Becton Dickinson BACTEC™ Blood Culture Media Bottles Shortage
Impact Questionnaire

Request for OMB approval of a New Information Collection

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Supporting Statement A

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- **Goal of the study:** The study will assess how facilities that are enrolled in the NHSN Patient Safety Component are impacted by the shortage of the Becton Dickinson (BD) BACTEC™ blood culture media bottles and how that impact might affect NHSN bloodstream infection surveillance.
- **Intended use of the resulting data:** The data collected will help identify any potential challenges or issues faced by healthcare facilities in conducting accurate surveillance for bloodstream infections during the shortage.
- **Methods to be used to collect:** Questionnaire
- **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 potential impact of this shortage on NHSN outcomes 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 6-month approval for one new information collection form for the National healthcare Safety Network (NHSN). CDC requests OMB approval for an estimated burden of 2,334hours.

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.

CMS collects some HAI data and healthcare personnel influenza vaccination summary data, which is done on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs, while others may report data required by a federal mandate. Facilities that fail to report quality measure data are subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. CMS links their quality reporting to payment for Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care facilities, oncology hospitals, inpatient psychiatric facilities, dialysis facilities, and ambulatory surgery centers. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS's quality reporting programs to receive full payment. Still, many healthcare facilities, even in states without HAI reporting legislation, submit limited HAI data to NHSN voluntarily.

The U.S. Food and Drug Administration (FDA) posted an announcement regarding interruptions in the supply of Becton Dickinson (BD) BACTEC™ blood culture media bottles because of recent supplier issues (Attachment C). The disruption in the supply is expected to impact patient diagnosis, follow up patient management, and antimicrobial stewardship efforts. The FDA and other entities recommend that facilities, laboratories, and health care providers consider conservation strategies to prioritize the use of blood culture media bottles, preserving the supply for patients at highest risk (D1-D3).

2. Purpose and Use of Information Collection

The intent of this data collection is to assess the impact of the Becton Dickinson (BD) BACTEC™ blood culture media bottles supply shortage on individual facilities and how CDC NHSN bloodstream infection surveillance might be affected.

Facilities enrolled in the NHSN Patient Safety Component will be asked to complete the questionnaire that will ask questions regarding the impact of the Becton Dickinson (BD) BACTEC™ blood culture media bottle shortage on their facility and thus surveillance data they submit to NHSN (Attachment E1 & E2. It will be collected electronically via the NHSN application. The questionnaire will be sent to facilities twice to collect data from July to October 2024 and then once more to collect data from November 2024 to April 2025.

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 how the shortage of blood culture bottles affected acute care facilities. Collecting the data less frequently could potentially prevent NHSN from understanding how the storage has affected surveillance data submitted to NHSN.

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 Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Infection Preventionist/Microbiologist	Blood Culture Bottle Shortage Questionnaire (Jul-Oct) *Attachment E1*	3,500	1	20/60	1167
Infection Preventionist/Microbiologist	Blood Culture Bottle Shortage Questionnaire (Nov-Mar) *Attachment E2*	3,500	1	20/60	1167
Total					2,334

B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Infection Preventionist/Microbiologist	Blood Culture Bottle Shortage Questionnaire (Jul-Oct) *Attachment E1*	1167	$58.60	$68,386
Infection Preventionist/Microbiologist	Blood Culture Bottle Shortage Questionnaire (Nov-Mar)	1167	$58.60	$68,386

	Attachment E2			
Total				$136,772

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 12 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 $167,357

Expense Item	**Description**		**Estimated Annual Cost**
Personnel	The personnel categories and their FTE contributions are as follows:		FTE annual compensation in FY2024 will be $121,818
	Supervisory Medical Officer	4	
	Medical Officer	1	
	Lead Statistician	1	
	Lead Epidemiologist	1	
	Health Scientist	1	
	Lead Nurse Consultant	1	
Programming contracts	Design, develop, and deploy enhancements to NHSN		$45,539
Total			$167,357

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