



## **Dialysis Patient Influenza Vaccination Protocol**

### **Background**

Influenza infections are associated with increased medical costs, hospitalizations, lost productivity, and thousands of deaths every year in the United States. The majority of deaths from seasonal influenza occur in adults aged  $\geq 65$  years.<sup>1-4</sup> Annual influenza vaccination is the best way to reduce the risk for complications from influenza infections and in the United States is now recommended for all persons aged  $\geq 6$  months.

Annual epidemics of seasonal influenza usually occur during the late fall through early spring each year. During these times, rates of infection with influenza are highest among persons aged  $\geq 65$  years of age, in children  $< 2$  years and persons of any age who have medical conditions placing them at increased risk for the complications of influenza.<sup>5-7</sup> Occasionally, a variant strain of influenza will emerge that is distinct from the expected seasonal strain and requires a separate vaccination for prevention. For example in 2009/2010, the non-seasonal strain was novel Influenza A (H1N1) 2009. Annual influenza vaccination is the most effective way to prevent influenza virus infection and its complications.

### **Methodology**

The Dialysis Patient Influenza Vaccination Module targets the dialysis facility's population, greater than 6 months of age. Monthly data collection (prospective surveillance) is used. When vaccinations for more than one subtype are recommended during a season, report denominator data separately for each vaccination subtype (i.e., seasonal and non-seasonal).

An individual, trained on this Protocol, shall initially seek to identify any and all maintenance dialysis patients treated at the facility as meeting criteria for seasonal vaccination during the review period, and determine if influenza vaccination was offered, and then either accepted or declined.

The CDC forms 57.505, 57.506 are used to collect all required data for this module. The minimum requirement to participate in this module is one month during the influenza season (September through April), but maximal benefit is obtained by completing the module for each month of the entire influenza season.



## Monthly Data Collection (Prospective Surveillance)

**Introduction:** Prospective surveillance requires the use of two forms, the *Dialysis Patient Influenza Vaccination Denominator* form (CDC 57.506), and the *Dialysis Patient Influenza Vaccination* form (CDC 57.505) to collect all data for the period of surveillance. The patient vaccination forms must be completed when the facility is performing an influenza vaccination campaign during the September-April influenza season or year-round, depending on the policies and procedures of the dialysis facility. The value of this method is that the information collected will assist facilities in identifying whether NHSN patients meeting criteria for influenza vaccination are actually receiving vaccination, and the details of those vaccinations. Additionally, dialysis facility staff will be able to identify specific gaps in adherence and recommend changes in practices to ensure that all eligible patients are being vaccinated.

**Settings:** This is a facility-wide surveillance in which all maintenance dialysis patients greater than 6 months of age are monitored during the selected month(s).

**Requirements:** Surveillance consists of a review of all maintenance dialysis patients greater than 6 months of age facility-wide to determine whether those patients who meet criteria for influenza vaccination are offered and receive influenza vaccination. Surveillance must be conducted for at least one calendar month during the influenza season as indicated in the *Dialysis Monthly Reporting Plan* (CDC 57.501). During seasons when seasonal and non-seasonal subtype vaccinations are recommended, such as 2009/2010, monitoring is required for all influenza vaccinations and dialysis facilities offering both season and non-seasonal vaccinations should report denominator data for each vaccination subtype (i.e., seasonal or non-seasonal) separately. Patients requiring a second vaccine should not be included in the count of those previously vaccinated. A *Dialysis Patient Influenza Vaccination Denominator* form (CDC 57.506) and a *Dialysis Patient Influenza Vaccination* form (CDC 57.505) need to be completed for each of the 2 doses given. (See latest CDC/ACIP recommendations for current season details). Ideally, the facility should conduct surveillance during each month of the influenza season (September through April).

Monthly surveillance requires determination of the number of maintenance dialysis outpatients greater than 6 months of age in the following categories for the month selected for review and submission of two separate denominator forms for each surveillance month if the facility offers both seasonal and non-seasonal vaccines. (All box numbers refer to the boxes found on the *Dialysis Patient Influenza Vaccination Denominator* form [CDC 57.506]):

- For the first month of your vaccination campaign, report the total patient census, separated by patient dialysis modality. In subsequent months of your vaccination campaign, count only new patients, by patient dialysis modality. (Only include patients 6 months or older.)



