

Questions & Answers: Vaccine Information Statements

1. 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 for vaccines that are administered to both adults and children are worded so they may be used by both.

2. 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 National Childhood Vaccine Injury Act. 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.

3. The law states that vaccine information materials be given to a child's legal representatives. Is this the same as "legal guardian?"

Not necessarily. A "legal representative" is a parent or other individual who is qualified under state law to consent to the immunization of a minor. It does not have to be the child's legal guardian (e.g., it could be a grandparent). There is not an overriding Federal definition.

4. 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. VISs contain information that may be useful 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 must offer them the opportunity to do so.

5. 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.

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

The National Childhood Vaccine Injury Act 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 access to the information they contain. VISs can be read to these patients, or video-tapes can be used as supplements. At least one CD-ROM is being produced on which users can hear the VIS's read. Audio files and versions of VISs that are compatible with screen reader devices are available on CDC's VIS website.

7. 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 affected the vaccine's adverse event profile, indications, or contraindications. If VISs were dated annually, there would be multiple editions in circulation that were identical but would have different dates. As it is, only the most recently-dated VIS for each vaccine is valid. VISs posted on CDC's VIS webpage will always be current, regardless of the edition date.

8. Sometimes a VIS contains recommendations 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. For example, a package insert may mention 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.

9. 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 criteria used in standard readability formulas are word length and sentence length. Neither is necessarily a reliable measure of readability. There are multi-syllable words that are widely understood and short words that are not. VISs often use bulleted lists, which a readability program might see as very long sentences (no period), even though they are actually quite easy to understand.

Applying a Fletch-Kincaid test to a VIS usually shows about a 10th grade reading level, but this should be taken with the caveats mentioned above.

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 (including non-native English speakers) in 1998, and the participants overwhelmingly rated them easy to read and understand. Another round of focus groups is scheduled to be conducted soon, probably in 2009.

10. Which VISs must be used?

The appropriate VIS must be provided to the recipient of any vaccine covered by the National Childhood Vaccine Injury Act (NCVIA). VISs are available for all vaccines licensed in the United States (except BCG). Their use is strongly encouraged, whether mandated by the NCVIA or not.

11. May providers develop their own vaccine information materials or modify the VISs?

Providers who administer vaccines covered by the National Childhood Vaccine Injury Act are required to use the official CDC VISs. However, providers may supplement the VISs with materials of their own. Health departments or providers may add clinic name and contact information to a VIS as long as no other changes are made. Any other addition to these documents or variations from their language or format must have the prior written approval of the Director of CDC's National Center for Immunization and Respiratory Diseases.

12. 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?

CDCs 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 doses.

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.

The following questions concern CDC's Multi-Vaccine VIS (www.cdc.gov/vaccines/pubs/vis/downloads/vis-multi.pdf).

13. Why was a Multi-Vaccine VIS developed?

It was developed with the earliest pediatric visits (i.e., birth through 6 months) in mind. Up to 6 vaccinations could be given during these visits, meaning (for the provider) that 6 individual VISs would have to be downloaded, printed and distributed and (for the patient) 6 documents would have to be read, containing much information that is duplicated. The multi-vaccine VIS is an effort to simplify and streamline this process.

E 14. May the existing, single-vaccine VISs still be used?

Yes. The Multi-Vaccine VIS 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, as they have always been.

15. Must all 6 vaccines be given at the same visit for the Multi-Vaccine VIS to be used?

No. Any time two or more of the vaccines are given together it makes sense to use the Multi-Vaccine VIS. The provider should check the appropriate boxes on the first page, corresponding to vaccines given during that visit.

16. 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.

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

If you use the Multi-Vaccine VIS, record its date for each of the vaccines given that day. If there is ever a question, this will make it clear that the Multi-Vaccine VIS was used and not the individual VISs.

18. Can the Multi-Vaccine VIS be used for children older than 6 months, or for adolescents or adults getting any of these same 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). However it should not be used for adolescents or adults. The information on this document applies to pediatric use of the vaccines. Risk factors that apply only to older persons, for example, are not discussed on this VIS. The individual VISs should be used.

19. May 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.

20. The Multi-Vaccine VIS covers "pneumococcal" vaccine. Is it just for PCV7, or may it also be used when PPV23 is given to children?

It was designed with PCV7 specifically in mind. For PPV23, use the single VIS.

21. Will there be other Multi-Vaccine VISs, for example, for vaccines administered at 12-months or during the pre-school or adolescent-visits?

There is a multi-vaccine VIS for adolescents in development now, and plans to develop one for the 12-month vaccines as well.