PREVENT HAIs Healthcare-Associated Infections

AHRQ Safety Program for Improving Antibiotic Use

Final Report

Agency for Healthcare Research and Quality

CUSP

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Final Report

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INTRODUCTION

This final report is intended to provide a summary of the AHRQ Safety Program for Improving Antibiotic Use ("Safety Program"), which was led by members of Johns Hopkins Medicine (JHM) and NORC at the University of Chicago and implemented in three cohorts—acute care hospitals, long-term care facilities, and ambulatory care practices—between 2016 and 2022. The purpose of this project was to develop and implement the Safety Program and assess its impact on patient safety culture and antibiotic prescribing practices across a total of 1,304 participating sites throughout the United States, including 476 units from 402 acute care hospitals, 439 long-term care facilities, and 389 ambulatory care centers. This work was accomplished through three aims: (1) develop or enhance antibiotic stewardship programs (ASPs) among participating sites, (2) develop a culture of safety around antibiotic prescribing, and (3) promote evidence-based practices and informed decision making around antibiotic prescribing for common infectious diseases syndromes by frontline providers. At the end of each intervention, a toolkit was developed that contained materials developed for each cohort as well as additional information to allow sites that did not participate to recreate the Safety Program at their own facilities.

The report begins with an overview of the Safety Program, including its key elements and associated educational activities used to engage frontline providers and to promote patient safety culture around appropriate antibiotic prescribing practices, followed by a description of results from each cohort, and then a discussion of limitations, lessons learned, and efforts to support sustainability across sites. Detailed reports for each cohort[1] as well as the setting-specific toolkits[2,3] and implementation guides are publicly available as well on the AHRQ Antibiotic Stewardship Toolkits web page.

BACKGROUND

Since their discovery, antibiotics have dramatically reduced morbidity and mortality from bacterial infections. However, misuse of antibiotics has led to avoidable harm such as emergence of antibiotic resistance, development of antibiotic-associated adverse events, and an increased risk of *Clostridioides difficile* (*C. difficile*) infection.[4–6] Recent data from the Centers for Disease Control and Prevention (CDC) estimates there are more than 28 million antibiotic-resistant infections in the United States each year resulting in more than 35,000 deaths.[5] Antibiotic resistance is associated with increased healthcare costs and delayed recovery among patients resistant to initial treatment.[5] Twenty-five percent of patients

who receive antibiotics in the hospital will develop an antibiotic-associated adverse event, many of which lead to additional testing and prolong hospitalization.[7,8] Exposure to antibiotics is the greatest risk factor for *C. difficile* infection, which can cause significant morbidity and mortality.[9,10]

To address concerns about inappropriate antibiotic use and its consequences, the CDC has recommended ASPs be established across all healthcare settings to improve practices and safety around appropriate prescribing.[11–14] The Joint Commission has standards that mandate ASPs in hospitals, long-term care facilities, and ambulatory practices in order to receive accreditation, and the Centers for Medicare & Medicaid Services requires ASPs in hospitals and long-term care facilities as a Condition of Participation.[15,16] However, establishing ASPs is often not enough to achieve sustainable improvement in antibiotic use. This may be due to staffing limitations such as lack of access to physicians and pharmacists with infectious diseases or antibiotic stewardship experience, inadequate time by such individuals devoted to antibiotic stewardship, the expected inability of a stewardship team to intervene on all patients receiving antibiotics, lack of knowledge of or interest in understanding up-to-date best practices in antibiotic prescribing by front-line providers, or communication failures about antibiotic decision making between providers and patients and their families. The Safety Program sought to address these issues via the three goals stated in the first paragraph, with an overall focus on implementation of robust stewardship activities and engagement of front-line providers across the healthcare spectrum.

In addition to establishing or enhancing AS activities among participating sites, the Safety Program applied Comprehensive Unit-Based Safety Program (CUSP) methodology, which is based on the premise that given the support and resources they need to succeed, staff will be empowered to engage in patient safety principles, will become more aware of their actions, and will be more likely to approach patient safety as a team and work together to reduce errors and improve the quality of care patients receive.[17] The Safety Program was specifically designed to improve antibiotic stewardship by increasing patient safety knowledge, improving culture around patient safety in the workplace through teamwork and communication, and fostering evidence-based decision making to ensure the initiation, type, and duration of antibiotics is most appropriate for each patient.

Safety Program Team

The Safety Program was led by JHM/NORC, with guidance from AHRQ and a Technical Expert Panel (TEP). **Exhibit 1** describes the respective roles of each group in the design, implementation, and

evaluation of the Safety Program. JHM faculty developed and delivered educational materials and webinar content while NORC facilitated the planning and implementation of the project, including recruitment and enrollment of sites. The TEP consisted of 27 subject-matter experts across disciplines with knowledge of AS in acute, long-term care, and ambulatory settings; they provided feedback on the design, content, and implementation of the Safety Program. To further support participating sites, JHM/NORC partnered with three Quality Improvement Networks/Quality Improvement Organizations: Health Quality Innovators, Health Services Advisory Group, and Stratis Health, who served in the role of Implementation Advisers. Implementation Advisers had direct contact with all participating sites, at least monthly, to assess progress and assist with identifying and solving barriers to implementation.

EXHIBIT 1: NATIONAL PROJECT TEAM AND PARTNERS

Organization	Role
Johns Hopkins Medicine (JHM)	JHM faculty led development of the Safety Program's educational toolkit and were responsible for leading all webinars and office hours, assisting participating sites with stewardship and clinical questions that arose over the course of the Safety Program, with overall Safety Program management, and with budget oversight.
NORC at the University of Chicago	NORC led recruitment of the acute care hospitals, long-term care facilities, and ambulatory care practices; onboarded participating sites in each cohort; and supported a range of implementation activities, including hosting the webinars and office hours; developing and hosting the program website; analyzing data from participating sites; and conducting the program evaluation.
Technical Expert Panel (TEP)	The TEP was composed of physicians, pharmacists, nurse practitioners, representatives from integrated healthcare delivery systems, representatives from patient advocacy groups, and *ex officio* members of government agencies. The panel provided guidance on program content, implementation, and evaluation during six meetings over the project period.
Implementation Advisers	Three quality improvement organizations—Health Quality Innovators, Health Services Advisory Group, and Stratis Health—served as Implementation Adviser organizations. Staff from each organization provided one-on-one support to participating sites and were responsible for assisting designated hospitals, facilities, or practices in each cohort with program implementation.

Pilot Period

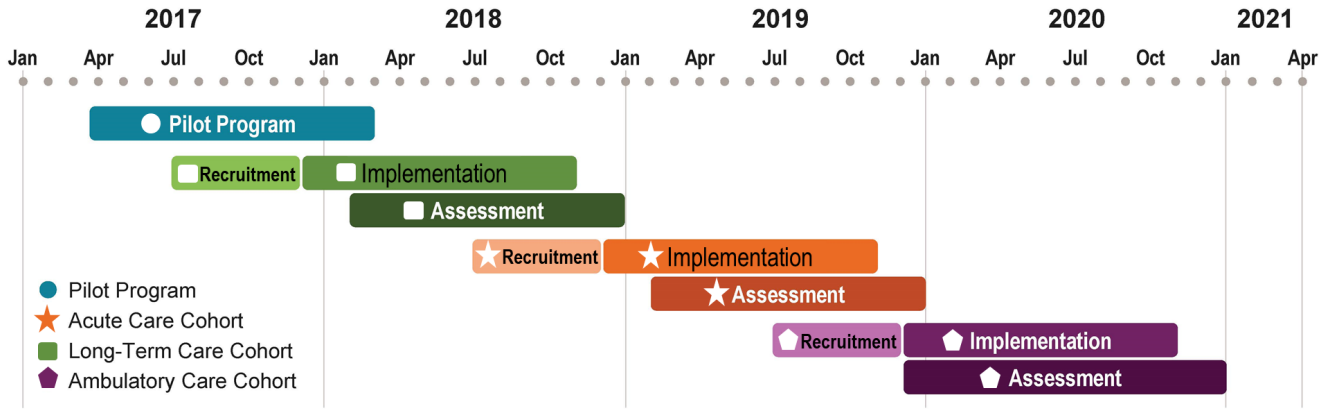
Prior to the formal program launch, a pilot period allowed for the generation and refinement of Safety Program materials and approach as well as testing of the Safety Program website. The pilot was initiated

in April 2017 among three Integrated Healthcare Delivery Systems: Geisinger Health System (Pennsylvania), Johns Hopkins Health System (Maryland), and Atrium Health[a] (North Carolina and South Carolina). From these health systems, 14 acute care hospitals, 7 long-term care facilities, and 9 ambulatory care practices participated. Over the course of a year, JHM/NORC obtained feedback from participating sites and the TEP, which led to several program additions and refinements including: revisions and additions to the education material, addition of more days and times live webinars were held to increase attendance, addition of office hours where sites could informally ask questions and discuss implementation challenges, revisions to the data collection template to reduce staff burden, revisions to the Safety Program outcomes to be more clearly defined, and addition of optional continuing medical education (CME), continuing education (CE), and continuing professional education credits for participating physicians, pharmacists, and nurses, respectively, to encourage participation.

