STEP 6:

Documentation and Related Issues

N THE PREVIOUS CHAPTERS, you learned that you need to provide your patient with a Vaccine Information Statement (VIS) before you administer a vaccine. You also need to document in the patient's record that you provided this VIS. Another important documentation task is to make certain that every

person you vaccinate goes home with a record of the vaccination. You can use the Adult Immunization Record Card that is available for purchase from the Immunization Action

Make certain that every person you vaccinate goes home with a record of the vaccination.

Coalition (IAC) at www.immunize.org/shop/record-cards.asp. You could also check with your state health department to see if they have similar cards available.



- Record federally required information about your patient's vaccinations in the patient's permanent medical record or in an office log
 - Follow CDC guidelines for documenting that you gave the patient current VISs
 - Record specific information about each administered vaccine in your clinic's vaccine administration record
 - Report adverse events that occur after vaccination
- Update your patient's personal vaccination record card or provide a record to your patient
- Update your patient's vaccination record in your state or local Immunization Information System (IIS or registry), if one is available



Record federally required information about your patient's vaccinations in the patient's permanent medical record or in an office log

Much of the documentation involved in administering vaccines is required under federal law, specifically Section 2125 of the Public Health Service Act [42 U.S.C. §300aa-25] found at http://wonder.cdc.gov/wonder/help/vaers/42USC300aa-25.htm. The National Childhood Vaccine Injury Act (NCVIA) of 1986 created the National Vaccine Injury Compensation Program (NVICP) (www.hrsa.gov/vaccine

compensation) to compensate individuals, or families of individuals, who have been injured by certain vaccines.

Much of the documentation involved in administering vaccines is required under federal law.

The vaccines needed by adults and covered by this law include those containing (either alone or in combination) diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), seasonal influenza, pneumococcal conjugate, meningococcal

Even though the term "childhood" is in the title of the National Childhood Vaccine Injury Act, the law includes certain vaccines whenever they are given to infants, children, AND adults.

(ACWY and B), human papillomavirus (HPV), or varicella (chickenpox). Even though the term "childhood" is in the title of the Act, the law includes these vaccines whenever they are given to infants, children, AND adults.

Under the law, there are three main requirements of vaccination providers. You must:

- Give the patient a copy of the relevant federal Vaccine Information Statement (VIS), found at www.immunize.org/vis, for the vaccine he or she is about to receive.
- Record certain information about the administered vaccine(s) in the patient's medical record or a permanent office log.
- Document any adverse event that the patient experiences following the vaccination and that becomes known to the provider, whether or not you think the vaccine caused the event. Submit the report to the Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/index.

Now we'll cover the details about complying with these three requirements.

Follow CDC guidelines for documenting that you gave the patient current VISs

The Centers for Disease Control and Prevention (CDC) is responsible for developing the VISs and updating them when necessary. Each VIS contains specific information about the disease the vaccine prevents, the vaccine, possible side effects, what to do about serious reactions, and the phone numbers of the National Vaccine Injury Compensation



The patient must always be offered a copy of the VIS to take home.

Program and the Vaccine Adverse Event Reporting System. VISs are available from CDC at www.cdc.gov/ vaccines/hcp/vis/index.html

or IAC at www.immunize.org/vis. The IAC VIS website is the source for VISs in many languages in addition to English.

Be sure to review CDC's Instructions for the Use of Vaccine Information Statements located at www.cdc.gov/vaccines/hcp/vis/about/required-useinstructions.pdf, as well as IAC's It's Federal Law! You must give your patients current Vaccine Information Statements (VISs), available at www.immunize. org/catg.d/p2027.pdf. Remember, "providing" a VIS typically means giving your patients a physical copy to take home. They can, however, review a laminated or electronic version – but the patient must always be offered a copy to take home. Be sure to give the VIS to the patient BEFORE you vaccinate, allowing them enough time to read it. Confirm that you are using the most current version of the VIS by checking the listing of current VIS dates on the IAC website at www.immunize.org/vis.

Record specific information about each administered vaccine in your clinic's vaccine administration record

A second federal requirement calls for the provider to record certain information about the vaccines administered. This information may be recorded in the patient's permanent medical record or in a permanent clinic log. The information required includes:

- date the vaccination was given;
- vaccine manufacturer and lot number of the vaccine administered;
- name, address (location where the information) will be stored), and title of the individual who administered the vaccine:
- edition (date of publication) of the VIS (found at the bottom of the back page of the VIS*); and
- date the VIS was given to the patient.
- * Each VIS also contains a barcode that allows the edition date to be scanned into the record, with the proper software.

