DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Information collection notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project (new): ''The AHRQ Safety Program for Healthcare Associated Infection Prevention.''

DATES: Comments on this notice must be received by January 21, 2025.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *REPORTSCLEARANCE OFFICER@ahrq.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *REPORTSCLEARANCE OFFICER@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

The AHRQ Safety Program for Healthcare Associated Infection Prevention

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 and resulting in as many as 700,000 infections per year. 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 events (VAP/VAE). The current estimated incidence in hospitalized patients is approximately 27,000 CAUTI cases annually and 30,000 CLABSI cases annually. VAE cases affect between 5–40% of patients requiring mechanical ventilator support for more than two days. VAE cases are considered the deadliest HAI, with all-cause mortality rates associated with VAE as high as 50% and a direct attributable mortality rate of 9%.

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 while integrating technical and adaptive/cultural approaches to making sustainable change. 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 intensive care units (ICUs), and CUSP for CAUTI in hospitals, which reduced CAUTI rates by 30% in more than 700 non-ICUs. 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 is also 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 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 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.

This project has the following goals:

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 (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 three 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.

(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.

(3) *CUSP Device Rounds:* The CUSP Device Rounds will be completed collaboratively by a CUSP 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 (*i.e.,* for all three cohorts).

(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 questions for self-report changes in HAI rates and HAI prevention processes at endline of each cohort.

(5) *Clinical Outcomes Data:* AHRQ will collect unit-level clinical outcomes data reported by Infection Prevention and Control Programs to assess 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. 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 HAIs associated with the medical device (central line, catheter, or ventilator).

This study is being conducted by AHRQ 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), pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement [42 U.S.C. 299a(a)(1) and (2)].

Method of Collection

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' capacities 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).

To minimize respondent burden and to permit the electronic submission of survey responses and data collection forms, the AHRQ HSOPS, CUSP Device Rounds, Gap Analyses (including self-reported change in HAI rates and HAI prevention processes), and the clinical outcomes data collection form from EHR extracts will be web-based and deployed using secure, well-designed, low-burden, and respondent-friendly survey administration instruments and process.

Estimated Annual Respondent Burden

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 eight interview participants from each of the three cohorts (for a total of 24 interviews) at endline only. Each interview requires 30 minutes on average to complete. We anticipate a 100% response rate.

2. *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, this results 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 nine months by two 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, this results in 800 respondents. An expected response rate of 75% should yield 600 respondents per time point (monthly).

4. *Gap Analysis:* Completed by two 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, this results 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 one 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, this results 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% 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% 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
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

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents *	Number of responses per respondent	Hours per response	Total burden hours
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	[a] $74.20	$296.80
2. HSOPS	1,200	[a] 74.20	44,520.00
3. CUSP Device Rounds	100	[a] 74.20	100,170.00
4. Gap Analysis	200	[a] 74.20	29,680.00
5. Clinical Outcomes data	100	[b] 49.07	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).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Marquita Cullom,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10320]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 21, 2025.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *https://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: __, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA