SUPPORTING STATEMENT

Part B

The AHRQ Safety Program for Healthcare Associated Infection Prevention

Submission of a New Information Collection Request

Version: October 29, 2024

Agency for Healthcare Research and Quality (AHRQ)

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B. Collections of Information Employing Statistical Methods

The data collection planned under this program is part of a comprehensive evaluation strategy to assess the adoption of the AHRQ Comprehensive Unit-based Safety Program (CUSP) for Healthcare Associated Infection (HAI) Prevention ("AHRQ Safety Program for HAI Prevention"). Specifically, the program team will use the data collected to evaluate participating units' experiences with the AHRQ Safety Program for HAI Prevention and changes in HAI processes and rates. A key component of the AHRQ Safety Program for HAI Prevention is the recruitment of three cohorts of acute care hospital units that will use AHRQ's updated HAI Prevention Toolkits to reduce central line-associated bloodstream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), and ventilator-associated pneumonia and ventilator-associated adverse events (VAP/VAE). These recruited units will implement the updated Toolkits in rolling cohorts, while the program team provides units with technical assistance. The program team will then use participant feedback to finalize the updated AHRQ HAI Toolkits for public use.

1. Respondent Universe and Sampling Methods

This data collection request covers planned activities that will occur over the course of nine months for each cohort. The CLABSI cohort will begin data collection first, the CAUTI cohort and VAP/VAE cohort will begin data collection approximately 7 months later and 14 months later, respectively.

Recruitment Methods. The AHRQ Safety Program for HAI Prevention will follow a phased approach, beginning with the CLABSI cohort, followed by recruitment for the CAUTI cohort, and finally, recruitment for the VAP/VAE cohort.

Targets. The program will recruit approximately 100 acute care units—intensive care units (ICUs) or non-ICUs for each of the CLABSI and CAUTI cohorts. The VAP/VAE cohort will recruit approximately 75 ICUs. All cohorts will include hospitals from across the 10 Department of Health and Human Services (HHS) geographic regions.

Hospital Characteristics. To meet recruitment targets, the program team will cast a wide net and ensure that eligibility criteria garner broader participation rather than unnecessarily excluding potential hospitals. In addition to ensuring coverage of all 10 HHS regions, the AHRQ Safety Program for HAI Prevention will seek to ensure diversity of recruited hospitals with various types of urbanicity (i.e., rural, suburban, and/or urban), number of beds, number of providers, types of Electronic Health Record (EHR) systems, ownership (independent and part of larger health system) and teaching status. This will include outreach to smaller, under-resourced hospitals, including safety net hospitals, to ensure recruitment of hospitals of varying sizes, geographies, and serving different types of populations.

Recruitment Strategy. The AHRQ Safety Program for HAI Prevention will use a multi-pronged approach for recruitment of hospitals for all cohorts. The program team will

draw on deep experience recruiting for CUSP programs to implement strategies to maximize success, including beginning "soft" outreach prior to the recruitment period, leveraging trusted recruitment channels, testing and refining recruitment messaging, offering continuing medical education (CME) and continuing education units (CEUs), and implementing high-touch outreach, including targeted outreach to large delivery systems and engagement with state hospital associations and professional societies (e.g., The Society for Healthcare Epidemiology of America, Infectious Diseases Society of America) and national organizations like The Joint Commission to build broad awareness of the program.

The AHRQ Safety Program for HAI Prevention will develop recruitment tools and enrollment materials for each cohort, working across program stakeholders including internal clinical and CUSP experts, external subject matter experts (SMEs), AHRQ, and Quality Innovation Network – Quality Improvement Organization (QIN-QIO) Implementation Advisers (IAs) for feedback and to ensure effective messaging for each cohort's target audience. Recruitment materials will list program benefits of participation and requirements.

Additional recruitment activities will include the following:
- Conduct informational webinars to garner interest in the program.
- Launch and maintain a public AHRQ Safety Program for HAI Prevention website to serve as an information hub, including Frequently Asked Questions (FAQs), registration links for informational webinars, program team contact information, and the Enrollment Form link.
- Highlight cohort-specific information while recruiting for each cohort but include notices on subsequent cohorts to generate early awareness/interest across cohorts.
- Leverage SMEs to promote the program within their institutions (as relevant) and to identify contacts at partner organizations and health systems.
- Collaborate with federal partners including CDC and CMS to ensure synergistic efforts across related programs.
- Work with professional societies and quality improvement organizations to promote the program
- Leverage contact lists from relevant past CUSP Programs (*AHRQ Safety Program for MRSA Prevention* and *AHRQ Safety Program for Improving Antibiotic Use*) to promote the new Safety Program to prior participants.

