Influenza Vaccination

Influenza

Influenza (flu) is an acute, highly contagious respiratory illness caused by an influenza virus – Influenza A or B. Flu cases can occur at any time of the year; however, the peak of activity generally occurs between December and February. Flu activity may continue into the spring, with cases occurring as late as May.[1]

The Centers for Disease Control and Prevention (CDC) has estimated that there were around 35 million flu-related illnesses in the U.S. during the 2019-2020 flu season, resulting in 380,000 hospitalizations and 20,000 deaths. The majority of deaths occurred in people aged 65 and older.[2] During the 2021-2022 flu season there were an estimated nine million flu-related illnesses, 100,000 hospital admissions, and 5,000 flu-related deaths.[a,3]

Older adults are particularly vulnerable to serious complications of the flu age-related diminishment in immune responses. Those living in a nursing facility (NF) are at increased risk, as the flu can easily spread in a congregate setting. Complications of the flu can include exacerbations of pre-existing medical conditions, such as bronchitis, asthma, or chronic heart disease. Secondary bacterial pneumonia is a common complication.[1]

Influenza is spread through close contact, droplet, and sometimes airborne transmission – such as through sneezing or coughing. People who are infected with influenza can be contagious up to 24 hours before symptoms appear and for five to seven days after the onset of illness.

Annual immunization is key to preventing flu outbreaks and flu-related complications in high-risk populations. The CDC estimates that between 2010 and 2018, influenza vaccines prevented around 70,000 hospitalizations and 6,400 deaths, particularly in people aged 65 and over.[1]

[a] Minimal flu activity was reported for the 2020-2021 flu season; therefore, no estimates of disease burden were available from the CDC.

Regulatory Requirements

Federal

Federal regulations regarding influenza vaccines can be found in Appendix PP of the State Operations Manual (SOM) at F883. These regulations require NF providers to develop policies and procedures that ensure each person or their representative:

- Has received education about the benefits and potential side effects of the influenza vaccine
- Is offered the influenza vaccine annually between October 1st and March 31st unless the person has already received the vaccine or has a medical contraindication
- Has an opportunity to refuse vaccination

The NF must document the education provided in each person's clinical record, including the benefits and potential side effects of vaccination. The facility must also document the vaccination administered. If the influenza vaccine was not given, the NF must document the refusal or the medical contraindication that prevented vaccination.

For more information, see the CMS Compliance Group, Inc. blog links below.[b]

- Ftag of the Week – F883 Influenza and Pneumococcal Vaccinations

Note: Additional information about how surveyors review vaccinations is available in the *Infection Prevention, Control & Immunization Critical Element Pathway* found in the *Surveyor Resources* folder on the Centers for Medicare and Medicaid Services (CMS) Nursing Homes page.

In addition, the National Vaccine Childhood Injury Act (NVCIA) requires anyone administering a vaccination to provide the person receiving the vaccine (or their representative), regardless of their age, with a copy of the current Vaccine Information Statement (VIS) ***prior*** to giving the vaccine. The VIS is developed by the CDC and includes information about the risks and benefits of the vaccine, as well as steps that should be taken if an adverse reaction occurs.

- VIS - Inactivated Influenza Vaccine: Issued 08/06/2021
- VIS - Live, Intranasal Influenza Vaccine: Issued 08/06/2021

More information about the NVCIA and the requirements for using a VIS are available from Immunize.org.

[b] Any links, information, or advertisements provided by private entities throughout this resource do not infer endorsement or recommendation by Texas HHSC of any products or services.

- You Must Provide Patients with Vaccine Information Statements (VISs) – It's Federal Law!

State

The Texas Administrative Code (TAC) also includes rules related to immunizations. TAC Title 26, Part 1, Chapter 554, Subchapter Q, §554.1601 Infection Control requires NF Providers to:

- Offer the influenza vaccine to each person, unless medically contraindicated or refused
- Complete administration of vaccinations by November 1 of each year
    - Continue to administer the influenza vaccine to those admitted after November 1 throughout the influenza season (through March of the following year)
- Develop and implement policies and procedures requiring:
    - Education for the person/their representative regarding the risks (potential side effects) and benefits of receiving the vaccine
    - Documentation in the clinical record indicating the person either received the vaccine, declined the vaccine, or that the vaccine was not given due to a medical contraindication
    - Documentation of the date of immunization or refusal

Quality Measure NO16.03 Percent of Residents Assessed and Appropriately Given the Seasonal Influenza Vaccine

Quality Measure (QM) NO16.03 reports the percentage of people who received the influenza vaccine appropriately during the most current influenza season. This includes people who:

- Received the vaccine, whether given by the facility or from another source
- Were offered the vaccine but declined
- Did not receive the vaccine due to a medical contraindication

When calculating the long-stay quality measure for influenza immunization, CMS notes "This measure is only calculated once per 12-month influenza season which begins on July 1 of a given year and ends on June 30 of the subsequent year, and reports data for residents who were in the facility for at least one day during the target period of October 1 through March 31."[5]

The Quality Measure Tip Sheet: Influenza Vaccine - Long & Short Stay from TMF provides additional guidance in this measure.

