



Vaccine Information Statements (VISs) Provide Informed Consent on Vaccines

For meaningful informed consent about vaccinations, you need materials that:

- Are accurate
- Cover necessary information in a way that is understandable to most people
- Link to more detailed information for those who want it

Vaccine Information Statements (VIS) provide informed consent about the risks and benefits of vaccinations. Materials that are too technical, lengthy, unclear or provide confusing information can undermine informed consent.

What is a VIS?

- VISs are important sources of vaccine information for the public. They are written in easy-to-understand language to help vaccine-recipients (or their parents/caregivers) better understand the risks and benefits of vaccines.
- Each VIS includes the benefits and risks of each vaccine, and clearly outlines the process for reporting to the Vaccine Adverse Event Reporting System (VAERS) as well as filing a claim with the National Vaccine Injury Compensation Program (VICP), if necessary.
- Federal law requires that a VIS be provided to patients or parents/caregivers *before* each and every vaccine is administered. It must be given regardless of the age of the vaccine recipient.
- Healthcare providers must also record specific information in the patient's medical record or permanent office log, including the edition date of the VIS, the date the VIS was given, the vaccine administration date, the office address and name and title of the person who administers the vaccine, and the vaccine manufacturer and lot number.

Who writes a VIS?

- Each VIS is written by the Centers for Disease Control and Prevention (CDC), and the content is informed by a group of independent experts and parents, including representatives from Vaccinate Your Family and the National Vaccine Information Center – two organizations with divergent views of vaccinations.
- The wording of each VIS is carefully crafted to ensure that it adheres to the health literacy criteria set forth in the health literacy standards of *The Patient Protection and Affordable Care Act of 2010*.
- Each VIS is reviewed and approved by the Advisory Committee on Childhood Vaccines (ACCV), which includes:
 - Three members of the general public, including at least two who are the parents or guardians of children who have suffered a vaccine-related injury.

- Three members who are attorneys, including at least one who represents individuals who may have been vaccine-injured.

Why are VISs given to patients instead of the vaccine package insert?

- Vaccine manufacturers are required by the FDA to report all events during a clinical trial. For example, if a child is involved in a car accident during the clinical trial and reports to the hospital with a broken arm, the manufacturer must report a broken arm as an adverse event of the vaccine even though we know they are not related.
- Sometimes, a VIS does not exactly match a manufacturer's product insert. That's because VISs follow the Advisory Committee for Immunization Practices' (ACIP's) recommendations. ACIP carefully considers whether adverse events reported during clinical trials could be causally linked to the vaccination.
- ACIP has the ability to remove non-related injuries for the sake of clarity on a VIS. However, it is important to note that the final section of each VIS - *How can I learn more?* - states that parents and patients can ask their healthcare providers for the package insert.

Where can I find more information about Vaccine Information Statements?

- The CDC has all of the English-language VISs on their website: www.cdc.gov/vaccines/hcp/vis/index.html
- The CDC has a page on Frequently-Asked Questions on VISs: www.cdc.gov/vaccines/hcp/vis/about/vis-faqs.html
- VISs have been translated into about 40 languages. These can be found on the Immunization Action Coalition's website: www.immunize.org/vis/

Vaccine Information Statements ensure patients and parents have enough information to make a truly informed decision whether to vaccinate themselves or their children.

Source

National Center for Immunization and Respiratory Diseases. "Vaccine Information Statements (VISs)." *Centers for Disease Control and Prevention*. www.cdc.gov/vaccines/hcp/vis/index.html. Last Accessed: October 3, 2018.