SUPPORTING STATEMENT

Part A

The AHRQ Safety Program for Improving Antibiotic Use

Version: May 15, 2017

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

As part of the Department of Health and Human Services (DHHS) Hospital Acquired Infection (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) to increase antibiotic stewardship (defined as organized efforts to promote the judicious use of antibiotics) across all healthcare settings, AHRQ is applying the principles and concepts that have been learned from these HAI reduction efforts to antibiotic stewardship (AS).

Antibiotic therapy has saved countless lives over the past several decades.[1] However, bacterial resistance to antibiotics has followed closely on the heels of each new agent's introduction. This has led to an epidemic of antibiotic resistance, with drug choices for some bacterial infections becoming increasingly limited, expensive, and in some cases nonexistent. While antibiotics remain a vital and necessary cornerstone to the treatment of infections, it is estimated that 20-50% of all antibiotics prescribed in U.S. acute care hospitals are either unnecessary or inappropriate.[2,3,4,5,6,7] When antibiotics are used inappropriately, bacterial development of resistance is supported in the *absence* of any therapeutic benefit, and patients receiving unnecessary or inappropriate antibiotics are also exposed to the risk of adverse effects such as rash or renal injury as well as the risk of *Clostridium difficile* infection which can cause a deadly diarrhea.[8] Unlike misuse of other medications, the misuse of antibiotics can adversely impact the health of patients who are not even exposed to them because of the potential for spread of resistant organisms. The Centers for Disease Control and Prevention (CDC) estimates that each year at least two million illnesses and 23,000 deaths are caused by drug-resistant bacteria in the United States alone.[9]

While approaches including development of new antibiotic agents, increased surveillance for antibiotic resistance, prevention of HAIs, and prevention of transmission of resistant infections are important efforts to combat antibiotic resistance, it is critical to curb the inappropriate use of antibiotics to slow the emergence of antibiotic resistance and to preserve efficacy of existing antibiotics and those under development.

As of January 1st, 2017, The Joint Commission (TJC)'s new Antimicrobial Stewardship Standard requires that all acute care hospitals have robust antibiotic stewardship programs. In addition, starting on November 28, 2017, the Centers for Medicare & Medicaid Services (CMS) will require that all long-term care facilities that receive reimbursement from CMS have antibiotic stewardship programs in place.

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[1] Davies, J. and D. Davies, *Origins and evolution of antibiotic resistance.* Microbiol Mol Biol Rev, 2010. 74(3): p. 417-33.

[2] Camins, B.C., et al., *Impact of an antimicrobial utilization program on antimicrobial use at a large teaching hospital: a randomized controlled trial.* Infect Control Hosp Epidemiol, 2009. 30(10): p. 931-8.

[3] Dellit, T.H., et al., *Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship.* Clin Infect Dis, 2007. 44(2): p. 159-77.

[4] . Fridkin, S., et al., *Vital signs: improving antibiotic use among hospitalized patients.* MMWR Morb Mortal Wkly Rep, 2014. 63(9): p. 194-200.

[5] Ingram, P.R., et al., *Point-prevalence study of inappropriate antibiotic use at a tertiary Australian hospital.* Intern Med J, 2012. 42(6): p. 719-21.

[6] Levin, P.D., et al., *Antimicrobial use in the ICU: indications and accuracy—an observational trial.* J Hosp Med, 2012. 7(9): p. 672-8.

[7] Patel, S.J., et al., *Antibiotic use in neonatal intensive care units and adherence with Centers for Disease Control and Prevention 12 Step Campaign to Prevent Antimicrobial Resistance.* Pediatr Infect Dis J, 2009. 28(12): p. 1047-51.

[8] Hensgens, M.P., et al., *Time interval of increased risk for Clostridium difficile infection after exposure to antibiotics.* J Antimicrob Chemother, 2012. 67(3): p.742-8.

[9] Center for Disease Control and Prevention, N.C.f.E.a.Z.I.D. *Making Healthcare Safer: Stop Spread of Antibiotic Resistance*. CDC Vital Signs August 2015; Available from: http://www.cdc.gov/vitalsigns/pdf/2015-08-vitalsigns.pdf.

