VIS Overview
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"Reviewed November 2014"
Vaccine Information Statement (VIS)

Hepatitis A Vaccine

What You Need to Know

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 pain 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 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 virus.

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 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.

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 albumin, and some hepatitis A vaccines contain 2-phenoxethanol.
• 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 a killed, whole virus vaccine, it is believed to be very safe. 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, hives, or swelling of the face, lips, tongue, or throat, a fast heart beat or dizziness.

What should I do?
• Call a doctor or, if the person is too sick to call, go to the nearest hospital emergency room.
• 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. 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.hrsa.gov/vaccinecompensation.

7 How can I learn more?
• Ask your doctor. They can give you the vaccine package insert or suggest other resources of information.
• Call your local or state health department.
• Contact the Centers for Disease Control and Prevention (CDC):
  • Call 1-800-CDC-INFO (1-800-232-4636) 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)

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 1 2 1 2 0 6

• 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

**Version Date: February 26, 2013**

<table>
<thead>
<tr>
<th>VIS Document Type Description / Concept Name</th>
<th>Edition Date</th>
<th>VIS Fully-encoded text string</th>
<th>VIS GDTI document code / Concept code</th>
<th>Edition Status</th>
<th>Last Updated Date</th>
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Vaccines & Immunizations

CDC en Español

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Barcodes on Vaccine Information Statements

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  - FAQs from Grantees
- Converting Barcode Data into English
  - Lookup Table
- List of VISs Containing Barcodes

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.
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.
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.