htm

Favorites: Vaccines: Pubs/VIS/main page

DIPHTHERIA/TETANUS/PERTUSSIS (DTaP) (5/17/07)

- DTaP [PDF-59KB] (compliant)
- Audio*
- Other languages** (including Spanish)

HEPATITIS A VACCINE (3/21/06)

- Hepatitis A [PDF-68KB] (compliant)
- Audio* (not current)
- Other languages** (not current)

Callouts:

- Edition date.
- Download pdf file for printing, or to PDA.
- Play audio file of VIS.
- Go to Immunization Action Coalition site to access translations.