

# Appendix C

## Vaccine Information Statements: Frequently Asked Questions

For an updated list of VIS FAQs, visit: <https://www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html>

### General Questions

#### **Q: Are VISs “informed consent” forms?**

**A:** No. People sometimes use the term “informed consent” loosely when referring to VISs. VISs are written to fulfill the information requirements of the National Childhood Vaccine Injury Act, not as informed consent forms. 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 may be used for informed consent as long as they conform to the appropriate state laws.

#### **Q: Why is it recommended that the patient be given a copy of the VIS to take away following vaccination?**

**A:** In addition to information about the vaccine’s risks and benefits, VISs contain information that may be useful later (e.g., information about what to do in the case of an adverse reaction, and where to find additional information about the disease or vaccine). Patients may choose not to take the VIS, but the provider should offer them the opportunity.

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

**A:** 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. Knowing that VISs posted on CDC’s VIS website are always current should help alleviate any concern. Annually changing the dates on VISs that haven’t changed otherwise could be confusing too, because there could be multiple VISs in circulation that are identical but have different dates. Providers using paper VISs shouldn’t be required to renew their stocks each year because the date changed.

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

**A:** Defining the readability of a VIS by a quantitative “grade level” measure can be difficult and misleading, particularly for a document in which certain long words can’t be avoided, and which is not formatted in a traditional block-text style. Applying a Flesch-Kincaid test to a VIS usually shows about a 10th grade reading level. Great care is taken to make VISs as easy to read and understand as possible, given the constraints imposed by the subject matter. When questioned, representative patients, including those considered “low-literacy,” have reported finding VISs easy to understand.

#### **Q: Some VISs contain recommendations that are at odds with the manufacturer’s package insert. Why?**

**A:** 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 believed to be causally linked to the vaccine.

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

**A:** Yes. 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. Exceptions are VISs for vaccines that are not licensed for adults, such as DTaP or rotavirus.

**Q: The law states that VISs may be given to a child’s “legal representative.” How is “legal representative” defined? Is it different from “legal guardian?”**

**A:** “Legal representative” is a parent or other individual who is qualified under state law to consent to the immunization of a minor. It could include people other than the child’s legal guardian.

**Q: Where can I find the edition dates of past VISs?**

**A:** See the [list of edition dates of all past VISs](#), and vaccine information materials predating VISs.

## Using Vaccine Information Statements

**Q: How do we determine when a VIS must be given to a “legal representative” rather than to the patient? For example, if an 18-year old is considered a child, would it be illegal to give a VIS to him or her directly, as opposed to a parent or guardian?**

**A:** The National Childhood Vaccine Injury Act does not define a “child” for purposes of the Act. “Legal representative” is defined as “a parent or an individual who qualifies as a legal guardian under State law.” A reasonable interpretation is that State law, and specifically the State’s medical consent law, should be deferred to for purposes of defining who is a minor. For example, if an 18 year old can consent to immunization under a State’s law, that 18 year old is the person who should be provided a copy of the VIS.

**Q: 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?**

**A:** When parents/legal representatives are not present at the time of vaccination of a minor (e.g., school-located vaccination clinics held during school hours, school-based health centers), several challenges arise related to provision of Vaccine Information Statements (VISs). Please see the questions and answers below for guidance on how to address these challenges.

**Q: How early can VISs be provided to parents/legal representatives prior to vaccination?**

**A:** The National Childhood Vaccine Injury Act requires that a current VIS be provided to parents/legal representatives prior to vaccination. Although the Act does not specify the amount of time allowed between VIS provision and vaccination, they must be provided as close to the time of vaccination as is programmatically feasible and reasonable, keeping in mind that VISs are designed to inform vaccine recipients (or their parents/legal representatives) about the risks and benefits of specific vaccines, as well as medical eligibility, prior to vaccine receipt. For example, providing VISs several weeks prior to a scheduled school-located vaccination clinic may be reasonable. However, providing VISs several months prior to vaccination (e.g., providing them in July for a January vaccination clinic or at the end of one school year for a vaccination clinic the next school year) is not acceptable as parents/legal representatives may not have retained the VISs to review just prior to vaccination, the VIS may have since been revised, and a student’s medical eligibility may have changed during that time.

**Q: Is there a requirement to verify that parents/legal representatives have actually received and reviewed the VIS?**

**A:** Yes. The mandatory instructions for use of the VIS require providers to make a notation in the patient’s medical record or permanent office log regarding provision of the VIS. If VISs (paper or electronic) are not provided to parents/legal representatives at the time of vaccination, parents/legal representatives must acknowledge in writing (or electronically) receipt and review of the current VIS. This can be accomplished by including a written statement that the parent/legal representative received and reviewed the current edition of the VIS, with the edition date specified, on the medical consent form authorizing vaccination. The parent’s/legal representative’s signature (or electronic signature if allowed under state law) then verifies receipt/review. Where allowed under the applicable state medical consent law, such verification/consent can be accomplished through electronic means. The signed verification of receipt/review of the VIS must be retained by the clinic/health care provider in the same manner and for the same timeframe as other medical consents are required to be retained by health care providers under the state’s medical consent law.

