







AHRQ Safety Program for Improving Antibiotic Use

Long-Term Care Cohort Final Report Time Period: September 2, 2018–June 1, 2020

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Prepared by: Johns Hopkins Medicine NORC at the University of Chicago

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EXECUTIVE SUMMARY

E.1. Background

The AHRQ Safety Program for Improving Antibiotic Use

The AHRQ Safety Program for Improving Antibiotic Use (Safety Program) is a multiyear program (2016– 2022) focused on developing and enhancing antibiotic stewardship programs (ASPs) across the continuum of care—acute care hospitals, long-term care (LTC) facilities, and ambulatory care practices throughout the United States—as well as equipping frontline providers with the necessary knowledge and skills to enhance their antibiotic prescribing practices. The Safety Program is a collaborative intervention funded and guided by the Agency for Healthcare Research and Quality (AHRQ), and led by Johns Hopkins Medicine (JHM) and NORC at the University of Chicago (NORC). JHM/NORC engaged with three organizations that also function as Quality Innovation Networks-Quality Improvement Organizations (QIN-QIO)—Health Services Advisory Group, Stratis Health, and Health Quality Innovators—to assist with implementing the Safety Program.

The Safety Program uses a multipronged approach to guide participating sites in developing and improving their ASPs. The Safety Program assisted sites with identifying local AS leaders, if not already identified, and then proceeded to teach them how to establish effective and sustainable ASPs. The Safety Program also worked closely with frontline providers to assist them with understanding how to address the attitudes, beliefs, and culture that often pose challenges to appropriate antibiotic use in the LTC setting. Additionally, participants were introduced to the Four Moments of Antibiotic Decision Making framework, which provides guidance on learning and incorporating best practices for the diagnosis and treatment of common infections into routine practices in the LTC setting. The Four Moments of Antibiotic Decision Making, an approach to evaluating and re-evaluating the need for antibiotic use in real time, was developed as part of the Safety Program.¹

Program Rollout and Metrics

The Safety Program consisted of a pilot period followed by three distinct cohorts: acute care, LTC, and ambulatory care. The pilot period focused on developing metrics and educational materials for each of the three cohorts and pilot testing all material across three integrated health care delivery systems: Geisinger Health System (Pennsylvania), Johns Hopkins Health System (Maryland), and Atrium Health^a

(North Carolina and South Carolina). All Safety Program content was accessible to participants on the Safety Program's project Web site. Metrics specific to long-term care during the pilot period included:

^a Formerly known as Carolinas HealthCare System

- (1) Structural assessment at the beginning and end of the 1-year program to understand the general facility infrastructure, local stewardship practices (if any), and experience with quality improvement initiatives at each participating site and any changes that occurred during the course of the Safety Program
- (2) An AHRQ Survey on Patient Safety Culture appropriate to the LTC setting completed by individual participants at each site at the beginning and end of each cohort
- (3) Team Antibiotic Review Forms completed by frontline staff and ASPs at each site to understand how sites incorporated the Four Moments framework into their decision making
- (4) Monthly antibiotic prescribing data during the course of the Safety Program
- (5) Quarterly Clostridioides difficile laboratory-identifiable (C. difficile LabID) events
- (6) Monthly urine cultures collected

This report focuses on the activities of the Safety Program in the post-pilot LTC Cohort, tasked to include 250–500 LTC facilities. Participants in the LTC cohort enrolled from July through November 2018. Safety Program implementation began in December 2018. Lessons learned from implementation of the acute care arm as well as from the LTC arm during the pilot period—such as quality and scope of the educational material, ease of data collection, clarity of outcomes, and feedback from the Safety Program's Technical Expert Panel and participating sites—were used to refine the Safety Program for the LTC Cohort. These refinements included reordering some aspects of the educational content, prerecorded narrated presentations, additional materials to support communication among team members and with family members, increased opportunities to attend each Webinar, the inclusion of office hours, revisions to the data collection template, inclusion of certificates for Safety Program participation, and provision of continuing medical education and nursing contact hours for physicians and nurses, respectively.

Participating Long-Term Care Facilities

During the long-term care cohort, 439 long-term care facilities in all 10 U.S. Department of Health and Human Services regions completed the Safety Program. **Exhibit E-1** shows the distribution of the participating facilities across the United States.



EXHIBIT E-1: 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 had no participating facilities. The number of facilities add up to 439.

Of the 439 LTC facilities that completed the Safety Program, 24 percent had fewer than 75 beds, 52percent had 75–149 beds, and 24percent had at least 150 beds, with a mean of 124 beds across the cohort and a range of 18 to 874 beds. **Exhibit E-2** displays the number of enrolled facilities by bed size, ownership, proportion of short-stay beds (compared to long-stay or residential beds), and geographic setting.