Centers for Disease Control and Prevention (CDC) Guidelines – Influenza Vaccines

Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022–23 Influenza Season provides detailed recommendations for influenza vaccination. Below is a summary of recommendations relevant to NFs.

An influenza vaccine is needed every flu season.

- The body's immune response from vaccination declines over time, so annual immunization is needed for optimal protection.[1]
- Flu virus strains change constantly as the virus mutates (i.e., antigenic drift). Experts conduct annual surveillance of circulating viruses and update the vaccine formulation as needed to include those viruses.[1]

Every person living in a NF should receive the influenza vaccine each flu season unless specifically contraindicated. While the vaccine may be available earlier, the CDC recommends offering it in September or October. NFs should continue to offer the vaccine as long as they have an unexpired supply available, and cases are still being reported.[6]

Currently, all licensed vaccines in the U.S. are "quadrivalent", meaning they include two Influenza A and two Influenza B viruses. Any licensed and age-appropriate vaccine can be used for vaccinating people living in a NF; however, for older adults, a higher dose or an adjuvanted vaccine is preferred:[6]

- Quadrivalent high-dose inactivated influenza vaccine (Fluzone High-Dose Quadrivalent vaccine)
- Quadrivalent recombinant influenza vaccine (Flublok Quadrivalent recombinant flu vaccine)
- Quadrivalent adjuvanted inactivated influenza vaccine (Fluad Quadrivalent adjuvanted flu vaccine)

Contraindications to immunization:

- Severe, life-threatening allergy to any component of a flu vaccine (except for egg proteins)
- Prior history of a severe allergic reaction to a dose of the flu vaccine

Egg allergy is no longer considered a contraindication to the flu vaccine, and people with an egg allergy may receive any licensed flu vaccine that is appropriate for their age. If the person has a history of severe allergic reactions to egg (other than hives), he/she should be vaccinated in a healthcare setting by a healthcare professional who is able to "recognize and manage severe allergic conditions."[6]

Note: Flublok Quadrivalent recombinant flu vaccine is manufactured without using chicken eggs or the flu virus.

Precautions:

- Acute illness that is moderate or severe, with or without fever
- Guillain-Barre syndrome within 6 weeks of a previous dose of the influenza vaccine

People with either of the above situations should discuss the flu vaccine with their physician. The risk and benefits of the vaccine should be considered, including the person's level of risk for developing severe flu-related complications.[6]

NF Immunization Systems

Documenting and Maintaining Records of Vaccination

Federal law requires documentation of vaccination in a person's clinical record, including:[8]

- Date of vaccination
- Name of the vaccine manufacturer and lot number
- Name, and title of the person administering the vaccine
- Address of the facility where the clinical record is kept
- Edition date of the VIS
- Date the VIS was provided to the person or his/her representative

The VIS may be provided in laminated, paper, or electronic/digital format, but must be given prior to administering the vaccine. The NF must offer a copy to the person receiving the vaccine to keep after receiving the vaccine, but he/she can decline to take it.[9]

Best practices for documentation include the following (in addition to the federally required information). These are required by licensing rules and important for adverse event reporting.

- Vaccine type/name
- Route of administration (e.g., subcutaneous or intramuscular)
- Injection site (i.e., left deltoid muscle)
- Dosage given (volume, i.e., mL)

The facility should maintain personalized vaccination records for everyone living in the NF that include all of the above information. Vaccination records should be kept up to date, readily available and should not be thinned from the chart. Accurate and

complete documentation will help facilities avoid vaccination errors and accidental re-vaccination.[10]

If the vaccine is administered outside of the NF, facility staff should attempt to obtain documentation from that provider. Immunize.org has developed a handout *Tips for Locating Old Immunization Records* that can help guide the search for documentation of prior vaccination. Self-reported doses of influenza vaccine are acceptable; however, positive evidence of other vaccines is needed.[11] A copy of the person's individual vaccination record should be sent with him/her at the time of discharge or when transferring to another facility.