Complete a *Dialysis Patient Influenza Vaccination* form (CDC 57.505) for each patient in the facility during the surveillance period. For those patients who decline influenza vaccination, reasons for declination (medical contraindications and personal) are captured (Table 2).

Medical Contraindications	Allergy to vaccine components History of Guillain-Barré syndrome within 6 weeks of previous influenza vaccination Current febrile illness (Temp >101.5°)
Personal (non-medical) reasons for declining vaccination	Fear of needles/injections Fear of side effects Perceived ineffectiveness of vaccine Religious or philosophical objections Concern for transmitting vaccine virus to contacts

**Definitions:** All box numbers refer to the boxes found on the *Dialysis Patient Influenza Vaccination Denominator* form (CDC 57.506).

- For the first month of your vaccination campaign, report the total patient census, by patient dialysis modality. In subsequent months of your vaccination campaign, count only new patients, by patient dialysis modality. (Only include patients 6 months or older.)

**Numerator and Denominator Data:** Numerator data are reported on the *Dialysis Patient Influenza Vaccination* form (CDC 57.505) (refer to the tables of instructions for completion details). Denominator data are reported on the *Dialysis Patient Influenza Vaccination Denominator* form (CDC 57.506) (refer to the tables instructions for completion details).

**Data Analysis:** Data aggregated across the entire facility are stratified (e.g., month, influenza subtype, influenza season, and patient dialysis modality). Table 3 shows the formulas for metrics that can be calculated.



<b>Metric</b>		<b>Patient Vaccination Formula (x 100)</b>
<p><b>Table 3: Formulas for Metrics:</b>            Data come from two CDC forms:            Boxes 1 - 4 of the <i>Dialysis Patient Influenza Vaccination Denominator</i> form (CDC 57.506)  <i>Dialysis Patient Influenza Vaccination (DPIV)</i> form (CDC 57.505)</p>		
1	Prevalence rate for patients not previously vaccinated among all patients	$\frac{\text{Box 4}}{\text{Box 1}}$
2	Adherence rate for offering influenza vaccination to patients among all eligible patients	$\frac{\text{Total \# DPIV Forms "Vaccine offered" = "Yes"}}{\text{Box 4}}$
3	Adherence rate for receiving influenza vaccination patients among all patients	$\frac{\text{Total \# DPIV Forms "Vaccine administered" = "Yes"}}{\text{Box 4}}$
4	Influenza vaccination administration adherence rate among all medically eligible patients	$\frac{\text{Total \# DPIV Forms) "Vaccine administered" = "Yes"}}{\text{Box 4} - \text{Total \# DPIV Forms "Vaccine declined" = "Yes" due to medical contraindications}}$
5	Influenza vaccination administration adherence rate among all medically eligible, willing patients	$\frac{\text{Total \# DPIV Forms "Vaccine administered" = "Yes"}}{(\text{Box 4} - \text{Total \# DPIV Forms "Vaccine declined" = "Yes" due to medical contraindication}) + \text{"Vaccine declined" = "Yes" due to personal reasons}}$
6	Declination rate for patients eligible for influenza vaccination among all patients offered vaccine	$\frac{\text{Total \# DPIV Forms "Vaccine declined" = "Yes"}}{\text{Total \# DPIV Forms "Vaccine offered" = "Yes"}}$
7	Declination rate due to personal (non-medical) reasons for patients eligible for influenza vaccination among all patients offered vaccine	$\frac{\text{Total \# DPIV Forms "Vaccine declined" = "Yes" due to personal reasons}}{\text{Total \# DPIV Forms "Vaccine offered" = "Yes"}}$
8	Declination rate due to medical contraindications for patients eligible for influenza vaccination among all patients offered vaccine	$\frac{\text{Total \# DPIV Forms "Vaccine declined" = "Yes" due to medical contraindications}}{\text{Total \# DPIV Forms "Vaccine offered" = "Yes"}}$
9	Failure rate for offering vaccine to patients medically eligible for influenza vaccination among all medically eligible patients	$\frac{\text{Box 4} - \text{Total \# DPIV Forms "Vaccine offered" = "Yes" "Vaccine declined" = "Yes" due to medical contraindications}}{\text{Total \# DPIV Forms "Vaccine offered" = "Yes"}}$
10	Prevalence rate of all patients previously vaccinated among all patient admissions	$\frac{\text{Box 3}}{\text{Box 1}}$



