SUPPORTING STATEMENT

Part A

The AHRQ Safety Program for Healthcare Associated Infection Prevention

Submission of a New Information Collection Request

Version: October 17, 2024

Agency for Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

About AHRQ:
The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see https://www.ahrq.gov/sites/default/files/wysiwyg/policymakers/hrqa99.pdf), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. Research that develops and presents scientific evidence regarding all aspects of health care; and

2. The synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3. Initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

Summary of this Information Collection Request (ICR):
This ICR is for a new information collection to update five of AHRQ's toolkits for the prevention of healthcare-associated infections (HAIs). There are five data collections, including surveys and a semi-structured interview, as described on pages 5-6. AHRQ requests three years approval for these data collections.

Background for this Collection:
Healthcare-associated infections (HAIs) are a major cause of illness in the U.S., affecting one out of every 31 hospital inpatients (3% of all hospitalized patients) *daily*[1] and resulting in as many as 700,000 infections per year.[2] Some of the most predominant HAIs include catheter-associated urinary tract infections (CAUTI), central line-associated blood stream infections (CLABSI), and ventilator-associated pneumonia and ventilator-associated adverse events (VAP/VAE). The current estimate for CAUTI incidence in hospitalized patients is approximately 27,000 cases annually and 30,000 CLABSI cases annually.[2,1] VAEs affect between 5-40% of patients requiring mechanical ventilator support for more than two days.[3] VAE is considered the deadliest HAI, with all-cause

mortality rates associated with VAE as high as 50% and a direct attributable mortality rate of 9%.[4]

To help hospitals reduce HAIs AHRQ created the Comprehensive Unit-based Safety Program (CUSP). CUSP is designed to engage clinical teams to make healthcare safer by combining improved teamwork, clinical best practices, and the science of safety. The CUSP approach improves safety culture at the unit level, enables harm prevention, and engages providers who are on the front lines[5] while integrating technical and adaptive/cultural approaches to making sustainable change.[6] The Core CUSP toolkit provides teams with training resources and tools to apply the CUSP method and build their capacity to address safety issues. This publicly available toolkit is modular and modifiable to meet individual unit needs (https://www.ahrq.gov/hai/cusp/modules/index.html).

AHRQ has had success across numerous national CUSP implementation programs, including CUSP for CLABSI, which showed a 41% CLABSI reduction in over 1,000 ICUs[7], and the CUSP for CAUTI in hospitals program, which reduced CAUTI rates by 30% in more than 700 non-ICUs.[8] These two programs, along with other AHRQ CUSP programs, resulted in the following toolkits:

1. Toolkit for Reducing CLABSI: https://www.ahrq.gov/hai/clabsi-tools/index.html
2. Toolkit for Reducing CAUTI in Acute Care Hospitals: https://www.ahrq.gov/hai/tools/cauti-hospitals/index.html
3. Toolkit to Improve Safety for Mechanically Ventilated Patients: https://www.ahrq.gov/hai/tools/mvp/index.html
4. Toolkit for Preventing CLABSI and CAUTI in ICUs: https://www.ahrq.gov/hai/tools/clabsi-cauti-icu/index.html

AHRQ and partners developed many of the tools in these toolkits several years ago, and some over 10 years ago. Some organizations may not want to use a tool that is older, or dated, and may wonder whether the information is still current. AHRQ also is aware that parts of some toolkits have supporting information that has been updated, but those updates have not been incorporated into current tools or resources on the AHRQ website. The fifth Toolkit for this program to update, the CUSP toolkit[9] that supports translating the evidence into practice, also requires modernization and updating to address the current healthcare environment and resource realities to ensure success in HAI reduction.

The AHRQ Safety Program for HAI Prevention Program will assess what components of the updated toolkits are routinely used and helpful and what components need additional updating and refinement. Current AHRQ HAI Prevention Toolkits provide a wealth of valuable information but also require revision to incorporate new evidence-based practices and remove those no longer supported by scientific evidence. Revised Toolkits based on lessons learned from the implementation of this program will enhance their utility to healthcare workers and support the adoption of the AHRQ Safety Program for HAI prevention practices.

The program goals are to:

1. Update the five existing AHRQ HAI Prevention Toolkits.
2. Finalize the updated Toolkits for public use, incorporating feedback from participating units.