Facility Characteristics	Category	# Participating Facilities (%)
Number of Beds	# certified beds in facility: mean (SD)	124 (96.0)
	0–74 beds	106 (24.1)
	75–149 beds	229 (52.2)
	150 or more beds	104 (23.7)
Ownership	Hospital-based	60 (13.7)
	Non-hospital based and owned by a larger system	246 (56.0)
	Non-hospital based and not owned by a larger system	133 (30.3)
Proportion of residents in	Less than 25%	233 (53.1)
short-stay beds	At least 25% and less than 50%	70 (15.9)
	At least 50% and less than 75%	45 (10.3%)
	At least 75%	91 (20.7)
Geographic location	Urban	108 (24.6)
	Suburban	156 (35.5)
	Rural	(39.9)

EXHIBIT E-2: CHARACTERISTICS OF THE 439 ENROLLED FACILITIES

E.2. Results

The AHRQ Safety Program employed a pre-post longitudinal design. Changes in facility AS infrastructure and AHRQ Nursing Home Survey on Patient Safety Culture (NHSOPS) were compared from the beginning to the end of the Safety Program. The primary outcomes of the Safety Program were facility-level antibiotic starts and days of antibiotic therapy, both per 1,000 resident-days, to evaluate the Safety Program's impact on participating LTC facilities. Changes in *C. difficile* LabID events per 10,000 resident-days and urine cultures collected per 1,000 resident-days were evaluated as secondary outcomes.

Adoption of the Safety Program

Adoption of the Safety Program was assessed by the Structural Assessment form, which was collected from each participating site at baseline and at the end of the 1-year LTC Safety Program (Appendix A-7). The Structural Assessment consisted of seven questions to understand AS infrastructure of participating sites at baseline and over the course of the Safety Program.

At the beginning of the Safety Program, 83 percent of facilities had an infection prevention nurse or practitioner and 62 percent had a medical director involved with their existing ASP. Those percentages increased to 93percent and 70 percent, respectively, by the end of intervention. The percent of facilities that had post-prescription review with feedback in place for select antibiotics increased over the course of the Safety Program, 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

All health care workers in participating facilities were encouraged to complete the AHRQ NHSOPS at both the beginning and the completion of the Safety Program. The AHRQ NHSOPS is a widely used, validated survey that assesses provider and staff perspectives on 12 domains of safety culture (ranging from communication openness to training and skills). 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.

Among all 12 domains, 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).

Antibiotic Use

There was a statistically significant decrease of 0.41 total antibiotic starts per 1,000 resident days from baseline (January–February 2019) to the end of intervention (November–December 2019) across all sites (95% CI: -0.76 to -0.07, p=0.020). **Exhibit E-3** presents bimonthly antibiotic starts per 1,000 resident-days.



EXHIBIT E-3: BIMONTHLY ANTIBIOTIC STARTS PER 1,000 RESIDENT-DAYS

For individual antibiotic classes, fluoroquinolone antibiotic starts (including ciprofloxacin, levofloxacin, and moxifloxacin) per 1,000 resident-days decreased significantly from Jan-Feb to Nov-Dec 2019 (-0.21, 95% CI -0.35 to -0.08, p=0.002).

There was a decrease of 3.1 DOT per 1,000 resident-days from 64.1 in Jan-Feb to 61.0 in Nov-Dec, but this did not reach statistical significance (-3.1, 95% -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 Jan-Feb to Nov-Dec (-9.8, 95% CI -16.5 to -3.0, p=0.005). 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).

C. difficile Laboratory-Identifiable 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).

Urine Cultures Collected

Urine culture collection per 1,000 resident-days decreased from Jan-Feb to Nov-Dec 2019 (-0.38, 95% CI -0.61 to -0.15, p=0.001); **Exhibit E-4** presents the estimated urine cultures collected per 1,000 residentdays over time throughout the Safety Program period. Urine cultures are often collected without an appropriate indication in health care facilities. As asymptomatic bacteriuria is common, collecting urine cultures unnecessarily often leads to unnecessary antibiotic prescriptions. For the Safety Program, urine culture collection rates was a proxy for improved diagnostic stewardship.





E.3. Conclusions

The AHRQ Safety Program included a diverse cohort of 439 LTC facilities and had a positive impact on developing and enhancing ASPs in LTC facilities across the United States. The Safety Program successfully equipped frontline providers with tools and resources to incorporate AS principles into their facility culture. The Safety Program provided LTC settings with the novel framework of the Four Moments of Antibiotic Decision Making coupled with education on the best practices in the diagnosis and treatment of common infections in the LTC setting, to support integration of AS principles into the daily care of residents. Moreover, the Safety Program reinforced the science of safety, teamwork, and communication among LTC staff to develop a culture of safety around antibiotic prescribing. The Safety Program led to significant reductions in antibiotic starts—including fluoroquinolone starts which was a large focus of the Safety Program. LTC facilities across the United States are encouraged to use the toolkit developed for the Safety Program that will be publicly available to improve the culture of antibiotic prescribing in their facility.