IAC's Vaccine Administration Record for Adults, a paper form suitable for use in a patient's medical chart, simplifies and organizes the information that must be documented. This form, which is available at www.immunize.org/catg.d/p2023.pdf, also provides examples of how you might fill in the form. In addition, most electronic health records contain space to record this information electronically.

Report adverse events that occur after vaccination

The Vaccine Adverse Event Reporting System (VAERS), located at https://vaers.hhs.gov/index, serves as a national database that gathers reports of adverse events that occur following immunizations. It provides a tool used by the Food and Drug Administration (FDA) and CDC to look for patterns of events following vaccine administration. VAERS attempts to detect previously unrecognized vaccine-related

events and unusual increases in previously reported events. Both FDA and CDC review data that are reported to VAERS.

All healthcare providers and vaccine manufacturers are required to report post-vaccination adverse events listed in the VAERS Table of Reportable Events Following Vaccination found at https://vaers.hhs.gov/ docs/VAERS_Table_of_Reportable_Events_Following_ Vaccination.pdf. Reports must be made whether or not the provider thinks the vaccine caused the event. Anyone, including vaccine recipients themselves, may submit a report. Healthcare providers should submit VAERS reports online on the VAERS website at https://vaers.hhs.gov/index.

https://vaers.hhs.gov/index

The Vaccine Adverse Event Reporting System (VAERS) serves as a national database that gathers reports of adverse events that occur following immunizations.

Update your patient's personal vaccination record card or provide a record to your patient

In Step 4: Deciding Whom to Vaccinate, we covered how to establish your patient's vaccination history. Once you have determined previous vaccinations (or lack thereof), be sure to note them on the immunization record you keep in your patient's chart

and/or in their electronic health record. Include in the record as much information as you've been able to find, even if it's incomplete. The most important elements to include are the type of vaccine and the date it was given (month, day, and year). Don't worry about not having all or any of the other information (such as the manufacturer and lot number) about vaccines that were given elsewhere. That information likely will have been recorded in the original clinic's records.

Don't forget to give the patient a record of the vaccination that he or she just received. If he or she has a personal record card, you can simply update it. If not, you can print out your patient's immunization record from your electronic medical record system, give the patient an Adult Immunization Record Card, available at www.immunize.org/shop/ record-cards.asp, or provide a similar document after you've filled in the information. This record



www.immunize.org/ shop/record-cards.asp

also should include a column to indicate when the next dose is due; you should complete this column for the patient. This is particularly important for vaccines that are given more than once (e.g.,

Td, hepatitis A, hepatitis B, varicella, and HPV).

If you are not the primary care provider, it's also important that you provide information about the vaccinations just administered to the patient's primary care provider. Remind the patient to have their primary care clinic update the clinic medical record from the information on the patient's personal immunization record card. You can offer to provide the information for the patient if she or he can give you the primary care clinic's name and address. To assist with this, IAC's Notification of Vaccination Letter Template is available at www.immunize.org/ catg.d/p3060.pdf.

Update your patient's vaccination record in your state or local Immunization Information System (IIS, or registry), if one is available

An IIS ("registry") is a confidential computerized database that records all vaccine doses administered by participating providers to persons residing within a given area, usually a county or state. At

An IIS can provide a consolidated immunization history to determine what vaccinations a patient needs now and during future visits.



the time of this writing, there is no nationwide database of individual vaccination records. In your clinic or

office, an IIS can provide a consolidated immunization history to determine which vaccinations a patient needs now and during future visits. This can eliminate the need to call other offices for records or have the patient search for his/her own written record. Having a complete vaccination history also will reduce missed opportunities to vaccinate and reduce duplicate vaccinations. Many IISs can accept data directly from an electronic health record, eliminating the need to enter the same vaccination data twice.

We strongly suggest that you participate in an IIS if one is available in your area. Contact the appropriate State/Territory/City Registry Staff for information about participating in your IIS. A list of staff in your area is available at www.cdc.gov/vaccines/ programs/iis/contacts-registry-staff.html.

That's it! Although properly documenting vaccinations is not complex, it is a critical part of the patient's medical record. Don't miss this important step.

STEP 6: DOCUMENTATION AND RELATED ISSUES Materials and Resources for You to Use

► TOOLS FOR PROVIDERS

Instructions for the Use of Vaccine Information **Statements (CDC)** – www.cdc.gov/vaccines/hcp/ vis/about/required-use-instructions.pdf

It's Federal Law! You Must Give Your Patients **Current Vaccine Information Statements (IAC)** www.immunize.org/catg.d/p2027.pdf

Notification of Vaccination Letter Template (IAC) www.immunize.org/catg.d/p3060.pdf

Vaccine Administration Record for Adults (IAC) www.immunize.org/catg.d/p2023.pdf

Vaccine Information Statements (VISs) and Translations (IAC) - www.immunize.org/vis

NOTE: The publisher of each resource is shown as an acronym in the parentheses following the title. A key to these acronyms is included in Appendix A: Acronyms and Abbreviations.