The AHRQ Safety Program for HAI Prevention will consist of three cohorts:

1. CLABSI cohort - comprised of approximately 100 acute care units (intensive care units [ICUs] and non-ICUs);
2. CAUTI cohort - comprised of approximately 100 ICUs and non-ICUs; and
3. VAP/VAE cohort - compromised of approximately 75 ICUs.

All cohorts will include acute care hospital units from all 10 Health and Human Services regions. AHRQ will utilize a pre-post design, comparing data collected at baseline and at the end of the program (endline) within each cohort.

The AHRQ Safety Program for HAI Prevention will include the following data collections:

1) **Semi-structured Interviews**: Conducted at the end of the assessment, the program will select participants from each of the 3 cohorts, focusing on participants who were active during the cohort (e.g., attended webinars and office hours regularly) to participate in virtual discussions to examine participants' experiences during the AHRQ Safety Program for HAI Prevention, including use and perceptions of materials, experiences with measurement, and feedback about the program (**Attachment A**).

2) **Hospital Survey on Patient Safety (HSOPS):** The HSOPS will be completed by all participating staff to assess patient safety issues, medical errors, and event reporting practices. Participants will complete the HSOPS at baseline and endline for all three cohorts (**Attachment B**).

3) **CUSP Device Rounds**: The CUSP Device Rounds will be completed collaboratively by a staff member with an infection preventionist at each participating unit once per month, to assess whether units are following best practices in HAI for the respective cohort for all three cohorts (CLABSI Device Rounds Checklist: **Attachment C**; CAUTI Device Rounds Checklist: **Attachment D**; VAP/VAE Device Rounds Checklist: **Attachment E**).

4) **Gap Analysis**: The Gap analysis is a tool used to understand the needs of participating units, prioritize areas for improvement, and advocate for institution-level and unit-level resources. The Gap Analysis will be completed collaboratively by a unit lead and an infection preventionist at baseline and endline for all three cohorts. The endline Gap Analysis will also include also ask a unit lead and infection preventionist to collaboratively self-report changes in HAI rates and HAI prevention processes at endline of each cohort. (CLABSI Gap Analysis: **Attachment F**; CAUTI Gap Analysis: **Attachment G**; VAP/VAE Gap Analysis: **Attachment H**).

5) **Clinical Outcomes Data**: AHRQ will collect unit-level clinical outcomes data to assess hospital-associated infection (HAI) rates across the program. Participating units will either extract clinical outcomes data from their Electronic Health Records (EHRs) and submit via the secure program website OR confer National Healthcare Safety Network (NHSN) data rights to the program group to eliminate data collection burden. The program will request participating units to retrospectively provide 12 months of pre-implementation clinical outcomes data, and monthly clinical outcomes data, reported quarterly, during the implementation period for all three cohorts. Participating units will submit monthly clinical outcomes implementation data on a quarterly basis (**Attachments I and J**). The data collected monthly include the number of patients in the medical unit, number of patients with a medical device in place (central line, catheter, or ventilator) and the number HAI infections associated with the medical device (central line, catheter, or ventilator). A staff member at each participating medical unit will submit this data via a secure website portal.

AHRQ will conduct the AHRQ Safety Program for HAI Prevention through its contractor, NORC at the University of Chicago (NORC) and NORC's subcontractor, the Johns Hopkins Armstrong Institute of Patient Safety and Quality (JHAI). The AHRQ Safety Program for HAI Prevention is an undertaken pursuant to AHRQ's mission to enhance the quality, appropriateness, and effectiveness of health services, and increase access to such services through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. 42 U.S.C. 299.

2. Purpose and Use of Information

This data collection effort will be part of a comprehensive strategy to assess:

1. participating units' experiences related to the AHRQ Safety Program for HAI Prevention (i.e., use and perceptions of revised AHRQ Toolkits and Technical Assistance (TA), experiences with measurement, and feedback about the program);
2. participating units' changes in HAI processes (i.e., self-reported improvements in CLABSI, CAUTI, or VAP/VAE prevention processes, interventions implemented by units, and units' capacity to improve HAI rates); and
3. participating units' changes in HAI rates (i.e., units' CLABSI, CAUTI, or VAP/VAE reported rates and self-reported improvements in HAI rates).

The assessment will utilize a pre-post design, comparing data collected at baseline and at the end of the program (endline) within each cohort.

3. Use of Improved Information Technology

To minimize respondent burden and to permit the electronic submission of survey responses and data collection forms, the AHRQ HSOPS, Device Rounds, Gap Analyses (and Self-Reported Change in HAI Rates and HAI Prevention Processes), and the clinical outcomes data collection form from Electronic Health Records (EHRs) extracts will be

web-based and deployed using secure, well-designed, low burden, and respondent-friendly survey administration instruments and process.

