

VIS Overview

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Vaccine Information Statement (VIS)

VACCINE INFORMATION STATEMENT

Hepatitis A Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite <http://www.immunize.org/vis>

1 What is hepatitis A?

Hepatitis A is a serious liver disease caused by the hepatitis A virus (HAV). HAV is found in the stool of people with hepatitis A.

It is usually spread by close personal contact and sometimes by eating food or drinking water containing HAV. A person who has hepatitis A can easily pass the disease to others within the same household.

Hepatitis A can cause:

- “flu-like” illness
- jaundice (yellow skin or eyes, dark urine)
- severe stomach pains and diarrhea (children)

People with hepatitis A often have to be hospitalized (up to about 1 person in 5).

Adults with hepatitis A are often too ill to work for up to a month.

Sometimes, people die as a result of hepatitis A (about 3-6 deaths per 1,000 cases).

Hepatitis A vaccine can prevent hepatitis A.

2 Who should get hepatitis A vaccine and when?

WHO?

Some people should be routinely vaccinated with hepatitis A vaccine:

- All children between their first and second birthdays (12 through 23 months of age).
- Anyone 1 year of age and older traveling to or working in countries with high or intermediate prevalence of hepatitis A, such as those located in Central or South America, Mexico, Asia (except Japan), Africa, and eastern Europe. For more information see www.cdc.gov/travel.
- Children and adolescents 2 through 18 years of age who live in states or communities where routine vaccination has been implemented because of high disease incidence.
- Men who have sex with men.
- People who use street drugs.

- People with chronic liver disease.
- People who are treated with clotting factor concentrates.
- People who work with HAV-infected primates or who work with HAV in research laboratories.
- Members of households planning to adopt a child, or care for a newly arriving adopted child, from a country where hepatitis A is common.

Other people might get hepatitis A vaccine in certain situations (ask your doctor for more details):

- Unvaccinated children or adolescents in communities where outbreaks of hepatitis A are occurring.
- Unvaccinated people who have been exposed to hepatitis A virus.
- Anyone 1 year of age or older who wants protection from hepatitis A.

Hepatitis A vaccine is not licensed for children younger than 1 year of age.

WHEN?

For children, the first dose should be given at 12 through 23 months of age. Children who are not vaccinated by 2 years of age can be vaccinated at later visits.

For others at risk, the hepatitis A vaccine series may be started whenever a person wishes to be protected or is at risk of infection.

For travelers, it is best to start the vaccine series at least one month before traveling. (Some protection may still result if the vaccine is given on or closer to the travel date.)

Some people who cannot get the vaccine before traveling, or for whom the vaccine might not be effective, can get a shot called immune globulin (IG). IG gives immediate, temporary protection.

Two doses of the vaccine are needed for lasting protection. These doses should be given at least 6 months apart.

Hepatitis A vaccine may be given at the same time as other vaccines.



U.S. Department of Health and Human Services
www.hhs.gov

3 Some people should not get hepatitis A vaccine or should wait.

- Anyone who has ever had a severe (life threatening) allergic reaction to a previous dose of hepatitis A vaccine should not get another dose.
- Anyone who has a severe (life threatening) allergy to any vaccine component should not get the vaccine. **Tell your doctor if you have any severe allergies**, including a severe allergy to latex. All hepatitis A vaccines contain alum, and some hepatitis A vaccines contain 2-phenoxyethanol.
- Anyone who is moderately or severely ill at the time the shot is scheduled should probably wait until they recover. Ask your doctor. People with a mild illness can usually get the vaccine.
- Tell your doctor if you are pregnant. Because hepatitis A vaccine is inactivated (killed), the risk to a pregnant woman or her unborn baby is believed to be very low. But your doctor can weigh any theoretical risk from the vaccine against the need for protection.

4 What are the risks from hepatitis A vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of hepatitis A vaccine causing serious harm, or death, is extremely small.

Getting hepatitis A vaccine is much safer than getting the disease.

Mild problems

- soreness where the shot was given (*about 1 out of 2 adults, and up to 1 out of 6 children*)
- headache (*about 1 out of 6 adults and 1 out of 25 children*)
- loss of appetite (*about 1 out of 12 children*)
- tiredness (*about 1 out of 14 adults*)

If these problems occur, they usually last 1 or 2 days.

Severe problems

- serious allergic reaction, within a few minutes to a few hours after the shot (*very rare*).

5 What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.frsa.gov/vaccinecompensation.

7 How can I learn more?

- Ask your doctor. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim) Hepatitis A Vaccine

10/25/2011

42 U.S.C. § 300aa-26



National Childhood Vaccine Injury Act

Required by law

Prior to vaccine administration, provide a copy of the relevant Vaccine Information Statement (VIS)

Vaccine Information Statement (VIS) – Objective information on vaccine advantages and risks

- Intense scrutiny by panel of experts, updated periodically

Why 2D Barcodes on VIS?