If the person declines vaccination, the facility should document the education provided regarding the risks and benefits of vaccination.[12] Documentation should include evidence that the VIS/fact sheet was provided to them. This information can help the NF track the reasons for refusal and work to address related barriers.[12] NFs may choose to implement written declination forms. For example:

- *Refusal to Consent to Adult Vaccination: 19 years and Older* developed by the Alliance for Immunization in Michigan
- *Declination of Influenza Vaccination* from Immunize.org

Centralized immunization systems or logs provide an efficient way for NF to track vaccinations of people living in the facility. They can identify those who remain unvaccinated at any given time and can assist the NF in quickly determining which people need prophylaxis during an outbreak. In addition, a centralized system will allow staff to readily identify the vaccine serum lot numbers in the event of a vaccine recall.[10]

ImmTrac2 Texas Immunization Registry also covers adults. People who provide written consent can have their vaccine information stored electronically in a secure, confidential registry. Consent can be withdrawn at any time. ImmTrac2 also allows people to request a copy of their record at any time.

Managing Medical Emergencies Related to Vaccination

Adverse reactions to vaccines can vary from minor localized reactions (such as pain, redness, swelling, or itching at the injection site) to severe reactions involving anaphylaxis. Localized reactions can often be managed with interventions such as an over-the-counter analgesic for pain and a cool compress to the injection site to reduce redness and swelling.

Anaphylaxis can involve a range of symptoms and requires urgent treatment. Symptoms include:

- Hives, flushed skin
- Swelling of the lips, tongue or eyes
- Respiratory distress such as stridor, wheezing, shortness of breath
- Nausea, vomiting, diarrhea, abdominal pain
- Tachycardia, hypotension, dizziness or feeling lightheaded

NF staff must be prepared to manage medical emergencies related to administration of vaccines. The NF needs to have written protocols in place (such as a policies and procedures or standing orders) and ensure staff have received training on those protocols.

The NF must have the medications and equipment available to respond to vaccine-related adverse reactions.[13]

- Epinephrine is the first line treatment for anaphylaxis, either through an autoinjector (e.g., an EpiPen® or generic equivalent) or another intramuscular formulation. After the initial injections, two additional doses of epinephrine may be given, with five to 15 minutes between doses.
- Necessary emergency equipment for performing CPR and maintaining a person's airway must be available.

Immunize.org has published Medical Management of Vaccine Reactions in Adults in a Community Setting. This resource can help the NF and its medical director develop facility-specific protocols for managing adverse reactions to vaccination.

Any adverse reactions and the treatment provided must be documented in the person's clinical record.[10] Staff must also report certain adverse vaccine reactions to the federal Vaccine Adverse Event Reporting System (VAERS) regardless of the age of the person who received the vaccine.[10] The Table of Reportable Events Following Vaccination provides more detail about reportable adverse reactions.

Additional Best Practices for Immunization Programs

The facility should designate a specific person/position to be responsible for coordinating all immunization activities in the NF.[14] Responsibilities and tasks include:

- Providing input on the facility's policies, procedures, and protocols related vaccination
- Planning and implementing the NF's annual flu vaccination campaign
- Logistics, including ordering vaccines and ensuring they are stored and handled correctly (according to manufacturer's recommendations)
- Providing training for and evaluating the competency of staff who administer vaccines

- Coordinating the "messaging" about the facility's immunization program to staff, physicians, people living in the NF/responsible parties
- Monitoring the effectiveness of the immunization program and identifying opportunities for improvement

In addition, the NF should have processes in place to ensure:

- Each person's vaccination status is identified at the time of admission and offer any appropriate vaccine[11]
    - Includes locating documentation of vaccinations received outside of the NF (previous healthcare providers, community-based vaccination clinics, etc.)
- Facility-specific policies and procedures are implemented consistently
    - Use of standing orders or protocols for immunizations
    - Documentation of vaccination or declinations
    - Educational resources for people receiving a vaccine or those who decline vaccination regarding the associated benefits and risk (for example, the current VIS)
    - Re-approaching those who have previously declined, providing education on the benefits of vaccination and the risks associated with vaccine-preventable diseases

Immunize.org has resources available to help providers develop standing orders or protocols for their facility.

- Ten Steps to Implementing Standing Orders for Immunization in Your Practice Setting
- Using Standing Orders for Administering Vaccines: What You Should Know
- Standing Orders for Administering Influenza Vaccine to Adults

The NF should establish goals and related metrics to ensure the program is effective and monitor the program processes and outcomes. Use the results to guide improvement efforts. For example:

- Percentage of people living in the facility who have received the current seasonal flu vaccine, compared to prior years
- Percentage of people living in the facility who did not receive a vaccination due to a medical contraindication
- Reasons given (other than a medical contraindication) for declining vaccination

Additional resources are available on the Quality Monitoring Program Immunizations web page.

References

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