4. Efforts to Identify Duplication

Program duplication:
CDC funds NHSN, a platform that allows for CAUTI and CLABSI clinical outcomes data entry as mandated by CMS via a Pay-for-Performance structure. Additionally, data on VAP/VAE clinical outcomes can be reported to NHSN but is not required. The program team will use the rest of the AHRQ Safety Program for HAI Prevention data to update and improve existing AHRQ Toolkits, as a significant investment in both the sustainability of and future HAI prevention efforts.

Avoidance of duplication on a data collection level:

- Clinical outcomes data: These data are already collected as part of the required infection control efforts at the hospitals and submitted to NHSN. The AHRQ Safety Program for HAI Prevention will offer the opportunity for participating hospitals to confer NHSN rights to the AHRQ Safety Program for HAI Prevention Group to further reduce data collection burden. To use NHSN data for those measures available, participating hospitals would need to confer rights for the AHRQ Safety Program for HAI Prevention to use their NHSN data for the evaluation. All three of the clinical outcome measures being collected for the program are available via NHSN.

  For hospitals that confer rights (90% of CLABSI and CAUTI cohorts), the program will be able to access these data via NHSN and will not need to request these data from EHR extracts. The information is therefore already available for entry into the program's data portal. As only 1,900 hospitals currently submitting VAP/VAE data to NHSN, the program team estimates a higher number of hospitals (60%) will use the secure program website portal to submit data for the VAP/VAE cohort.

- HSOPS: The program team will be collecting original data from most hospitals. Some may already use HSOPS as part of meeting their CMS requirements. In those cases, the hospitals will share the data they have already collected.

- Gap Analysis: These versions of the Gap Analysis have been adapted for this program from previously created AHRQ toolkits, i.e., the ICU Assessment of Current CLABSI & CAUTI Prevention Practices; this instrument will collect original data.

- CUSP Device Rounds: These have been adapted from previously created tools for this program, i.e., the Daily Goals Checklists. The data we are requesting is original.

5. Involvement of Small Entities

The information collected may involve small entities, as some of the participating hospitals may involve smaller units. For this program, only items that provide critical information for conducting the evaluation will be included, and the information being requested has been held to the absolute minimum required for the intended use.

6. Consequences if Information is Collected Less Frequently

This data collection effort will be part of a comprehensive evaluation strategy to assess the adoption of the AHRQ Safety Program for HAI Prevention among participating acute care hospital units; measure the effectiveness of the program among participating units; evaluate participants' experiences in the program; and use participant feedback to update the five existing AHRQ HAI Prevention Toolkits. The planned frequency of the data collection activities is necessary to accurately assess the efficacy of the updated Toolkits and further refine them based on participant feedback.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), the 60-day Federal Register notice was published on November 20, 2024 (Vol. 89, No. 224, pg. 91753) (see **Attachment K**). One public comment was received (see **Attachment M)** and provided a response (see **Attachment N**).

8.b. Outside Consultations

NORC and JHAI are consulting with external subject matter experts (SMEs) to provide expertise and guidance to support the development and implementation of the AHRQ Safety Program for HAI Prevention. The external SMEs have extensive knowledge of the identification and prevention of HAIs, long-standing leadership in developing and executing research and improvement implementations for HAIs, and knowledge of implementation methodologies, including CUSP. The external SMEs will provide input and advice regarding the Environmental Scan and modifications to the Toolkits and will be engaged through the duration of the program. In addition to regular communications regarding Toolkit updates, the external SMEs will meet annually with the program team and AHRQ.

AHRQ has consulted with other Federal partners including the CDC and the CMS to ensure synergistic efforts are undertaken and that there is no duplication of Federal initiatives.

9. Payments/Gifts to Respondents

The semi-structured qualitative interviews will take approximately 30 minutes. Each interview participant (8 per cohort, totaling 24 participants) will receive $40 for their participation. The semi-structured interviews are critical to the success of the program.

They will provide invaluable feedback and insight into the usefulness of the updated Toolkits and program resources, their experiences with measurement, general feedback regarding the Toolkit website, and suggestions for how to improve the overall implementation.