CHAPTER 1: BACKGROUND

Chapter Summary

The overarching goal of the AHRQ Safety Program for Improving Antibiotic Use (Safety Program) was to improve antibiotic prescribing in the long-term care (LTC) setting. This chapter describes the Johns Hopkins Medicine/NORC at the University of Chicago (JHM/NORC) team, which was closely supervised and guided by AHRQ in the design and execution of the Safety Program. Additionally, it discusses the roles of the Technical Expert Panel (TEP), and the three organizations, which also operate as Quality Improvement Network-Quality Improvement Organizations (QIN-QIOs), that assisted the JHM/NORC team throughout the Safety Program in the role of Implementation Advisers.

Overview of the AHRQ Safety Program for Improving Antibiotic Use

The fundamental goal of the Safety Program is to improve antibiotic prescribing across acute care, LTC, and ambulatory care facilities in the United States. The overarching goals for participating sites are to:

- Develop and/or enhance existing antibiotic stewardship programs (ASPs) that allow for sustained optimized antibiotic use
- Understand how to address the attitudes, beliefs, and culture that often pose challenges to improving antibiotic prescribing
- Incorporate best practices for the diagnosis and treatment of common infections into daily practice using the Four Moments of Antibiotic Decision Making framework

The LTC component of the Safety Program was implemented from December 2018 through November 2019. Findings are presented in this report. **Exhibit 1** provides an overview of the LTC program.

EXHIBIT 1: OVERVIEW OF LONG-TERM CARE COHORT PROGRAM



The JHM/NORC Project Team

The AHRQ Safety Program for Improving Antibiotic Use is a collaborative intervention funded and guided by AHRQ and led by JHM/NORC. A TEP provided input into the design of the Safety Program and implementation strategies. The TEP consisted of 27 subject matter experts representing leaders in ASPs across acute care, LTC, and ambulatory care settings, patient leaders/patient advocacy groups, experts with experience conducting large-scale quality improvement work, executives from integrated health care delivery systems, and ex-officio members from government agencies. The TEP met twice prior to the implementation of the LTC Safety Program.

Three quality improvement organizations that also function as QIN-QIOs—Health Quality Innovators, Health Services Advisory Group, and Stratis Health—also supported the Safety Program. Individuals from these organizations served as Implementation Advisers for the participating LTC facilities.

1.1. Background

Although antibiotics can be vital for improving patient outcomes, their use is not always benign and they can cause unintended harm. Examples of antibiotic-associated harm include *Clostridioides difficile* infections, organ dysfunction, allergic reactions, and the development of antibiotic resistance on both an individual and a population level.² Thus, the relative pros and cons of antibiotic use should be carefully weighed every time they are considered.

AS is a concerted effort to ensure antibiotics are prescribed in the most effective way when antibiotics are needed, and to avoid antibiotic use when the benefits outweigh the risks. ASPs help health care practitioners with prescribing the right antibiotic, at the right dose, by the right route, for the right

length of therapy, and for the right indication. In LTC settings, determining if a resident has a bacterial infection that may benefit from antibiotic therapy can sometimes be challenging. Reasons include diagnostic uncertainty, limited access to and delays in results from diagnostic tests, prescribers who are mostly offsite, and the need to balance family members' preferences.

In 2016, the Centers for Medicare & Medicaid Services (CMS) published the Reform of Requirements for LTC Facilities, requiring LTC settings to implement "ASPs that include antibiotic use protocols and a system to monitor antibiotic use"³. Furthermore, CMS includes the ASP within the broader infection prevention and control program, which typically falls under the purview of infection control nurses or preventionists. The accompanying interpretive guidance that accompanies the Reform of Requirements summarizes the Centers for Disease Control and Prevention's Core Elements for Antibiotic Stewardship for Nursing Homes and specifies using standardized tools and criteria to assess residents for infections^{4,5,6}. Unlike in hospitals, where physicians are present daily to make decisions about antibiotic prescribing, in LTC settings, nurses must communicate concerns about residents, including changes in condition, to physicians who are often offsite. This means that in LTC settings, nurses and other frontline staff need to become familiar with the principles of antibiotic stewardship well as recognize opportunities to incorporate them into the daily care of their residents.