► Additional Provider Resources

Current Dates of Vaccine Information Statements

(IAC) – www.immunize.org/catg.d/p2029.pdf IIS State/Territory/City Registry Staff - Main and Technical Contacts (CDC) – www.cdc.gov/ vaccines/programs/iis/contacts-registry-staff.html **National Vaccine Injury Compensation Program** (HRSA) – www.hrsa.gov/vaccinecompensation Vaccine Adverse Event Reporting System (VAERS)

► INFORMATION FOR PATIENTS

(HHS) - https://vaers.hhs.gov/index

Adult Immunization Record Card (IAC) www.immunize.org/shop/record-cards.asp

► GENERAL INFORMATION

Immunization Action Coalition (IAC) www.immunize.org

To access the current, ready-to-copy version of this piece, visit

www.immunize.org/catg.d/p2027.pdf

It's Federal Law! You must give your patients current Vaccine Information Statements (VISs)

Vaccine Information Statements (VISs) are documents produced by the Centers for Disease Control and Prevention (CDC), in consultation with panels of experts and parents, to properly inform vac-cinees (or their parents/legal representatives) about the risks and benefits of each vaccine. VISs are not meant to replace interactions with health care providers, who should address any questions or concerns that the vaccinee (or parent/legal representative) may have.

Using VISs is legally required!

Federal law (under the National Childhood Vaccine Injury Act) requires a health care provider to give a copy of the current VIS to an adult patient or to a child's parent/legal representative before vaccinating an adult or child with a dose of the following vaccines: diphtheria, tetanus, pertussis, measles, mumps, rubella hepatitis A, hepatitis B, Haemophilus influenzae type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox).

Where to get VISs

All available VISs can be downloaded from the websites of the Immunization Action Coalition at www.immunize.org/vis or CDC at www.cdc.gov/vaccines/hcp/vis/index.html. Ready-to-copy versions may also be available from your state or local health department.

Translations: You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis.

To obtain translations of VIS in languages other than English, go to www.immunize.org/vis.

According to CDC, the appropriate VIS must be given:

- Prior to the vaccination (and prior to each dose of a multi-dose series);
- Regardless of the age of the vaccinee;
- Regardless of whether the vaccine is given in a public or private health care setting.

Top 10 Facts About VISs



1 It's federal law! You must give current to all your patients before vaccinating them. It's federal law! You must give current* VISs

Federal law requires that VISs must be used for patients of **ALL** ages when administering these vaccines:

- Td and Tdap
- DTaP (includes DT) MMR and MMRV meningococcal (MenACWY, MenB)
- hepatitis A
- polio rotavirus
- hepatitis B HPV varicella (chickenpox)
- influenza (inactivated and live, intranasal)

For the vaccines not covered under the National Childhood Vaccine Injury Act (i.e., adenovirus, anthrax, Japanese encephalitis, pneu-

· pneumococcal conjugate

fever), providers are not required by federal law to use VISs unless they have been purchased under CDC contract. However, CDC recommends that VISs be used whenever these vaccines are given *Federal law allows up to 6 months for a new VIS to be used.

mococcal polysaccharide, rabies, shingles, typhoid, and yellow



FACT 2 VISs can be given to patients in a variety of ways.

In most medical settings, VISs are provided to patients (or their parents/legal representatives) in paper form. However, VISs also may be provided using electronic media. Regardless of the format used, the goal is to provide a current VIS just prior to vaccination. CONTINUED ON NEXT PAGE

Most current versions of VISs (table)

As of July 6, 2017, the most recent versions of the VISs are as follows:

Adenovirus	6/11/14
Anthrax	3/10/10
Chickenpox	3/13/08
Cholera	7/6/17
DTaP	5/17/07
Hib	4/2/15
Hepatitis A	7/20/16
Hepatitis B	7/20/16
HPV	12/2/16
Influenza	8/7/15
Japanese enceph	1/24/14
MenACWY	3/31/16
MenB	8/9/16

4	MMR	4/20/12
0	MMRV	5/21/10
8	Multi-vaccine	11/5/15
7	PCV13	11/5/15
7	PPSV	4/24/15
5	Polio	7/20/16
6	Rabies	10/6/09
6	Rotavirus	4/15/15
6	Shingles	10/6/09
5	Td	4/11/17
4	Tdap	2/24/15
6	Typhoid	5/29/12
6	Yellow fever	3/30/11

A handy list of current VIS dates is also available at www.immunize.org/catg.d/p2029.pdf

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vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide a current VIS right before administering vaccines.