SAFETY PROGRAM IMPLEMENTATION AND EVALUATION

The Safety Program was implemented in an acute care cohort in 2018, a long-term care cohort in 2019, and an ambulatory cohort in 2020 (**Exhibit 2**).

EXHIBIT 2: TIMELINE OF SAFETY PROGRAM



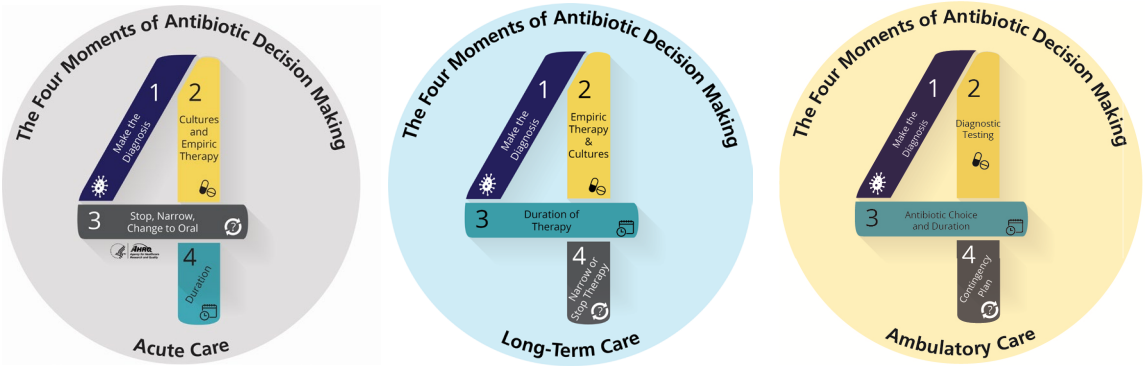
Although the general content and implementation approach was the same across cohorts, materials were tailored to meet the specific needs of each cohort. The next section provides an overview of the educational program and the Four Moments of Antibiotic Decision Making Framework. This is followed by a detailed description of the implementation activities, evaluation methods and measures, and key findings for each cohort.

[a] Formerly known as Carolinas HealthCare System

Educational Program and the Four Moments of Antibiotic Decision-Making Framework

The educational program for all three cohorts included the use of live (and recorded) webinars, office hours, narrated presentations, one-page documents and pocket guides (for quick access to diagnosis, management, treatment), commitment posters, patient handouts (ambulatory cohort only), and other tools. The live webinar series addressed aspects of development and sustainability of AS activities, cultural and behavioral drivers of antibiotic decision making, and reviews of best practices in the diagnosis and treatment of patients presenting with common infections. The presentations on management of common infectious diseases were organized according to the Four Moments of Antibiotic Decision Making Framework (**Exhibit 3**). The educational materials and the Four Moments of Antibiotic Decision Making were tailored to each practice setting. The goal of the Four Moments was to provide a framework for antibiotic decision making that could be followed for all patients receiving antibiotics to ensure optimal prescribing decisions. The Four Moments prompted prescribers to consider whether antibiotics were indicated, the best empiric antibiotic choices if they were indicated, the need for additional testing such as cultures, evaluation of the patient after the antibiotics are started, and appropriate durations of therapy.

EXHIBIT 3: THE FOUR MOMENTS OF ANTIBIOTIC DECISION MAKING



The remainder of the report includes a detailed description of each cohort including recruitment and retention strategies, implementation activities designed by Safety Program goal, and Safety Program metrics. The report concludes with a discussion of findings across the cohorts as well as recognized limitations, lessons learned, and implications for future antibiotic stewardship approaches and activities.

Cohort 1: Acute Care Cohort

Recruitment and Retention

Recruitment activities began in June 2017, enrolling sites through November 2017. During that time several webinars were held to provide interested sites with an overview of the Safety Program and the benefits of participation. Academic medical centers, community hospitals, critical access hospitals, Indian Health Service hospitals, military and U.S. Department of Veterans Affairs hospitals, and inpatient psychiatric facilities were among those recruited for enrollment. The acute care cohort consisted of 476 units from 402 acute care hospitals across 10 U.S. Department of Health and Human Services (HHS) regions (**Exhibit 4**). Forty percent of sites had fewer than 100 beds and 25 percent had 300 or more beds.

EXHIBIT 4: ACUTE CARE FACILITY PARTICIPATION BY STATE

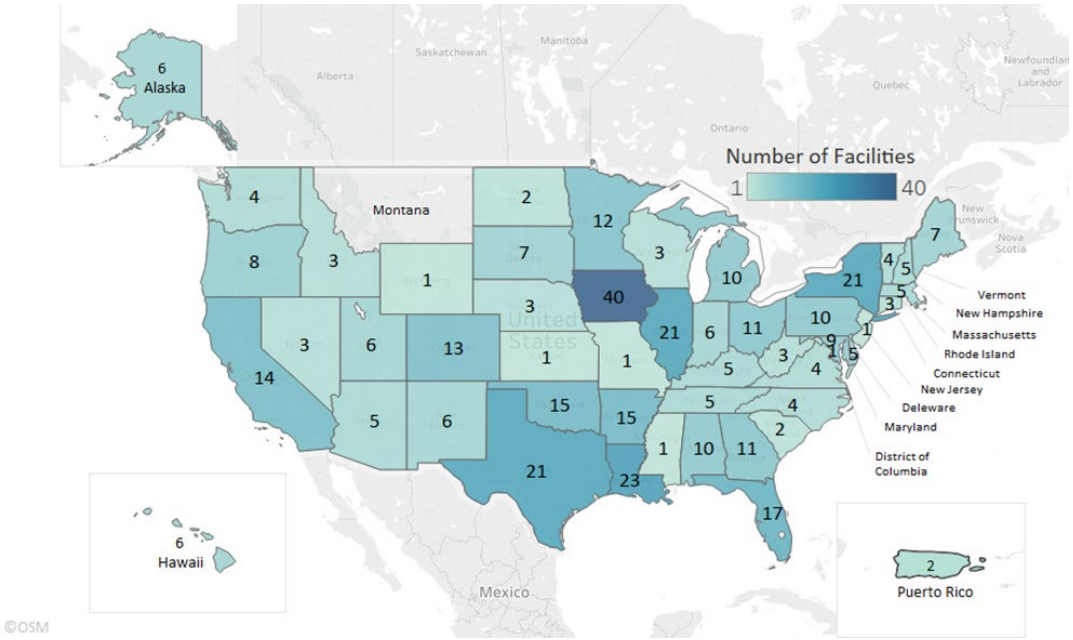
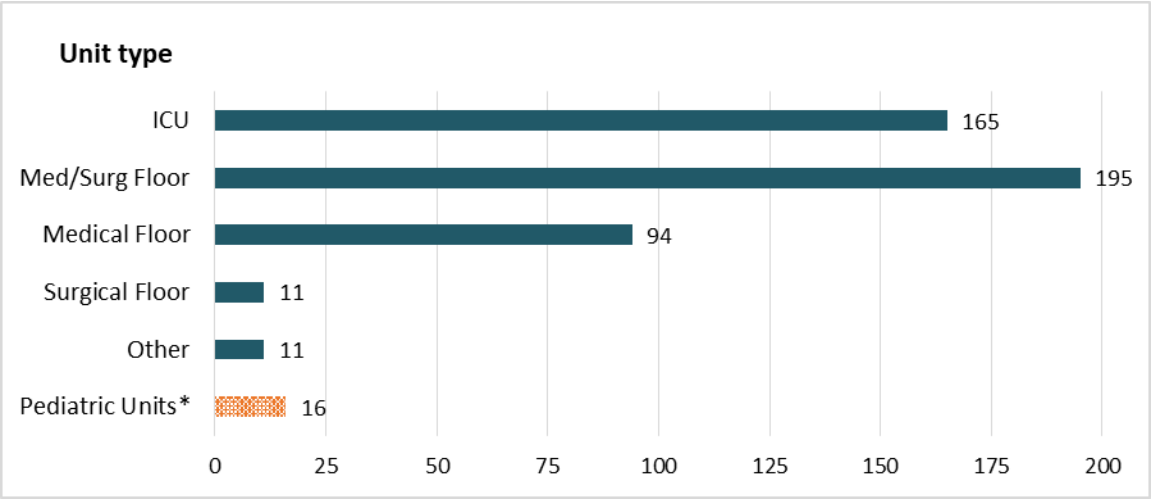


Exhibit 5 provides frequencies of participating sites by unit type.