## References

1. Simonsen L, Reichert TA, Viboud C, Blackwelder WC, Taylor RJ, Miller MA. Impact of influenza vaccination on seasonal mortality in the US elderly population. *Arch Intern Med.* 2005;165(3):265-72.
2. Thompson WW, Moore MR, Weintraub E, Cheng PY, Jin X, Bridges CB, et al. Estimating influenza-associated deaths in the United States. *Am J Public Health.* 2009;99 Suppl 2:S225-30.
3. Thompson WW, Shay DK, Weintraub E, Brammer L, Cox N, Anderson LJ, et al. Mortality associated with influenza and respiratory syncytial virus in the United States. *JAMA.* 2003;289(2):179-86.
4. Thompson WW, Weintraub E, Dhankhar P, Cheng PY, Brammer L, Meltzer MI, et al. Estimates of US influenza-associated deaths made using four different methods. *Influenza Other Respi Viruses.* 2009;3(1):37-49.
5. Barker WH. Excess pneumonia and influenza associated hospitalization during influenza epidemics in the United States, 1970-78. *Am J Public Health.* 1986;76(7):761-5. PMID: 1646876.
6. Barker WH, Mullooly JP. Impact of epidemic type A influenza in a defined adult population. *Am J Epidemiol.* 1980;112(6):798-811.
7. Monto AS, Kioumeh F. The Tecumseh Study of Respiratory Illness. IX. Occurrence of influenza in the community, 1966--1971. *Am J Epidemiol.* 1975;102(6):553-63.



## Instructions for the Dialysis Patient Influenza Vaccination form (CDC 57.505)

\*Indicates a required field.

^Indicates a conditionally required field.

Data Field	Instructions for Data Collection
*Facility ID	<b>Required.</b> The NHSN-assigned facility ID number will be auto-entered by the computer.
*Event #	<b>Required.</b> Event ID number will be auto-entered by the computer.
*Patient ID	<b>Required.</b> Enter the alphanumeric patient ID number. This is the patient identifier assigned by the dialysis center and may consist of any combination of numbers and/or letters.
Social Security #	Optional. Enter the 9-digit numeric patient Social Security Number.
Secondary ID	Optional. Enter the alphanumeric ID number assigned by the facility.
Medicare #	Optional. Enter the patient's Medicare number.
Patient name	Optional. Enter the last, first, and middle name of the patient.
*Gender	<b>Required.</b> Select Female, Male or Other to indicate the gender of the patient.
*Date of Birth	<b>Required.</b> Record the date of the patient birth using this format: MM/DD/YYYY
Ethnicity	Optional. Specify whether the patient's ethnicity is Hispanic or Latino.
Race	Optional. Specify the following that identify the patient's race: American Indian/Alaska Native; Asian; Black or African American; Native Hawaiian/Other Pacific Islander; and White.
*Event Type	<b>Required.</b> FLUVAX.
*Influenza subtype	<b>Required.</b> Check one: <ul style="list-style-type: none"> <li>• Seasonal</li> <li>• Non-Seasonal</li> </ul> If patient received both vaccines, complete two separate forms (one for information regarding the seasonal vaccine and one for information regarding the non-seasonal vaccine).
*Flu Season	<b>Required.</b> Enter (or select from the pull-down menu) the fall to spring year range for the flu season being reported.
*Patient Dialysis Modality	<b>Required.</b> Check one: <ul style="list-style-type: none"> <li>• In-center hemodialysis</li> <li>• Home hemodialysis</li> <li>• Peritoneal dialysis</li> </ul>
*Patient vaccinated in this facility	<b>Required.</b> Indicate whether the patient was vaccinated in your dialysis facility.
*Patient previously vaccinated elsewhere	<b>Required.</b> Indicate whether the patient was previously vaccinated elsewhere for the flu season.
*Patient declined vaccine	<b>Required.</b> Indicate whether the patient declined the vaccine for any reason.





