



Billing Code 4160-90-M

**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:** 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 *“Expanding the Comprehensive Unit-based Safety Program (CUSP) to Reduce Central Line-Associated Blood Stream Infections (CLABSI) and Catheter-Associated Urinary Tract Infections (CAUTI) in Intensive Care Units (ICU) with Persistently Elevated Infection Rates.”*

This proposed information collection was previously published in the Federal Register on July 28, 2017, and allowed 60 days for public comment. AHRQ did not receive any substantive public comments. In response to internal project team feedback, the proposed data collection has been modified in order to increase efficiency and decrease respondent burden. Modifications include consolidation of two data collection tools (the Team Checkup Tool and the ICU Assessment) into one ICU Assessment and decreasing the frequency of administration. The modifications also now require broad administration of the ICU Action Plan, which previously was administered only to those sites that had a site visit. The purpose of this notice is to allow an additional 30 days for public comment.

**DATES:** Comments on this notice must be received by (insert date 30 days after date of publication).

**ADDRESSES:** Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by email at [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) (attention: AHRQ's desk officer).

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at [doris.lefkowitz@ahrq.hhs.gov](mailto:doris.lefkowitz@ahrq.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

*Expanding the Comprehensive Unit-based Safety Program (CUSP) to reduce Central Line-Associated Blood Stream Infections (CLABSI) and Catheter-Associated Urinary Tract Infections (CAUTI) in Intensive Care Units (ICU) with persistently elevated infection rates.*

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

Healthcare-associated infections, or HAIs, are a highly significant cause of illness and death for patients in the U.S. health care system. At any given time, HAIs affect one out of every 25 hospital inpatients. More than a million of these infections occur across the health care system every year, leading to significant patient harm and the annual loss of tens of thousands of lives, and costing billions of dollars each year. Some of the most prevalent HAIs include: surgical site infections (SSIs), catheter-associated urinary tract infections, central-line associated blood stream infections, and ventilator-associated pneumonia (VAP). It is estimated that CAUTIs affect approximately 250,000 hospital patients per year, and approximately 40,000 CLABSI cases occur annually with a mortality rate from 12 to 25 percent.

From 2008-2012, AHRQ supported the National Implementation of the Comprehensive Unit-Based Safety Program (CUSP) to reduce Central Line-Associated Blood Stream Infections (CLABSI) under an ACTION contract with the Health Research and Educational Trust (HRET), in partnership with Johns Hopkins University and the Michigan Hospital Association. From 2011-2015, AHRQ expanded its CUSP efforts to include the national implementation of CUSP for CAUTI in hospitals across the United States. This effort was carried out under an ACTION II contract with HRET, in partnership with Johns Hopkins University and the Michigan Hospital Association.

As part of the Department of Health and Human Services National Action Plan to Prevent Healthcare-Associated Infections, AHRQ has supported the implementation and adoption of the CUSP for CLABSI and CUSP for CAUTI, and is applying the principles and concepts that have been learned from these HAI reduction efforts to ICUs with persistently elevated infection rates.

### **Results of Implementation of CUSP for CLABSI and CAUTI**

The nationwide CUSP for CLABSI project was implemented with teams at more than 1,100 adult ICUs in 44 states over a 4-year period. ICUs participating in this project reduced the rate of CLABSIs nationally from 1.915 infections per 1,000 central line days to 1.133 infections per 1,000 line days, an overall reduction of 41 percent. However, not all ICUs performed equally well.

The CUSP for CAUTI project implemented CUSP in nine cohorts, representing over 1,600 hospital units in over 1,200 hospitals located across 40 states, the District of Columbia, and Puerto Rico. Inpatient CAUTI rates in non-ICUs were decreased by 30%. However, CAUTI rates in ICUs were not reduced significantly.

In other words, while the overall results of the implementation of CUSP for CLABSI and CUSP for CAUTI have shown remarkable progress, not all ICUs in the projects have achieved the intended rate reductions, nor have all ICUs participated in the two projects. Moreover, a significant number of institutions and ICUs continue to have persistently elevated infection rates. There are institutions that have varying rates of infections within the same institution, indicating that infection control is often a unit-based issue.

In sum, despite the significant overall reductions in CLABSI and CAUTI rates that have been achieved in these two projects, there is evidence that ICUs have generally faced challenges in reducing CAUTI rates, and that many hospitals still are not where they should be in reducing CLABSI rates. Modified approaches and strategies for the CUSP intervention need to be developed and implemented to reach ICUs with persistently elevated CLABSI and CAUTI rates and help them succeed in preventing these infections. To address this need, AHRQ will launch this project aimed at spreading nationally implementation of an adaptation of CUSP for CLABSI and CAUTI for ICUs with persistently elevated rates, optimizing the approach to maximize effectiveness and further preventing these infections throughout the United States.

