

Pathogens of High Consequence

Request for OMB approval of a revised Information Collection

December 23, 2024

Supporting Statement A

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Goal of the study: The collection of data on the Pathogens of High Consequence form will advise CDC on which patient populations ((i.e., pediatric and adult) are being affected by specific pathogens and the need for healthcare infection control and prevention. The data collection will also provide information on the severity of illness a disease is causing, and what region(s) of the country may be more affected by specific outbreaks.

Intended use of the resulting data: The data collected will help ensure that local and state authorities are equipped to contain and prevent further spread.

Methods to be used to collect: NHSN

The subpopulation to be studied: Facilities enrolled in NHSN Patient Safety Component

How data will be analyzed: (e.g., logistic regression) Multiple statistical methods will be used to measure the impact of disease in the U.S. such as significance tests on pooled means, non-parametric tests on benchmark distributions, and negative binomial regression to assess independent associations.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting Emergency six-month approval for a Revision to one approved data collection form for the National healthcare Safety Network (NHSN). CDC requests OMB approval for an estimated burden of 111,021 hours. This will bring the total burden to 777,146 hours for NHSN Form 57.130 – Pathogens of Concern. The overall burden will increase to 4,508,255 burden hours.

Background

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. NHSN provides facilities, health departments, 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 also 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.

Enrollment in NHSN has continuously increased, with over 37,000 actively reporting healthcare facilities across the U.S. Of the total enrolled healthcare facilities, there are over 6,000 acute care facilities. NHSN currently has eight components, and the collection of information is authorized by the Public Health Service Act (42 USC 242b, 242k, and 242m (d)), (*Attachment A1-A3*).

Data reported under NHSN's Patient Safety Component are used to determine the magnitude of the healthcare-associated adverse events and trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention practices. Data will help detect changes in the

epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data is being used to describe the epidemiology of antimicrobial use and resistance and to better understand the relationship of antimicrobial therapy to this rising problem.

NHSN's data is used to aid in the tracking of HAIs and guide infection prevention activities/practices that protect patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance at healthcare facilities across the US and surrounding territories, and members of the public may use some protected data to inform their selection among available providers. Each of these parties is dependent on the completeness and accuracy of the data. CDC and CMS work closely and are fully committed to ensuring complete and accurate reporting, which are critical for protecting patients and guiding national, state, and local prevention priorities.

CDC's Office of Readiness and Response (ORR) helps the nation prepare and respond to public health emergencies and threats and is monitoring many active CDC responses across the globe. Therefore, it is crucial for CDC to be aware of cases of these select infectious diseases of public health concern to ensure that local and state authorities are equipped to contain, care for patients and prevent further spread, because, as stated by CDC's Office of Readiness and Response, what starts locally can quickly become a global emergency. The collection of this data is also tied to Division of Healthcare Quality and Promotion's (DHQP) Surveillance Branch (SB) objectives, including creating new surveillance measures to support preparedness, emergency response, and resilience in healthcare systems, as well as growing our (SB's) leadership in the nation's evolving healthcare and public health informatics infrastructure.

The form captures the number of patients newly admitted and currently hospitalized with certain diseases in acute care hospitals, (i.e. Crimean-Congo Hemorrhagic Fever (CCHF), Dengue, Ebola, Lassa, Measles, Mpox, MERS-CoV, Nipah, and Toxigenic *Vibrio cholerae*) broken down by adult patients and pediatric patients. Three additional diseases are being added to the data collection, Influenza A (H5), Marburg, and Oropouche.

Influenza A has been a concern since Summer 2024. H5 bird flu is widespread in wild birds worldwide and is causing outbreaks in poultry and U.S. dairy cows with several recent human cases in U.S. dairy and poultry workers. While the current public health risk is low, CDC is watching the situation carefully and working with states to monitor people with animal exposures. CDC is using its flu surveillance systems to monitor for H5 bird flu activity in people. As human cases continue to be detected and the fact that avian flu is a pathogen of public health concern, it is now being added to the collection to ensure NHSN is capturing all active responses to pathogens of concern.

Marburg and Oropouche were recently added to the list of active responses due to international outbreaks, which began this Fall.

2. Purpose and Use of Information Collection

It is crucial for CDC to be aware of cases of these select infectious diseases of public health concern to ensure that local and state authorities are equipped to contain, care for patients and prevent further

spread, because, as stated by CDC's Office of Readiness and Response, what starts locally can quickly become a global emergency. The collection of this data is also tied to Division of Healthcare Quality and Promotion's (DHQP) Surveillance Branch (SB) objectives, including creating new surveillance measures to support preparedness, emergency response, and resilience in healthcare systems, as well as growing our (SB's) leadership in the nation's evolving healthcare and public health informatics infrastructure.

It is important for CDC to be aware of which patient populations (i.e., pediatric, and adult populations) are being affected by these pathogens and the potential need for additional healthcare infection prevention and control. Since this form is collecting data on hospitalized patients, it may also help inform on the severity of illness a high consequence pathogen is causing, and what region(s) of the country may be more affected.

Acute care hospitals enrolled in NHSNs Patient Safety Component will begin collecting this data beginning March 2025. Data collection is optional, and facilities will only need to complete the data collection for days in which they have a case(s) of Infectious Diseases of Public Health Concern to report. If they do not have any cases to report, the form will default to zero cases to help reduce reporting burden.

3. Use of Improved Information Technology and Burden Reduction

Data will be 100% collected via the secure NHSN internet application. Only the minimum amount of information necessary for data collection is requested. Institutions that participate in NHSN are required to have a computer and Internet Service Provider (ISP).

4. Efforts to Identify Duplication and Use of Similar Information

NHSN is the only modern national system that collects surveillance data on healthcare-associated infections, infection prevention process measure data, data on healthcare personnel safety measures such as blood and body fluid exposures and vaccination practices, and adverse events related to the transfusion of blood and blood products.

There are other organizations within the Department of Health and Human Services (HHS) (e.g., Patient Safety Task Force, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services) that work to improve patient safety and healthcare outcomes. In many cases, these agencies use the information generated from the NHSN to support their mission, and currently, the data collections do not overlap.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

This is a data collection request to determine the number of cases of specific infectious diseases of public health concern that affect acute care hospitals. Data collection is optional, and facilities need to complete the data collection for days in which they have a case(s) of Infectious Diseases of Public Health Concern to report. If they do not have any cases to report, the form will default to zero cases to help reduce reporting burden. Collecting the data less frequently could potentially prevent NHSN from understanding how these specific infectious diseases are affecting acute care hospitals across the United States.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Because this is a request for an emergency clearance, OMB has waived the 60-day comment period. CDC is posting a 60-day notice in the Federal Register seeking additional notice and comment (Attachment B).

9. Explanation of Any Payment or Gift to Respondents

No monetary incentive is provided to NHSN participants.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by NCEZID who determined that the Privacy Act does not apply (Attachment F).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that information collection is not research involving human subjects. IRB approval is not required (Attachment G).

Justification for Sensitive Questions

Sensitive questions will not be asked on this questionnaire.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The table below provide the burden hours and cost estimates for the proposed NHSN data collection tool.

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Infection Preventionist /Microbiologist	57.130 Pathogens of High Consequence	3650	365	5/60	111,021
Total- 777,146					

B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Infection Preventionist/Microbiologist	57.130 Pathogens of High Consequence	777,146	\$58.60	\$45,540,756
Total - \$45,540,756				

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

A total of 11 FTEs/contractor personnel are actively involved in the development of this information collection. The estimated cost to the government is based on expenses incurred in the following categories: personnel and programming contracts. The items and their costs relevant to the proposed modifications to NHSN are shown in the table below. The total cost to the government in 2024 is estimated to be \$2395.

Expense Item	Description	Estimated Annual Cost
Personnel	The personnel categories and their FTE contributions are as follows:	FTE annual compensation in FY2024 will be \$
	Supervisory Medical Officer	2 \$269
	Lead Statistician	1 \$102

Expense Item	Description	Estimated Annual Cost	
	Lead Epidemiologist	1	\$256
	Health Scientist	3	\$300
	Lead Nurse Consultant	1	\$76
Programming contracts	Design, develop, and deploy enhancements to NHSN		\$1,392
Total			\$2,395

With this additional cost, the Total Cost for NHSN would be increased to \$49,994,530 for 2024.

14. Explanation for Program Changes or Adjustments

This is an Emergency Revision of an existing data collection (OMB Control No. 0920-0666). The Revision modifies Form 57.130 Pathogens of High Consequence to add four (4) viruses/conditions. Addition of these pathogens will add 111,021 burden hours to the collection. The increased burden raises the total burden hours for Form 57.130 to 777,146. The total burden for the 0920-0666 package will increase to 4,508,255 hours.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

CDC NHSN does not have any definitive plans to publish results currently.

Project Time Schedule	
Activity	Time Schedule

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

- A. Authorizing Legislation
- B. 60-Day FRN
- C. FDA Announcement
- D. Supplemental Announcements
- E. Information Collection instruments
- F. Privacy Impact Assessment
- G. Human Subjects Determination Memo