May 6, 2024 Weekly Clinical Update

Apparently Vaccine Declinations are getting increase surveyor scrutiny. Fortunately, AHCA has provided extremely valuable tools. On the AHCA LTC Infection Control Forum there has been a LOT of discussion about how to get signed permissions for vaccinations at the time of admission. Many facilities have included physician orders for annual or as needed vaccinations in "Standing Orders", but for the resident consents, the exact influenza or pneumococcal vaccine being offered must be included in the education and the consent obtained.

In the forum, the 2 resources from AHCA were provided to participants. It seems apparent that following these 2 tip sheets would be helpful to the facility's Infection Preventionist and the Infection Prevention and Control Committee including the facility's Medical Director

DECEMBER 2023

AHCA/NCAL Infection Preventionist Hot Topic Brief

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. 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

* Not a member of the AHCA National Infection Prevention Forum? Click here for instructions on how to join!

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AHCA/NCAL Infection Preventionist Hot Topic Brief

Vaccine Information Statements (VISs)

- 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

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

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The 2nd resource includes "Tips for Meeting the Immunization Requirements"

TIPS FOR MEETING THE IMMUNIZATION REQUIREMENTS IN SKILLED NURSING AND LONG-TERM CARE FACILITIES

Centers for Medicare and Medicaid Services (CMS) regulations require facilities to develop policies and procedures to educate about and offer residents the influenza and pneumococcal immunizations[1] and both residents and staff about the COVID-19 immunizations[2]. CMS Surveyors will review the facilities' policy and procedure about vaccines and review a sample of residents' medical records and talk with staff to confirm that they received education. They will review the medical records to determine if documentation shows if the resident received the vaccine or declined. See CMS's State Operating Manual Appendix PP updated 2-03-23 for F-883 regulatory language and guidance to surveyors about Influenza and Pneumococcal Immunizations (pages 806-812) and the CMS QSO memo 23-10-nh for F887 COVID-19 Immunization.

We have listed below the components of the regulatory requirements for immunization programs with tips on how to ensure compliance based on a review of the common reasons facilities received citations for **F883 - Influenza, Pneumococcal Immunizations or F887 - COVID-19 Immunization for Residents and Staff**. It is important that you have a systemic process for offering, educating, documenting, and administering the vaccine that you periodically audit to catch residents or staff that may have dropped through the cracks. In consistent following of the process, failure to follow-up on pending information and "drop through the cracks" cases were common emphasizing that you have a robust system in place with a person responsible for auditing all the steps are done and documented.

Policy and Procedure

The facility must develop policies and procedures to ensure their residents and staff have been educated and offered vaccines for potentially preventable diseases.

TIP: The policies and procedures must contain an education component for residents, resident representatives, and for COVID-19 for staff.

TIP: Before each vaccine season, review the Advisory Committee on Immunization Practices (ACIP) recommendations to ensure your policy and procedures are current with latest guidance and updated accordingly.

TIP: Subscribe to the CDC Morbidity and Mortality Weekly Report (MMWR)[3], which is free. This report is CDC's primary vehicle for scientific publication of timely, reliable, authoritative, accurate, objective, and useful public health information and recommendations where CDC typically announces changes to ACIP vaccine recommendations. To receive free online MMWR subscription go to https://tools.cdc.gov/campaignproxyservice/subscriptions.aspx

[1] https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf

[2] https://www.cms.gov/files/document/qso-23-10-nh.pdf

[3] https://www.cdc.gov/mmwr/

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TIPS FOR MEETING THE IMMUNIZATION REQUIREMENTS IN SKILLED NURSING AND LONG-TERM CARE FACILITIES

Confirm Vaccination Status

Upon admission and throughout the resident's stay, ensure each is offered an influenza, pneumococcal, and COVID-19 immunization unless the immunization is medically contraindicated, or the resident has already been immunized during this time period.

TIP: Make sure to follow through in obtaining information on the resident's vaccination status. Set a reminder to check on the information that is sent after a reasonable amount of time and if unavailable to obtain, proceed with vaccinating the resident with their permission.

TIP: Check the resident's hospital record If you have access to it, this may be another location where vaccination status has been documented by their PCP or hospital staff.

TIP: Review your state's immunization registry to obtain vaccination history of the resident to assess need for vaccinations and to document in medical record. (for Contacts for state Immunization Records-see https://www.cdc.gov/vaccines/programs/iis/contacts-locate-records.html)

Educate on Risk and Benefits & Offer

Before offering the influenza, pneumococcal, or COVID-19 immunizations, ensure each resident or the resident's representative and staff were provided education regarding the benefits and potential side effects of the immunization.

TIP: Utilize the current CDC Vaccine Information Statement (VIS) for each vaccine (available in multiple languages) to ensure federally required education of risks and benefits and document provision of this information in the resident's medical record.