The premise of the Safety Program is that ASPs alone will be unlikely to improve long-term antibiotic prescribing practices in LTC facilities. Rather, improving prescribing practices in these settings involves changes to the culture surrounding antibiotic prescribing (e.g., understanding the potential harm associated with antibiotics, improving teamwork, improving communication, and respecting and encouraging dissenting opinions), as well as an improved understanding of diagnostic criteria specific to LTC residents with suspected infections. The Safety Program comprehensively addresses these issues by supporting ASPs in LTC facilities with educational content as well as content targeting the culture of safety, teamwork, and communication that helps lead to long-lasting improvements. The overarching goal of the Safety Program is to improve antibiotic prescribing practices and assist facilities with implementing effective ASPs.

1.2. Project Governance

The Safety Program was developed and executed by JHM/NORC under the close guidance of AHRQ and a TEP. Additional program support was provided by a group of implementation advisers. **Exhibit 2** describes the respective roles in the design, implementation, and evaluation of these groups in the LTC Safety Program.

EXHIBIT 2: NATIONAL PROGRAM TEAM PLUS PARTNERS, AHRQ SAFETY PROGRAM FOR IMPROVING ANTIBIOTIC USE

Organization	Role
Johns Hopkins Medicine (JHM)	JHM faculty led development of the educational toolkit for the Safety Program. JHM was responsible for leading Webinars and office hours, assisting participating sites with site-specific clinical questions that arose over the course of the Safety Program, overall program management, and budget oversight.
NORC at the University of Chicago	NORC led recruitment of long-term care facilities and onboarding of participating facilities, and supported a range of implementation activities, including hosting Webinars and office hours, developing and hosting the program Web site for the educational materials and data collection tools, collecting and analyzing data from participating facilities, and conducting the program evaluation.
Technical Expert Panel (TEP)	The TEP was composed of physicians, pharmacists, nurse practitioners, representatives from integrated health care delivery systems, representatives from patient advocacy groups, and ex-officio members of government agencies. The TEP provided guidance on program content, implementation, and evaluation. Appendix A-1 details the members and qualifications of the TEP.
Implementation Advisers	Three quality improvement organizations—Health Quality Innovators, Health Services Advisory Group, and Stratis Health—served as Implementation Adviser organizations. Staff members at each organization provided one-on-one support to participating sites. Each organization was responsible for providing assistance on program implementation to designated facilities.

The following two sections describe the program roles and responsibilities of the TEP and the Implementation Advisers.

1.2.1. Technical Expert Panel

Development of the AHRQ Safety Program for Improving Antibiotic Use included establishing a TEP—a panel of subject matter experts from crosscutting disciplines with knowledge of AS approaches in acute care, LTC, and ambulatory settings that provided input into the design of the Safety Program. Totaling 27 members (including nine ex-officio members), this multidisciplinary group exemplified a broad range of expert representation including leaders of ASPs, leaders of patients/patient advocacy groups, experts with experience conducting large-scale quality improvement projects, executives from health care systems, and ex-officio government officials. **Appendix A-1** details the TEP members and their professional affiliations.

TEP National Long-Term Care Meeting

The AHRQ Safety Program for Improving Antibiotic Use discussed the LTC cohort over two TEP meetings. **Appendix A-2** details the focus of the LTC discussions at each TEP meeting.

The first TEP meeting focusing on the LTC Safety Program took place on September 7, 2018, at the NORC offices in Bethesda, MD. The goals of the meeting specific to LTC were to discuss:

- 1. Additional material to be included in the educational toolkit
- 2. Progress to date with recruitment of facilities
- 3. Keeping facilities engaged throughout the program
- 4. Encouraging timely data submission from participating sites

The TEP discussed lessons learned from the pilot cohort, as well as preliminary results from the pilot evaluation. The JHM/NORC team used the TEP findings to improve the LTC cohort educational toolkit materials, recruitment, and implementation efforts.

The TEP members provided numerous recommendations and suggestions throughout the discussions, including:

- Suggestions to enhance educational content geared toward stewardship leaders as well as frontline staff at sites participating in the Safety Program
- Strategies to encourage more engagement during Webinars and office hours
- Ideas to improve communication strategies among frontline staff and residents/family members
- Suggestions to enlist the feedback of QIOs in disseminating educational materials at the end of the LTC cohort and to help with the sustainability of the Safety Program after the formal 1-year period.

The second TEP meeting in advance of the LTC Safety Program occurred on October 17, 2019 at the NORC offices in Bethesda, MD. The LTC-related goals of the meeting were to discuss suggestions for organizing and disseminating the LTC Safety Program toolkit and to discuss plans for analyzing the findings of the LTC Safety Program.

The TEP discussed program participation, LTC sites' engagement in education Webinars and site feedback, data collection and submission, the role of Implementation Advisers, and various challenges and ways they were addressed for this cohort.

TEP members provided a number of valuable recommendations and suggestions throughout the discussion, including strategies for sustaining activities after the program officially ends. The TEP emphasized the importance of creating a standard process or brief training to inform new staff members about stewardship efforts.