These participants are busy clinicians, frontline healthcare providers and acute care unit leads, and the $40 incentive will facilitate obtaining eight interviews for each program cohort. Completing the semi-structured interviews is the first goal in the conceptual framework for the HAI Prevention assessment and the $40 incentive will help ensure these interviews are completed to provide crucial feedback needed to achieve the overall goals of the program in creating the most useful, practical, and high-quality Toolkits.

10. Assurance of Confidentiality

Data will be kept private to the extent allowed by law. Individuals will be assured of the confidentiality of their replies under Section 944(c) of the Public Health Service Act. 42 U.S.C. 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied.

Information that can directly identify the respondent, such as name and/or social security number will not be collected. A statement of confidentiality will appear on online surveys and contain the following statement:

This survey is authorized under 42 U.S.C. 299a. This information collection is voluntary and the confidentiality of your responses to this survey is protected by Sections 944(c) and 308(d) of the Public Health Service Act [42 U.S.C. 299c-3(c) and 42 U.S.C. 242m(d)]. Information that could identify you will not be disclosed unless you have consented to that disclosure. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The data provided will help AHRQ's mission to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (OMB control number 0935-*xxxx*) AHRQ, 5600 Fishers Lane, Room #07W42, Rockville, MD 20857, or by email to REPORTSCLEARANCEOFFICER@ahrq.hhs.gov.

The data will be collected by AHRQ's contractor, NORC. All hospital and respondent-level data, as well as survey response data, will be stored on NORC's secure servers.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this information collection. The total annual burden hours are estimated to be 2,854 hours for the following data collection tools:

1. **Semi-structured Interviews**: Conducted with 8 interview participants from each of the 3 cohorts (for a total of 24 interviews) at endline only. Each interview requires 30 minutes on average to complete. We anticipate a 100 percent response rate.

2. **Hospital Survey on Patient Safety (HSOPS):** To be completed by an average of 20 staff at each participating unit at both baseline and endline. Across the three cohorts, with a maximum of 400 units, resulting in 8,000 respondents. An expected response rate of 45% should yield 3,600 completed respondents at each time point (baseline/endline). The survey is administered at baseline and endline for each cohort to measure the changes in patient safety culture resulting from participation in the program. The survey takes approximately 15 minutes to complete.

3. **CUSP Device Rounds**: Completed monthly for 9 months by 2 staff members at each participating unit throughout implementation and requires 45 minutes for each staff member equaling 90 minutes to complete in total. Across the three cohorts, with a maximum of 400 units, resulting in 800 respondents. An expected response rate of 75% should yield 600 respondents per time point (monthly).

4. **Gap Analysis:** Completed by 2 staff members at each participating unit, once at baseline and again at endline for each cohort. Across the three cohorts, with a maximum of 400 units, resulting in 800 respondents. An expected response rate of 75% should result in 600 respondents per time point (baseline/endline). This data collection is expected to require 60 minutes to complete.

5. **Clinical Outcomes Data**: Completed by 1 staff member at each participating unit to provide 12 months of pre-implementation clinical outcomes data, and monthly clinical outcomes data, reported quarterly, during the implementation period for all three cohorts. Across the three cohorts, with a maximum of 400 units, resulting in 400 respondents. An expected response rate of 75% should result in 300 respondents per time point (baseline for retrospective data and quarterly for monthly data). This data collection is expected to require 3.5 hours to complete at baseline followed by 30 minutes to complete quarterly, averaging 75 minutes across implementation. We anticipate approximately 90 percent of hospitals in the CLABSI and CAUTI cohorts to confer NHSN data rights to the AHRQ Safety Program for HAI Prevention. In the VAP/VAE cohort, we expect approximately 40 percent of hospitals to confer NHSN data rights to the program.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents*	Number of responses per respondent	Hours per response	Total burden hours
1. Semi-structured Interviews	8	1	30/60	4
2. HSOPS	1,200	2	15/60	600

Form Name	Number of respondents*	Number of responses per respondent	Hours per response	Total burden hours
3. CUSP Device Rounds	100	9	90/60	1,350
4. Gap Analysis	200	2	60/60	400
5. Clinical Outcomes data	100	4	75/60	500
Total	**1,608**			**2,854**

*Annualized number of respondents is based on the maximum number of units recruited, times the estimated response rate, and divided by three to capture an annualized number.

Exhibit 2 shows the estimated annual cost burden associated with the respondents' time to participate in this information collection. The annual cost burden is estimated to be $199,201.80.