EXHIBIT 5: ACUTE CARE FACILITY PARTICIPATION BY UNIT TYPE



*There were 16 pediatric units, including 6 ICUs, 9 medical/surgical floors, and 1 other type

Retention of hospitals in the cohort remained high; 402 of the 437 hospitals (92 percent) enrolled in the program remained in the cohort for the duration of the Safety Program. Factors associated with high retention likely include high satisfaction with the webinars and office hours, provision of CME and CE credit to participating physicians and pharmacists, at least monthly direct interaction between each site and the site's assigned Implementation Adviser to promote engagement and address barriers, and involvement of the JHM team if sites were having content-specific issues.

Implementation Activities

Implementation activities began in December 2017 and were centered around the Safety Program's three goals. A description of activities and strategies used to achieve each goal are described below.

Development or enhancement of ASPs. Acute care hospitals with no existing ASP were encouraged to establish an ASP team, including identification of a leader to assist with oversight, implementation, and sustainability of the ASP. The ASP team was encouraged to do the following: establish relationships and open channels of communication with frontline providers and other relevant staff; develop local guidelines aligned with appropriate antibiotic prescribing practices; establish an AS committee including identifying members for inclusion; discuss relevant ASP metrics aligned with the ASP's goals; and assess improvements and to encourage accountability among providers. A series of four live webinars (also recorded) provided further guidance and examples of how to develop or enhance ASPs in acute care settings, including techniques for sustainability.

Changes to patient safety culture. Several webinars conveyed key principles of patient safety culture including recognition that AS is a patient safety issue; identification of relevant ASP targets for improvement; learning from adverse events associated with inappropriate prescribing practices; and improving communication and teamwork among providers, ASP leadership, and patients/caregivers. Commitment posters were developed for providers and units to indicate their pledge to prescribe antibiotics only when indicated.

Implementation of best practices in the management of patients with common infectious diseases.

Best practices for the evaluation and management of hospitalized patients presenting with common infections were presented in a series of eight webinars focusing on the following syndromes: asymptomatic bacteriuria and urinary tract infections (UTIs); community-associated lower respiratory tract infections including: community-associated pneumonia, chronic obstructive pulmonary disease, aspiration events and aspiration pneumonia; ventilator-assisted pneumonia and hospital-acquired pneumonia; cellulitis and skin/soft tissue abscesses; diverticulitis and biliary tract infections; *C. difficile* infections; sepsis; and bacteremia. One-page documents for the majority of these topics were developed to provide a quick reference to healthcare practitioners about best practices; sites were instructed to revise them according to local epidemiology, patient populations, and formularies. In addition, these documents could form the basis of local diagnostic and treatment guidelines or could be displayed in common work areas. The presentations and one-page documents were organized according to the Four Moments of Antibiotic Decision Making for Acute Care (**Exhibit 6**).

EXHIBIT 6: THE FOUR MOMENTS OF ANTIBIOTIC DECISION MAKING FOR ACUTE CARE COHORT

1. Does my patient have an infection that requires antibiotics?
2. Have I ordered appropriate cultures before starting antibiotics? What empiric therapy should I initiate?
3. A day or more has passed. Can I stop antibiotics? Can I narrow therapy or change from intravenous to oral therapy?
4. What duration of antibiotic therapy is needed for my patient's diagnosis?

Team Antibiotic Review Forms (TARFs) were developed to encourage review of antibiotic decision making using the Four Moments of Antibiotic Decision Making Framework. ASPs were asked to visit the participating units and complete 10 forms per month during the intervention in conjunction with the

frontline providers and teams to encourage engagement of frontline staff. Sites were requested to submit a minimum of 10 completed TARFs each month as part of participation in the Safety Program. Office hours were also held throughout the intervention to facilitate peer-to-peer discussions and provided sites the opportunity to ask the JHM team questions or to share implementation challenges.

Evaluation Methods and Measures

A baseline period was established from January to February 2018 during which sites completed the Structural Assessment and AHRQ Hospital Survey on Patient Safety (HSOPS) and began monthly reporting of antibiotic use and quarterly reporting of *C. difficile* LabID events. During the intervention period from March 2018 to December 2018, teams continued to report antibiotic use and *C. difficile* LabID events and submitted TARFs. During the endline period, from November through December 2018, sites completed the Structural Assessment and HSOPS again to examine changes over the course of the intervention period. **Exhibit 7** lists the measures used as well as the purpose and timing of collection for each.

EXHIBIT 7: DESCRIPTION OF MEASURES USED IN ACUTE CARE COHORT

Data Source	Purpose	Frequency of collection
Structural Assessment	Administered to understand the site's infrastructure and any existing antibiotic stewardship practices or experience with quality improvement initiatives	Baseline, endline
AHRQ Hospital Survey on Patient Safety (HSOPS)	Administered to understand attitudes and perceptions of patient safety culture among participating frontline staff and within their setting	Baseline, endline
Team Antibiotic Review Forms (TARFs)	Used to encourage discussion and coordination among care team of patients being considered for antibiotics	Monthly from March 2018 to November 2018
Days of antibiotic therapy/1,000 patient days	Used to monitor rate of antibiotic use	Monthly from January 2018 to December 2018
Clostridioides difficile lab-identifiable events	Used to monitor rate of *Clostridioides difficile* infections	Quarterly

Monthly unit-level days of antibiotic therapy per 1,000 patient-days was the primary outcome of interest for this cohort, measured using submissions of antibiotic use data received from participating sites each quarter. Antibiotic use was stratified by individual antibiotics. Three secondary outcomes

were also evaluated: *C. difficile* laboratory-identifiable events per 10,000 patient-days, compliance with and timely completion of the TARF, and changes in the structural assessment and HSOPS domain scores measured pre- and post-intervention. Sites received reports of their antibiotic use compared to that of similar hospitals and units quarterly during the intervention period.

Monthly antibiotic prescribing data among acute care hospitals in the United States were obtained from the Premier Healthcare Database for comparison of the primary outcome. The Premier Healthcare Database contains administrative, financial, and hospital utilization data for nearly a quarter of U.S. hospitals and healthcare systems.[18]

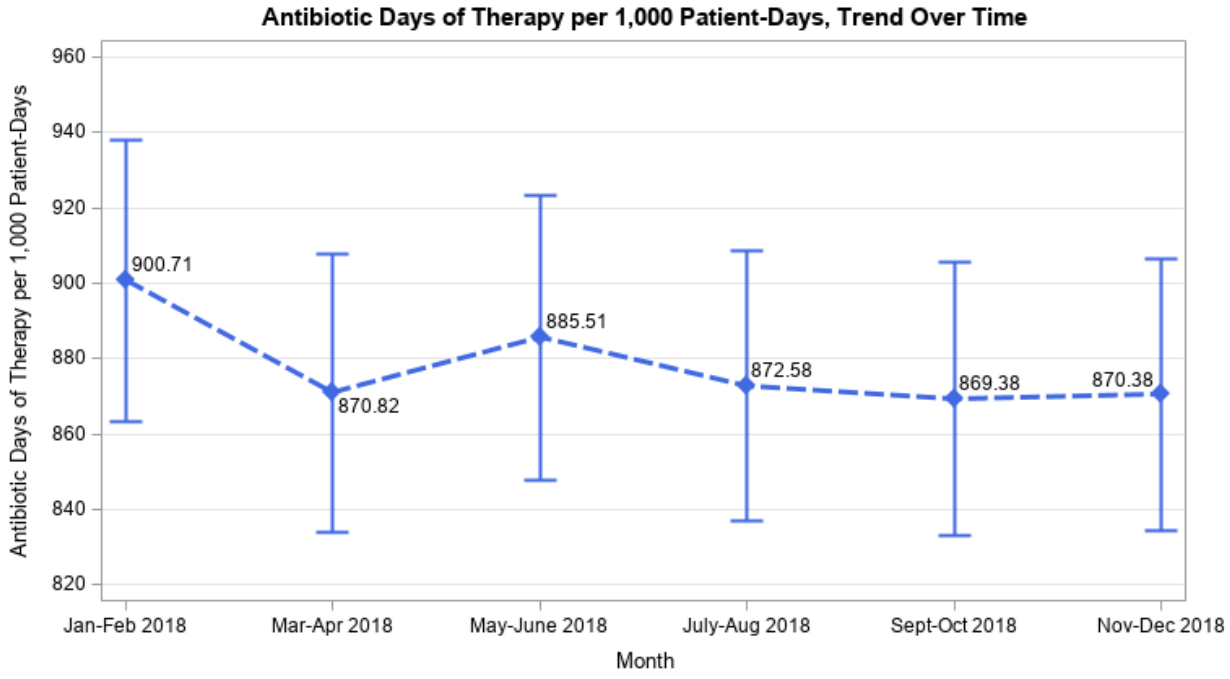
Key Findings[19]

Antibiotic Prescribing. A statistically significant decrease of 30.3 total antibiotic days of therapy (DOT) per 1,000 patient-days (95% confidence interval [CI]: -52.6 to -8.0, p<.01) from baseline to the end of the one-year Safety Program was found across all sites (**Exhibit 8**). A significant decrease in the use of fluoroquinolones over the course of the intervention was found across all sites.