1.2.2 Implementation Advisers

JHM/NORC partnered with three QIN-QIOs to serve as Implementation Adviser organizations for the Safety Program:

- **HQI** is an independent, nonprofit consulting organization established in 1984. HQI serves as the Maryland and Virginia Quality Improvement Organization, and as the regional "boots on the ground" for two major Hospital Improvement Innovation Networks. HQI has experience working with health care professionals developing internal improvement capacity.
- HSAG provides health care quality expertise to both care providers and care recipients. Established in 1979, HSAG is a multistate quality improvement organization that, among other successes, has experience in reducing health care-associated conditions in nursing homes, improvement in antibiotic stewardship in outpatient settings, and improvement in infection control practices in ambulatory surgical centers.
- Stratis Health is an independent nonprofit organization that leads collaboration and innovation in health care quality and patient safety. Stratis Health has more than 40 years of experience, specializing in reducing health care-associated infections in hospitals and nursing homes. Stratis Health has supported quality improvement on behalf of Medicare for Minnesota since 1971.

Dedicated staff members at each QIN-QIO provided frequent and consistent one-on-one support to enrolled facilities participating program to assist with ensuring successful implementation of the Safety Program. Of note, the three quality improvement organizations were assigned to facilities in states for which they did not have other federally funded activities underway. The Implementation Advisers were the primary point-of-contact for facility members, and they helped to answer questions and troubleshoot issues that arose. Throughout the 12-month implementation period of the LTC cohort, the Implementation Advisers provided ongoing support to facilities for Safety Program implementation and data collection activities, with communication between the participating sites and Implementation Advisers occurring at least monthly through prearranged telephone calls.

CHAPTER 2: PROGRAM IMPLEMENTATION

Chapter Summary

This chapter describes the different facets of Safety Program implementation for the Long-Term Care (LTC) Safety Program, including: (1) development and refinement of the educational program, (2) recruitment and retention of LTC facilities, (3) Webinars and office hours, and (4) additional technical assistance and support for the LTC cohort.

Educational Program and the Four Moments of Antibiotic Decision Making Framework

The Safety Program incorporated aspects of: (1) antibiotic stewardship program (ASP) development, (2) cultural and behavioral change surrounding antibiotic decision making; (3) improved understanding of applying diagnostic criteria to the diagnosis and treatment of common infections in LTC residents; and (4) communicating concerns about infections with prescribers and with residents and their family members. These topics were addressed in Webinars and narrated presentations describing the diagnosis, management, and antibiotic therapy for common infectious disease syndromes. The Safety Program also offered office hours as an opportunity for participants to talk with each other and to ask questions of infectious diseases and antibiotic stewardship experts familiar with the care of LTC residents. The Safety Program provided participants with access to an array of other tools, including pocket cards, commitment posters demonstrating commitment to judicious antibiotic prescribing, and sample dialogues to discuss infectious concerns with caregivers to assist LTC staff in incorporating antibiotic stewardship principles into routine care.

The Four Moments of Antibiotic Decision Making framework, developed specifically for the Safety Program, was incorporated throughout the educational content. It reminds prescribers to consider the following questions every time antibiotics are considered (**Exhibit 3**):

EXHIBIT 3: THE FOUR MOMENTS OF ANTIBIOTIC DECISION MAKING



Does the resident have symptoms that suggest an infection?

What type of infection is it? Have we collected appropriate cultures before starting antibiotics? What empiric therapy should be initiated?

What duration of antibiotic therapy is needed for the resident's diagnosis?



It's been 2-3 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?

Recruitment and Retention of Long-Term Care Facilities

Recruitment into the LTC Safety Program took place from July through December 2018 and involved engagement with both Federal and non-Federal partners.

Recruitment Strategies

• AHRQ worked with the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) to ensure synergy across Federal stewardship initiatives and programs.

- Johns Hopkins Medicine/NORC at the University of Chicago (JHM/NORC) worked with non-Federal groups—including LTC associations, The Joint Commission, the Institute for Healthcare Improvement, and others—to assist with recruitment efforts.
- The program leveraged the listservs and newsletters of numerous organizations as dissemination channels, including AHRQ LTC and patient safety listservs and newsletters, the Armstrong Institute contact list, the QIN-QIO National Coordinating Team listserv, and the QIN Lake Superior newsletter, as well as the organizations' social media accounts (e.g., via LinkedIn, Twitter, and Facebook).
- JHM/NORC worked with the Society for Post-Acute and Long-Term Care Medicine (AMDA) to host a home page advertisement for the program and distribute e-blasts and Twitter posts to their community of over 5,000 medical directors, physicians, nurse practitioners, physician assistants, and other practitioners in long-term care settings.
- The program conducted email outreach to State health departments, as well as national and regional nonprofit organizations and nursing home chains, health care consulting companies, public and private health systems, university health systems, state and county public health departments and entities, and individual LTC facilities.
- JHM/NORC created a public facing Web site <u>SafetyProgram4AntibioticStewardship.org</u> to inform interested sites about the Safety Program and develop recruitment material.
- JHM/NORC led 13 Informational Webinars to inform interested sites about the Safety Program and field questions about the Safety Program.

