Vaccine Information Statements (VISs)

Focal Problem or Issue
Nursing home staff who provide vaccines to residents and staff should provide a Vaccine Information Statement (VIS) to recipients in their native language whenever possible. In the absence of a VIS, for example when a vaccine is administered under emergency use authorization, or for newly recommended vaccines, use approved alternatives. Do not delay vaccination waiting for a VIS.

Background and Scope
All vaccine providers, public or private, are required by the National Vaccine Childhood Injury Act to give the appropriate VIS to the patient (or parent or legal representative) prior to every dose of specific vaccines, including pneumococcal conjugate and influenza vaccines. As an exception, vaccines authorized under an Emergency Use Authorization (EUA) may not have a VIS available. Instead, the Food and Drug Administration (FDA) requires that vaccine recipients or their caregivers are provided with certain vaccine-specific information to help make an informed decision about vaccination.

Providing patients or their caregivers with accurate information about the benefits and risks of vaccination is important for both ethical and legal reasons. VISs are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain both the benefits and risks of a vaccine and are based on the Advisory Committee on Immunization Practices’ (ACIP) recommendations.

VISs for Influenza, RSV, COVID-19, Pneumococcal, and other vaccines are available in English on the CDC website. Visit Vaccine Information Statement | Current VISs | CDC. The Immunization Action Coalition maintains VIS in other languages on the website Immunize.org.

Suggestions for Practice and Resources
According to the CDC, there are specific provider responsibilities, types of VISs, and legal requirements for using VISs.

- Prior to administration of each dose of the vaccine, provide a copy of the relevant current edition of vaccine information materials that have been produced by the CDC for the recipient to keep.
- Make a notation in each patient’s permanent medical record at the time vaccine information materials are provided, indicating the edition date of the VIS distributed and the date the VIS was provided.
- “Legal representative” is defined as a parent or other individual who is qualified under state law to consent to the immunization of a minor child or incompetent adult.
- In the case of an incompetent adult, relevant VISs shall be provided to the individual’s legal representative.

Additional Resources
For VISs for multi, routine, & non-routine-vaccines, visit: VACCINE INFORMATION STATEMENT | CURRENT VISs | CDC
To access copies of VISs in other languages, visit: VACCINE INFORMATION STATEMENTS - VISs - CDC INFORMATION SHEETS FOR PATIENTS (immunize.org)
To learn more about Emergency Use Authorizations, visit: https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained
For COVID-19 Vaccine Recipient Education resources, visit: https://www.cdc.gov/vaccines/covid-19/hcp/index.html
Talking with Patients about COVID-19 Vaccination visit https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html

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If the incompetent adult is living in a long-term care facility, all relevant VISs may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each vaccination.

- It is possible, particularly for a newly-approved vaccine, that the vaccine could become available before a VIS can be produced.

- Until a VIS is available for a particular vaccine, a provider may use the manufacturer’s package insert, written FAQs, or any other document – or produce their own information materials – to inform patients about the benefits and risks of that vaccine. Once a VIS is available it should be used, but providers should not delay use of a vaccine because of the absence of a VIS.

**Additional Resources**

For VISs for multi, routine, & non-routine-vaccines, visit: [VACCINE INFORMATION STATEMENT | CURRENT VISS | CDC](https://www.cdc.gov/vaccines/biologics/vaccines/emergency-use-authorization-vaccines-explained)

To access copies of VISs in other languages, visit: [VACCINE INFORMATION STATEMENTS - VISS - CDC INFORMATION SHEETS FOR PATIENTS (immunize.org)](https://www.cdc.gov/vaccines/biologics/vaccines/emergency-use-authorization-vaccines-explained)

To learn more about Emergency Use Authorizations, visit: [https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained](https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained)

For COVID-19 Vaccine Recipient Education resources, visit: [https://www.cdc.gov/vaccines/covid-19/hcp/index.html](https://www.cdc.gov/vaccines/covid-19/hcp/index.html)

Talking with Patients about COVID-19 Vaccination visit [https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html](https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html)

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