SUPPORTING STATEMENT

Part A

The AHRQ Safety Program for Methicillin-Resistant *Staphylococcus aureus* (MRSA) Prevention

June 17, 2021

Agency for 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

As part of the HHS HAI National Action Plan (NAP), 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 subsequently applied CUSP to other clinical challenges, including reducing surgical site infections and improving care for mechanically ventilated patients. As part of the National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB NAP), the HHS HAI National Action Plan, and Healthy People 2030 goals, AHRQ will now apply the principles and concepts that have been learned from these HAI reduction efforts to the prevention of MRSA invasive infections (defined as MRSA bacteremia).

Healthcare-associated infections, or HAIs, are a highly significant cause of illness and death for patients in the U.S. At any given time, HAIs affect one out of every 31 hospital inpatients. More than a million of these infections occur across our health care system every year. This leads to significant patient harm and loss of life, and costs billions of

dollars each year in medical and non-medical costs. In addition, the 3 million Americans currently residing in U.S. nursing homes experience a staggering 2-3 million HAIs each year.[1]

Particular concern has arisen related to the persistent prevalence of methicillin-resistant *Staphylococcus aureus* (MRSA). This bacterium affects both communities and healthcare facilities, but the majority of morbidity and mortality occurs in critically and chronically ill patients. While MRSA was rare in the US through the 1970s, its prevalence in US health care facilities began rising in the 1980s and had continued to do so. In 2000, MRSA was responsible for 133,510 hospitalizations in children and adults. This number more than doubled by 2005, with 278,203 hospitalizations along with 56,248 septic events and 6,639 deaths being attributed to MRSA.[2] MRSA has become a major form of hospital associated *Staphylococcus aureus* infection.[3]

For various patient safety initiatives, AHRQ has promoted the implementation and adoption of the Comprehensive Unit-based Safety Program (CUSP) approach which combines clinical and cultural (i.e., technical and adaptive) intervention components to facilitate the implementation of technical bundles to improve patient safety. For MRSA prevention, it is likely that a combination of technical approaches is indicated, including decolonization, along with classic infection control practices such as hand hygiene, environmental cleaning, general HAI prevention, and contact precautions/isolation. Implementation of these technical approaches would benefit greatly from the cultural and behavioral interventions incorporated in CUSP. AHRQ expects that this approach, which includes a focus on teamwork, communication, and patient engagement, will enhance the effectiveness of interventions to reduce MRSA infection that will be implemented and evaluated as part of this project.

This project will assist hospital units and long-term care (LTC) facilities in adopting and implementing technical approaches to reduce MRSA infections. It will be implemented in four cohorts:

- at least 400 ICUs
- at least 400 non-ICUs
- at least 300 hospital surgical services
- at least 300 LTC facilities.

The goals of this project are to 1) develop and implement a program to prevent MRSA invasive infection (defined as MRSA bacteremia) in intensive care units (ICUs), non-ICUs, inpatient surgery, and LTC facilities, 2) assess the adoption of the *AHRQ Safety Program for MRSA Prevention*, and 3) evaluate the effectiveness of the implementation in the participating units. AHRQ is requesting a 3-year clearance to perform the data collection activities needed to assess the adoption of the program and evaluate its effectiveness in the participating units and facilities.

The project is being conducted by AHRQ through its contractor, Johns Hopkins University (JHU) and JHU's subcontractor, NORC at the University of Chicago. The project 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 *AHRQ Safety Program for MRSA Prevention* in ICUs, non-ICUs, surgical services, and LTC settings; and measure the effectiveness of the implementation in the participating facilities or units. The evaluation has four main goals:

1. Program participation: Assess the ability of sites to successfully encourage full participation of unit/facility staff in educational activities.
2. Implementation and adoption: Assess the implementation and adoption of *AHRQ Safety Program for MRSA Prevention*.
3. Program effectiveness: Measure the effectiveness of the *AHRQ Safety Program for MRSA Prevention* bundle.
4. Causal pathways: Describe the characteristics of teams that are associated with successful implementation and improvement outcomes.

The evaluation will utilize an interrupted time series design to assess MRSA invasive infections (defined as MRSA bacteremia) and secondary clinical outcomes, using 18 months of implementation data and 12 months of retrospective data. We will also assess needs of participating units and capacity to implement the intervention, awareness of MRSA prevention, implementation fidelity and effectiveness, communication and teamwork, and changes in patient safety culture and behavior.

The data collection will include both primary and secondary data sources. The primary data collection includes the following:

1) Unit -level clinical outcome change data: The program will use a secure online portal to collect clinical outcomes measures extracted from site electronic health record (EHR) systems for the 12 month period prior to the start of the implementation, as well as for the 18 month implementation period. These data will be used to evaluate the effectiveness of the *AHRQ Safety Program for MRSA Prevention* (Attachments J, K, L, M, N, and O).

   For the ICU and non-ICU cohorts, the clinical outcomes data will be collected quarterly and will include:

   - Hospital onset MRSA invasive infection (MRSA bacteremia LabID Day 3 or after of admission)
   - Community onset MRSA invasive infection (MRSA bacteremia LabID prior to Day 3 after admission)
   - Patient days
   - Central Line-Associated Blood Stream Infections with causative organism(s)
   - Central Line Days
   - Hospital onset bacteremia (Day 3 or after of admission) with causative organisms, including MSSA

- MRSA-positive clinical cultures

In addition, hospitals that are already conducting MRSA point prevalence surveys in participating ICU and non-ICU units will be asked to submit this optional data via the secure online portal.

For the surgical services cohort, the clinical outcomes data will be collected quarterly and will include:

- Surgical site infection (SSI) events and causative organisms
- Number of surgical procedures performed, by type of surgical procedure

For the LTC cohort, the clinical outcomes data will be collected monthly via the secure online portal, or via fax submission, and will include:

- Transfer of facility resident(s) to an acute care hospital, with reason of suspected or confirmed infection
- Transfer of facility resident(s) to an acute care hospital, with reason other than infection
- All-cause bacteremia with causative organisms
- Resident days

2) Survey of Patient Safety: The NORC/JHU team will administer AHRQ Surveys of Patient Safety Culture to all eligible *AHRQ Safety Program for MRSA Prevention* staff at the participating units or facilities at the beginning (month 1) and end (month 18) of the implementation. We will administer the Hospital Survey of Patient Safety Culture (HSOPS) in the ICU, non-ICU, and surgical cohorts, and the Nursing Home Survey on Patient Safety (NHSOPS) in the LTC cohort. These surveys ask questions about patient safety issues, medical errors, and event reporting in the respective setting. NORC/JHU will request that all staff on the unit or facility that is implementing the *AHRQ Safety Program for MRSA Prevention* complete the survey. As unit and facility size vary, we estimate the average number of respondents to be 25 for each unit (Attachments H, I).

3) Infrastructure Assessment Tool- Gap Analysis: The NORC/JHU team will administer the Gap Analysis at month 1 and month 18 of the implementation to an Infection Preventionist and one of the unit's team leaders (most likely a nurse). Information on current practices in MRSA prevention on the unit will be collected (Attachments B, C, D).

4) Implementation Assessments- Team Checkup Tool: The implementation assessments will be conducted to monitor the program's progress and determine what the participating sites have learned through participating in the program. The Team Checkup Tool will be requested monthly, and we anticipate participation from approximately 1 frontline staff (most commonly a nurse) per unit. The program will use the Team Checkup Tool (Attachments E, F, and G) to monitor key actions of staff. The Tool asks about use of safety guidelines, tools, and resources throughout three different phases: Assessment (1), Planning, Training, and Implementation (2), and Sustainment (3).

The secondary data collection strategy includes use of National Healthcare Safety Network (NHSN) data from hospitals that confer rights to the *AHRQ Safety Program for MRSA Prevention* to use their NHSN data for the evaluation. NHSN data will serve as secondary data sources for clinical outcomes in ICU, non-ICU, and surgical services units. Clinical outcome measures in LTC settings are not available in NHSN.

For hospitals that confer NHSN rights to the program for the ICU and non-ICU cohorts, the secondary data will include the five out of seven clinical outcome measures that are available via NHSN:

- Hospital onset MRSA invasive infection (MRSA bacteremia LabID Day 3 or after of admission)
- Community onset MRSA invasive infection (MRSA bacteremia LabID prior to Day 3 after admission)
- Patient days
- Central Line-Associated Blood Stream Infections with causative organism(s)
- Central Line Days

For hospitals that confer NHSN rights to the program for the surgical services cohort, the secondary data will include the two clinical outcome measures that are available via NHSN:

- Surgical site infection (SSI) events and causative organisms
- Number of surgical procedures performed, by type of surgical procedure

3. Use of Improved Information Technology

In order to minimize respondent burden and to permit the electronic submission of survey responses and data collection forms, the Team Checkup tool, Gap Analysis, and AHRQ Surveys on Patient Safety Culture will be web-based and deployed using a well-designed, low burden, and respondent-friendly survey administration process and instruments.

In addition, the clinical outcome change data collected via primary data collection will be extracted by unit or facility staff from their EHR systems. The EHR data requested for this project may already be collected by hospitals and LTC facilities as part of their ongoing quality improvement initiatives. Respondents will receive access to the online data collection platform and step-by-step instructions on extracting and submitting the EHR data. LTC settings and hospitals that do not have strong enough internet access to upload files will be offered a fax option to provide their data.

NHSN is the domestic tracking and response system from the Centers of Disease Control and Prevention (CDC) to identify emerging and enduring threats across healthcare, including healthcare-associated infections (HAIs) and antibiotic-resistant infections. Healthcare facilities participate in HAIs surveillance via NHSN to monitor HAIs and the impact of their own prevention efforts; benchmark facility performance against risk-adjusted national data; and fulfill state-mandated reporting requirements or comply with the Centers for Medicare and Medicaid (CMS) Hospital Inpatient Quality Reporting Program requirements. In order to utilize NHSN data, participating hospitals would need

to confer rights to their NHSN data to the *AHRQ Safety Program for MRSA Prevention*. Any entity, such as hospital systems, state health departments, and quality improvement organizations, can maintain a Group in NHSN. These entities, such as hospitals, can share data with partners and agencies, such as the *AHRQ Safety Program for MRSA Prevention***,** using NHSN's Group function. The hospitals can join Groups and provide access to data requested by the Group within the NHSN application. Groups are responsible for creating a Confer Rights Template of data they are requesting from facilities; the template is automatically sent to the Group's member facilities upon completion. After facilities confer rights and join the MRSA Prevention Program group in NHSN, they will not need to take any further action. The data they submit to NHSN will automatically become available to the MRSA program team for analysis.

4. Efforts to Identify Duplication

Program duplication:
The project team is aware of two initiatives that are focusing on a potentially similar topic as the *AHRQ Safety Program for MRSA Prevention*.

1) The CMS Hospital Quality Improvement Contractor Initiative – the initiative's intent is to provide targeted quality improvement assistance to rural and critical access hospitals, as well as hospitals serving vulnerable and underserved populations to achieve measurable outcomes with a focus on patient safety, care transitions and opioids. The initiative also provides support to hospitals during public health emergencies, epidemics, pandemics and other crises as they arise. The HQIC initiative will focus on three CMS goals, which align with the CMS Rural Health Strategy: Goal 1: Improve behavioral health outcomes, with a focus on decreased opioid misuse Goal 2: Increase patient safety, with a focus on reduction of harm Goal 3: Increase the quality of care transitions, with a focus on high utilizers in an effort to improve overall utilization. Goal 2, as part of harm reduction, may include a metric related to MRSA as it will include reduction of hospital acquired infections.

2) Similar to the hospital quality improvement contractor's initiative, QIN-QIOs serving under the 12th Statement of Work will provide targeted assistance to nursing homes and communities in small and rural practices, those serving the most vulnerable populations, and those in need of customized quality improvement. The work with nursing homes will also include the goal for reduction in harm, and includes efforts to reduce healthcare acquired infections. This may include tracking admissions from the hospital for patients with hospital acquired MRSA.

Avoidance of duplication on a data collection level:

- Unit -level clinical outcome change data: These data are already collected as part of the required infection control efforts at the hospitals and LTC facilities. The ICU/non-ICU and Surgical Services data are then submitted to NHSN. The *AHRQ Safety Program for MRSA Prevention* will also offer the opportunity for

participating hospitals to confer NHSN rights to the Program in order to further reduce data collection burden. In order to utilize NHSN data for those measures available, participating hospitals would need to confer rights for the *AHRQ Safety Program for MRSA Prevention* to use their NHSN data for the evaluation. In ICU and non-ICU settings, five of the seven clinical outcome measures are available via NHSN. In surgical settings, both clinical outcome measures are available via NHSN. For hospitals that confer rights, the program will be able to access this data via NHSN and will not need to request this data from unit-level EHR extracts. LTC data is not generally submitted to NHSN, but collected for internal use. The information is therefore already available for entry into the project's data portal.

- Survey of Patient Safety (SOPS): We will be collecting original data from most sites. Some sites may already use SOPS as part of meeting their CMS requirements. In those cases, the sites will share the data they have already collected.
- Gap Analysis: The Gap Analysis has been developed for this program. The data we are requesting is original.
- Team Checkup Tool (TCT): This version of the TCT has been developed for this program. The data we are requesting is original.

AHRQ has engaged with CMS to explore possible coordination and to familiarize them with the *AHRQ Safety Program for MRSA Prevention*. CMS personnel will serve on the Technical Expert Panel to assure coordination and avoid duplication of efforts. The *AHRQ Safety Program for MRSA Prevention* can synergize with and compliment these existing national incentives. The *AHRQ Safety Program* provides extensive technical and adaptive tools and approaches for preventing MRSA infections to infection preventionists and frontline providers. Through engaging webinars and e-learning modules, participants will learn how to optimize their existing resources for MRSA prevention efforts. As with previous *AHRQ Safety Program* initiatives (e.g. the *AHRQ Safety Program for Improving Antibiotic Use* and the *AHRQ Safety Program for ICUs: Preventing CLABSI and CAUTI*), technical assistance provided in this program will not overlap, but will assist facilities participating in CMS quality improvement initiatives to reach established goals.

5. Involvement of Small Entities

The information collected may involve small entities, as some of the participating hospitals and LTC facilities may involve smaller units. 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 *AHRQ Safety Program for MRSA Prevention* in ICU, non-ICU, surgical

services units, and LTC settings, and measure the effectiveness of the implementation in the participating units and facilities. The planned frequency of data collection is necessary to accurately assess the adoption and effectiveness of the program.

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), a notice was published in the Federal Register on May 3, 2021 on Page 23366 Volume 86 for 60 days (see **Attachment A**).

8.b. Outside Consultations

AHRQ, Johns Hopkins University, and NORC is consulting with a technical expert panel (TEP) to provide expertise and guidance to develop the plan and design for this project, including the development of the toolkits and the evaluation for which this data collection is designed. The multi-disciplinary TEP consists of individuals with knowledge and experience in MRSA prevention, HAI prevention, and change management and implementation in hospitals, surgical services, and LTC settings, as well as experts in neurosurgery, cardiac surgery, and orthopedic surgery. The first TEP meeting was held on May 3, 2021 and included a review of the data collection and analysis plans.

The TEP is providing critical feedback on all aspects of this program, including reviewing the proposed plan for the setting-specific toolkits and project approach, including the evaluation plan.

AHRQ has consulted with other Federal partners including CDC and CMS to ensure synergistic efforts are being undertaken and that there is no duplication of Federal initiatives.

9. Payments/Gifts to Respondents

No remuneration of respondents or participating units is planned.

10. Assurance of Confidentiality

Individuals 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. A statement of confidentiality will appear on the online and paper surveys and contain the following statement:

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

The data will be collected by AHRQ's subcontractor, NORC at the University of Chicago. All facility and respondent-level data, as well as survey response data, will be stored on NORC's secure servers.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The primary data collection activities are summarized in Exhibit A.1 and below. For the secondary data collection via NHSN, we assume no burden. After hospitals confer rights and join the MRSA Prevention Program group in NHSN, they will not need to take further action.

Exhibit A.1: Summary of Primary Data Collection Activities

Primary Data Collection Sources	Data Collection Tools	Target population	Data collection frequency
Surveys	AHRQ Surveys of Patient Safety Culture (HSOPS, NHSOPS)	Frontline staff at all participating sites • Estimated 25 staff per facility or unit • Estimate at least 75% of units within one facility	All cohorts: ▪ Once during month 1 of implementation ▪ Once during month 18 of implementation
Infrastructure Assessment Tool	Gap Analysis	Unit leader and Infection Preventionist (IP) at the participating sites • Estimated 2 staff per facility, unit or service	All cohorts: Once during month 1 of implementation Once during month 18 of implementation
Implementation Assessments	Team Checkup Tool	Frontline staff on CUSP teams • Estimated 1 staff per facility, unit or service	All cohorts: ▪ Conducted monthly over the over the course of the program from month 1 of the implementation to month 18
EHR extracts of unit-level data (unless conferring rights to NHSN data)	EHR extraction tool	Data coordinator at participating sites Estimated 1 staff per facility, unit or service	All cohorts: ▪ Conducted quarterly over the 18 month implementation period (monthly for LTC settings)

a. **Surveys of Patient Safety Culture (HSOPS or NHSOPS) (Attachments H and I).** The program will administer the AHRQ Surveys of Patient Safety Culture to eligible *AHRQ Safety Program for MRSA Prevention* staff at the participating units or facilities at the beginning and end of the implementation. The survey has separate versions adapted for hospital settings and LTC care settings:
    1. The Hospital Survey on Patient Safety (HSOPS) will be utilized to evaluate safety culture for ICU, Non-ICU and surgical sites.
    2. The Nursing Home Survey on Patient Safety (NHSOPS) will be administered in LTC facilities.

    Each survey asks questions about patient safety issues, medical error, and event reporting in the respective setting, and takes approximately 15 minutes to complete. For patient safety culture surveys, the program will reach out to all eligible providers and staff in accordance with the HSOPS and NHSOPS User's Guides. All eligible staff on the unit or facility that is implementing the *AHRQ Safety Program for MRSA Prevention* will be asked to complete the survey. As unit and facility size vary, the program estimates the average number of respondents to be 25 for each unit. Participating staff should have enough knowledge about the day-to-day activities in the unit or facility and interact regularly with other staff working in the unit or facility in order to provide informed answers. These staff, who spend all or most of their time at work within the unit or facility, may include the following:
        1. Staff who have direct contact or interaction with patients or residents;
        2. Staff who may not have direct contact or interaction with patients or residents but whose work directly affects patient or resident care;

b. **Gap Analysis (Attachments B, C, and D).** The unit or facility team lead and Infection Preventionist at each participating unit or facility will complete the Gap Analysis at the beginning and end of the implementation period for each of the four cohorts. For each administration of the tool, the Gap Analysis takes approximately one hour for both participants to complete.

c. Implementation assessments: Team Checkup Tool (Attachments E, F, and G). The program will use the Team Checkup Tool monthly throughout the program to monitor key actions of staff. The Tools ask about use of safety guidelines, tools, and resources throughout three different phases: Assessment (1), Planning, Training, and Implementation (2), and Sustainment (3). For each administration of this tool, the TCT takes approximately ten minutes to complete.

d. Clinical Outcomes Data of unit-level data (Attachment J, K, and L). For ICU, non-ICU, and surgical settings, unit-level clinical outcomes data will be extracted by each site's data coordinator quarterly to obtain clinical outcome measures not available via NHSN and to obtain all clinical outcome measures among hospitals that do not confer rights to their NHSN data to the program. Clinical outcome measures will be collected monthly for LTC settings. The clinical outcomes data collected will differ by ICU and non-ICU units, surgical units, and LTC settings.

ICU and non-ICU units

For the unit-level EHR extracts, the burden hours and costs for the initial data pull will vary based on hospital participation as follows:

1. About 10% of hospitals with units participating in the ICU and non-ICU cohorts are not expected to confer rights to the program to pull their NHSN data. For these hospitals, the extraction process for the initial data pull is estimated to take about 5 hours to extract the following clinical outcomes: hospital onset MRSA invasive infection – MRSA bacteremia LabID Day 3 or after of admission, patient days, Central-Line-Associated Blood Stream Infections with causative organism(s), central line days, and community onset MRSA invasive infection – MRSA bacteremia LabID prior to Day 3 after of admission.
2. All hospitals will provide two clinical outcome measures – hospital onset bacteremia (Day 3 or after of admission) with causative organisms (including MSSA) and MRSA-positive clinical cultures – via the EHR extract tool since these data are not available via NHSN. The extraction process for the initial data pull for these outcomes is an estimated 3.5 hours.
3. Participating hospitals that provide optional point prevalence data will also use the EHR extract tool. The extraction process for the initial data pull is approximately 30 minutes.

It is expected that the burden hours for the subsequent quarterly data pulls should reduce to 30 minutes through the duration of data collection, as IT members and unit leaders become more familiar with the data collection process.

Surgical services units

For the unit-level EHR extracts, the burden hours and costs are assumed for participating hospitals that do not confer rights to their NHSN data and, therefore, will provide all data via the EHR extract tool. About 20% of hospitals are not expected to confer rights to the program to pull their NHSN data for the clinical outcomes data collected in surgical units. These outcomes include surgical site infections with causative organisms and number of surgical procedures performed, by type of procedure. The extraction process for the initial data pull in surgical units is estimated to take 30 minutes and remain at 30 minutes for the subsequent quarterly data pulls.

LTC units

For the facility-level EHR extracts, the burden hours and costs are based on all clinical outcomes data in LTC settings obtained by EHR extracts. During the initial data pull for LTC settings, the extraction process is estimated to take about five hours. LTC facilities that do not have IT support or strong enough internet access to upload files will be offered a fax option to provide their data. It is expected that the burden hours for this effort should reduce to 30 minutes through the duration of data

collection, as IT members and unit leaders become more familiar with the data collection process.

Exhibit A.2 shows the total estimated annualized burden hours for the data collection efforts.

All data collection activities are expected to occur within the three-year clearance period. The total estimated annualized burden is 11,552 hours.

Exhibit A.2 Estimated annualized burden hours

Form Name	Number of Respondents +	Number of responses per respondent	Hours per response	Total Burden hours
Survey of Patient Safety Culture				
HSOPS (Attachment H) *(25 respondents per unit, pre- and post-implementation for ICU (400), non-ICU (400), and surgical (300) cohorts, 1,100 units total)*	9,167	2	0.25	4,584
NHSOPS (Attachment I) *(25 respondents per facility, one response per pre- and post-implementation for LTC cohort, 300 facilities total)*	2,500	2	0.25	1,250
Infrastructure Assessment				
Gap Analysis (Attachments B-D) *(1 assessment per unit or facility, pre and post-implementation for all four cohorts, 1,400 sites total)*	467	2	1	934
Implementation Assessments:				
Team Checkup Tool (Attachments E and F) *(1 checklist conducted monthly during the 18 months of implementation for ICU, non-ICU, and Surgical cohorts, 1,100 units total)*	367	18	0.17	1,123
Team Checkup Tool (Attachment G) *(1 checklist conducted monthly per facility during the 18 month*	100	18	0.17	306

implementation period for LTC cohort, 300 facilities total)				
Electronic Health Record (EHR) Extracts				
Initial data pull for 10% of hospitals that do not confer rights to their NHSN data (Attachment J)- (*once at baseline for ICU and non-ICU cohorts, 800 units total*)	27	1	5	135
Initial data pull for hospital onset bacteremia (including MSSA) and MRSA-positive clinical cultures (not available in NHSN) (Attachment J) (*once at baseline for ICU and non-ICU cohorts, 800 units total*)	267	1	3.5	935
Initial data pull for 10% of units that submit point prevalence survey data (Attachment J) (*once at baseline for ICU and non-ICU cohorts, 800 units total*)	27	1	0.5	14
Initial data pull for 20% of surgical units that do not confer rights to NHSN data (Attachment K)- (*once at baseline for Surgical cohort, 300 settings total*)	20	1	0.5	10
Initial data pull (Attachment L)- (*once at baseline for LTC cohort, 300 facilities total*)	100	1	5	500
Quarterly data collection of monthly data (Attachments J)- *(quarterly during 18 months of implementation for ICU and non-ICU, cohorts, 800 units total)*	267	6	0.5	801
Quarterly data collection of monthly data for 20% of hospitals that do not confer rights to their NHSN data (Attachment K) (*quarterly during 18*	20	6	0.5	60

months of implementation for surgical cohorts, 300 units total)				
Monthly data (Attachment L)- *(monthly per facility during 18 months of implementation for LTC cohort, 300 facilities total)*	100	18	0.5	900
Total	**13,429**			**11,552**

+ The number of respondents per data collection effort is calculated by multiplying the number of respondents per unit by the total number of units. The result is divided by three to capture an annualized number.

Exhibit A.3 shows the estimated annualized cost burden based on the respondents' time to complete the data collection activities. The total annualized cost burden is estimated to be $540,325.83.

Exhibit A.3 Estimated annualized cost burden

Form Name	Number of Respondents	Total Burden Hours	Average Hourly Wage Rate	Total Cost Burden
Survey of Patient Safety Culture				
HSOPS (Attachment H) *(25 respondents per unit, pre- and post-implementation for ICU (400), non-ICU (400), and surgical (300) cohorts, 1,100 units total)*	9,167	4,584	$51.53*	$236,187.76
NHSOPS (Attachment I) *(25 respondents per facility, one response per pre- and post-implementation for LTC cohort, 300 facilities total)*	2,500	1,250	$51.53*	$64,412.50
Infrastructure Assessment				
Gap Analysis (Attachments B-D) *(1 assessment per unit or facility, pre and post-implementation for all four cohorts, 1,400 sites total)*	467	934	$51.53*	$48,129.02
Implementation Assessments:				
Team Checkup Tool (Attachments E and F) *(1 checklist conducted monthly during 3 months of ramp-up and 15 months of implementation periods for ICU, non-ICU, and*	367	1,123	$51.53*	$57,868.19

Surgical cohorts, 1,100 units total)				
Team Checkup Tool (Attachment G) *(1 checklist conducted monthly per facility during 18 months of implementation for LTC cohort, 300 facilities total)*	100	306	$51.53*	$15,768.18
Electronic Health Record (EHR) Extracts				
Initial data pull for 10% of hospitals that do not confer rights to their NHSN data (Attachment J)- (*once at baseline for ICU and non-ICU cohorts, 800 units total*)	27	135	$35.17^	$4,747.95
Initial data pull for hospital onset bacteremia (including MSSA) and MRSA-positive clinical cultures (not available in NHSN) (Attachment J) (*once at baseline for ICU and non-ICU cohorts, 800 units total*)	267	935	$35.17^	$32,866.37
Initial data pull for 10% of units that submit point prevalence survey data (Attachment J) (*once at baseline for ICU and non-ICU cohorts, 800 units total*)	27	14	$35.17^	$474.80
Initial data pull for 20% of surgical settings that do not confer rights to NHSN data (Attachment K)- (*once at baseline for Surgical cohort, 300 settings total*)	20	10	$35.17^	$351.70
Initial data pull (Attachment L)- (*once at baseline for LTC cohort, 300 facilities total*)	100	500	$35.17^	$17,585.00
Quarterly data (Attachments J)- *(quarterly during 18 months of implementation for ICU and non-ICU cohorts, 1,100 units total)*	267	801	$35.17^	$28,171.17
Quarterly data collection of monthly data for 20% of hospitals that do not confer	20	60	$35.17^	$2,110.20

rights to their NHSN data (Attachment K) (*quarterly during 18 months of implementation for surgical cohorts, 300 units total*)				
Monthly data (Attachment L)- *(monthly per facility during 18 months of implementation for LTC cohort, 100 facilities total)*	100	900	$35.17^	$31,653.00
Total	**13,429**	**11,552**		**$540,325.83**

*This is an average of the average hourly wage rate for physician, nurse, nurse practitioner, physician's assistant, and nurse's aide from the May 2019 National Occupational Employment and Wage Estimates, United States, U.S. Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).
^This is an average of the average hourly wage rate for nurse and IT specialist from the May 2019 National Occupational Employment and Wage Estimates, United States, U.S. Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).