Using the list of antibiotics from the Safety Program, antibiotic days of therapy per 1,000 patient-days from January through December 2018 were obtained from 1,711 acute care units in 614 hospitals.[19] Entropy balancing was used to ensure the distribution of hospitals was similar by hospital type (academic vs. nonacademic) and unit type (general ward vs. intensive care unit). Analysis of acute care hospitals in the Premier Healthcare Database revealed no significant decrease in antibiotic DOT during the same time period.

Hospitals with higher engagement in the Safety Program, defined as completing an average of 10 or more TARFs per month, had greater reductions in antibiotic days than those with lower engagement, defined as completing an average of less than 10 TARFs per month. Between January-February and November-December 2018, antibiotic use in the 276 high-engagement sites decreased from 912 to 877 DOT per 1,000 PD; −34.2 DOT ($P < .01$), while antibiotic use in the 200 lower engagement sites decreased from 861 to 845 DOT per 1,000 PD −15.6 DOT ($P = .55$).

EXHIBIT 8: BIMONTHLY ANTIBIOTIC DAYS OF THERAPY PER 1,000 PATIENT-DAYS, BASELINE TO ENDLINE



***C. difficile* Lab ID Events**. The number of *C. difficile* events per 10,000 patient-days decreased from 6.3 at baseline to 5.1 at endline; overall incidence also decreased significantly by 19.5% (95% CI: -33.5% to -2.4%, p=0.03).

Adoption of AS. When comparing pre- and post-structural assessments from each site, the percentage of participating hospitals that reported having an ASP increased significantly from 91 percent to 98 percent over the course of the program (p<0.01). Compliance with key elements of the Safety Program (e.g., establishment of local guidelines and AS metrics, dedicated ASP leader), also significantly improved from 8 percent to 74 percent over the 1-year intervention period (p<0.01).

Patient Safety Culture. When comparing the pre- and post-intervention HSOPS scores (N=162 units for baseline and N=68 units for endline), frontline providers reported significant improvement in self-reported teamwork across sites by 4.5 percent (p=0.017). The other domains assessed did not change significantly over time.

Improved Decision Making. TARF submissions, including 450 units from 385 hospitals who submitted at least five forms for at least one intervention quarter, indicated all aspects of the Four Moments of Antibiotic Decision Making improved over the one-year study period; "suspected/confirmed infection," "appropriate culture ordered," "decision made to discontinue antibiotics," "decision to narrow

antibiotics," and "planned duration of therapy documented in progress notes" were all statistically significant.

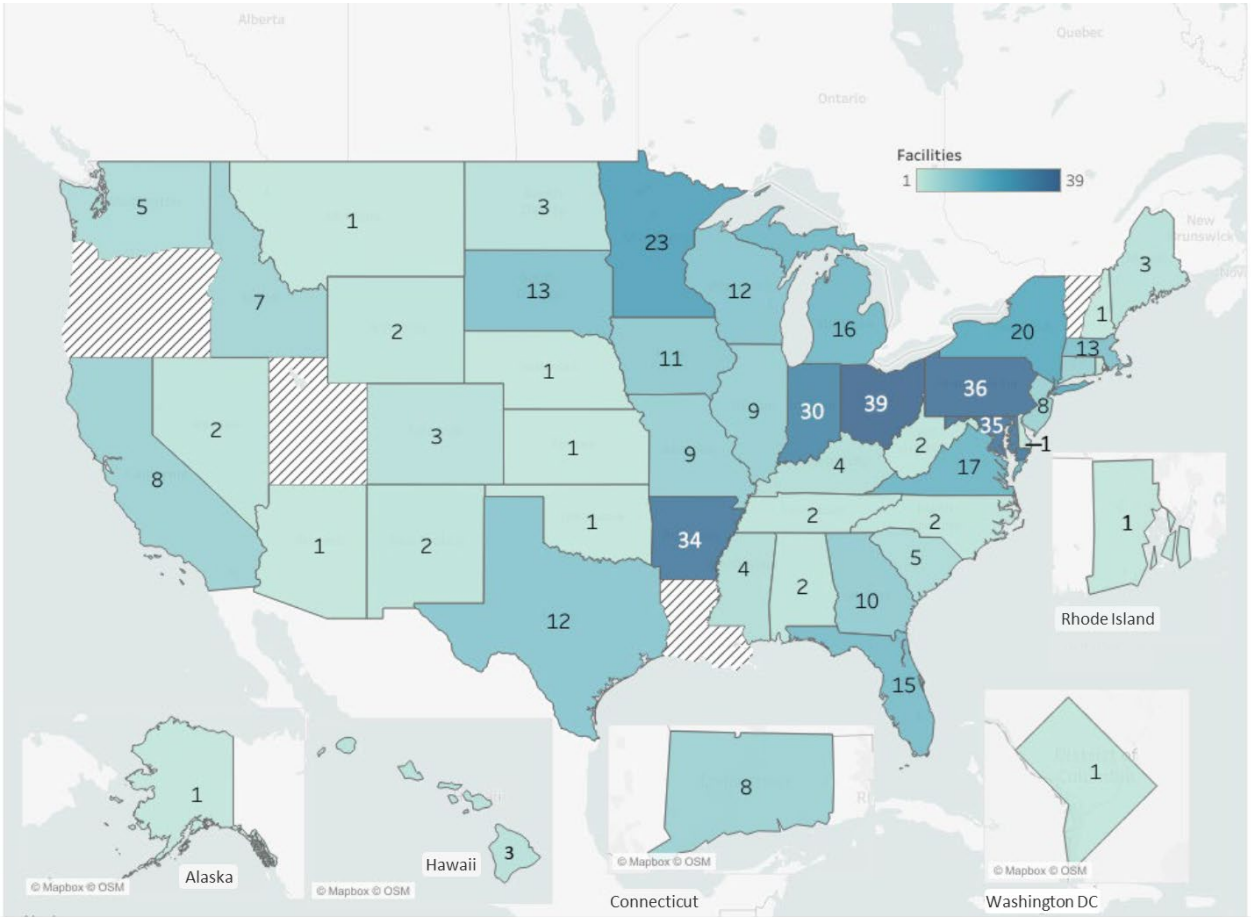
For more information, please see the Acute Care Final Report at https://www.ahrq.gov/sites/default/files/wysiwyg/hai/antibiotic-stewardship/acute-care-cohort-report/acute-care-cohort-report.pdf.

Cohort 2: Long-Term Care Cohort

Recruitment and Retention

Recruitment of long-term care facilities occurred from July 2018 through November 2018. JHM/NORC worked closely with Federal partners such as the Centers for Medicare & Medicaid Services (CMS) and the CDC as well as non-Federal partners to recruit and enroll long-term care facilities. Similar to the acute care cohort, recruitment webinars were held to convey Safety Program information and to answer questions from interested sites. Of the 523 long-term care facilities that initially enrolled in the program, 439 (84 percent) remained for the 12-month intervention period. Facilities included in the cohort included nursing homes, dementia care facilities, and residential and continuing care facilities and were distributed across all 10 HHS regions (**Exhibit 9**). In total, 24 percent of participating long-term care facilities had fewer than 75 beds, 52 percent had 75–149 beds, and 24 percent had at least 150 beds, with a mean of 124 beds across the cohort and a range of 18–874 beds.

EXHIBIT 9: LONG-TERM CARE FACILITY PARTICIPATION BY STATE



Note: The numbering in the above map refers to the number of facilities in each state. The states with diagonal stripes (Louisiana, Oregon, Utah, and Vermont) had no participating facilities. The number of facilities add up to 459.