A total of 1,634 individuals attended one of the 13 informational Webinars, which averaged approximately 125 attendees per Webinar. The National Program Team hosted informational Webinars from early July through early November 2018 on the following topics:

- Program overview
- Benefits of participation
- Data submission requirements
- Program timeline
- Key points of contact for program staff at JHM/NORC
- How to learn more about the program

A total of 523 long-term care facilities enrolled in the LTC cohort, with 23 accepted off of the 34 sites on the waitlist in the first 3 months; 439 facilities remained in the cohort for the duration of the Safety Program. These 439 facilities consisted of:

- Nursing homes
- Dementia care facilities
- Residential and continuing care facilities

Please refer to Exhibit E-2: Characteristics of Enrolled Facilities for additional information.

National Educational Webinars and Office Hours

Over the 12-month LTC Safety Program period, participating facilities were invited to attend 15 national educational Webinars. Each of these Webinars was offered two to three times on different days and times, to give participating facilities an opportunity to find a time that worked for staff in their facility. The Webinars focused on changing the culture of antibiotic prescribing and improving antibiotic prescribing for common infections, and on best practices, coinciding with intervention component of the Safety Program.

All content also was available on the Safety Program Web site. Live Webinars and office hours provided an opportunity for direct engagement between JHM/NORC and participating sites. To encourage Webinar participation, continuing medical education (CME) and continuing education units (CEUs) for nurses were offered for the educational webinars through the Postgraduate Institute for Medicine. Physicians at enrolled LTC facilities who attended the Webinars live were able to claim 0.5 AMA PRA Category 1 Credit(s)[™] and nurses were able to claim 0.5 contact hours.

In addition to participation on Webinars, sites were encouraged to participate in optional office hours led by JHM/NORC, which were held 1 to 2 weeks following each Webinar. Twenty-four office hours sessions were held over the course of the LTC Safety Program. The main goal of these calls was to give sites a venue for informal discussion on how program implementation was progressing at their sites. Along with discussions on implementation of ASPs, changing behavior, guideline development, and general resident management questions, these calls also facilitated peer-to-peer sharing. Participants could learn about: (1) struggles with ASP implementation faced by other sites and (2) strategies other sites developed to address barriers.

Implementation Adviser Activities

Within each Implementation Adviser organization there were several individual Implementation Advisers working with an assigned set of facilities (usually grouped by State). The Implementation Advisers were the primary point-of-contact for facility members, and answered questions and helped troubleshoot issues that arose. Questions and issues beyond the scope of their expertise or existing resources were relayed to the JHM/NORC team who subsequently contacted the relevant site.

An Implementation Adviser was assigned to each facility to provide assistance with program implementation as well as technical aspects of the Safety Program (e.g., ensuring all participants had access to the educational toolkit, ensuring awareness of when Webinars or office hours were being held, and assisting with data submission questions). Throughout the 12-month implementation period of the LTC Safety Program, the Implementation Advisers provided ongoing support to facilities for Safety Program implementation and data collection activities.

Communication between participating sites and Implementation Advisers occurred at least monthly through prearranged telephone calls. The JHM/NORC team had scheduled calls with all Implementation Adviser groups every other week throughout the LTC Safety Program, both to receive regular updates of

Safety Program progress and to assist with troubleshooting. The Implementation Advisers also triaged their respective facilities both qualitatively (through monthly phone calls) and quantitatively (through reviewing data collection status updates and Webinar attendance metrics) to identify sites that needed additional support—based on program participation, program activity implementation, and data collection progress. **Exhibit 4** details how the Implementation Advisers provided support for the hospitals' activities.