13. Estimates of Annualized Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the project.

14. Estimates of Total and Annualized Cost to the Government

Exhibit A.4a and Exhibit A.4b show the estimated annualized cost to the government for the contractors and government personnel. The cost is estimated to be $1,977,501 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 A.4.a Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$1,511,877	$503,959
Data Collection, Processing and Analysis	$3,186,877	$1,062,292
Project Management	$918,222	$306,074
Total	**$5,616,976**	**$1,872,325**

Exhibit A.4.b Federal Government Personnel Cost

Activity	Federal Personnel	Annual Salary	% of time	Cost
Management Support: GS-15, Step 5 average	2	163,345	25%	$81,673

Program Management Analysis: GS-13, Step 5 average	1	117,516	20%	$23,503
Total				**$105,176**

Annual salaries based on 2021 OPM Pay Schedule for Washington/DC area: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/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 V.** The exact start date for data collection activities is contingent on the OMB clearance date.

AHRQ will make the final toolkit publicly available on its website. Results of the project will be compiled in a final report and posted on the AHRQ website. Analyses and findings will also be submitted for publication in academic journals.

	Start Date	End Date
ICU and Non-ICU Cohorts		
ICU data collection	4/1/2022	10/1/2023
Non-ICU data collection	4/1/2022	10/1/2023
Final Interim Report		12/30/2022
Final *AHRQ Safety Program for MRSA Prevention* Toolkit		9/5/2024
Final Report		6/5/2024
Surgical Services Cohort		
Data collection	1/2/2023	7/2/2024
Final Interim Report		9/30/2023
Final *AHRQ Safety Program* for MRSA Prevention Toolkit		10/12/2025
Final Report		07/31/2025
LTC Facility Cohort		
Data collection	6/1/2023	12/30/2024
Final Interim Report		2/28/2024
Final *AHRQ Safety Program* for MRSA Prevention Toolkit		1/12/2026
Final Report		7/31/2025

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments

Attachment A: Federal Register Notice
Attachment B: ICU/Non-ICU Gap Analysis
Attachment C: Surgical Services Gap Analysis
Attachment D: LTC Gap Analysis
Attachment E: ICU/Non-ICU Team Checkup Tool
Attachment F: Surgical Services Team Checkup Tool
Attachment G: LTC Team Checkup Tool
Attachment H: Survey of Patient Safety Culture – HSOPS
Attachment I: Survey of Patient Safety Culture – NHSOPS
Attachment J: Clinical Outcomes Data for ICU/Non-ICU
Attachment K: Clinical Outcomes Data for Surgical Services
Attachment L: Clinical Outcomes Data for LTC
Attachment M: Completion Guide for ICU/Non-ICU Clinical Outcomes Data
Attachment N: Completion Guide for Surgical Services Clinical Outcomes Data
Attachment O: Completion Guide for LTC Clinical Outcomes Data
Attachment P: Schedule of Evaluation Activities

References

[1] Strausbaugh LJ, Joseph CL. (2000). The burden of infection in long-term care. *Infect Control Hosp Epidemiol*. 21(10):674-9.

[2] Klein E, Smith DL, Laxminarayan R. (2007). Hospitalizations and Deaths Caused by Methicillin-Resistant Staphylococcus aureus, United States, 1999–2005. *Emerging Infectious Diseases*, 13(12):1840-1846. doi:10.3201/eid1312.070629.

[3] Klevens RM, Morrison MA, Nadle J, et al. (2007). Invasive methicillin-resistant Staphylooccus aureus infections in the United States. *Journal of the American Medical Association*, 298(15): 1763-1771. doi: 10.1001/jama.298.15.1763.