Respondent Selection and Sample Sizes.
For all cohorts, the AHRQ Safety Program for HAI Prevention will collect the following unit-level data from all participating units when possible:
- **Gap Analysis.** Together, one unit lead and one infection preventionist from each participating unit will collaboratively complete the Gap Analysis at month 1 (baseline) and month 9 (endline) to measure changes in units' HAI prevention processes.
- **CUSP Device Rounds.** Each units' CUSP staff will collaborate with an infection preventionist to complete this assessment once a month to collect data on participating units' use of best practices in device-associated HAI prevention.

- **Self-Reported Changes in HAI Rates and HAI Prevention Processes.** Each unit lead and infection preventionist will collaboratively complete this assessment post-implementation within the Gap Analysis to assess units' change in HAI rates and HAI prevention processes.
- **Clinical Outcomes Data (National Health Safety Network [NHSN] or EHRs).** Participating units will retrospectively provide 12 months of pre-implementation clinical outcomes data and monthly clinical outcomes data during implementation (months 1 through 9). Infection Prevention and Control Programs (IPCs) at participating units will report pre-implementation data once and implementation data on a quarterly basis.
    - **NHSN data.** For clinical outcomes data, participating hospitals can confer rights to their NHSN data to the AHRQ Safety Program for HAI Prevention Group. Any entity, such as a hospital or hospital systems, can maintain a Group in NHSN. These entities can share data with partners and agencies, such as the AHRQ Safety Program for HAI Prevention, using NHSN's Group function. These hospitals can join Groups and provide access to data requested by the Group within the NHSN application. After sites confer rights and join the AHRQ Safety Program for HAI Prevention Group in NHSN, they will not need to take any further action. The data they submit to NHSN will automatically become available to the AHRQ Safety Program for HAI Prevention.
    - **EHR data.** If a hospital does not report to NHSN or refuses to confer data rights to the AHRQ Safety Program for HAI Prevention, the unit or hospital staff within their IPC can submit these data by extracting them from their EHR and submitting to the program directly via a secure program website portal.

For all cohorts, the AHRQ Safety Program for HAI Prevention will collect the following individual-level data from all participating units when possible:
- **The Semi-structured Interviews.** The program team will recruit approximately eight unit leads and staff at endline for each cohort (24 total participants) to examine participants' experiences during the program, including use and perceptions of materials, experiences with measurement, and feedback about the program.
- **The Hospital Survey on Patient Safety (HSOPS).** The AHRQ Safety Program for HAI Prevention will collect these data from all eligible staff within each participating unit; because unit size varies, the program team estimates the average number of respondents to be 20 per unit.

Response Rates. The program team anticipates a variety of cooperation rates depending on cohort and data collection tool. See Exhibit 1 for a summary on the projected response rates.

Exhibit 1: Response Rate Summary

Cohort	Median	Response Rates for Each Data Collection Tool

	Recruited Units	
CLABSI	N=100	• Semi-structured Interviews: 100% • NHSN CLABSI data: 90% • CUSP Device Rounds, Gap Analysis (Baseline, Endline) and Quarterly Submissions of EHR Clinical Outcomes: 75% • AHRQ Survey on Patient Safety Culture (HSOPS): 45%
CAUTI	N=100	• Semi-structured Interviews: 100% • NHSN CAUTI data: 90% • CUSP Device Rounds, Gap Analysis (Baseline, Endline) and Quarterly Submissions of EHR Clinical Outcomes: 75% • AHRQ Survey on Patient Safety Culture (HSOPS): 45%
VAP/ VAE	N=75	• Semi-structured Interviews: 100% • NHSN VAP/VAE data: 40% • CUSP Device Rounds, Gap Analysis (Baseline, Endline) and Quarterly Submissions of EHR Clinical Outcomes: 75% • AHRQ Survey on Patient Safety Culture (HSOPS): 45%
Total: N=275		

2. Information Collection Procedures

This section describes procedures for collecting data (i.e., semi-structured interviews, HSOPS, Gap Analyses, CUSP Device Rounds, self-reported change in HAI rates and HAI prevention processes, and unit-level clinical outcomes data via EHR data extracts or NHSN).

Data Collection

The program will collect a range of data to contribute substantively to the evaluation and to facilitate analysis of progress over time. Data collection includes interviews, surveys, assessments, and clinical outcomes data.

Semi-structured Interviews. The program will conduct eight virtual, semi-structured interviews with unit leads and staff at endline for each cohort (24 total interviews) 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. (See **Attachment A** for sample interview guide.) The interviews will last approximately 30 minutes per respondent and interview participants will receive $40 incentives for their participation.