Attrition of participating sites was expected due to frequent turnover of staff in the long-term care setting, including those who may have initially been designated to lead the Safety Program work; thus, a waitlist was created for sites who had expressed an interest in participation but were unable to enroll initially because recruitment goals of the Safety Program were already achieved (n=500). Waitlisted sites were invited to join the educational webinars for the first 3 months of the intervention period, and if a site dropped within the first quarter, they were invited to be part of the cohort. Twenty-three facilities were accepted from the waitlist in the first 3 months of the program. Additionally, JHM/NORC worked with sites following enrollment to ensure any initial barriers were addressed (e.g., long-term care facility administration approval, assistance with programming for electronic health record (EHR) data extraction). Similar to the acute care cohort, sites considering withdrawal were contacted by the JHM team to attempt to resolve barriers to participation. Continuing education units/CME credits were

provided to nurses and physicians who attended webinars to increase participation and certificates of program completion were provided for facilitates who attended the majority of educational webinars or submitted the majority of data elements requested throughout the intervention.

Implementation Activities

Implementation of the intervention began in December 2018. A description of activities and strategies used to achieve each goal are described below, with an emphasis on unique aspects designed to address the challenges of optimizing stewardship practice in long-term care facilities where nurses and certified nursing assistants provide most of the frontline care to residents with physicians generally located off site.

Development or enhancement of ASPs. Unlike the acute care cohort, many long-term care facilities did not have an existing ASP or were not performing AS activities. Several live webinars were focused on steps needed to develop an ASP to including identification of a leader and a team of providers to assist with oversight and development, engagement of senior leadership within the facility, identification of areas for improvement and strategies for measuring performance. ASP leaders were encouraged to focus on one common infection every few months, to increase knowledge and sustainability of evidence-based practices.

Changes to patient safety culture. Live webinars and supporting materials were provided to assist with enhancing safety culture and improving communication of infection concerns with relevant stakeholders including physicians, the residents, and their families. Pocket cards and posters encouraging facilities' commitment to patient safety and appropriate prescribing practices were developed for use by participating facilities and sample dialogues of discussions with concerned family members were developed and shared with frontline staff. Target outcomes included: recognition that AS is a patient safety issue, improvement in communication and teamwork around antibiotic prescribing practices, identification of quality improvement targets, and learning from adverse events associated with inappropriate prescribing practices.

Implementation of best practices in the management of patients with common infectious diseases. Best practices for the evaluation and management of long-term care residents presenting with common infections were presented in a series of five live webinars, each of which focused on a different infectious disease issue including: management and assessment of residents with suspected UTIs,

respiratory tract infections, and skin or soft tissue infection, appropriate sampling techniques for collection of microbiological cultures, and management of penicillin allergy.

The presentations were organized according to the Four Moments of Antibiotic Decisions Making for Long-Term Care whenever possible **(Exhibit 10)**. These were modified to be more applicable to the long-term care setting, with the major difference being reversal of moments 3 and 4 to reflect the need for duration of therapy to be specified at the time of the antibiotic order to prevent unintended prolonged durations. TARFs based on the Four Moments were designed specifically for the long-term care facility staff to complete and sites were encouraged to use them regularly to reinforce key concepts and encourage teamwork and communication among staff.

EXHIBIT 10: THE FOUR MOMENTS OF ANTIBIOTIC DECISION MAKING FOR LONG-TERM CARE COHORT

1. Does the resident have symptoms that suggest an infection?
2. What type of infection is it? Have we collected appropriate cultures before initiating antibiotics? What empiric therapy should be used?
3. What duration of antibiotic therapy is needed for the resident's diagnosis?
4. It's been 2 to 3 days since we started antibiotics. Re-evaluate the resident and review results of diagnostic tests. Can we stop antibiotics? Can we narrow therapy? Can we change to oral antibiotics?

Evaluation Methods and Measures

A baseline period was established from December 2018 to February 2019 during which sites completed the Structural Assessment and AHRQ Nursing Home Survey on Patient Safety (NHSOPS) and began monthly reporting of antibiotic use and urine cultures collected and quarterly reporting of *C. difficile* LabID events. During the intervention period from March 2019 to November 2019, teams continued to report antibiotic use, urine cultures collected and *C. difficile* LabID events. During the endline period, from November 2019 through December 2020, sites completed the Structural Assessment and NHSOPS again to examine changes over the course of the intervention period.

The primary outcome was facility-level antibiotic starts per 1,000 resident-days. Antibiotic use was stratified by individual antibiotics. Secondary outcomes included days of antibiotic therapy per 1,000 resident-days, C. *difficile* LabID events per 10,000 resident-days, and urine cultures collected per 1,000

resident-days, as well as structural and cultural changes assessed via the assessment and NHOSPS. Sites received reports of their antibiotic use compared to that of similar facilities quarterly during the intervention period.

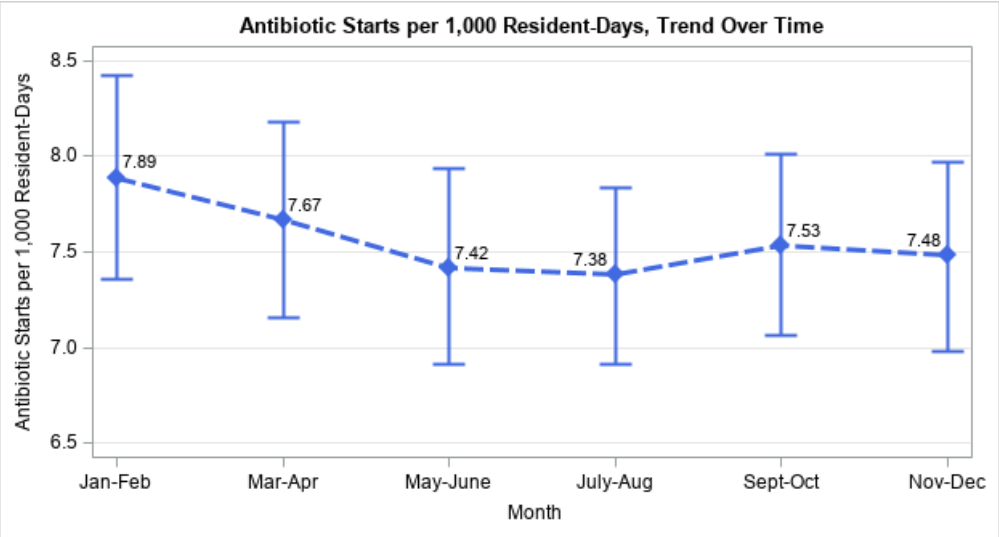
Key Findings[20]

Antibiotic Prescribing. A statistically significant decrease of 0.41 total antibiotic starts per 1,000 resident days throughout the course of the intervention was found across all sites (95% CI: -0.76 to -0.07, p=0.020) (see **Exhibit 11**). Further, fluoroquinolone antibiotic starts (i.e., ciprofloxacin, levofloxacin, and moxifloxacin) per 1,000 resident-days decreased significantly throughout the course of the intervention (-0.21, 95% CI -0.35 to -0.08, p=0.002).

When assessing total antibiotic DOT, there was a decrease of 3.1 DOT per 1,000 resident-days (64.1 at baseline to 61.0 at endline period), but this did not achieve statistical significance (-3.1, 95% CI: -6.3 to 0.23, p = 0.068). Among facilities with at least 75 percent short-stay residents, DOT per 1,000 resident-days significantly decreased from baseline to endline (-9.8, 95% CI -16.5 to -3.0, p=0.005). Finally, fluoroquinolone DOT significantly decreased across the entire cohort from Jan-Feb to Nov-Dec 2019 (-1.2, 95% CI: -2.1 to -0.24, p=0.014).

Facilities with higher engagement in the Safety Program, defined as attending at least eight webinar sessions, had greater reductions in antibiotic starts than those with lower engagement, defined as attendance at fewer than eight webinars, or no webinar attendance. Antibiotic starts in the 103 high engagement facilities were reduced by 1.12 per 1,000 resident-days (95% CI, –1.75 to –0.49; *P* < .001), from 8.3 to 7.2, while differences in the 254 low-engagement facilities (–0.29; 95% CI, –0.74 to 0.17) and the 82 no-engagement facilities (0.40; 95% CI, –0.55 to 1.35) were not significant. DOT in the high-engagement facilities was reduced by 9.97 per 1,000 resident-days (95% CI, –15.37 to –4.56; *P* < .001), from 71.9 to 61.9, while differences in low (–1.85; 95% CI, –6.07 to 2.37) and no-engagement facilities (3.51; 95% CI, –6.73 to 13.75) were not significant.

