SUPPORTING STATEMENT

Part B

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

Version: January 4, 2018

Agency of Healthcare Research and Quality (AHRQ)

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B. Collections of Information Employing Statistical Methods

The data collection planned under this project is part of a comprehensive evaluation strategy to assess the adoption of the Comprehensive Unit-Based Safety Program (CUSP) for central-line associated infections (CLABSI) and catheter-associated urinary tract infections (CAUTI) in intensive care units (ICUs) with persistently elevated rates; measure the effectiveness of the interventions in the participating facilities or units; and evaluate the characteristics of teams that are associated with successful implementation and improvements in outcomes. A key component of the *Expanding CUSP to reduce CLABSI and CAUTI in ICUs* is the recruitment of units with persistently elevated infection rates to reduce or eliminate CLABSI and CAUTI using the CUSP model.

1. Respondent Universe and Sampling Methods

This data collection request covers the activities of 450-600 ICUs with persistently elevated rates to ensure participation from all 10 HHS regions over the course of the project.

Recruitment Methods:

ICUs with persistently elevated infection rates will be recruited in a phased, cohort approach. Specifically, in recognition of the likely scattered distribution of ICUs with persistently elevated rates, the recruitment approach will:

- involve collaboration with CDC, which is intended to include a CDC-designated "ICU identification coordinator" to identify candidate hospitals/ICUs whose CLABSI and/or CAUTI rates place them in the upper part of the national range of such rates or whose past performance would indicate that they would be likely to benefit from the project. In this approach, CDC would make the initial contact to the hospital, and the recruitment process would be completed by the AHRQ contractor the Health Research and Educational Trust (HRET);
- include additional approaches identifying and recruiting ICUs with persistently elevated rates of CLABSI and/or CAUTI (e.g. Hospital Compare).
- include involvement of 450-600 units, with participation from each of the 10 HHS regions;
- include a mix of types of hospitals and ICUs within hospitals as part of the overall recruitment strategy.
- take place in 4-6 cohorts over 4 years.

Respondent Selection and Sample Sizes

The project will aim to recruit 450-600 ICUs with persistently elevated rates over 4-6 cohorts. Each cohort will include 100-150 ICUs.

Response Rates

Completion rates for the ICU Assessment and ICU Action Plan, based on previous CUSP interventions focusing on CAUTI and CLABSI, is estimated at 90%. Two hundred (200) units will undergo a site visit over the entire program.

The NHSN data submission rate (for CAUTI and CLABSI rates as well as device utilization) is estimated at 95% based on NHSN data submission rates from similar, previous efforts.

2. Information Collection Procedures

Primary Data Collection
The project will collect a range of data to contribute substantively to the evaluation and facilitate analysis of progress over time. Primary data collection includes baseline assessment, action plans and site visits.

Assessment Tools
The project will collect data by administering assessment tools to staff members involved with *Expanding CUSP for CLABSI and CAUTI in ICUs with persistently elevated rates.*

1) 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.

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 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.

Further Measurement: The project will also use 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 already following the CAUTI[1] and CLABSI[2] data collection protocols defined by CDC. In most cases, data from participating units are 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 more detailed analyses be required to support evaluation of progress. The primary outcome for this program will be NHSN CAUTI/CLABSI rates and device utilization.

Evaluation Design

[1] http://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf
[2] http://www.cdc.gov/nhsn/pdfs/pscmanual/4psc_clabscurrent.pdf

All of the infection and utilization outcome measures (i.e., the, the NHSN CAUTI/CLABSI rates, and device utilization rates) are ratios. The distributions of NHSN rates are typically skewed strongly to the right and we expect at least half of the ICU level monthly rates to be zero. Thus, it is problematic to treat them as normally distributed numeric variables. The ratios can be considered as count variables, with each numerator (number of monthly CAUTIs/CLABSIs) being dependent on the denominator. Count regression models which include offsets for ratios are a natural way to model count variables. Binomial, Poisson, and negative binomial, zero inflated Poisson, and zero inflated negative binomial models will be compared using Akaike Information Criterion (AIC) (and deviance if a nested model approach is used) values to determine which is most appropriate given the distribution of our outcome data. Unit identifiers will be entered into the model as a random effect to account for clustering of scores within facilities

The time trend approach tests for a trend over time in rates, with time measured in months relative to the start of intervention. Data will be available in NHSN on CAUTI and CLABSI rates prior to the start of the intervention. This will allow the creation of an interrupted time series analysis and test explicitly for a difference between pre-intervention versus post-intervention as well as the impact of time in the project.

Facility and unit-level characteristics will also be incorporated in the models, to evaluate whether the outcome rates of certain types of facilities and/or units change differently than other types over the course of the project. If there are clear interaction effects between facility and/or unit type and time, results will be reported stratified by these variables. If needed, differences can be tested for between cohorts, by examining the interaction between time and the cohort.