This project has the following goals:

- Reduce CLABSI and CAUTI in ICUs with persistently elevated rates.
- Revise and augment current CUSP training resources and materials for CUSP for CLABSI and CAUTI in ICUs with persistently elevated rates. The resulting toolkit will be intended for use in ICUs whose infection rates for either or both of these HAIs are persistently elevated compared to other ICUs.
- Recruit 450-600 ICUs nationally with persistently elevated rates to demonstrate the utility of applying a modified CUSP for CLABSI and CUSP for CAUTI during the performance period to reduce rates of CLABSI and CAUTI in these ICUs.
- Assess the adoption of the modified CUSP for CLABSI and CAUTI and evaluate the effectiveness of the intervention in the participating ICUs

This study is being conducted by AHRQ through its contractor HRET. *Expanding the Comprehensive Unit-based Safety Program (CUSP) to reduce Central Line-Associated Blood Stream Infections (CLABSI) and Catheter-Associated Urinary Tract Infections (CAUTI) in Intensive Care Units (ICU) with persistently elevated infection rates* is being undertaken 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**

To achieve the goals of this project the following data collections will be implemented:

- 1) ICU Assessment Tool: The ICU assessment tool will be completed by the unit project team leader in collaboration with individuals with strong knowledge of current clinical and safety practices in the ICU, such as the ICU manager, infection preventionist, quality leader, clinical educator, or clinical nurse specialist at the start of the cohort. The purpose of this assessment is to understand current HAI prevention practices, policies, and

procedures to tailor the educational program to meet the needs of the ICU. The assessment also addresses unit safety culture and CUSP safety practices with questions from the AHRQ Team Checkup Tool. Results from this assessment will be one of the key tools participating ICUs will use in developing their action plans.

- 2) Action plans: After completing and receiving the results of their ICU assessment, the unit team members (such as the ICU manager, quality leader, clinical educator, or clinical nurse specialist) will complete an action plan. The unit team will be encouraged to use other data sources (e.g., CAUTI and/or CLABSI rates from the National Healthcare Safety Network [NHSN], culture assessments) to identify gaps that they plan to address through participation in the project. ICU teams, with coaching support from their state lead, clinical mentor, and subject matter experts, will determine which educational materials will help the ICU achieve its action plan goals. ICU teams, state leads, and clinical mentors will refer to these action plans to monitor progress in achieving the goals.
- 3) Site Visits: State leads and clinical mentors will coordinate state-level, in-person site visits for 200 participating hospital units over the entire project. Site visits are an opportunity for state leads and clinical mentors to meet with ICU teams and their leadership to strengthen relationships, engage in open discussion about infection prevention, and discuss the unit's progress in implementing its action plan. The Site Visit Guidance document helps state leads identify ICUs to visit, plan agendas, schedule visits, prepare for visits, and plan discussion questions.

This data collection effort will be part of a comprehensive evaluation strategy to assess the adoption of the Expansion of the Comprehensive Unit-Based Safety Program (CUSP) for CLABSI and CAUTI in ICUs with persistently elevated rates; measure the effectiveness of the interventions in the participating units; and evaluate the characteristics of teams that are associated with successful implementation and improvements in outcomes.

The evaluation of this data collection is largely foundational in nature as AHRQ seeks information on the implementation and effectiveness of the CUSP for CLABSI and CAUTI in ICUs with persistently elevated rates. The evaluation of the tools above will utilize a pre-post

design, comparing practices, policies and procedures before and after participating in the program.

## Estimated Annual Respondent Burden

### Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
ICU Assessment	150	1	1.25	187.5
ICU Action Plan	150	1	2	300
Site Visits	100	1	4	400
<b>Total</b>	400	N/A	N/A	887.5

### Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
ICU Assessment Tool	150	187.5	\$52.58 <sup>a</sup>	\$9,858.75
ICU Action Plan	150	300	\$52.58 <sup>a</sup>	\$15,774
Site Visits	100	100	\$27.87 <sup>b</sup>	\$2,787
		200	\$34.70 <sup>c</sup>	\$6,940
		50	\$52.58 <sup>a</sup>	\$2,629
		50	\$98.83 <sup>d</sup>	\$4,941.50
<b>Total</b>	400	887.5	N/A	\$42,930.25

National Compensation Survey: Occupational wages in the United States May 2016 "U.S. Department of Labor, Bureau of Labor Statistics:" [http://www.bls.gov/oes/current/oes\\_stru.htm](http://www.bls.gov/oes/current/oes_stru.htm)

<sup>a</sup> Based on the mean wages for 11-9111 *Medical and Health Services Managers*

<sup>b</sup> Based on the mean wages for 29-9099 *Miscellaneous Health Practitioners and Technical Workers: Healthcare Practitioners and Technical Workers, All Other*

<sup>c</sup> Based on the mean wages for 29-1141 *Registered Nurse*

<sup>d</sup> Based on the mean wages for 29-1069 *Physicians and Surgeons, All other*

## Request for Comments

In accordance with the Paperwork Reduction Act, 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.

Karen J. Migdail

Chief of Staff

[FR Doc. 2018-02289 Filed: 2/5/2018 8:45 am; Publication Date: 2/6/2018]