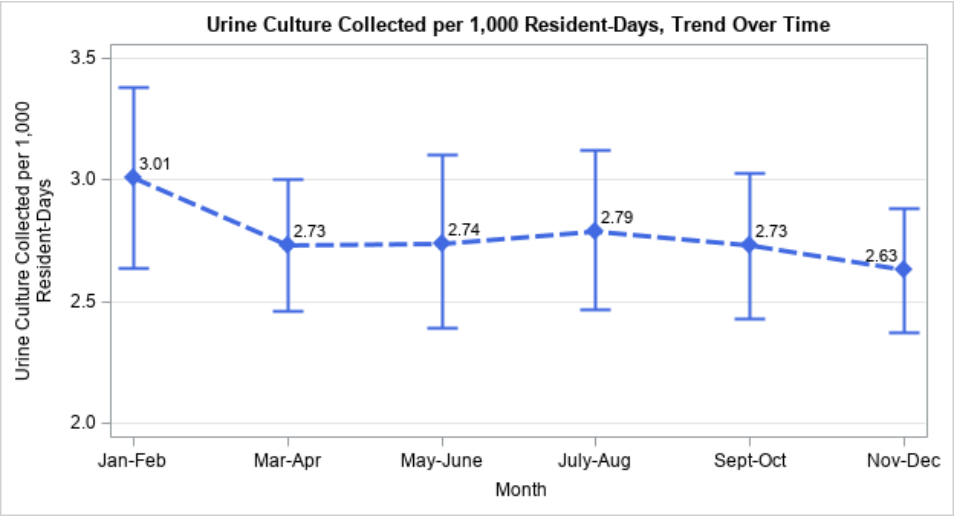
EXHIBIT 11: BIMONTHLY ANTIBIOTIC STARTS PER 1,000 RESIDENT-DAYS



C. *Difficile* Lab ID Events. C. *difficile* LabID events did not significantly decrease over the course of the Safety Program (-0.16 per 10,000 resident-days, 95% CI -0.64 to 0.33, p=0.524).

Number of Urine Cultures Collected. Urine culture collection per 1,000 resident-days decreased from baseline to study completion (-0.38, 95% CI: -0.61 to -0.15, p=0.001) (**Exhibit 12**).

EXHIBIT 12: BIMONTHLY URINE CULTURES COLLECTED PER 1,000 RESIDENT-DAYS OVER 12-MONTH INTERVENTION PERIOD



Adoption of AS. Results from the Structural Assessment indicated an increase in stewardship staffing; at the beginning of the Safety Program, 83 percent of facilities had an infection preventionist and 62 percent had a medical director involved with their existing ASP. Those percentages increased to 93

percent and 70 percent, respectively by the end of intervention. Over the course of the Safety Program, the percent of facilities that had post-prescription review with feedback in place for select antibiotics increased from 38 percent to 61 percent. At baseline, 87 percent of facilities tracked antibiotic use (using at least one of the following: antibiotic starts, days of antibiotic therapy [DOT], or defined daily doses); this increased to 98 percent by the end of the Safety Program.

Patient Safety Culture. A total of 227 (52%) and 142 (32%) of facilities submitted usable data at baseline and endline, respectively, to evaluate changes in composite scores for each of the 12 NHSOPS domains. Of the 12 domains measured, only the staffing dimension (i.e., there are enough staff to handle the workload, meet residents' needs during shift changes, and keep residents safe) improved significantly from 44 percent at baseline to 59 percent at endline (+14.7%, 95% CI: 12.2% to 17.2%, p<0.001).

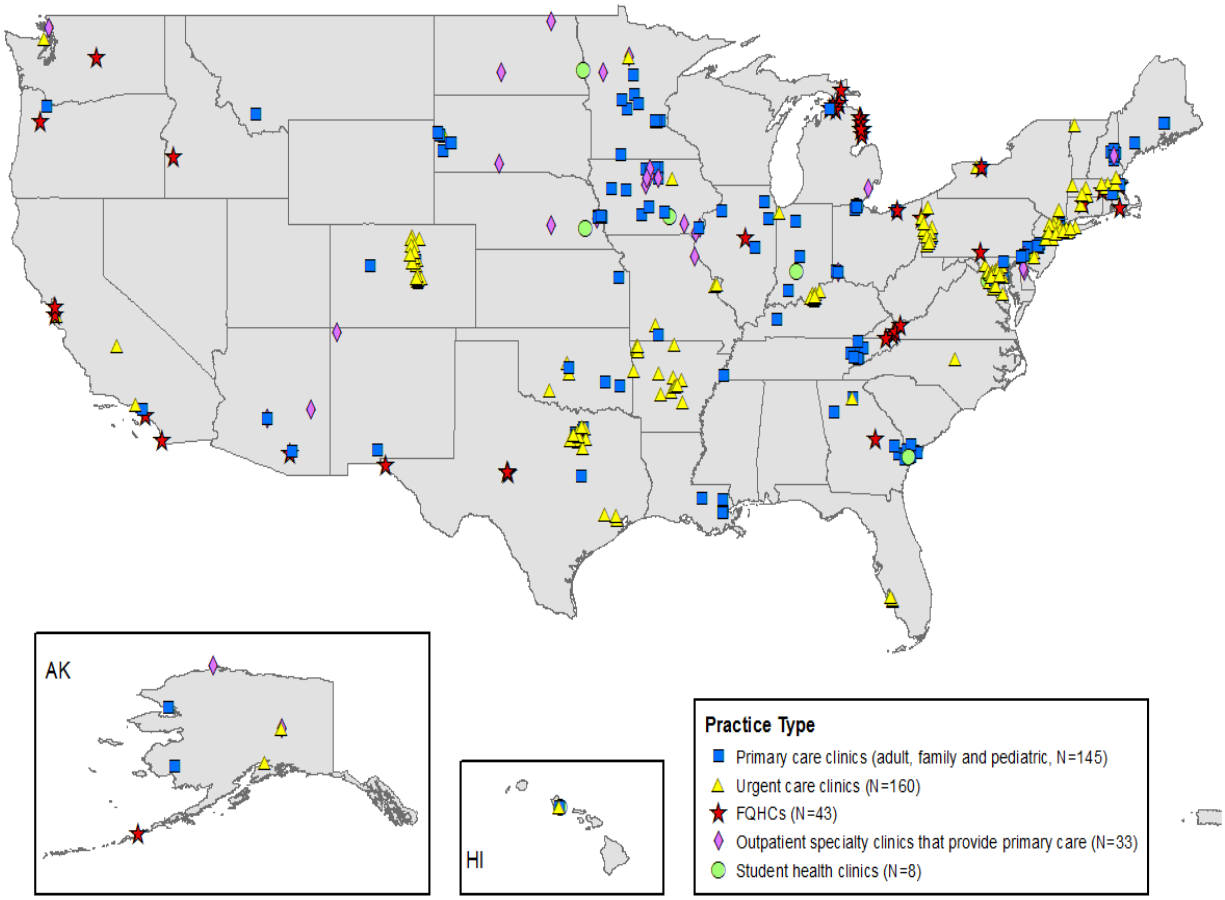
For more information, please see the Long-Term Care Final Report at https://www.ahrq.gov/sites/default/files/wysiwyg/hai/antibiotic-stewardship/ltc-cohort-report/ltc-cohort-report.pdf.

Cohort 3: Ambulatory Care Cohort

Recruitment and retention

Recruitment and enrollment of sites began in July 2019 and lasted through December 2019. The ambulatory care cohort initially enrolled 467 ambulatory care practices across all 10 HHS regions with 389 practices completing the Safety Program. Primary care clinics (serving adults, children, and families), urgent care clinics, federally qualified health centers, outpatient specialty clinics that provide primary care, and student health clinics participated (**Exhibit 13**).

EXHIBIT 13: ENROLLED AMBULATORY CARE CENTERS BY TYPE



The completion rate of 83 percent was realized despite the emergence of the COVID-19 pandemic during the intervention period. Incentives were provided to encourage participation including provision of CME credit for physicians and advanced practitioners as well as Maintenance of Certification credits for physicians who participated in webinars and audio presentations.

Implementation Activities

Implementation of the intervention began in December 2019 and are described below.

Development or enhancement of AS activities. The majority of ambulatory care practices do not have established AS teams or ongoing AS activities; thus, the focus of the Safety Program live webinars was identifying individuals to lead AS activities—specifically a physician and an administrative lead, determining how to extract data from the EHR on antibiotic prescriptions and specific ICD-10 codes, and feeding back data on antibiotic use.

Changes to patient safety culture. Several live webinars were used to provide information about developing a safety culture around antibiotic prescribing and improving communication regarding antibiotic use among healthcare practitioners and between healthcare practitioners and patients. Specific webinar topics included recognition that AS is a patient safety issue, identification of relevant AS targets for improvement, learning from adverse events associated with inappropriate prescribing practices, and improving teamwork and communication. In addition, other materials were developed to assist practices in enhancing communication including a commitment poster pledging use of antibiotics only when needed for practices to sign and place in a visible location, and specific discussion points for many of the best practice topics for ambulatory sites to bring to practicewide meetings to obtain consensus on prescribing.