FACT You must provide a current VIS for each dose of vaccine you administer. of vaccine you administer.

The most current VIS must be provided before each dose of vaccine is given, including vaccines given as a series of doses. For example, if 5 doses of a single vaccine are required (e.g., DTaP), the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.



FACT You must provide VISs whenever you administer combination vaccines.

If you administer a combination vaccine that does not have a stand-alone VIS (e.g., Kinrix, Quadracel, Pediarix, Pentacel, Twinrix) you should provide the patient with individual VISs for the component vaccines, or use the Multi-Vaccine VIS (see below)

cine Information Statements (VISs) (continued) page 2 of 2

The Multi-Vaccine VIS may be used in place of the individual VISs for DTaP, Hib, hepatitis B, polio, and pneumococcal when two or more of these vaccines are administered during the same visit. It may be used for infants as well as children through 6 years of age. The Multi-Vaccine VIS should not be used for adolescents or adults.



VISs should be given in a language / format that the recipient can understand, whenever possible.

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. To obtain VISs in more than 30 languages, visit the Immunization Action Coalition website at www.immunize.org/vis. Providers can supplement VISs with visual presentations or oral explanations as needed.



FACT Federal law does not require signed consent in order for a person to be vaccinated.

Signed consent is not required by federal law for vaccination (although some states may require it).



FACT To verify that a VIS was given, providers must record in the patient's medical record (or permanent office log or file) the following information:

- The edition date of the VIS (found on the back at the right bottom corner)
- The date the VIS is provided (i.e., the date of the visit when the vaccine is administered)
- In addition, providers must record:
- The office address and name The date the vaccine is and title of the person who administers the vaccine
- - administered The vaccine manufacturer and lot number



FACT VISs should not be altered before giving them to patients, but you can add to be should be patients, but you can add some information.

Providers should not change a VIS or write their own VISs. However, it is permissible to add a practice's name, address, and contact information to an existing VIS.

Additional resources on VISs and their use are available from the following organizations:

Immunization Action Coalition

- VIS general information and translations in more than 30 languages: www.immunize.org/vis
- Current Dates of Vaccine Information Statements: www.immunize.org/catg.d/p2029.pdf

Centers for Disease Control and Prevention

- VIS website: www.cdc.gov/vaccines/hcp/vis
 VIS Facts: www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html
 VIS FAQs: www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html

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ww.immunize.org/catg.d/p2027.pdf • Item #P2027 (7/17)

To access the current, ready-to-copy version of this piece, visit

www.immunize.org/vis



To access the current, ready-to-copy version of this piece, visit

www.immunize.org/catg.d/p2029.pdf

Current Dates of Vaccine Information Statements (VISs) as of July 6, 2017

Check your supply of VISs against this list. If you have outdated VISs, get current versions at www.immunize.org/vis.

, 0	
Adenovirus	6/11/14
Anthrax	3/10/10
Chickenpox	3/13/08
Cholera	7/6/17
DTaP	5/17/07
Hib	4/2/15
Hepatitis A	7/20/16
Hepatitis B	7/20/16
HPV	12/2/16
Influenza	8/7/15
Japanese enceph	1/24/14
MenACWY	3/31/16
MenB	8/9/16

	O1
MMR	4/20/12
MMRV	5/21/10
Multi-vaccine	11/5/15
PCV13	11/5/15
PPSV	4/24/15
Polio	7/20/16
Rabies	10/6/09
Rotavirus	4/15/15
Shingles	10/6/09
Td	4/11/17
Tdap	2/24/15
Typhoid	5/29/12
Yellow fever	3/30/11

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Polio	7/20/16
Rabies	10/6/09
Rotavirus	4/15/15
Shingles	10/6/09
Td	4/11/17
Tdap	2/24/15
Typhoid	5/29/12
Yellow fever	3/30/11



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MenB	8/9/16

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MMRV	5/21/10
Multi-vaccine	11/5/15
PCV13	11/5/15
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Rabies	10/6/09
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Shingles	10/6/09
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Typhoid	5/29/12
Yellow fever	3/30/11

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MenACWY	3/31/16
MenB	8/9/16

MMR	4/20/12
MMRV	5/21/10
Multi-vaccine	11/5/15
PCV13	11/5/15
PPSV	4/24/15
Polio	7/20/16
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