Facility Activity	Implementation Adviser Support Activity
 Antibiotic Stewardship Program (ASP) engagement with Implementation Advisers 	 Have an initial call with the ASP with all participating facilities to assess current state of the facility ASP efforts and what they hope to achieve from their participation in the project. Hold at a minimum monthly calls with each participating facility to assess progress, identify issues, and provide technical assistance.
2. Participate in Webinars	Promote participation on Webinars to enrolled facilities.Track attendance.
3. Hold regular ASP team meetings	 On an ongoing basis check in with facilities' staff to ensure that ASP meetings are being conducted.
4. Use Team Antibiotic Review Form (TARF) to inform facility intervention focus	 Provide support as needed to sites for completion of TARFs.
5. Identifying local interventions	 Assist facilities with their self-identified interventions.
6. Review quarterly benchmarking reports	 Distribute to and review with facilities their quarterly benchmarking reports.
7. Participate in office hours (optional)	 Participate in office hours for facilities to provide a forum to discuss challenges, areas where further assistance is needed, and share lessons learned with peers.
8. Disseminate National Educational Webinars materials	 Ensure that ASP leadership teams are sharing educational Webinar materials with other staff members within their respective organizations.
9. Submit data	 Register users as needed to the project Web site (Private section of the Web site). Review data collection status reports from NORC to identify facilities that need additional assistance with data submission.

EXHIBIT 4: IMPLEMENTATION ADVISER SUPPORT ACTIVITIES

JHM/NORC held a Stakeholder/Train-the-Trainer meeting for Implementation Adviser organizations to review and understand their key role in orienting and advising recruited facilities regarding program goals, educational content of the toolkit, and data collection requirements. The meeting took place on October 10, 2018, at NORC's offices in Bethesda, MD. Its purpose was to train HQI, HSAG, and Stratis Health on their role as Implementation Adviser organizations—with the following specific discussion goals:

1. Provide an overview of the AHRQ Safety Program focusing on the LTC Safety Program.

- 2. Review the Educational Toolkit content.
- 3. Discuss lessons learned from the pilot for the LTC setting.
- 4. Provide an overview of facility recruitment.
- 5. Provide examples of daily, weekly, and monthly activities of participating facilities.
- 6. Review roles and responsibilities of the Implementation Advisers.
- 7. Review the schedule of Webinars and Office Hours.
- 8. Review the data requirements and the data submission process.

The stakeholder meeting discussed the program's general goals, scope, and timeline, as well as clarified roles and responsibilities. The meeting helped ensure attendees understood their required tasks and the overarching goals of the Safety Program. The meeting also enabled the group to quickly identify and address any potential barriers to success before the implementation phase began. In addition, the meeting attendees reviewed the data collection requirements and data submission process and clarified the Implementation Adviser's role in helping facilities with data collection and submission. **Appendix A-3** lists the Stakeholder/Train-the-Trainer attendees.

The meeting solicited the Implementation Adviser organizations' suggestions and ideas in the following areas:

- Recommendations to keep sites engaged during the course of the Safety Program
- Approaches to evaluate the progress of participating sites
- Additional information necessary to support participating sites
- Additional technical issues for which the JHM/NORC team should develop further guidance

Additional Technical Assistance and Support

In addition to the Webinars and office hours, health care workers at participating sites had access to the Program Web site and the Help Desk, created specifically for the AHRQ Safety Program.

Program Web Site

The NORC-developed Program Web site (<u>SafetyProgram4AntibioticStewardship.org</u>) included both a public-facing component with general information on the Safety Program, and a secure log-in component that served as both a repository for content developed for the Safety Program, as well as a data submission portal. The Web site hosted content for users. Within each participating facility, staff members involved in the Safety Program were given log-in credentials for the user side of the program Web site. By the end of the Cohort, the Web site had 1,879 individual or unique users. The program materials were heavily used by participating facilities. The 20 most popular materials on the Web site had more than 4,000 unique downloads (averaging 200 downloads per material).

Help Desk

JHM/NORC also established a Safety Program email address, <u>antibioticsafety@norc.org</u>, as a centralized resource for information and technical assistance for participating facilities, Implementation Advisers, and JHM/NORC staff. The Help Desk provided a point of contact for questions, concerns, and participation requests for information.

JHM/NORC received implementation inquiries via the Help Desk from facility staff or their Implementation Advisers. Help Desk staff followed up with appropriate parties to ensure all questions were answered. For 2019, the Help Desk received a total of 2,889 inquiries.

Retention Strategies

Anticipating program enrollment attrition due to staff turnover typically seen at LTC facilities, the team employed a program waitlist, messaging to wait-listed facilities that an opening in the Safety Program could become available in the first few months of the program's implementation period. These waitlisted sites were able to join the national educational Webinars for the duration of the program so they were up to date if an opening became available. The JHM/NORC team limited replacements from the waitlist to the first 1–3 months of the program for evaluation purposes.