The Comprehensive Unit-Based Safety Program (CUSP), developed at the Armstrong Institute at Johns Hopkins University, combines improvement in patient safety culture, teamwork, and communication together with a technical bundle of interventions to improve patient safety. CUSP is a powerful culture change tool, which has been successfully utilized to reduce CLABSI in ICUs in Michigan and Rhode Island[10,11] and subsequently to reduce CLABSI by 41% in more than 1,000 ICUs in 44 states, Puerto Rico and the District of Columbia.[12] Although evidence-based recommendations for prevention of CLABSI had existed for years, the combination of safety culture change on units and implementation of technical interventions that resulted in significant reductions in CLABSI and introduced the concept that a rate of zero CLABSIs is achievable. CUSP is also being used to reduce other HAIs in multiple settings (http://www.ahrq.gov/professionals/quality-patient-safety/hais/index.html).

This project will assist hospitals, nursing homes, and ambulatory care sites across the United States in adopting and implementing antibiotic stewardship (AS) programs and interventions.

This project has the following goals:

- Identify best practices in the delivery of antibiotic stewardship in the acute care, long-term care and ambulatory care settings
- Adapt the Comprehensive Unit-Based Safety Program (CUSP) model to enhance antibiotic stewardship efforts in the health care settings
- Develop a bundle of technical and adaptive interventions and associated tools and educational materials designed to support enhanced antibiotic stewardship efforts
- Provide technical assistance and training to health care organizations nationwide (using a phased approach) to implement effective antibiotic stewardship programs and interventions
- Improve communication and teamwork between health care workers surrounding antibiotic decision-making
- Improve communication between health care workers and patients and families surrounding antibiotic decision-making
- Conduct a comprehensive evaluation to assess the adoption of the Comprehensive Unit-Based Safety Program (CUSP) for antibiotic stewardship (AS) in acute care, long-term care and ambulatory care settings to identify the effectiveness of the program, process outcomes, and lessons learned.

The project will be implemented in four cohorts; 1) Cohort 1 is a pilot limited to 10 facilities each in three integrated delivery systems spanning acute care, long-term care,

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[10] DePalo, V.A., et al., *The Rhode Island ICU collaborative: a model for reducing central line-associated bloodstream infection and ventilator-associated pneumonia statewide.* Qual Saf Health Care, 2010. 19(6): .p. 555-61

[11] Pronovost, P., et al., *An intervention to decrease catheter-related bloodstream infections in the ICU.* N .Engl J Med, 2006. 355(26): p. 2725-32

[12] Quality, A.f.H.R.a. *Eliminating CLABSI, A National Patient Safety Imperative: Final Report*. January 2013 [cited 2016 February 29]; Available from: http://www.ahrq.gov/professionals/quality-patient-safety/cusp/clabsi-final/index.html

and ambulatory settings; 2) Cohort 2 will expand to include 250-500 acute care hospitals; 3) Cohort 3 will include 250-500 long-term care facilities; and 4) Cohort 4 will include 250-500 ambulatory care facilities.

To achieve the goals of the *AHRQ Safety Program for Improving Antibiotic Use* project, the following data collections will be implemented:

1) Structural Assessments: A brief (five to seven questions), online Structural Assessment Tool will be administered in all settings (acute care, long-term care and ambulatory care) at baseline (pre-intervention) and at the end of the intervention period to obtain general information about facilities and existing stewardship infrastructure and changes in stewardship infrastructure and interventions as a result of the AHRQ Safety Program.

2) Team Antibiotic Review Form: The Stewardship Team in hospitals and nursing homes will conduct monthly reviews of at least 10 patients who received antibiotics and fill out an assessment tool in conjunction with frontline staff to determine if the "four moments of antibiotic decision-making" are being considered by providers. The four moments can be summarized as: 1) Is an infection present requiring antibiotics? 2) Are appropriate cultures being ordered and is the most optimal initial choice of antibiotics being prescribed? 3) (after at least 24 hours) Is it appropriate to make changes to the antibiotic regimen (e.g., stop therapy, narrow therapy, change from intravenous to oral therapy)? 4) What duration of therapy is appropriate?

3) The AHRQ Surveys on Patient Safety Culture: The surveys will be administered to all participating staff at the beginning and end of the intervention. Each survey asks questions about patient safety issues, medical errors, and event reporting in the respective settings.
    a. The *Hospital Survey on Patient Safety Culture (HSOPS)* will be utilized to evaluate safety culture for acute care hospitals.
    b. The *Nursing Home Survey on Patient Safety Culture (NHSOPS)* will be administered in long-term care.
    c. The *Medical Office Survey on Patient Safety Culture (MOSOPS)* will be administered in ambulatory care centers.

4) Semi-structured qualitative interviews: During the project pilot period with Cohort 1, in-person and/or telephone discussions will be held before and after implementation with stewardship champions/organizational leaders, physicians, pharmacists, nurse practitioners, physician assistants, nurses, certified nursing assistants and others deemed relevant, to learn about the facilitators and barriers to a successful antibiotic stewardship program. Specific areas of interest include stakeholder perceptions of implementation process and outcomes, including successes and challenges with carrying out project tasks and perceived utility of the project; staff roles, engagement and support; and antibiotic prescribing etiquette & culture (i.e., social norms and local cultural factors that contribute to prescribing behavior at the facility/unit-level).

5) Electronic Health Record (EHR) data: Unit-level antibiotic usage and clinical outcomes will be extracted from the EHRs of participating healthcare facilities and used to assess the impact of the *AHRQ Safety Program for Improving Antibiotic Use*.

The project is being conducted by AHRQ through its contractors, Johns Hopkins University (JHU) and JHU's subcontractor, NORC at the University of Chicago. The *AHRQ Safety Program for Improving Antibiotic Use* 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 Comprehensive Unit-Based Safety Program (CUSP) for antibiotic stewardship (AS) in acute care, long-term care and ambulatory care settings; measure the effectiveness of the interventions in the participating facilities or units; evaluate the characteristics of teams that are associated with successful implementation and improvements in outcomes; and understand drivers of antibiotic prescribing.

The evaluation is largely formative in nature as AHRQ seeks information on the implementation and effectiveness of the CUSP for antibiotic stewardship program. The evaluation will utilize a pre-post design, comparing data from each of the three facility settings (acute care, long-term care, and ambulatory care).

1) Structural Assessments: The structural assessment will be administered to the *AHRQ Safety Program for Improving Antibiotic Use* antibiotic stewardship physician, pharmacist or nurse lead in all three facility settings. The assessment will be administered at baseline (pre-intervention) and at the end of the intervention. The data will provide information about the facilities, their existing stewardship infrastructure and capacity to carry out the program, as well as changes in the stewardship infrastructure as a result of the implementation of the antibiotic stewardship program. Data from the pre- and post-intervention time points will be analyzed to assess the extent to which the program had an impact on antibiotic stewardship infrastructure in the participating facilities. **Attachments A, B, and C** contain the Structural Assessment forms for all three facility settings.

2) Team Antibiotic Review Form: A representative from the Antibiotic Stewardship Teams in hospitals and nursing homes will complete a monthly Team Antibiotic Review Form for patients who are prescribed antibiotics during the intervention period (at least 10 cases per month during the intervention period). The assessment tool is designed to help determine if the CUSP "four moments of antibiotic decision-making" are being considered by providers. The four moments can be summarized as:

The four moments can be summarized as: 1) Is an infection present requiring antibiotics? 2) Are appropriate cultures being ordered and is the most optimal initial choice of antibiotics being prescribed? 3) (after at least 24 hours) Is it appropriate to make changes to the antibiotic regimen (e.g., stop therapy, narrow therapy, change from intravenous to oral therapy)? 4) What duration of therapy is appropriate?

3) The data from the assessments will provide a more detailed understanding of whether the intervention is associated with improved antibiotic decision making by participating clinicians. **Attachment D** contains the Team Antibiotic Review Form; **Attachment E** contains the Completion Guide for the Team Antibiotic Review Form.

4) The AHRQ Surveys on Patient Safety Culture: The surveys will be administered to all *AHRQ Safety Program for Improving Antibiotic Use* participating staff at baseline (pre-intervention) and end of the intervention. The surveys are adapted for the three types of health care settings. The surveys collect information on patient safety issues, unit culture, medical errors, and event reporting. The data will assess the changes in safety culture resulting from implementation of the program. The questionnaires are contained in **Attachments F through H**.
    a. The *Hospital Survey on Patient Safety Culture (HSOPS)* will be utilized to evaluate safety culture for acute care hospitals.
    b. The *Nursing Home Survey on Patient Safety Culture (NHSOPS)* will be administered in long term care.
    c. The *Medical Office Survey on Patient Safety Culture (MOSOPS)* will be administered in ambulatory care centers.

5) Semi-structured qualitative interviews: During the Cohort 1 pilot, in-person and/or telephone discussions will be administered before and after implementation with stewardship champions/organizational leaders, physicians, pharmacists, nurse practitioners, physician assistants, nurses, certified nursing assistants and others deemed relevant to prescribing by setting. The qualitative data collected will help AHRQ understand the characteristics of teams associated with successful implementation and improvements in outcomes, barriers to a successful implementation of an antibiotic stewardship program, and understand drivers of antibiotic prescribing. The data collected will be used to improve the implementation and intervention approaches in later expanded cohorts in each of the settings—acute care, long-term care, and ambulatory care. **Attachments I and J** contain the draft interview guides for the Antibiotic Stewardship Leads and frontline healthcare workers.

6) Electronic Health Record (EHR) data: Every month starting in the baseline (pre-intervention) period until the end of the intervention, each participating facility will extract clinical measures data from their EHR system. The clinical measures will evaluate the changes in antibiotic usage, clinical outcomes, and other effectiveness measures resulting from the *AHRQ Safety Program for Improving Antibiotic Use*. The clinical measures template is contained in **Attachment K** and the instructions for the clinical measures extraction is contained in **Attachment L.**

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 Structural Assessments, Team Antibiotic Review Form, and AHRQ Surveys on Patient Safety Culture Patient Safety will be web-based and deployed using a well-designed, low burden, and respondent-friendly survey administration process and instruments. In addition, the EHR data will be extracted by facility staff from their electronic systems. The EHR data requested for this project may already be collected by hospitals as part of their ongoing quality improvement initiatives.

Facility respondents will receive access to the online data collection platform and detailed instructions on completing the online forms and EHR data submissions (see **Attachment M:** *AHRQ Safety Program for Improving Antibiotic Use* Data Collection Frequently Asked Questions and Timeline for Data Collection and Submission).

4. Efforts to Identify Duplication

AHRQ is aware of two other national patient safety and antibiotic stewardship (AS) efforts underway in acute care hospitals across the United States, and is working to identify potential opportunities for the *AHRQ Safety Program for Improving Antibiotic Use* 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 *C. difficile* (CDI) infections. 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. The HIINs initiative tasks include implementing and strengthening hospitals' prevention of CDI efforts. The HIINs will evaluate their CDI reduction efforts according to their personalized CDI reduction plans, and CMS has recommended that they use the evaluation measures recommended by the CDC's Core Elements of Hospital Antibiotic Stewardship Programs (ASPs).

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 the Health Research & Educational Trust (HRET) of the American Hospital Association 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 CDI, CLABSI, CAUTI and MRSA. STRIVE is a one-year program that begins in April 2017 and ends in June 2018.

AHRQ has engaged with CMS to explore possible collaboration and with the HIINs to familiarize them with the *AHRQ Safety Program for Improving Antibiotic Use* and identify strategies on how best to coordinate efforts to avoid duplication. Additionally,

AHRQ will engage with CDC and HRET STRIVE leadership to explore the potential to coordinate educational tools and resources. The *AHRQ Safety Program on Improving Antibiotic Use* can synergize with and compliment these existing national incentives. The *AHRQ Safety Program* provides extensive technical and adaptive tools and approaches to improving antibiotic use for both antibiotic stewardship teams and frontline providers. For facilities and practices that do not have stewardship programs, it provides details on how to develop an effective and sustainable stewardship program. In addition, it engages frontline providers to take ownership of improving their antibiotic prescribing and in effect teaches them to become their own stewards. Through engaging webinars and e-learning modules, participants will learn how to optimize their existing resources to develop local antibiotic prescribing guidelines, incorporate antibiotic-decision tools into their daily practice, and form multidisciplinary teams focused on a common goal of improving antibiotic use. Furthermore, the program is not limited only to the acute care setting, but also includes long-term care and ambulatory settings.