Exhibit 2. Estimated annualized cost burden

Form Name	Total burden hours	Average hourly wage rate*	Total cost burden
1. Semi-structured Interviews	8	$74.20[a]	$296.80
2. HSOPS	1,200	$74.20[a]	$44,520.00
3. CUSP Device Rounds	100	$74.20[a]	$100,170.00
4. Gap Analysis	200	$74.20[a]	$29,680.00
5. Clinical Outcomes data	100	$49.07[b]	$24,535.00
Total	**1,608**		**$199,201.80**

* National Compensation Survey: Occupational wages in the United States May 2023, "U.S. Department of Labor, Bureau of Labor Statistics." May 2023 National Occupational Employment and Wage Estimates (bls.gov)

[a] Average of the mean hourly wage for physicians (29-1210), registered nurses (29-1141), nurse practitioners (29-1171), and physician's assistants (29-1071).

[b] Mean hourly wage for Healthcare Practitioners and Technical Occupations (29-0000).

13. Estimates of Annualized Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the program.

14. Estimates of Total and Annualized Cost to the Government

The estimated annualized contractor cost to the government to conduct the data collection activities for the program is estimated to be $1,416,853. As shown in Exhibit 3a, this includes annualized costs for data collection tool and platform development ($311,706), data collection and technical assistance ($480,695), data processing and analysis ($446,450), and program management costs ($178,002).

Exhibit 3a. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development (data collection tool development, programming the data collection tools, and data collection training materials	$935,118	$311,706

development for all 3 cohorts)		
Data Collection (data collection management and maintenance of the data collection systems for all 3 cohorts)	$1,442,084	$480,695
Data Processing and Analysis (data review and analysis for all 3 cohorts)	$1,339,349	$446,450
Project Management	$534,006	$178,002
TOTAL	**$4,250,557**	**$1,416,853**

Government personnel will be responsible for project management and oversight. The estimated cost to the Federal Government for these activities is estimated to be $74,691.12 (Exhibit 3b).

Exhibit 3b. Federal Government Personnel Cost

Activity	Federal Personnel	Annual Salary	% Time	Cost
Management Support: GS-15, Step 5 average	1	$185,824	25%	$46,456.00
Management Support: GS-15, Step 5 average	1	$185,824	5%	$9,291.20
Program Management Analysis: GS-15, Step 5 average	1	$185,824	3%	$5,574.72
Program Management Analysis: GS-13, Step 5 average	1	$133,692	10%	$13,369.20
Total				**$74,691.12**

Annual salaries based on 2024 OPM Pay Schedule for Washington/DC area: SALARY TABLE 2024-DCB (opm.gov)

The estimated total **annualized cost** for this activity is **$1,491,544.12.** This cost includes annualized contractor costs ($1,416,853) and Federal personnel costs ($74,691.12).

15. Changes in Hour Burden

This is a new collection of information, thus no changes in hour burden are expected or reported here.

16. Time Schedule, Publication and Analysis Plans

The draft schedule of assessment activities is contained in **Attachment L.** The exact start date for data collection activities is contingent on the OMB clearance date.

AHRQ will make the final toolkit for each cohort publicly available on its website. The findings from the AHRQ Safety Program for HAI Prevention will be submitted for publication in academic journals. See Exhibit 4 for data collection and analysis timeline.

Exhibit 4. Data Collection and Analysis Timeline

	Start Date	End Date
CLABSI Cohort		
Data Collection	7/1/2025	3/31/2026
Final CLABSI Toolkit	4/1/2026	11/9/2026
Final Report	4/1/2026	1/12/2028
CAUTI Cohort		
Data Collection	2/1/2026	10/31/2026
Final CAUTI Toolkit	11/1/2026	6/8/2027
Final Report	11/1/2026	1/12/2028

	Start Date	End Date
VAP/VAE Cohort		
Data Collection	9/1/2026	5/31/2027
Final VAP/VAE Toolkit	6/1/2027	10/8/2027
Final Report	6/1/2027	1/12/2028

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments

Supporting Document	Attachment
Semi-structured Interviews	A
AHRQ HSOPS	B
CLABSI Device Rounds Checklist	C
CAUTI Device Rounds Checklist	D
VAP/VAE Device Rounds Checklist	E
CLABSI Gap Analysis	F
CAUTI Gap Analysis	G
VAP/VAE Gap Analysis	H
Clinical Outcomes Data Template	I
Submission Guide for Clinical Outcomes Data Collection	J
60-day Federal Register Notice	K
Draft Schedule of Evaluation Activities	L
Public Comment	M
Response to Public Comment	N

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