

HAWAII IMMUNIZATION REGISTRY INFORMATION

INFORMATION CONTAINED IN THE REGISTRY

- Immunization information including but not limited to vaccine type, date of vaccine administration, vaccine administration site and route, lot number, expiration date, patient's history of vaccine preventable diseases, contraindications, precautions, adverse reactions, and/or comments regarding vaccinations.
- Personal information including but not limited to an individual's first, middle, and last name, date of birth, gender, mailing address, phone number, parent/guardian name, parent/guardian relationship to the individual, their contact information, and mother's maiden name.

CONFIDENTIALITY AND PRIVACY INFORMATION

All authorized users and the Department of Health Immunization Branch acknowledge that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (PL 104-191 and 45 CFR Parts 160 and 164, "Standards for Privacy of Individually Identifiable Health Information") governs the use and disclosure of individually identifiable information by entities subject to the Privacy Rule. Although HIPAA standards for privacy were used as a guide to assist in the development of the Registry Confidentiality and Privacy policies, the Registry and the Department of Health Immunization Branch are not "covered entities" under HIPAA. Providers, health plans and other covered entities who are authorized users must comply with the HIPAA Privacy Rule.

Registry information will be entered by and available to authorized users for authorized purposes only. All authorized users will be required to safeguard the privacy of patient participants by protecting confidential information in the Registry in accordance with the Hawaii Immunization Registry Confidentiality and Privacy Policy, the Hawaii Immunization Registry Security Policy, as well as all applicable State and Federal Laws.

AUTHORIZED USERS

Authorized users of the Registry may include individuals and/or entities that require regular access to patient immunization and other individually identifiable health information to provide immunization services to specific patients, maintain a computerized inventory of their public and private stock of vaccines, assess immunization status to determine immunization rates, and/or ensure compliance with mandatory immunization requirements. All authorized users are required to sign a Hawaii Immunization Registry Confidentiality and Security Statement indicating that they have received a copy of the Hawaii Immunization Registry Confidentiality and Privacy Policy and the Hawaii Immunization Registry Security Policy, understand the terms, including penalties for violation of the policies, and agree to comply with the policies.

The Department of Health Immunization Branch is responsible for oversight of the Registry and therefore will be designated as an authorized user.

USES OF REGISTRY INFORMATION (AUTHORIZED PURPOSES)

Registry immunization data and other individually identifiable health information shall be utilized by authorized users for the purposes of:

- Consolidating, maintaining, and accessing computerized immunization records;
- Consolidating and maintaining vaccine inventory information;
- Determining the immunization history of individuals and delivering health care treatment accordingly;
- Generating notices for individuals who are due or overdue for immunizations and in the event of a vaccine recall;
- Staying abreast of the complex immunization schedule by utilizing registry-supplied immunization forecasting tools;
- Assessing the immunization rate of their patient population (or subsets thereof);
- Generating official immunization records (e.g. Student's Health Record);
- Ensuring compliance with mandatory immunization requirements;
- Recording the distribution of prophylactic and treatment medications administered or dispensed in preparation for and in response to a potentially catastrophic disease threat;
- Complying with Hawaii Vaccines For Children and other State-provided vaccine programs' vaccine ordering and accountability policies and procedures; and
- Other purposes determined at the discretion of the Department of Health Immunization Branch.

Registry immunization data and other individually identifiable health information shall be utilized by the Department of Health Immunization Branch for the following public health purposes including but not limited to:

- Ensuring compliance with mandatory immunization requirements;
- Performing Quality Improvement/Quality Assessment activities;
- Complying with Hawaii Vaccines For Children and other State-provided vaccine programs' vaccine ordering and accountability policies and procedures;
- Preventing and managing outbreaks of vaccine-preventable diseases and other public health emergencies;
- Producing immunization assessment reports to aid in the development of policies and strategies to improve public health;
- Managing and maintaining the Registry system; and
- Other purposes determined at the discretion of the Department of Health Immunization Branch.

AVAILABILITY OF IMMUNIZATION RECORD INFORMATION

An individual's immunization data and other individually identifiable health information in the Registry will be made available to the individual's immunization provider, the Department of Health, and other Registry authorized users for authorized purposes only.

OPT-OUT

Individuals may choose not to include their or their child's immunization data in the Registry ("opt-out"). Individuals must opt-out in writing by completing a "Hawaii Immunization Registry Opt-Out Form" which is available from the individual's immunization provider or the Department of Health Immunization Branch. The Registry will retain only core demographic information necessary to identify the individual has chosen to opt-out of the Registry. This information is necessary to enable the Registry to filter and refuse entry of immunization information for the individual. Core demographic data will be for Hawaii Department of Health use only and will be non-displaying to all other Registry authorized users. An individual's decision not to authorize the inclusion of immunization data in the Registry will not affect whether or not they receive immunizations.

