APPENDIX C

Vaccine Information Statements

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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.

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/hcp/vis/index.html. Ready-to-copy versions may also be available from your state or local health department.

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 June 11, 2014, the most recent versions of the VISs are as follows:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Date</th>
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<tbody>
<tr>
<td>Adenovirus</td>
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<td>DTaP</td>
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<td>Hib</td>
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<tr>
<td>Hepatitis A</td>
<td>10/25/11</td>
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<tr>
<td>Hepatitis B</td>
<td>2/2/12</td>
</tr>
<tr>
<td>HPV-Cervarix</td>
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</tr>
<tr>
<td>HPV-Gardasil</td>
<td>5/17/13</td>
</tr>
<tr>
<td>Influenza</td>
<td>7/26/13</td>
</tr>
<tr>
<td>Japanese enceph.</td>
<td>1/24/14</td>
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<tr>
<td>MMR</td>
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<td>Expected mid-2014</td>
<td></td>
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<tr>
<td>PCV13</td>
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<td>PPSV</td>
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<tr>
<td>Polio</td>
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</tr>
<tr>
<td>Rabies</td>
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<tr>
<td>Shingles</td>
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<tr>
<td>Td</td>
<td>2/4/14</td>
</tr>
<tr>
<td>Tdap</td>
<td>5/9/13</td>
</tr>
<tr>
<td>Typhoid</td>
<td>5/29/12</td>
</tr>
<tr>
<td>Yellow fever</td>
<td>3/30/11</td>
</tr>
</tbody>
</table>
Appendix C

Top 10 Facts about VISs

Fact 1 It’s federal law!
Federal law requires that VISs must be used for the following vaccines when vaccinating patients of ALL ages:
- DTaP (includes DT)
- Td and Tdap
- Hib
- hepatitis A
- hepatitis B
- HPV
- influenza (inactivated and live vaccines)

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine 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 — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination. There are also VISs for vaccines not covered by NCVIA: anthrax, Japanese encephalitis, pneumococcal polysaccharide, rabies, shingles, smallpox, typhoid, and yellow fever. CDC recommends the use of VISs whenever these vaccines are given. The VIS must always be used if vaccine was purchased under CDC contract.

Fact 2 VISs are required for both public and private sectors
Federal law requires use of VISs in both the public and private sector settings and regardless of the source of payment for the vaccine.

Fact 3 VIS must be provided before vaccine is administered to the patient
The VIS provides information about the disease and the vaccine and should be given to the patient before vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide the VIS right before administering vaccines.

Fact 4 You must provide a current VIS for each dose of vaccine
The most current VIS must be provided before each dose of vaccine is given, including vaccines given as a series of doses. If five doses of a single vaccine are required, the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

Fact 5 You must provide VISs for combination vaccines too
There is a VIS available for MMRV (ProQuad). 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). However, when giving combination vaccines for which no VIS exist (e.g., Twinrix), give out all relevant single VISs. For example, before administering Twinrix give your patient the VISs for both hepatitis A and hepatitis B vaccines.

Fact 6 VISs are available in other formats, including more than 30 languages
You may use laminated copies of VISs for patients and parents to read and return before leaving the clinic, but you must also offer the patient (parent/legal representative) a printed copy of the VIS to take home.

Fact 7 Federal law does not require signed consent in order for a person to be vaccinated
Signed consent is not required by federal law (although some states may require them).

Fact 8 To verify that a VIS was given, providers must record in the patient’s chart (or permanent office log or file) the following information:
- The published date of the VIS
- The date the VIS is given to the patient
- 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 of each dose administered

Fact 9 VISs should not be altered before giving them to patients
Providers should not change a VIS or write their own VISs. It is permissible to add a practice’s name, address, or phone number to an existing VIS. Providers are encouraged to supplement the VIS with additional patient-education materials.

Fact 10 Provide VISs to all patients
For patients who don’t read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive a VIS, regardless of their ability to read English. If available, provide a translation of the VIS in the patient’s language.

Translations of VISs in more than 30 languages are available from IAC. Go to www.immunize.org/vis for VISs in multiple languages as well as in other formats.

Immunization Action Coalition • Saint Paul, Minnesota • (651) 647-9009 • www.immunize.org • www.vaccineinformation.org
Appendix C

Instructions for the Use of Vaccine Information Statements

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 representative1 of any child to whom the provider intends to administer such vaccine, or
• to any adult2 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.

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

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Edition Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP/DT</td>
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</tr>
<tr>
<td>Hib</td>
<td>2/4/14</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>10/25/11</td>
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<tr>
<td>Hepatitis B</td>
<td>2/2/12</td>
</tr>
<tr>
<td>HPV (Cervarix)</td>
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<tr>
<td>HPV (Gardasil)</td>
<td>5/17/13</td>
</tr>
<tr>
<td>Influenza (inactivated)</td>
<td>8/19/14</td>
</tr>
<tr>
<td>Influenza (live)</td>
<td>8/19/14</td>
</tr>
<tr>
<td>MMR</td>
<td>4/20/12</td>
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<tr>
<td>MMRV</td>
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</tr>
<tr>
<td>Varicella</td>
<td>3/13/08</td>
</tr>
<tr>
<td>Multi-Vaccine*</td>
<td>10/22/14</td>
</tr>
</tbody>
</table>

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

Reference 42 U.S.C. §300aa-26

October 22, 2014

Centers for Disease Control and Prevention
Epidemiology and Prevention of Vaccine-Preventable Diseases, 13th Edition

April, 2015

Appendix C-3
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.
Appendix C

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:
Appendix C-7

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.
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.