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## **Q: What are the acceptable methods of VIS provision to parents/legal representatives?**

**A:** If the parent/legal representative is present at the time of vaccination, the VIS (paper or electronic) must be provided to the parent/legal representative before the child is vaccinated. If the parent/legal representative is not present, provision of the VIS prior to vaccination must be coupled with a method to verify parent/legal representative receipt of the VIS, in addition to parent/legal representative consent to vaccination in compliance with the applicable state medical consent law. Some examples of methods of VIS provision are as follows\*:

- Providing a physical copy of the VIS to the parent/legal representative;
- Providing a link to the VIS in a physical letter sent to the parent/legal representative;
- Providing the VIS as an attachment or weblink contained within an email sent to the parent/legal representative.

\*As noted above, if not provided directly to the parent/legal representative at the time of vaccination, the VIS must be provided prior to vaccination along with a requirement to acknowledge receipt/review of the VIS. This requirement can be accomplished by adding a written statement that the parent/legal representative received and reviewed the current edition of the VIS, with the edition date specified, on the medical consent form authorizing vaccination. Where allowed under the applicable state medical consent law, such verification/consent can be accomplished through electronic means.

## **Q: Our state allows parents/legal representatives to provide a single, one-time consent for vaccines that require multiple doses given over weeks or months. In this case, do we have to provide a VIS prior to every dose administered?**

**A:** Yes. Since a child's medical condition might change between doses, a VIS must be provided prior to administration of each dose to allow the parent to review the child's situation and determine whether or not to withdraw consent for additional doses. However, an additional acknowledged verification of receipt/review of the VIS and consent to vaccination for the following doses is not required if a single consent for a vaccine series is authorized under the applicable state medical consent law. In that instance, the original verification of receipt/review of the VIS and consent to the vaccination series sent prior to administration of the first dose must comply with any state medical consent requirement related to providing a process through which the parent/legal representative may later withdraw consent for additional doses, if such a requirement exists.

## **Q: How should we comply with the law for patients who cannot read the VISs (e.g., those who are illiterate or blind)?**

**A:** 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.

## **Q: How should we deal with combination vaccines for which there is not a VIS?**

**A:** Unfortunately, it is impractical to produce VISs for all licensed combination vaccines. When administering a combination vaccine, one option is to use the individual VISs for each component. For example, when administering Pediarix, use the VISs for DTaP, hepatitis B, and polio.

A second option is to use the Pediatric Multi-vaccine VIS when the combination vaccine contains components that are part of that VIS (DTaP, hepatitis B, Hib, PCV13, and polio). Using the same example, the Pediatric Multi-vaccine VIS can be used when administering Pediarix, and will require only one VIS to be used, rather than three.

## New and Updated VISs

### **Q: What should be done if there is not a VIS for a particular vaccine?**

**A:** It is possible, particularly for a newly-approved vaccine, that the vaccine could become available before a VIS can be produced. The law does not require that a vaccine be withheld if a VIS for it does not yet exist. Until a VIS is available for a particular vaccine, a provider may use the manufacturer's package insert, written FAQs, or any other document – or produce their own information materials – to inform patients about the benefits and risks of that vaccine. Once a VIS is available it should be used; but providers should not delay use of a vaccine because of the absence of a VIS.

### **Q: When do we have to start using a new VIS?**

**A:** The date for a new VIS's required use is announced when the final draft is published in the Federal Register. Ideally, providers will begin using a new VIS immediately. A provider might be reluctant to discard existing stocks of a VIS when a new edition is published. This will become less an issue as providers and patients begin to rely more on electronic, rather than paper, versions of VISs. As a general rule, when changes to a VIS concern the safety of the vaccine (e.g., contraindications or precautions, or adverse events), it is essential that the new edition be used immediately upon publication.

### **Q: What should we do if recommendations for a vaccine change but there is a delay in updating the appropriate VIS?**

**A:** Production of a VIS can be held up for a variety of reasons. As we say for newly-approved vaccines, never withhold a vaccine because there is not a current VIS for it. The existing VIS should continue to be used, and the provider can supplement it, as appropriate, either verbally or with the manufacturer's package insert or other print materials.

## The Pediatric Multi-Vaccine VIS

### **Q: May the existing, single-vaccine VISs still be used?**

**A:** 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.

### **Q: 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?**

**A:** When you use the Multi-Vaccine VIS, record its date 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.

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

**A:** 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.

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

**A:** 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.