HSOPS. The program team will request that participating unit staff complete the HSOPS at baseline (month 1) and endline (month 9). The HSOPS asks questions about patient safety issues, medical errors, and event reporting, and takes approximately 15 minutes to complete (**Attachment B**). The program team will request that all frontline staff implementing the AHRQ Safety Program for HAI Prevention complete the survey. As

unit size vary, we estimate the average number of respondents to be 20 for each unit. Participating staff should have enough knowledge about the day-to-day activities in the unit and interact regularly with other staff working in the unit to provide informed answers. These staff members, who spend all or most of their time at work within the unit, may include the following: staff who have direct contact or interaction with patients or staff who may not have direct contact or interaction with patients but whose work directly affects patient care.

CUSP Device Rounds. The CUSP Device Rounds will draw upon the Four Moments for Prevention of Device-Associated Infections. CUSP staff will collaborate with an infection preventionist to complete these checklist assessments once per month, which take 90 minutes to collect and submit data. This innovative strategy will serve as a framework to organize education and build communication among infection preventionists and CUSP teams, as well as a method of collecting data on participating units' use of best practices in device-associated HAI prevention (**Attachments C-E**).

Gap Analysis. The unit lead and an infection preventionist per unit will collaboratively complete this online tool at baseline (month 1) and endline (month 9) of the implementation period. At the start of implementation, the program team will use the Gap Analysis to understand the needs of participating units, prioritize areas for improvement, and advocate for hospital-level and unit-level resources. At the end of implementation, the program team and participating units will use the Gap Analysis to assess progress in building infrastructure and capacity to sustainably reduce HAIs. The Gap Analysis addresses unit infrastructure and capacity to reduce the relevant device-associated infection as well as current prevention activities on the participating unit. The Gap Analysis will also ask for self-reported change in HAI rates and HAI prevention processes at endline (month 9). The Gap Analysis takes approximately 60 minutes to complete (**Attachments F-H**).

Clinical Outcomes Data. The program team will collect clinical outcomes reported by Infection Prevention and Control Programs at participating units. The clinical outcomes by cohort include: 1) changes to CLABSI rate per 10,000 central line-days, 2) changes to CAUTI rate per 10,000 catheter days, and 3) changes to VAP/VAE incidence rate per 10,000 ventilator days.

The program team will request participating units to provide 12 months of pre-implementation clinical outcomes data once, and monthly clinical outcomes data during implementation (months 1 through 9) on a quarterly basis.

The program team assumes most participating sites will confer NHSN rights to the program for CLABSI and CAUTI. However, if a hospital does not report to NHSN or refuses to confer data rights to the AHRQ Safety Program for HAI Prevention, participating units can submit these data by extracting them from their EHRs and submitting to the AHRQ Safety Program for HAI Prevention directly via a secure program website portal. Given that only 1,900 U.S. hospitals currently submit VAP/VAE data to NHSN, we anticipate a higher number of participating sites will use the hybrid

option in this cohort submitting these data via the secure program portal while other hospitals may confer NHSN rights. The use of NHSN data from hospitals that confer rights to the AHRQ Safety Program for HAI Prevention to use their NHSN data for the evaluation reduces respondent burden. NHSN data will serve as the primary data source for clinical data.

Exhibit 2 describes the requested clinical outcomes data. (See **Attachment I** for the clinical outcomes data template.) If a hospital does not confer NHSN data rights, the program team estimates the EHR data extraction will take 3.5 hours for the pre-implementation data, and approximately 30 minutes for quarterly implementation data. (See **Attachment J** for the Submission Guide for Clinical Outcomes Data Collection.)

Exhibit 2: Clinical Outcomes Data

Clinical Outcomes	Description
Patient days	Count of the number of patients in a patient care location during the reporting month.
Device-associated infection	An infection meeting the HAI definition is considered a device-associated HAI (for example, associated with the use of a ventilator, central line, or indwelling urinary catheter) if the device was in place for >2 calendar days on the date of event, and was also in place on the date of event or the day before the event (with date of insertion and date of removal counted as a Device Day). a. CLABSl: A laboratory confirmed bloodstream infection (LCBI) where an eligible bloodstream infection (BSI) organism is identified, and an eligible central line is present on the date of event or the day before. b. CAUTI: A urinary tract infection (UTI) where an indwelling urinary catheter (IUC) was in place for more than two consecutive days in an inpatient location on the date of event or the day before, with day of device placement being Day 1. c. VAP: A pneumonia where the patient is on mechanical ventilation for > 2 consecutive calendar days on the date of event, with day of ventilator placement being Day 1, AND the ventilator was in place on the date of event or the day before. d. VAE: Identified by using a combination of objective criteria: deterioration in respiratory status after a period of stability or improvement on the ventilator, evidence of infection or inflammation, and laboratory evidence of respiratory infection. Patients must be mechanically ventilated for at least 4 calendar days (where the day of intubation and initiation of mechanical ventilation is Day 1). The earliest date of event for VAE (the date of onset of worsening oxygenation) is Day 3 of mechanical ventilation.
Device days	A count of the number of patients with a specific device in place during the reporting month (central line, catheter, and ventilator days)