^Reason(s) vaccine declined	Conditionally required. If answered “Yes” to “Patient declined vaccine,” required to complete either section A or B. May not complete both sections. If both sections are applicable to the patient, only complete section A.
^Date Vaccine Administered	Conditionally required. If answered “Yes” to “Patient vaccinated in this facility” or “Yes” to “Patient vaccinated elsewhere for this flu season,” required to enter date vaccine administered using this format: mm/dd/yyyy.
^Type of influenza vaccine administered	Conditionally required. If answered “Yes” to “Patient vaccinated in this facility” or “Yes” to “Patient previously vaccinated elsewhere for this flu season,” required to enter the type of vaccine administered. For this section, complete information regarding the influenza subtype selected in the “Influenza subtype” field at the top of the form. Only mark “Other (specify)” if the influenza type administered is not listed. If mark “Other (specify),” list the brand name or type administered.  If patient received both season and non-seasonal influenza vaccines, complete two separate vaccination forms, one for each vaccine subtype.
Manufacturer	Optional. If answered “Yes” to “Patient vaccinated in this facility,” enter the name of the vaccine manufacturer.
Lot number	Optional. If answered “Yes” to “Patient vaccinated in this facility,” enter the vaccine’s lot number.
^Route of administration	Conditionally required. If answered “Yes” to “Patient vaccinated in this facility” or “Yes” to “Patient previously vaccinated elsewhere for this flu season,” required to check one: Intramuscular or Subcutaneous.
Vaccine Information Statement	Optional. Indicate whether the Vaccine Information Statement (VIS) was provided to the patient.
Edition Date	Optional to enter the edition date of the vaccine information statement provided to patient. Enter date in the format: MM/DD/YYYY
Vaccinator ID	Optional. If vaccine is administered, indicate the vaccinator’s identifier. This is an identifier assigned by the facility and may consist of any combinations of numbers and/or letters.
Title	Optional. If vaccine is administered, indicate the vaccinator’s identifier.
Name	Optional. If vaccine is administered, indicate the last, first, and middle name of the staff member who administered the vaccine.
Custom Fields	Optional. Up to 50 fields may be customized for local or group use in any combination of the following formats: date (MM/DD/YYYY), numeric, or alphanumeric.  NOTE: Each Custom Field must be set up in the Facility/Custom Options section of NHSN before the field can be selected for use. CDC does not typically analyze these data.
Comments	Optional. Use this field to add any additional information about this vaccination that would help you to interpret your surveillance data. CDC typically does not analyze these data.



## Instructions for the Dialysis Patient Influenza Vaccination Denominator form (CDC 57.506)

\*Indicates a required field.

Data Field	Instructions for Data Collection
*Facility ID	The NHSN-assigned facility ID number will be auto-entered by the computer.
*Month	<b>Required.</b> Enter name of the month for which denominator count is being reported.
*Year	<b>Required.</b> Enter the year for which the denominator count is being reported in the format: YYYY.
*Vaccination type	<b>Required.</b> Influenza.
*Vaccination subtype	<b>Required.</b> Choose one: <ul style="list-style-type: none"> <li>• Seasonal</li> <li>• Non-Seasonal</li> </ul> If your facility intends to offer both seasonal and non-seasonal vaccines to at least one patient, complete a separate denominator form for each subtype each month.
*Number of dialysis Patients	<b>Required.</b> When completing the form for the <u>first month of the vaccination campaign</u> , report the total patient census, separated by patient dialysis modality. Include all patients who received one or more treatments at any time during the month. Include only patients age 6 months and older.  For <u>each month following the first month of the campaign</u> , enter the number of new patients, separated by patient dialysis modality. Include only patients age 6 months and older.
Custom Fields	Optional. Up to 50 fields may be customized for local or group use in any combination of the following formats: date (MM/DD/YYYY), numeric, or alphanumeric.  NOTE: Each Custom Field must be set up in the Facility/Custom Options section of NHSN before the field can be selected for use. CDC does not typically analyze these data.
Comments	Optional. Use this field to add any additional information about this vaccination that would help you to interpret your surveillance data. CDC typically does not analyze these data.