

Change Memo for
National Healthcare Safety Network (NHSN)
Surveillance in Healthcare Facilities
(OMB Control Nos. 0920-0666)
Expiration Date: 12/31/2026

Program Contact

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The Centers for Disease Control and Prevention (CDC), Division of Healthcare Quality Promotion (DHQP) requests approval of a non-substantive change to five data collection instruments in the National Healthcare Safety Network (NHSN) OMB Package (OMB Control No. 0920-0666).

1. Hemovigilance Module Monthly Incident Summary (57.302)
2. Hemovigilance Module Adverse Reaction Transfusion Associated Circulatory Overload (57.318)
3. Long Term Care (LTC) Module Monthly Reporting Plan for LTCF (57.141)
4. Long Term Care (LTC) Respiratory Pathogens Event Module Denominator Form (57.142)
5. Long Term Care (LTC) Respiratory Pathogens Event Module Resident Respiratory Pathogens Event Form (57.144)

CDC NHSN is requesting an expedited review of this Change Memo by March 1, 2024, as the Hemovigilance Module Team is looking to publish data collected under the Hemovigilance Module Monthly Incident Summary form (57.302).

The changes to the forms and associated burden are described below. The changes are minor and do not constitute more than a 10% change to the original OMB package. The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920-0666. During the early stages of its development, NHSN began as a voluntary surveillance system in 2005 managed by DHQP. NHSN provides facilities, states, regions, and the nation with data necessary to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) nationwide. NHSN allows healthcare facilities to track blood safety errors and various HAI prevention practice methods such as healthcare personnel influenza vaccine status and corresponding infection control adherence rates.

Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are reported and analyzed to provide national estimates of adverse reactions and incidents.

Under the Long-Term Care Facility Component (LTCF), data is captured from skilled nursing facilities. Reporting methods under the LTCF component have been created by using forms from the Patient Safety Component as a model with modifications to specifically address the specific characteristics of LTCF residents and the unique data needs of these facilities reporting into NHSN.

Hemovigilance Module Monthly Incident Summary (57.302)

1. The Hemovigilance Module Monthly Incident Summary form 57.302 was inadvertently overlooked and was not included in the 2023 NHSN Revision Package for 0920-0666. The data collection form is being submitted for approval. This form provides national surveillance for the tracking of transfusion-related incidents/errors.

Justification:

1. The form is being submitted in this change memo for approval, so that the important data collection on transfusion-related errors that occur in hospitalized patients will be tracked at a national level.

Time Burden: estimate 30 minutes to complete the form.

Hemovigilance Module Adverse Reaction Transfusion Associated Circulatory Overload (57.318)

1. The Hemovigilance Module Adverse Reaction Transfusion Associated Circulatory Overload Data collection form did not include the approved update from the 2023 NHSN Revision Package for the addition of Sex at Birth and Gender Identity questions. This was inadvertently overlooked and was not included on this form.
2. The time to report new onset or exacerbation of transfusion associated circulatory overload symptoms after cessation of the transfusion increased from 6 hours to 12 hours.

Justification:

1. Demographic characteristics such as gender identity is a critical component for understanding and addressing disparities and improving the health and well-being for gender diverse populations. Collecting these data will afford facilities the opportunity to include information on gender identity into their internal quality improvement and HAI prevention efforts.

The current NHSN 'Gender' data field is intended to collect sex assigned at birth. However, the instructions do not specify the information being collected - sex assigned at birth vs. gender identity - and as such the data collected in the 'Gender' field may represent either of these concepts based on the respondent's interpretation. This varied interpretation may lead to mismeasurement in the data among individuals for whom sex assigned at birth and gender identity differs. To improve accuracy in measurement of these data, NHSN is transitioning to a two-step approach to measuring gender by adding two new data collection fields – 'Sex at Birth' and 'Gender Identity' – that will replace the current 'Gender' field. The addition of these fields is intended to provide an opportunity to more clearly identify and better understand reported data that may be related to these concepts as well as more accurately address the unique needs in the LGBTQI+ population. In response to the increased and appropriate shift to focus on health equity and informed decisions for all populations, it is a Division of Healthcare Quality Promotion (DHQP) priority to improve collection of data that will move this priority forward.