Evaluation Design

The HAI Unit Assessment will address three broad goals: 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, experiences with

measurement, and feedback about the program); 2) participating units' self-reported change in HAI processes (i.e., self-reported changes in CLABSI, CAUTI, or VAP/VAE prevention processes, interventions implemented by unit, unit capacity to improve HAI rates, and self-reported improvements in HAI prevention processes); 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 program team will use a conceptual framework to guide the design of measurement and outcomes for the HAI Unit Assessment, and has organized the conceptual framework based on basic elements of widely used program evaluation logic models (i.e., inputs, short-term outcomes, and long-term outcomes) and theories of change (i.e., incorporating contextual factors to understand changes to processes and outcomes).[1] The program team will populate the framework using the goals of measurement domains of the assessment.

Quantitative Analysis. The program team will conduct a series of quantitative analyses for each cohort. Descriptive analyses will include descriptive tables, including mean scores and standard deviations, frequency counts, and data visualizations. The program team will use descriptive analyses to assess units' self-reported improvement in HAI prevention processes and HAI rates and will assess responses to the CUSP Device Rounds, Gap Analysis, and HSOPS cross-sectionally. In addition, the team will use linear regression to compare responses from baseline to endline for the CUSP Device Rounds, the Gap Analysis, the HSOPS, and HAI rates.

For the primary clinical outcomes, the project team will assess change from baseline to endline for HAI infection rates per 10,000 device days. The AHRQ Safety Program for HAI Prevention is designed to be powered at 80 percent to detect a change from baseline to endline for 4.57 CLABSI per 10,000 central line days (assuming SD of 17.3), 4.97 CAUTI per 10,000 urinary catheter days (assuming SD of 18.8), and 73.1 VAP/VAE per 10,000 ventilator days (assuming SD of 206.3) (see Exhibits 3-5). The following assumptions were used in the power calculations: 1) 2-sided significance level of 0.05, 2) within-practice correlation of 0.4, and 3) 150 units with response rate of 90 percent for CAUTI cohort and CLABSI cohort, and 100 units with response rate of 75 percent for VAP/VAE cohort.

Exhibit 3: Power Analysis for the CLABSI Cohort

Total number of units	Effective Sample Size After Non-Response	Correlation within unit	Detectable Change in CLABSI per 10,000 central line days
150	135	0.2	5.28
150	**135**	**0.4**	**4.57**
150	135	0.6	3.73
100	90	0.2	6.46
100	90	0.4	5.60
100	90	0.6	4.57
50	45	0.2	9.14
50	45	0.4	7.91

| 50 | 45 | 0.6 | 6.46 |

Exhibit 4: Power Analysis for the CAUTI Cohort

Total number of units	Effective Sample Size After Non-Response	Correlation within unit	Detectable Change in CAUTI per 10,000 central line days
150	135	0.2	5.73
150	**135**	**0.4**	**4.97**
150	135	0.6	4.05
100	90	0.2	7.02
100	90	0.4	6.08
100	90	0.6	4.97
50	45	0.2	9.93
50	45	0.4	8.60
50	45	0.6	7.02

Exhibit 5: Power Analysis VAP/VAE Cohort

Total number of units	Effective Sample Size After Non-Response	Correlation within unit	Detectable Change in VAE/VAP per 10,000 ventilator days
100	75	0.2	84.4
100	**75**	**0.4**	**73.1**
100	75	0.6	59.7
75	56	0.2	97.7
75	56	0.4	84.6
75	56	0.6	69.1
50	37	0.2	120.2
50	37	0.4	104.1
50	37	0.6	85.0

Qualitative Analysis. The program team plans to collect and analyze endline data from a total of 24 semi-structured interviews (i.e., 8 interviews per cohort). The team will code qualitative data using NVivo10 software and develop a set of *a priori* codes that reflect hypotheses, topics of interest, and subgroup characteristics (e.g., site, years of experience, etc.). The program team will develop and refine the analytic categories based on research questions and salient analytic dimensions and operationalize the research questions by developing and then refining the codebook.

