

SUPPORTING STATEMENT

Part A

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.

Version: January 4, 2018

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

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 <http://www.ahrq.gov/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.

Background for this 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.¹ More than a million of these infections occur across our 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 (CAUTI), central-line associated blood stream infections (CLABSI), 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.²

Magill SS, Edwards JR, Bamberg W, et al. Multistate Point-Prevalence Survey of Health Care-Associated Infections. *N Engl J Med*. ¹ .2014;370:1198-208

Liang SY. Vital Signs: Central Line--Associated Blood Stream Infections --- United States, 2001, 2008, and 2009s. *Ann Emerg Med*. ² .2011 Nov ;58(5):447-450

From 2008-2012, the Agency for Healthcare Research and Quality (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 & 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 Medicine Armstrong Institute for Patient Safety and Quality, Michigan Health & Hospital Association Keystone Center for Patient Safety & Quality, St. John Hospital and Medical Center, and University of Michigan Health System.

DHHS Action Plan to Prevent Healthcare-Associated Infections

In January 2009, the Department of Health and Human Services (HHS) released the first iteration of the National Action Plan to Prevent Healthcare-Associated Infections (HAI NAP). The HAI NAP was developed by the HHS Office of Public Health and Science, AHRQ, Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), and other offices and operating divisions of HHS.

As part of the Department of Health and Human Services (DHHS) National Action Plan (NAP) to Prevent Healthcare-Associated Infections (HAI), AHRQ has supported the implementation and adoption of the Comprehensive Unit-based Safety Program (CUSP) to reduce Central-Line Associated Bloodstream Infections (CLABSI) and Catheter-Associated Urinary Tract Infections (CAUTI), and is applying the principles and concepts that have been learned from these HAI reduction efforts to ICUs with persistently elevated infection rates.³

Results of Implementation of CUSP for CLABSI and CAUTI

The nationwide CUSP for CLABSI project implemented CUSP with ICU 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

AHRQ's Healthcare Associated Infections Program, Tools & Resources to Prevent HAIs: CUSP. ³
<http://www.ahrq.gov/professionals/quality-patient-safety/hais/index.html>

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 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 central line-associated bloodstream infections (CLABSI) and catheter-associated urinary tract infections (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 with persistently elevated rates nationally 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

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

- 1) ICU Assessment: 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; questions from the AHRQ Team Checkup Tool are included in this assessment. 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 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 their 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 program. 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 their 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 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 mission 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. 42 U.S.C. 299.

2. Purpose and Use of Information

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 below will utilize a pre-post design, comparing practices, policies and procedures before and after participating in the program.

- ICU Assessment: The ICU assessment 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; questions from the AHRQ Team Checkup Tool are included in this assessment. Results from this assessment will be one of the key tools participating ICUs will use in developing their action plans. See **Attachment A**.
- 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 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 their action plan goals. ICU teams, state leads, and clinical mentors will refer to these action plans to monitor progress in achieving the goals. See **Attachment B**.
- Site Visit Guidance: State leads and clinical mentors will coordinate state-level, in-person site visits for 200 participating hospital units. 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 their 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. See **Attachment C**.

Further Measurement: The project will also use outcome data already being submitted by participating sites to the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) in order to assess the effectiveness of the intervention. Units are expected to already be following the [CAUTI](#)⁴ and [CLABSI](#)⁵ data collection protocols defined by CDC. In most cases, data from participating units is made available to the contractor via an NHSN group established for this program, thereby utilizing secondary analysis of pre-existing data. Via the group, the contractor will have access to unit-level aggregate monthly infection counts (CAUTIs and CLABSIs), device days (urinary catheter days and central line days), patient days, and predicted infections. These data allow the contractor to monitor CAUTI and CLABSI rates and device utilization, as well as the Standardized Infection Ratio (SIR) and the Cumulative Attributable Difference (CAD). The group also has access to infection-level data, should

<http://www.cdc.gov/nhsn/pdfs/pscmanual/7pscclabcurrent.pdf>⁴

<http://www.cdc.gov/nhsn/pdfs/pscmanual/7pscclabcurrent.pdf>⁵

more detailed analyses be required to support evaluation of progress. The primary outcomes for this program will be NHSN CAUTI/CLABSI rates and device utilization.

The program will monitor the following rates on a monthly basis (note that SIRs are monitored quarterly and as stated earlier will be used as a confirmatory measure):

- NHSN CAUTI rate
- Population CAUTI rate
- Urinary catheter utilization rate
- NHSN CLABSI rate
- Population CLABSI rate
- Central line utilization rate

3. Use of Improved Information Technology

The ICU assessment and ICU Action Plan are made available both in paper format and electronically. Data collection may occur using the paper forms, with subsequent data entry and submission electronically. Data collection and entry can occur simultaneously.

4. Efforts to Identify Duplication

AHRQ is aware of other national healthcare-associated infection efforts underway in acute care hospitals across the United States, and is working to identify potential opportunities for the *AHRQ Expanding CUSP to reduce CLABSI and CAUTI in ICU with persistently elevated infection rates* to leverage and align with these efforts. They are described below.