5. Involvement of Small Entities

The information collected may involve small entities, as some of the participating acute care, ambulatory care, and long term care 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 CUSP for antibiotic stewardship in acute care, long-term care and ambulatory care settings; measure the effectiveness of the *AHRQ Safety Program for Improving Antibiotic Use* interventions in the participating facilities; and evaluate the characteristics of teams and senior leaders that are associated with successful implementation and improvements in outcomes. The planned frequency of data collection is necessary to accurately assess the adoption and effectiveness of the program.

The Structural Assessments will be administered at baseline (pre-intervention) and at the end of the intervention to measure the extent to which the program was adopted by the participating facilities.

The Team Antibiotic Review Form will be collected on a sample of patients monthly during the intervention in the acute and long-term care settings to provide a more detailed understanding of the use of antibiotics being prescribed and provide to clinicians the opportunity to assess antibiotic use in the unit.

The AHRQ Surveys on Patient Safety Culture will be collected at the baseline (pre-intervention) and end of the intervention to measure the changes in safety culture resulting from implementation of the program.

The semi-structured interviews will be conducted for the pilot period only before and after implementation to collect qualitative information on the pilot implementation of the program.

The Electronic Health Record (EHR) data will be collected every month starting in the baseline (pre-intervention) period until the end of the intervention to measure changes in antibiotic usage, clinical outcomes, and other effectiveness measures resulting from the *AHRQ Safety Program for Improving Antibiotic Use*.

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 May 5th, 2017 on page 21233 for 60 days (see **Attachment *N***).

8.b. Outside Consultations

The JHU and NORC team have consulted with a technical expert panel (TEP) to provide expertise and guidance to develop the plan and design for this project, and each phase, including the development of the antibiotic stewardship program and toolkit, and evaluation for which this data collection is designed. The TEP consists of individuals with knowledge and experience in antibiotic stewardship, including knowledge of application of antibiotic stewardship to each of the settings: hospital, long-term care, and ambulatory settings, and also in integrated systems (see **Attachment O** for list of TEP members). The first TEP meeting was held in-person on January 12, 2017. The second TEP meeting, which will take place via phone and web, is scheduled for May 9, 2017.

The TEP is tasked with providing critical feedback on all aspects of this program, including reviewing the evidence review report, providing expert input on the essentials of antibiotic stewardship and the information most appropriate to include in the educational toolkits for each setting, and measures to assess the effectiveness of the program. The TEP provided feedback regarding data collection for the *AHRQ Safety Program for Improving Antibiotic Use*. TEP members recommended evaluation measures and practices that would reduce the burden on participating facilities; for example, they suggested administering the HSOPS for a participating unit rather than an entire hospital in the acute care setting, which was incorporated into the evaluation plan.

AHRQ has consulted with other federal partners including CMS and the CDC to ensure synergistic efforts across the AS 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 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 survey 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 contractor, 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

Exhibit A.1 shows the estimated annualized burden hours for the respondents' time to complete the Structural Assessments, Team Antibiotic Review Forms, AHRQ Patient Safety Culture Surveys, semi-structured qualitative interviews, and EHR data extractions. Data will be collected from 30 acute care, long-term care, and ambulatory care sites during the Cohort 1 one-year pilot period; up to 500 acute care hospitals in Cohort 2; up to 500 long-term care facilities in Cohort 3; and up to 500 ambulatory care sites in Cohort 4. For Cohort 4, the data collection activities that are expected to occur within this three-year clearance period are in the baseline (pre-intervention) period. For the three-year clearance period, the estimated annualized burden hours for the data collection activities are 22,441.