TIP: Develop a process to ensure all residents receive education on the risk and benefits such as including the CDC VIS in the resident's admission package and obtain an order from the attending physician to administer the vaccines per CDC's ACIP recommendations. This way you can ensure and document how education and offering the vaccine was provided to all residents if it is part of the admission process.

Document Education

Ensure the resident's medical record includes documentation that indicates the resident or resident's representative was provided education regarding the benefits and potential side effects of influenza, pneumococcal, or COVID-19 immunizations. Documentation is important since residents may be discharged to home or receive care from multiple physicians or nurse practitioners throughout their stay who will not be aware of past efforts without documentation.

TIPS FOR MEETING THE IMMUNIZATION REQUIREMENTS IN SKILLED NURSING AND LONG-TERM CARE FACILITIES

Document Education (cont.)

TIP: Designate a facility point of contact to provide information on how residents and staff are educated about and offered the influenza, pneumococcal, and COVID-19 immunizations, including samples of educational materials.

TIP: Make sure to document the date and time of education occurred in the resident's medical record and for each staff.

TIP: Review the medical records or run a report from your electronic medical record (if it has a vaccine module) to ensure documentation about providing education is present.

Document Decision

The resident or the resident's representative has the opportunity to refuse immunization.

TIP: Ensure the resident's medical record includes documentation on their decision. If they refuse the vaccine, make sure to document their refusal and/or if due to medical contraindications.

TIP: Utilize the vaccine module in your electronic medical record to document the resident's or their representative's decision.

TIP: If you keep a separate log for immunizations, make sure someone on a regular basis ensures the information on the log matches information in the resident's medical record.

Act on Decision

Continue to educate and explain the benefits and risks of the vaccine. Individuals want clear and consistent information about vaccines.

TIP: Make sure you have a process to close the loop that when the individual wants the vaccine, they receive it. If they decline it, make sure it is documented. Such as running reports from your medical record to determine that all residents who have not declined have received the vaccine.

TIP: Refer to the CDC Recommended Adult Immunization Schedule for ages 19 years or older. This document provides a table of what vaccinations are recommended, age to be administered, and contraindications and precautions.

https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf#page=6%20

TIPS FOR MEETING THE IMMUNIZATION REQUIREMENTS IN SKILLED NURSING AND LONG-TERM CARE FACILITIES

Act on Decision (cont.)

TIP: Utilize the CDC PneumoRecs VaxAdvisor (app or web-based version). It assists vaccination providers to quickly and easily determine which pneumococcal vaccines a resident needs and when. The app incorporates recommendations for all ages. The app provides resident-specific guidance consistent with the immunization schedule recommended by ACIP.

TIP: Utilize resources to share clear and accurate information about the vaccines such as the CDC Vaccine Information Sheets (VIS), raise awareness about the benefits of vaccination, and address common questions and concerns about what to expect when getting vaccinated.

Document Administration

Ensure documentation of vaccine(s) administered to the resident is in the medical record.

TIP: In addition to documenting administration of the vaccine, make sure all information about the vaccine is documented in the medical record (and EMR). Document the date, injection site, any side effects, vaccine manufacturer, and vaccine lot number in the resident's medical record. This will help with submitting information from the medical record to NHSN or state immunization registries. Also, it helps with follow-up when there are any issues with any of the vaccine lots.

TIP: Monitor and track vaccinations. Use audit reports (e.g., about missing entries, vaccination consents/declinations/administration) available from the facility's medical record system to ensure documentation is accurate and complete, and the facility is compliant with CMS regulations. Run the reports at least weekly during influenza season and at least monthly for pneumococcal and COVID-19.

TIP: Assign who is responsible to run the reports, who is responsible for ensuring any required follow-ups based on the audit reports are completed and set target dates for completion.

TIP: To ensure consistent and accurate reporting of resident and staff COVID-19 vaccination, utilize resources on reporting to the NHSN for residents and staff:

- NHSN Weekly HCP COVID-19 Vaccination - https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html
- NHSN FAQs on Reporting COVID-19 Vaccination Data- January 2024 - https://www.cdc.gov/nhsn/hps/weekly-covid-vac/faqs.html
- NHSN COVID-19/Respiratory Pathogens Vaccination - https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html

TIPS FOR MEETING THE IMMUNIZATION REQUIREMENTS IN SKILLED NURSING AND LONG-TERM CARE FACILITIES

Resources for Influenza, Pneumococcal, & COVID-19 Immunizations

#getvaccinated AHCA online toolkit for vaccines

ahcancalED - Preparing for Respiratory Season in LTC: Vaccines, Therapeutics, and Indoor Air Quality

COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals: https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf

CDC's Clinical Resources for COVID-19 Vaccine https://www.cdc.gov/vaccines/covid-19/index.html

Post Vaccine Considerations for Residents and HCP: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

Vaccine recipient education - https://www.cdc.gov/vaccines/covid-19/hcp/index.html

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Hope these help.