REVOCAION

An individual may revoke their decision to opt-out of the Hawaii Immunization Registry at any time. Revocations must be made in writing by completing a "Hawaii Immunization Registry Reauthorization Form" obtained from the individual's immunization provider or the Department of Health Immunization Branch.

RIGHT TO INSPECT, COPY, CORRECT OR AMEND PERSONAL AND IMMUNIZATION INFORMATION

Individuals may inspect, copy, correct or amend their or their child's immunization record information via their or their child's immunization provider or the Department of Health Immunization Branch. For information on how to inspect, copy, correct or amend your or your child's information, please speak with your doctor, call the Department of Health Immunization Branch at 586-4665 (Oahu) or 1-888-447-1023 (neighbor islands), or e-mail your request to RegistryHelp@doh.hawaii.gov.

QUESTIONS?

If you have any questions about the Registry, please speak with your doctor, call the Department of Health Immunization Branch at 586-4665 (Oahu) or 1-888-447-1023 (neighbor islands), e-mail your question to RegistryHelp@doh.hawaii.gov, or visit our website at: <http://hawaii.gov/health/immunization/HIR.html>.

Influenza Vaccine

What You Need to Know

(Flu Vaccine, Live, Intranasal)

2013-2014

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 www.immunize.org/vis

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease that spreads around the United States every winter, usually between October and May.

Flu is caused by the influenza virus, and can be spread by coughing, sneezing, and close contact.

Anyone can get flu, but the risk of getting flu is highest among children. Symptoms come on suddenly and may last several days. They can include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Flu can make some people much sicker than others. These people include young children, people 65 and older, pregnant women, and people with certain health conditions—such as heart, lung or kidney disease, or a weakened immune system. Flu vaccine is especially important for these people, and anyone in close contact with them.

Flu can also lead to pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized.

Flu vaccine is the best protection we have from flu and its complications. Flu vaccine also helps prevent spreading flu from person to person.

2 Live, attenuated flu vaccine—LAIV, Nasal Spray

There are two types of influenza vaccine:

You are getting a **live, attenuated influenza vaccine** (called LAIV), which is sprayed into the nose.

“Attenuated” means weakened. The viruses in the vaccine have been weakened so they can’t make you sick.

A different vaccine, the “flu shot,” is an **inactivated** vaccine (not containing live virus). It is given by

injection with a needle. *This vaccine is described in a separate Vaccine Information Statement.*

Flu vaccine is recommended every year. Children 6 months through 8 years of age should get two doses the first year they get vaccinated.

Flu viruses are always changing. Each year’s flu vaccine is made to protect from viruses that are most likely to cause disease that year. While flu vaccine cannot prevent all cases of flu, it is our best defense against the disease. LAIV protects against 4 different influenza viruses.

It takes about 2 weeks for protection to develop after the vaccination, and protection lasts several months to a year.

Some illnesses that are **not** caused by influenza virus are often mistaken for flu. Flu vaccine will not prevent these illnesses. It can only prevent influenza.

LAIV may be given to people **2 through 49 years of age**, who are not pregnant. It may safely be given at the same time as other vaccines.

LAIV does not contain thimerosal or other preservatives.

3 Some people should not get this vaccine

Tell the person who gives you the vaccine:

- **If you have any severe (life-threatening) allergies**, including an allergy to eggs. If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you should not get a dose.
- **If you ever had Guillain-Barré Syndrome** (a severe paralyzing illness, also called GBS). Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.
- **If you have gotten any other vaccines in the past 4 weeks, or if you are not feeling well.** They might suggest waiting. But you should come back.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

- **You should get the flu shot instead of the nasal spray if you:**
 - are pregnant
 - have a weakened immune system
 - have certain long-term health problems
 - are a young child with asthma or wheezing problems
 - are a child or adolescent on long-term aspirin therapy
 - have close contact with someone who needs special care for an extremely weakened immune system
 - are younger than 2 or older than 49 years. (Children 6 months and older can get the flu shot. Children younger than 6 months can't get either vaccine.)

The person giving you the vaccine can give you more information.

4 Risks of a vaccine reaction

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own.

Serious side effects are also possible, but are very rare. LAIV is made from weakened virus and **does not cause flu**.

Mild problems that have been reported following LAIV:

Children and adolescents 2-17 years of age:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Adults 18-49 years of age:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe problems that could follow LAIV:

- A severe allergic reaction could occur after any vaccine (estimated less than 1 in a million doses).

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

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What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS is only for reporting reactions. They do not give medical advice.

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The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

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.

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How can I learn more?

- Ask your doctor.
- 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/flu

Vaccine Information Statement (Interim)
Live Attenuated Influenza Vaccine

07/26/2013

42 U.S.C. § 300aa-26

Office Use Only