Partners input:

- If you're going to put barcodes on vaccine vials and syringes what about the VIS?

Reasons Why

- Record the VIS data more accurately
- Increase in completeness for data elements
 - Simplify immunizer data entry
 - Reduce the time spent by immunizers recording that the VIS was provided
 - Ensure legal compliance
 - Enhance record keeping for provider
- Promote use of barcoding technology

Decisions

Use GS1 standards and tools

- Collaboration with GS1 Healthcare US

Use GS1 data matrix 2D barcode

Use GS1 Application Identifier (AI) - Global Document Type Identifier (GDTI)

Global Document Type Identifier (GDTI)

(253) 0 3 1 2 3 4 5 6 7 8 9 0 6

AI

Position 1 - Position 12

Position 13

GS1 Company Prefix + Document Type

Check Digit

Although the length of the *GS1 Company Prefix* and the length of the *document type* may vary, they will always be a combined total of 12 digits.

Global Document Type Identifier (GDTI)

- For record keeping
- GDTI database is created which holds master copy of document
- GDTI is assigned for life of document
- Can be encoded into GS1-128 barcode using AI(253)

GDTI enables

- Tracking documents
- Retrieval of key data
- Control and efficiency
- Unique identification of documents
- Reference-able by other systems

Capture Edition Date of the VIS

Example Data in 2D Barcode

(253) 0 8 8 6 9 8 3 0 0 0 0 1 1 1 1 1 2 1 2 0 6

AI

GDTI (13 char)

Serial Component

GS1 Application Identifier (AI) for GDTI

GS1 Company Prefix + Document Type + Check digit

Edition date
11 then (YYMMDD)

- Provider - required per law to record this information
- Starts with the digit 11
- Followed by the version date of the VIS in the YYMMDD format

VIS GDTI

- VIS GDTI document code / Concept code will not change over time
 - For example – Adenovirus VIS document type code, 0886983000011, will remain the same
- When all VIS document type GDTI codes are assigned vendors will not need to rely on the external Lookup table for every instance
- The Lookup Table is available on CDC 2D VIS Web-page and in PHINVADS

Lookup Table

VIS Lookup Table					
Version Date: February 26, 2013					
VIS Document Type Description / Concept Name	Edition Date	VIS Fully-encoded text string	VIS GDTI document code / Concept code	Edition Status	Last Updated Date
Adenovirus VIS	7/14/2011	253088698300001111110714	0886983000011	Current	2/24/2012
Anthrax VIS	3/10/2010	253088698300002811100310	0886983000028	Current	2/24/2012
Diphtheria/Tetanus/Pertussis VIS	5/17/07	253088698300003511070517	0886983000035	Current	2/8/2013
Hepatitis A VIS	10/25/2011	253088698300004211111025	0886983000042	Current	5/21/2012
Hepatitis B VIS	2/2/2012	253088698300005911120202	0886983000059	Current	5/21/2012
Haemophilus Influenzae type b VIS	12/16/1998	253088698300006611981216	0886983000066	Current	2/24/2012
Human papillomavirus Vaccine (Cervarix) VIS	5/3/2011	253088698300007311110503	0886983000073	Current	2/24/2012
Human papillomavirus Vaccine (Gardasil) VIS	2/22/2012	253088698300008011120222	0886983000080	Current	5/21/2012
Influenza Vaccine - Live, Intranasal VIS	7/2/2012	253088698300009711120702	0886983000097	Current	7/2/2012
Influenza Vaccine - Inactivated VIS	7/2/2012	253088698300010311120702	0886983000103	Current	7/2/2012
Japanese Encephalitis VIS	12/7/2011	253088698300011011111207	0886983000110	Current	5/21/2012
Measles/Mumps/Rubella VIS	4/20/2012	253088698300012711120420	0886983000127	Current	4/12/2012
Measles/Mumps/Rubella/Varicella VIS	5/21/2010	253088698300013411100521	0886983000134	Current	2/24/2012
Meningococcal VIS	10/14/2011	253088698300014111111014	0886983000141	Current	5/21/2012
Pneumococcal Conjugate (PCV13) VIS	4/16/2010	253088698300015811100416	0886983000158	Historic	2/27/2013
Pneumococcal Conjugate (PCV13) VIS	2/27/2013	253088698300015811130227	0886983000158	Current	2/27/2013
Pneumococcal Polysaccharide VIS	10/6/2009	253088698300016511091006	0886983000165	Current	2/24/2012
Polio VIS	11/8/2011	253088698300017211111108	0886983000172	Current	5/21/2012
Rabies VIS	10/6/2009	253088698300018911091006	0886983000189	Current	2/24/2012
Rotavirus VIS	12/6/10	253088698300019611101206	0886983000196	Current	2/8/2013
Shingles VIS	10/6/2009	253088698300020211091006	0886983000202	Current	2/24/2012
Tetanus/Diphtheria/(Pertussis) VIS	1/24/2012	253088698300022611120124	0886983000226	Current	5/21/2012
Typhoid VIS	5/29/2012	253088698300023311120529	0886983000233	Current	5/29/2012
Varicella (Chickenpox) VIS	3/13/08	253088698300024011080313	0886983000240	Current	2/8/2013
Yellow Fever VIS	3/30/11	253088698300025711110330	0886983000257	Current	2/8/2013
Multiple Vaccines	11/16/2012	253088698300026411121116	0886983000264	Current	11/16/2012