Power Calculations:

The power analysis presented here was based on pilot study data on CLABSI and CAUTI rates collected over 12 months from 165 ICUs similar to those that will be targeted for inclusion in this project. The data were used to estimate mixed effect negative binomial models in order to obtain estimates of the within-unit correlation over time, τ^2 and the dispersion parameter α for each of the primary measures. These two parameters, along with the mean count λ were used to calculate the intra-unit correlation ρ by [3]

$$\rho = \tau^2/(\tau^2 + \ln(1 + 1/\lambda + \alpha)$$

which in turn was used to estimate the variance inflation factor (VIF) using VIF $= (1 + (m-1)\rho)$ where m is the anticipated number of monthly measurements per unit. We applied this VIF, along with α and the observed baseline rates to a formula for the sample size for negative binomial models.[4] We assumed 450 units, with each unit having 12 monthly measurements prior to intervention and 3 measurements post. Table 1 reports the

[3] Nakagawa SJ, Schielzeth H. 2017 The coefficient of determination R2 and intra-class correlation coefficient from generalized linear mixed effects models revisited and expanded. *J. R. Soc. Interface* 14: 20170213

anticipated power to detect relative reductions in the baseline infection rates for the CLABSI and CAUTI for a range of a true relative reductions.

Table 1: Statistical Power for Detecting the Intervention Effect by the Magnitude of the Infection Rate Standard Error using the CLABSI and CAUTI Measures of Infection

					N=450 Units	N = 600 Units
	alpha	ICC	baseline	reduction	Power	Power
CAUTI	0.35	0.067	0.39	30%	93%	98%
				25%	80%	90%
				20%	59%	71%
				15%	36%	46%
				10%	18%	22%
CLABSI	0.52	0.007	0.22	30%	100%	100%
				25%	96%	99%
				20%	83%	92%
				15%	57%	70%
				10%	29%	36%

Thus, for example, with 450 units participating, we will have 80% power to detect a true relative reduction of 25% in the CAUTI rate and 83% power to detect a 20% reduction in the CLABSI rate.

3. Methods to Maximize Response Rates

The data collection planned under this project is part of an evaluation to assess the adoption of the CUSP. The results of the evaluation will be used to inform CUSP for persistently elevated ICU's; they will not yield generalizable results or be used for statistical estimation purposes. The project will recruit units that have indicated a willingness to participate in the project and meet the inclusion criteria, and who will be supportive of and likely to spread the CUSP model.

To encourage the participating facilities to complete and submit the ICU Assessment and Action Plan, the project will implement the following strategies:

- Ensure that data collection tools are simple, easy to use, and succinct
- Discuss data management and submission methods with the participating sites early in the process
- Ensure team understands the value of data collection for their ongoing efforts to decrease their infection rates.
- Offer technical assistance webinars and onboarding calls (including information related to submitting data) to participating sites

[4]Cundill B, Alexander ND. Sample size calculations for skewed distributions. *BMC Med Res Methodol*. 2015 Apr 2;15:28. doi: 10.1186/s12874-015-0023-0.

- Work closely with each on-site data coordinator to address any data collection issues and develop site-specific data collection strategies when necessary
- Provide step-by-step instructions on data sharing via the central data collection platform
- Ensure missing or inaccurate data is identified early and that issues are resolved in a systematic, highly-reliable way
- Prompt the on-site data coordinator and unit/facility leader for feedback from each participating unit regarding the data collection activities
- Share data collection strategies/best practices to simplify processes through coaching calls
- Perform small tests of change through the use of Plan-Do-Study-Act (PDSA) to increase engagement in the education and submission of data among participating units.
- Continue to monitor and respond to opportunities for improvement.

4. Tests of Procedures

Data collection procedures and instruments are virtually identical to ones used previously with satisfactory results.

5. Statistical Consultants

HRET will serve as the primary consultants for statistical aspects of the design and analysis of the evaluation data. Staff listed in Exhibit B.8 have participated in the design of the evaluation, under the overall direction of Ms. Albert Lesher.

.**Exhibit B.8:** List of Statistical Consultants

Name	Title and Institution	Telephone Number
Mariana I. Albert Lesher, MS	Director, Data Management, HRET	484-533-7152
Jeffrey Herrin, PhD	Senior Statistician, HRET	434-295-5342
Andrew Rolle, MPH	Senior Program Manager, HRET	312-422-2664
Mark Plunkett, PhD	Senior Data Analyst, HRET	602-319-8835
Richard Rodriguez, MPH	Data Analyst, HRET	312-422-2626
Paul Cholod, MA	Data Analyst, HRET	312-422-2612
Kayla Thomas Wu, MPH	Data Analyst, HRET	312-422-2642
Brittany Schwartz, MPH	Program Specialist, HRET	312-422-2625