2. The criteria to define a transfusion-associated circulatory overload was increased from 6 hours to 12 hours in 2018. The change does not affect data collection burden, the update is related to the clinical time in which the patient is being observed after transfusion to report new onset or exacerbation of transfusion associated circulatory overload symptoms in the patient’s medical record. The data collection form is being updated to match what is happening clinically and to align the CDC NHSN criteria for Transfusion Associated Circulatory Overload with the International Society of Blood Transfusion (ISBT), International Haemovigilance Network (IHN), and American Association of Blood Banks (AABB) definition. <https://academic.oup.com/ajcp/article/156/4/529/6210494>

Reference: Tayler A van den Akker, Zachary M Grimes, Mark T Friedman, Transfusion-Associated Circulatory Overload and Transfusion-Related Acute Lung Injury: A Review of Underreported Entities With Current Updates, *American Journal of Clinical Pathology*, Volume 156, Issue 4, October 2021, Pages 529–539, <https://doi.org/10.1093/ajcp/aqaa279>

Time Burden: The change does not impact burden estimate of 21 minutes to complete the form. The total burden for this collection instrument has been modified to reflect accurate estimates and changed from 350 hours to 56.

Monthly Reporting Plan for LTCF (57.141)

1. An option was added to allow facilities to select Respiratory Pathogens as part of their Monthly Reporting Plan (i.e., COVID-19, RSV, and Flu).
2. Updated title of “Healthcare Associated Infection (HAI)” section to “Urinary Tract Infection Event (UTI)”
3. Decreasing burden from 3297 to 2499.

Justification:

1. This will allow NHSN to understand the reporting frequency/cadence for this module as well as understand if the facility plans to report these data (i.e., COVID-19, RSV, and Flu). This also helps to understand if this facility will also need to submit summary data.
2. Verbiage updates are needed to maintain consistency with other NHSN modules/pathways that use this language and enhance clarity for the users.
3. The Number of Respondents decreased from 1099 to 833 and the total burden decreased from 3297 to 2499.

Time Burden: 15 minutes, no change, the Number of Respondents decreased from 1099 to 833 and the total burden decreased from 3297 to 2499.

Long Term Care (LTC) Respiratory Pathogens Event Module Denominator Form (57.142)

1. Adding a non-editable section to the NHSN application to display denominator data that will be populated from an existing module.

Justification:

1. A non-editable section will be added to the NHSN application as a visual feature for the user. This section will be populated with data from an existing/approved module within the NHSN application.

Time Burden: 35 minutes, no change, total burden increased from 4998 to 5005 as the Number of Respondents increased from 714 to 715.

Long Term Care (LTC) Respiratory Pathogens Event Module Resident Respiratory Pathogens Event Form (57.144)

1. Update title from “Resident Viral Respiratory Tract Infection (RTI) Event Form” to “Resident Respiratory Pathogens Event Form”
2. Update Vaccination Status questions:
Has the resident received any influenza (flu) vaccine during the current flu season?
(Previous question: Has the resident received any influenza (flu) vaccine during the current flu season (2023 – 2024)?)

Has the resident received any COVID-19 vaccination? (Previous question: Is the resident up to date with COVID-19 vaccinations?)

Has the resident received a RSV vaccine? (Previous question: Has the resident received any RSV vaccine during the 2023 – 2024 season (if available))
3. Remove “Date Unknown” option from Vaccination Status questions.
4. Update Antiviral Treatment description to “Select one.” (Previous statement: Select all that apply.)
5. Update Hospitalization question to “Was the resident hospitalized after this positive test result?” (Previous question: Has the resident been admitted to a hospital or transferred to an acute care facility within 10 days of this newly positive viral test result?)
6. Update Death question to “Did the resident die in the 30 days after this positive test result?” (Previous question: Did the resident die within 30 days of this newly positive viral test result?)

Justification:

These updates will allow for consistency with other NHSN modules/pathways that use this language and enhance clarity for the users.

Time Burden: 25 minutes, no change

Burden Estimates – 0920-0666

As a result of proposed changes to the forms, the estimated annualized burden is expected to decrease by 1,031 hours, from 2,434,196 to 2,433,165.

Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Hemovigilance Module Monthly Incident Summary (57.302)	9	12	30/60	54
Hemovigilance Module Adverse Reaction Transfusion Associated Circulatory Overload (57.318)	40	4	21/60	56
Monthly Reporting Plan for LTCF (57.141)	833	12	15/60	2499
Long Term Care (LTC) Respiratory Pathogens Event Module Denominator Form (57.142)	715	12	35/60	5005
Long Term Care (LTC) Respiratory Pathogens Event Module Resident Respiratory Pathogens Event Form (57.144)	16,500	24	25/60	165,000
Total Burden				2,433,165

Hours for 0920-0666				
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