CDC VIS 2D Webpage



Department of Health and Human Services
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CDC en Español

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Publications:

Barcodes on Vaccine Information Statements

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Barcodes Added to VIS

Beginning in April 2012 new and updated VISs will contain a 2D Barcode.

As part of a modernization initiative, CDC is adding two-dimensional (2D) "data matrix" barcodes to Vaccine Information Statements. Currently this technology is designed primarily to help immunization providers record required information about the VIS, by allowing them to scan the name and edition date of a VIS into an electronic medical record, immunization information system, or other electronic database.



Figure 1: A two-dimensional Data Matrix barcode
Click image to see larger

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FAQ – Required?

Q: Does CDC require any new reporting from the VIS barcodes?

A: No. The CDC does not require new reporting from the VIS barcodes which contain information on the VIS document type and edition date. The reporting process by grantees and immunizers should remain the same.

Opportunity to allow providers to scan VIS related information

Multiple Vaccines VIS

Healthcare providers have an option to use the multi-vaccine VIS for:

- DTaP
- Hib
- Hepatitis B
- Polio
- Rotavirus
- PCV13

or use vaccine-specific VIS for:

- DTaP
- Hepatitis B
- Rotavirus
- Hib
- Polio
- PCV13

When using the multi-vaccine VIS, indicate which vaccine(s) were administered by checking the appropriate box.

VACCINE INFORMATION STATEMENT

Your Baby's First Vaccines

What You Need to Know

Your baby will get these vaccines today:

<input type="checkbox"/> DTaP	<input type="checkbox"/> Polio
<input type="checkbox"/> Hib	<input type="checkbox"/> Rotavirus
<input type="checkbox"/> Hepatitis B	<input type="checkbox"/> PCV13

(Provider: Check appropriate boxes.)

Ask your doctor about "combination vaccines," which can reduce the number of shots your baby needs. Combination vaccines are as safe and effective as these vaccines when given separately.



Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite <http://www.immunize.org/vis>.

These vaccines protect your baby from **8 serious diseases**:

- diphtheria
- tetanus
- pertussis (whooping cough)
- *Haemophilus influenzae* type b (Hib)
- hepatitis B
- polio
- rotavirus
- pneumococcal disease

ABOUT THIS VACCINE INFORMATION STATEMENT

Please read this Vaccine Information Statement (VIS) before your baby gets his or her immunizations, and take it home with you afterward. Ask your doctor if you have any questions.

This VIS tells you about the benefits and risks of certain childhood vaccines. It also contains information about reporting an adverse reaction and the Vaccine Injury Compensation Program, and how to get more information about these vaccines.)

HOW VACCINES WORK

Immunity from Disease: Some diseases produce protective "antibodies" that help your body fight off the disease. This is how you get immunity from disease. It can be dangerous and sometimes fatal.

Immunity from Vaccines: Vaccines contain weakened or killed forms of the germs that cause disease. They produce antibodies, just as if you had the disease. This gives you immunity in the same way.

VACCINE BENEFITS: Vaccines have helped prevent many diseases. They have saved millions of lives. Without vaccines, many diseases would be common and deadly. Some are common in other countries, and if we stop vaccinating they will come back here. This has already happened in some parts of the world. When vaccination rates go down, disease rates go up.

Your baby will get these vaccines today:

<input type="checkbox"/> DTaP	<input type="checkbox"/> Polio
<input type="checkbox"/> Hib	<input type="checkbox"/> Rotavirus
<input type="checkbox"/> Hepatitis B	<input type="checkbox"/> PCV13

(Provider: Check appropriate boxes.)

Ask your doctor about "combination vaccines," which can reduce the number of shots your baby needs. Combination vaccines are as safe and effective as these vaccines when given separately.



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42 U.S.C. § 300aa-26
11/16/2012

Office Use Only



Questions?

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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