

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 National Childhood Vaccine Injury Act (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 may 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. Anyone receiving a covered vaccine should be given the appropriate VIS. VISs for vaccines that may be administered to both children and adults are worded so they may be used by both. 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., 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. VISs are available electronically, and may be taken away in electronic form.

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 allows 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 several years 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 CDC website are always 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 recommendations of the Advisory Committee on Immunization Practices (ACIP), the committee that advises CDC on immunization policy. The ACIP's recommendations 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. ACIP may also harmonize recommendations for similar vaccines produced by different manufacturers, for which approved indications differ slightly.

What is the reading level of VISs?

VIS's generally test at about a 10th grade reading level, according to Fletch-Kincaid. However, traditional "grade level" measures may be misleading for VISs. VISs are carefully written to be accessible to a diverse audience while remaining technically accurate. Several representative VISs have been subjected to focus group testing among low-literacy parents in a variety of racial and ethnic groups (some not native English speakers), and were generally judged to be easy to read and understand. VISs are always reviewed for readability, within the constraints imposed by the need for technical accuracy.

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.

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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.

Questions concerning use of VISs for minors when the legal representative is not present at the time of vaccination:

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:

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

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.

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

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.

What if the VIS is updated after it has been provided to parents/legal representatives but before vaccination occurs?

The VIS provided to parents/legal representatives must be current at the time of vaccination. If a VIS is updated and becomes effective after a previous version has been provided to parents/legal representatives, the parents/legal representatives must be notified of the updated VIS, a current VIS must be redistributed prior to vaccination, and verification of receipt/review of the current VIS must be obtained. Programs may wish to consider requiring parents/legal representatives to re-consent to vaccination in such a situation.

Appendix C

What are the acceptable methods of VIS provision to parents/legal representatives?

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.

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?

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.