Implementation of best practices in the management of patients with common infectious diseases. A series of live webinars focused on best practices for the evaluation and management of patients presenting with suspected bacterial infection. Topics on respiratory tract infections were divided into those that never require antibiotics (bronchitis, viral upper respiratory tract infection), sometimes require antibiotics (sinusitis and pharyngitis), and usually require antibiotics (community-acquired pneumonia). Other topics included management of skin and soft tissue infections, urinary tract infections, and patients with antibiotic allergies. One-page documents were created for clinicians to improve decision-making practices. Webinars and one-page documents were organized according to the Four Moments of Decision-Making Framework that was modified to be applicable to the practice of ambulatory medicine (**Exhibit 14**). Specifically, because ambulatory patients are not followed in person on a daily basis, the Four Moments for the ambulatory care cohort were designed to all be addressed during the initial patient encounter. Thus, duration is determined at the same time as antibiotic selection and included in Moment 3, and Moment 4 addresses the importance of defining a followup plan for the patient regarding the expected course of the illness and when to call the clinic or seek emergency care.

EXHIBIT 14: THE FOUR MOMENTS OF ANTIBIOTIC DECISION MAKING FOR AMBULATORY CARE COHORT

1. Does my patient have an infection that requires antibiotics?
2. Do I need to order any diagnostic tests?
3. If antibiotics are indicated, what is the narrowest, safest, and shortest regimen I can prescribe?
4. Does my patient understand what to expect and the followup plan?

Evaluation Methods and Measures

During the baseline period from December 2019 to February 2020 the structural assessment and AHRQ's Medical Office Survey on Patient Safety (MOSOPS) were administered to participating sites and healthcare practitioners. Sites submitted antibiotic prescriptions stratified by antibiotic, total number of visits, and visits for acute respiratory tract infections (determined by ICD-10 code) monthly from September 2019 to the end of the intervention in November 2020. Initially, only in-person visits were collected but after the COVID-19 pandemic began, both in-person and synchronous telemedicine visits were included from March 2020 through the end of the Safety Program. In November 2020, sites were asked to submit a second structural assessment and providers were asked to submit a second MOSOPS.

The primary outcome was antibiotic prescriptions per 100 acute respiratory tract infection visits. Secondary outcomes were antibiotic prescriptions per 100 visits. Changes in structural assessment and HSOPS domain scores measured pre- and post-intervention were also assessed. Sites received reports of their antibiotic use compared to that of similar practices quarterly during the intervention period.

Key Findings[21]

Antibiotic Prescribing. Acute respiratory infection (ARI) visit antibiotic prescribing decreased significantly from 39 percent at baseline to 25 percent at endline (95% CI: -17% to -12%) (**Exhibit 15**) and total antibiotic prescribing significantly decreased by 50 percent; starting with 18 percent of visits at baseline to 9 percent by the end of the intervention (95% CI: -10% to -8%) (**Exhibit 16**).

There was no difference in antibiotic use between practices with higher engagement in the Safety Program, defined as attendance at 8–14 webinars (n=43), compared with those with lower engagement, defined as attendance at 1–7 webinars (n=142), and those that attended no webinars (n=204). Of note, attending live webinars during the middle of the workday is challenging in the ambulatory setting and

may not be an accurate proxy for actual engagement with the project activities and materials. The project was not able to collect data on access to recorded webinars and audio presentations.

EXHIBIT 15: MONTHLY ARI VISITS PER PRACTICE AND ANTIBIOTIC PRESCRIPTIONS PER 100 ARI VISITS

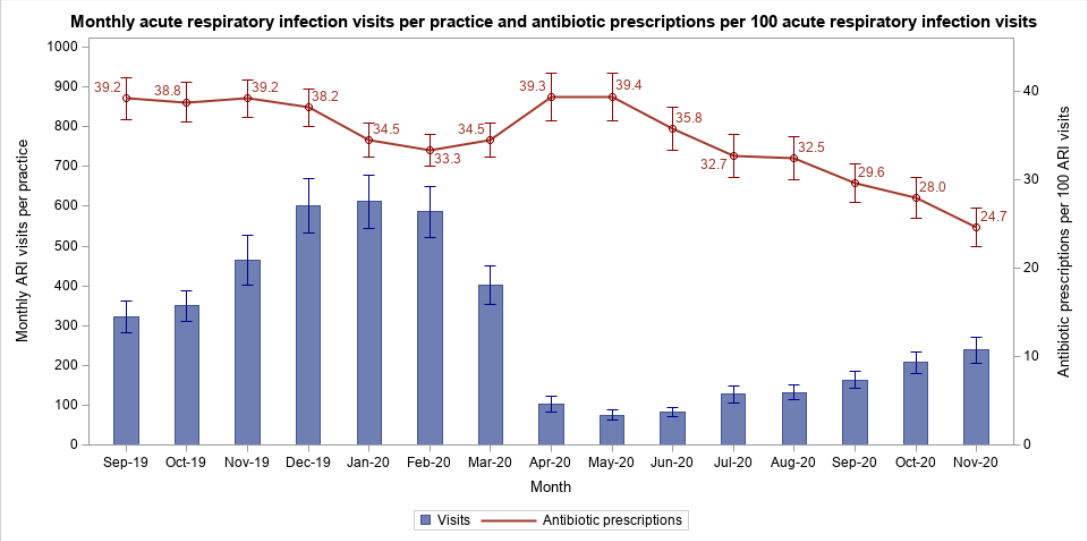
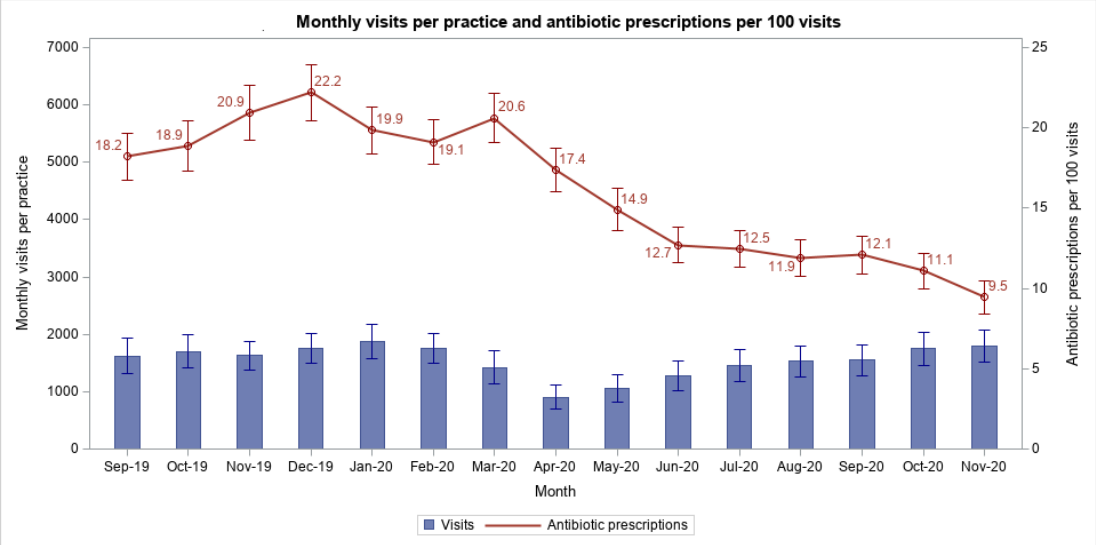


EXHIBIT 16: MONTHLY VISITS PER PRACTICE AND ANTIBIOTIC PRESCRIPTIONS PER 100 VISITS



Adoption of AS. When comparing pre- and post-intervention structural assessments from participating sites, significant improvements in facility infrastructure related to ASPs were reported. Specifically, practices that reported formally tracking antibiotic prescriptions increased from 21 percent to 76 percent ($p<0.001$). Further, practices that reported having local guidelines for common bacterial conditions increased from 40 percent to 66 percent ($p<0.001$). Finally, there was a significant increase in

the number of practices that reported existence of local guidelines for antibiotic prescribing from 48 percent at baseline to 61 percent at endline ($p<0.001$).

Patient Safety Culture. When comparing pre- and post-intervention responses to the AHRQ MOSOPS, including 157 practices for the baseline survey and 67 practices for the endline survey, composite scores for all domains improved, five of which were statistically significant including work pressure and pace, leadership support for patient safety, communication openness, overall perceptions of patient safety and quality, and communication about error.

For further information, please see the Ambulatory Care Final Report at https://www.ahrq.gov/sites/default/files/wysiwyg/antibiotic-use/ambulatory-care/ambulatory-cohort-report/pdf.