3. Methods to Maximize Response Rates

The data collection planned under this program is part of an evaluation to assess participating units' experiences with the AHRQ Safety Program for HAI Prevention and changes in HAI processes and rates. The results of the evaluation will be used to inform the AHRQ Safety Program for HAI Prevention; they will not yield generalizable results or be used for statistical estimation purposes. The AHRQ Safety Program for HAI Prevention will recruit hospitals that have indicated a willingness to participate and meet

the inclusion criteria, and who will be supportive of and likely to spread the AHRQ Safety Program for HAI Prevention model.

To encourage the participating hospitals to complete and submit the HSOPS, CUSP Device Rounds, Gap Analysis, clinical outcomes NHSN/EHR data, and semi-structured interviews, the AHRQ Safety Program for HAI Prevention will implement the following strategies:

- Offer onboarding calls and technical assistance webinars (including information related to submitting data) to participating units.
- Prompt the on-site hospital data coordinator and unit lead for feedback from each participating unit regarding the data collection activities and HAI-related performance.
- Work closely with the program's implementation advisors (IAs) to encourage timely completion of each assessment.
- Work closely with each on-site data coordinator to address any data collection issues and develop unit-specific data collection strategies, as necessary.
- Discuss data management and submission methods with the participating units early in the program period.
- Provide units with a secure website program portal to submit data. Users will receive a login and password to access the site.
- Provide step-by-step instructions on data sharing via the central data collection platform.
- Ensure that data collection tools are simple, easy to use, and succinct.
- Ensure missing or inaccurate data are identified early and that issues are resolved in a systematic, reliable way.
- Share data collection strategies/best practices to simplify processes through coaching calls.
- Provide a $40 incentive for the semi-structured interview.

4. Tests of Procedures

The AHRQ Safety Program for HAI Prevention data collection procedures and instruments include semi-structured interview guides, surveys, assessments, and collection of clinical outcomes.

- **Semi-structured interview.** Consistent with well-established, qualitative methodology[2,3], the semi-structured interview guides include open-ended questions that address the key elements of the assessment, while allowing respondents to elaborate on their answers and provide rich details in their responses.
- **Survey.** The HSOPS is a validated instrument and the most frequently used survey to assess safety culture in hospitals.[4]
- **Assessments.** The CUSP Device Rounds will measure the use of best practices in device-associated HAI prevention. The CUSP Device Rounds draw upon the Four Moments for Prevention of Device-Associated Infections, which was adapted from a successful approach used in the *AHRQ Safety Program for Improving Antibiotic Use* and previously created tools for this program, i.e., the Daily Goals Checklists. These will serve as a method of collecting data on participating units'

use of best practices in device-associated HAI prevention. The Gap Analysis assessments are adapted from previously created AHRQ Toolkits used in intensive care unit assessments in the *AHRQ Safety Program for Preventing CLABSI and CAUTI.*

- **Clinical outcomes.** The NHSN is the nation's most widely used HAI tracking system.[5]

5. Statistical Consultants

NORC at the University of Chicago will serve as the primary consultants for statistical aspects of the design and analysis of the evaluation data. Exhibit 6 provides the names, titles, affiliations, and contact details for the program's three main statistical consultants.

Exhibit 6: List of Statistical Consultants

Name	Title and Institution	Telephone Number
Roy Ahn, ScD, MPH	Vice President, Public Health Department, NORC	312-759-4068
Jessica Fernandez, PhD	Senior Research Scientist, Health Sciences Department, NORC	518-321-4471
Yue Gao, MPH	Senior Research Scientist, Health Care Evaluation Research Department, NORC	301-634-9440

The data will be collected by NORC at the University of Chicago.

[1] Kohut MR, Keller SC, Linder JA, et al. The inconvincible patient: how clinicians perceive demand for antibiotics in the outpatient setting. Fam Pract. 2020;37(2):276-282. doi:10.1093/fampra/cmz066

[2] Corbin, J., & Strauss, A. Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory (3rd ed.). Thousand Oaks, CA: Sage. 2008.

[3] Dicicco-Bloom B, Crabtree BF. The qualitative research interview. Med Educ. 2006 Apr;40(4):314-21.

[4] Churruca K, Ellis LA, Pomare C, et al. Dimensions of safety culture: a systematic review of quantitative, qualitative and mixed methods for assessing safety culture in hospitals. *BMJ Open*. 2021;11(7):e043982. Published 2021 Jul 27.

[5] Centers for Disease Control and Prevention. National Healthcare Safety Network (NHSN). 2024. Retrieved from: https://www.cdc.gov/nhsn/index.html.