- 1) **Centers for Medicare & Medicaid Services (CMS) Hospital Improvement Innovation Networks.** This effort involves 16 national, regional, or state hospital associations and health system organizations to serve as Hospital Improvement Innovation Networks (HIINs). The HIINs are working to reduce 11 areas of patient harm including CAUTI and CLABSI. The HIINs initiative began in September 2016 and will end in September 2019 and aims to recruit 4,000 short-stay, acute care hospitals in the United States to participate in the reduction of all-cause patient harm and readmissions.
- 2) **States Targeting Reduction in Infections via Engagement (STRIVE).** As part of States Targeting Reduction in Infections via Engagement (STRIVE), the Centers for Disease Control and Prevention (CDC) funded HRET to bring together state hospital associations, state health departments, and CMS QIN-QIOs to 1) improve general infection prevention and control practices in acute care hospitals and 2) to reduce healthcare associated infections (HAIs) such as *C. difficile* infection ([CDI](#)), [CLABSI](#), [CAUTI](#) and methicillin-resistant *Staphylococcus aureus* ([MRSA](#)). STRIVE is a three-year program that began in September 2015 and ends in September 2018.

AHRQ has engaged with CMS to explore coordination and collaboration with the HIINs to familiarize them with their efforts and identify strategies on how best to coordinate to avoid duplication. This project can synergize with and expand this existing national initiative, offering resources and technical assistance through the project, allowing

hospitals to invest resources in other areas to support their efforts toward reaching HIIN goals. Additionally, AHRQ will engage with CDC and HRET STRIVE leadership to explore the potential to coordinate educational tools and resources and avoid duplication of efforts.

5. *Involvement of Small Entities*

The information collected should not involve small entities; it will only involve ICUs within hospitals. For this project, 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 Collected Less Frequently*

This data collection effort will be part of a comprehensive evaluation strategy to assess the adoption of CUSP for CAUTI and CLABSI in the ICU with persistently elevated rates. The planned frequency of data collection is necessary to accurately assess the adoption and effectiveness of the program.

The ICU Assessment is obtained once, before the intervention, to identify opportunities for improvement and assess the effectiveness of the intervention.

The ICU action plan is completed once to outline interventions and education needed to address gaps.

Site visits are performed once and allow the participating sites and state leads the opportunity to discuss progress toward the action plan goals.

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), notice was published in the Federal Register on July 28, 2017, page 35210 for 60 days and again on February 6, 2018 on page 5262 (see **Attachment D**). No substantive comments were received.

The contractor, HRET, will consult with a technical expert panel (TEP) to provide expertise and guidance to develop the plan and design for this project, each phase, including the continued development of the Expanding CUSP to reduce CLABSI and CAUTI in ICUs with persistently elevated rates project and toolkit, and evaluation for which this data collection is designed. The TEP consists of individuals with knowledge

and experience in HAI and infection prevention, change management and implementation in ICUs, and diffusion of innovation. The first TEP meeting will be held in-person within 4 months of the effective date of the contract.

The TEP is tasked with providing critical feedback on all aspects of this program, including reviewing the data from the original project, lessons learned, and the proposed revision plan for the toolkit and project approach including the preliminary plans submitted with the proposal and any updates to these plans.

AHRQ has consulted with other federal partners including CMS and the CDC to ensure synergistic efforts across efforts being undertaken as part of the HIIN and STRIVE initiatives.

9. Payments/Gifts to Respondents

No remuneration of respondents or participating facilities is planned.

10. Assurance of Confidentiality

Individuals and organizations 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.

“The confidentiality of your responses are 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.”

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

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
Total	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	150	187.5	\$52.58 ^a	\$9,858.75
ICU Action Plan	150	300	\$52.58 ^a	\$15,774
Site Visits	100	100	\$27.87 ^b	\$2,787
		200	\$34.70 ^c	\$6,940
		50	\$52.58 ^a	\$2,629
		50	\$98.83 ^d	\$4,941.50
Total	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

^a Based on the mean wages for 11-9111 *Medical and Health Services Managers*

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

^c Based on the mean wages for 29-1141 *Registered Nurse*

^d Based on the mean wages for 29-1069 *Physicians and Surgeons, All other*

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Total and Annualized Cost to the Government

Exhibit A.3a and Exhibit A.3b show the estimated annualized cost to the government for the contractors and government personnel. The cost is estimated to be \$1,559,243 annually.

The costs associated with the data collection activities for the project include the contractor project development costs and project management costs, as well as the costs to design the data collection protocols, develop and host an online data collection platform, develop and program the online instruments, provide technical assistance and support to facilities for submission of data, data processing, and data analysis.

Exhibit 3a. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	\$1,500,000	\$375,000
Data Collection, Processing and Analysis	\$2,500,000	\$625,000
Project Management	\$500,000	\$125,000
Overhead	\$1,200,000	\$300,000
Total	\$5,700,000	\$1,425,000

Exhibit 3b. Federal Government Personnel Cost

Activity	Federal Personnel	Annual Salary	% of time	Cost
Management Support: GS-15, Step 5 average	2	\$149,337	25%	\$74,669
Management Support: GS-14, Step 5 average	1	\$126,958	30%	\$38,087
Program Management Analysis: GS-13, Step 5 average	1	\$107,435	20%	\$21,487
Total				\$134,243

Annual salaries based on 2017 OPM Pay Schedule for Washington/DC area: <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB.pdf>

15. Changes in Hour Burden

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

16. Time Schedule, Publication and Analysis Plans

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

AHRQ will make the final toolkit publically available on its website. The findings from the project will be submitted for publication in academic journals.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

- Attachment A: ICU Assessment
- Attachment B: Action Plan
- Attachment C: Site Visit Guidance
- Attachment D: Federal Register Notice
- Attachment E: Draft Schedule of Evaluation Activities