Exhibit A.1 Estimated annualized burden hours

Form Name	Number of Respondents	Number of responses per respondent	Hours per response	Total Burden hours
1. Structural Assessments:				
a. Structural Assessments – Cohorts 1, 2 and 3 (baseline, post-intervention)	343	2	0.2	137
b. Structural Assessments – Cohort 4 (baseline)	167	1	0.2	33
2. Team Antibiotic Review Form (Cohorts 1, 2, and 3)	337	90	0.25	7,583

3. AHRQ Patient Safety Culture Surveys:				
a. HSOPS, NHSOPS, MOSOPS (Cohort 1)	83	2	0.5	83
b. HSOPS (Cohort 2)	4,167	2	0.5	4,167
c. NHSOPS (Cohort 3)	4,167	2	0.5	4,167
d. MOSOPS (Cohort 4)	4,167	1	0.5	2,083
4. Semi-structured qualitative interviews (Cohort 1): a. Physicians	30	2	1	60
b. Other Health Practitioners	60	2	1	120
5. EHR data (Cohorts 1, 2, and 3)	334	12	1	4,008
Total	**13,855**			**22,441**

Exhibit A.2 shows the estimated annualized cost burden based on the respondents' time to complete the data collection forms. The total cost burden is estimated to be $1,179,360.

Exhibit A.2 Estimated annualized cost burden

Form Name	Number of Respondents	Total Burden hours	Average Hourly Wage Rate*	Total Cost Burden
1. Structural Assessments:				
a. Structural Assessments – Cohorts 1, 2 and 3 (baseline, post-intervention)	343	137	$98.83[a]	$13,540
b. Structural Assessments – Cohort 4 (baseline)	167	33	$98.83[a]	$3,261
2. Team Antibiotic Review Form (Cohorts 1, 2, and 3)	337	7,583	$98.83[a]	$749,428
3. AHRQ Patient Safety Culture Surveys:				
a. HSOPS, NHSOPS, MOSOPS (Cohort 1)	83	83	$27.87[b]	$2,313
b. HSOPS (Cohort 2)	4,167	4,167	$27.87[b]	$116,134
c. NHSOPS (Cohort 3)	4,167	4,167	$27.87[b]	$116,134
d. MOSOPS (Cohort 4)	4,167	2,083	$27.87[b]	$58,053
4. Semi-structured qualitative interviews (Cohort 1): a. Physicians	30	60	$98.83[a]	$5,930
b. Other Health Practitioners	60	120	$27.87[b]	$3,344
5. EHR data (Cohorts 1, 2, and 3)	334	4,008	$27.87[b]	703
Total	**13,855**	**22,441**		**$1,189,114**

*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 *29-1069 Physicians and Surgeons, All Other*

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

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.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 $1,983,765 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.3.a Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$1,335,385	$445,128
Data Collection, Processing and Analysis	$2,683,392	$894,464
Project Management	$475,530	$158,510
Overhead	$1,745,456	$485,663
Total	**$6,239,763**	**$1,983,765**

Exhibit A.3.b 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
Program Management Analysis: GS-13, Step 5 average	1	107,435	20%	$21,487
Total				**$96,156**

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

Note that these oversight costs are included in "Overhead" in Exhibit A3a.

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 P.** 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: Structural Assessment for Acute Care Setting
Attachment B Structural Assessment for Ambulatory Care Setting
Attachment C: Structural Assessment for Long Term Care Setting
Attachment D: Team Antibiotic Review Form
Attachment E: Completion Guide for Team Antibiotic Review Form
Attachment F: The Hospital Survey on Patient Safety Culture (HSOPS)
Attachment G: The Nursing Home Survey on Patient Safety Culture (NHSOPS)
Attachment H: The Medical Office Survey on Patient Safety Culture (MOSOPS)
Attachment I: Draft Interview Guide for Semi-Structured Interviews – Antibiotic Stewardship Leads
Attachment J: Draft Interview Guide for Semi-Structured Interviews – Frontline workers
Attachment K: Clinical measures template for EHR data extracts
Attachment L: Instructions for Clinical measures template for EHR data extracts
Attachment M: *AHRQ Safety Program for Improving Antibiotic Use* Data Collection Frequently Asked Questions and Timeline for Data Collection and Submission
Attachment N: Federal Register Notice
Attachment O: Technical Expert Panel Members
Attachment P: *AHRQ Safety Program for Improving Antibiotic Use*: Schedule of evaluation activities, 2017-2021