FINAL AHRQ SAFETY PROGRAM TOOLKIT

After the completion of the three Safety Program cohorts, the JHM team worked with AHRQ to develop enduring content available on a public-facing website (https://www.ahrq.gov/antibiotic-use/index.html). The website includes Safety Program toolkits specific for the acute care, long-term care, and ambulatory care settings. For each setting, the final toolkit explains the Four Moments of Antibiotic Decision Making specific to the setting, and includes tools to develop and improve an antibiotic stewardship program/team, create a safety culture around antibiotic prescribing, and disseminate best practices for common infectious diseases. Each of the three toolkits includes Implementation Guides on how the content in the Safety Program toolkit can be integrated into institutional efforts to improve antibiotic use.

DISCUSSION OF CHALLENGES, LIMITATIONS, AND LESSONS LEARNED

The Safety Program successfully engaged cohorts of acute care hospitals, long-term care facilities, and ambulatory care practices across all ten HHS regions. Participating sites were of different sizes, served different patient populations, and had different levels of baseline resources to establish or enhance AS activities. The intervention was associated increases in AS activities and decreases in rates of antibiotic use across all three cohorts and decreased rates in C. *difficile* LabID events among participating sites in the acute care cohort.

Although the Safety Program was generally a success, there were challenges, some of which were experienced across cohorts while others were unique to a given setting. Among all three cohorts, there were different levels of engagement at sites with some attending the majority of webinars and coming to office hours with questions and observations and others engaging minimally with the project. Of note in both the acute and long-term care cohorts, greater engagement in the project, measured by completion and submission of TARFs and participation in webinars, respectively, was associated with greater reductions in antibiotic use, although this was not seen in the ambulatory cohort. Submissions of TARFs and participation in webinars are only proxies for actual participation in the work of the project and may not completely reflect the level of engagement of sites. Efforts to enhance engagement included robust access to the investigators via office hours and emails and monthly calls to sites by the implementation advisers. Recognizing that neither of these resources would be available to sites who did not participate in the live Safety Program but wish to mimic it using materials from the AHRQ Safety Program Toolkit, the Toolkit contains detailed gap analyses and implementation guides for each cohort. The gap analyses allow facilities to assess the current status of their AS activities as well as track them over time, and the implementation guides provide detailed instructions for how to use the material in the toolkit to implement AS activities. Sites in all cohorts were also limited by how much time they could devote to the project. While the Safety Program asked sites to invest time in attending webinars and engaging with front-line staff, efforts were made to make participation easier by ensuring that the webinars were short, recording the webinars to individuals to view at their convenience, and providing simple and accessible materials (e.g., one-page documents, posters) available on demand from the project website.

In addition to engagement, the team recognized that it would be challenging for sites to sustain the work that occurred during the intervention period. Unfortunately, it has not been possible to perform followup with sites to determine how much AS work started during the Safety Program continued after it ceased. To assist sites, the importance of sustainability and changing long-term practice was considered while creating all material and interventions for the Safety Program. Specific content developed include a webinar titled “Sustaining Stewardship Activities” and a Gap Analysis Tool to assist sites with internally determining what resources they currently have and what additional resources might be of benefit to them to continue to see positive results with their local ASP. This content was paired with a Guide to Sustainability Planning, which provides a template to help healthcare workers continue to apply what they learned throughout the course of the Safety Program and incorporate these strategies into everyday practice. The guide addresses six key components to consider when assessing

sustainability: leadership, culture of improvement, hardwiring change, data collection and feedback, assessment, and resources.

Another issue common to all cohorts was challenges with collection of antibiotic use data. While larger academic and community hospitals, particularly those in large health systems, have developed approaches to extract antibiotic use data from the EHR, many smaller hospitals, critical access hospitals, long-term care facilities, and ambulatory practices have not developed approaches to obtain antibiotic use data electronically. Recognizing that manual collection of data is likely not sustainable over time, for the acute and long-term care cohorts, the Safety Program team emphasized the desirability of determining approaches to obtaining electronic data and provided extensive technical assistance, including individual calls with sites as well as coordination of peer-to-peer discussions among sites with the same EHR. While some sites in the acute and long-term care cohorts collected antibiotic use data manually, the majority developed approaches to extract data electronically. Sites participating in the ambulatory cohort were required to be able to extract antibiotic use data electronically; however, this likely led to exclusion of smaller practices from participating in the project. Because many participating sites in all cohorts were inexperienced with collection of antibiotic use data, rigorous quality control processes were implemented and included data quality checks and timely follow up with sites that provided incomplete data.

A final concern across cohorts is that although the educational content in the AHRQ Safety Program was developed after a comprehensive review of the literature, the medical literature continues to evolve at a relatively rapid pace. Developing an approach to ensuring the AHRQ Safety Program Toolkit content accurately reflects best practices moving forward may be challenging; however, a mechanism that would allow for the materials to be updated every 3–5 years would ensure that the Toolkit remains clinically accurate and relevant.

Issues specific to the acute care cohort included the need for increased access to physicians and pharmacists with infectious diseases expertise to optimally perform AS activities. The majority of participating hospitals had non-infectious diseases-trained pharmacists as stewardship leads. Many had been “assigned” to run the local ASP with minimal training. Consequently, the Safety Program provided this needed training, with the infectious diseases syndrome specific topics being of particular importance. In addition, office hours with two infectious diseases physicians offered the opportunity to ask specific questions about particular management issues both regarding stewardship practice and patient care. The lack of access to infectious disease trained physicians and pharmacists to perform AS

activities is a national barrier to improving antibiotic use that in the long-term should be solved by training more individuals in these fields and in AS in particular and ensuring facilities have access to trained individuals. However, in the short term, access to expertise in the form of the Safety Program Toolkit is an important first step.

In the long-term care cohort, retention of participating sites was particularly challenging. This was largely due to ongoing staffing changes and shortages as well as nursing leads having many responsibilities within a facility, all common challenges in the long-term care setting. One mitigation strategy for this problem was to identify more than one person to serve as a lead for the program so that if one person was not available, the second person could continue involvement the Safety Program. A second issue unique to the long-term care setting is availability of pharmacists to assist with AS activities. Long-term care facilities contract with consulting pharmacists to guide medication prescribing; however, these individuals have different levels of knowledge about AS, sometimes limited time to devote to AS activities, and are often off site. In addition, long-term care facilities can be served by more than one dispensing pharmacy, and imperfect communication between the site and the dispensing pharmacies can also interfere with AS efforts. The Safety Program addressed these concerns by encouraging sites to engage their consulting pharmacists in the Safety Program and to improve communication with dispensing pharmacies whenever possible. Despite these issues, the proportion of sites retained in the long-term care cohort was quite high. In addition to efforts made by the Safety Program, retention may also have been enhanced by the introduction of the CMS requirement for nursing homes to have ASPs by 2019.

The ambulatory care cohort was implemented from November 2019 through December 2020 and coincided with the COVID-19 pandemic. Many participating sites had to shift their staff and resources to the pandemic which led to less time to devote to the project and the associated data collection. Further, some sites were forced to withdraw because of leadership changes due to mergers and acquisitions of practices followed by a reduction in prioritization of AS activities. Finally, some sites went out of business. While these issues may have been exacerbated by the pandemic, they occur routinely and are difficult to mitigate.

An important challenge in the ambulatory setting was the availability of prescribers to participate in the Safety Program activities. While in the acute and long-term care setting, individuals are likely able to attend a webinar during working hours, ambulatory providers usually have full schedules with patient visits during working hours. Further, there are generally numerous competing topics for discussion

during practice-wide meetings leaving only a small amount of time to discuss AS issues. The Safety Program attempted to mitigate these concerns by ensuring that webinars were limited to 30 minutes and recorded for future viewing, developing audio presentations of the material that could be downloaded and listened to at a clinician's convenience, and providing questions via a discussion guide that could be used during practice meetings to facilitate brief discussions about practicewide antibiotic use. Finally, there is likely a difference between antibiotic prescribing during the baseline period of the project before the COVID-19 pandemic and during the endline period during the COVID-19 pandemic related to changes in health-seeking behavior and reductions community transmission of respiratory viruses in the setting of pandemic precautions. These differences make it challenging to determine what proportion of reduced antibiotic use was due to the Safety Program versus external factors, although a reduction in antibiotic prescribing was observed between June 2020 and November 2020 despite both numbers of visits and ARI visits increasing to or near baseline levels.

PUBLICATION LIST

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CONCLUSION

The AHRQ Safety Program included three diverse cohorts of hospitals, long-term care facilities, and ambulatory care practices, spanning the continuum of care. Results indicate the Safety Program aided participating sites to develop and enhance their AS activities and to reduce antibiotic prescribing. Hospitals, long-term care facilities, and ambulatory care practices across the United States are encouraged to use the setting-specific toolkits developed for the Safety Program available on AHRQ's website (https://www.ahrq.gov/antibiotic-use/index.html) to improve the culture of antibiotic prescribing among ASP leaders and frontline providers.

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