JHM/NORC structured the overall cohort to foster LTC facility engagement and support via the following retention strategies:

- Define participation requirements through informational Webinars, online FAQs, and other program materials throughout the recruitment period to clarify program expectations, address questions, and allow sufficient time to address any potential or initial barriers to participation (e.g., LTC facility administrator approval and sign off, programming for electronic health record [EHR] data extraction) well in advance of program implementation.
- Conduct informational and national educational Webinars at different days and times to accommodate conflicting schedules.
- Offer CME credits and CEUs for attending live Webinars.
- Record Webinars and post them to the program Web site for participating staff to listen to at their convenience.
- Hold regular office hours to allow for informal discussions and assistance regarding program implementation and access to subject matter experts for questions, and to facilitate peer-to-peer learning.
- Provide one-on-one support to participating facilities, answer questions, direct staff to available program resources, and follow up regarding data collection and submission issues.
- For any sites considering withdrawal, one of the program's principal investigators would reach out to the site to assist with troubleshooting any issues limiting participation.
- Provide participating staff and LTC facility's certificates of program involvement and completion for attending a majority of Webinars or submitting a majority of monthly EHR data elements.

2.1. Educational Program

The LTC Safety Program addressed: (1) ASP development, (2) cultural and behavioral change surrounding antibiotic decision making, (3) improved understanding of applying diagnostic criteria to the diagnosis and treatment of common infections in LTC residents, and (4) communicating concerns about infections with prescribing clinicians and with residents and their family members. These topics were presented through modalities that included:

- Monthly or bimonthly educational Webinars
- Monthly office hours
- Narrated presentations
- Commitment posters to demonstrate the LTC facility's commitment to judicious antibiotic prescribing
- Pocket cards and small posters for display in the LTC facility

ASP development emphasized the development or improvement of each site's ASP. Subtopics covered forming an antibiotic stewardship team; identifying antibiotic-related problems, engaging with a senior executive, developing an intervention, measuring the outcomes from the intervention, and the importance of sharing the results with stakeholders through the LTC facility including staff, administration, leadership, and residents and their family members.

Cultural and behavioral change included Webinars on four major aspects of cultural and behavioral change: (1) making the case that AS is a patient safety issue, (2) improving communication and teamwork, (3) identifying targets for improved antibiotic prescribing, and (4) learning from antibiotic-associated adverse events.

Diagnosis and treatment of common infections began by reviewing appropriate collection of microbiological specimens following the assessment and management of residents with a suspected urinary tract infection or respiratory tract infection. These topics were also presented as narrated presentations, with additional narrated content about approaching residents with a penicillin allergy and those with suspected skin or soft tissue infections.

Communicating concerns about infections offered communication tools to use during interactions with prescribing clinicians as well as with residents and their family members.

The Webinars included case examples based on real-world scenarios common to LTC residents. They also incorporated the Four Moments of Antibiotic Decision Making framework specific to LTC. To encourage teamwork, communication, and critical thinking using the Four Moments approach, the Safety Program recommended that sites complete at least five Team Antibiotic Review Forms each month. ASP members were requested to select residents either actively receiving antibiotics or those for whom there was concern about an infection. The staff would then use the Team Antibiotic Review form to go through the Four Moments for each of the selected residents.

2.2. Recruitment and Retention of Long-Term Care Facilities

Target enrollment for the LTC Cohort was 250–500 facilities encompassing the 10 HHS regions (See **Appendix A-4**). JHM/NORC undertook a systematic strategy to recruit, enroll, and retain facilities for the Safety Program. The multistep process is described in the next sections.

2.2.1. Recruitment Strategy

The National Program Team broke outreach and recruitment into three distinct phases to ensure Safety Program targets were met. Prerecruitment activities, which spanned January–June 2018, involved development and refinement of recruitment materials, and development and finalization of a recruitment plan. Active recruitment spanned July through December 2018 and involved engagement with recruitment partners, 13 informational Webinars, receipt and processing of facility applications and signed letters of commitment, and preparation of facilities for program activities (particularly around development of their antibiotic stewardship team and data collection activities). Enrolled facilities started program participation in December 2018. **Exhibit 5** provides an overview and of Safety Program activities during the LTC cohort's recruitment and immediate post-enrollment period.



EXHIBIT 5: RECRUITMENT PROCESS FLOW, JANUARY–DECEMBER 2018

LTC = long-term care

Federal Recruitment Partners

JHM/NORC used a multipronged recruitment approach, working with a wide range of recruitment partners, including Federal and non-Federal groups (**Exhibit 6**). JHM/NORC and AHRQ worked with Federal partners—including the CMS and CDC—to ensure synergy across federal antibiotic stewardship initiatives and programs. CMS staff disseminated information on the AHRQ Safety Program via monthly newsletters and Webinars. CDC staff disseminated AHRQ Safety Program information and recruitment efforts via their listservs, and also made announcements and distributed recruitment materials at relevant LTC conferences. JHM/NORC coordinated with AHRQ to increase awareness of the Safety Program on AHRQ's weekly electronic newsletter (118,000+ subscribers) and listserv (55,000+ subscribers).

Other Recruitment Partners

Concurrently, JHM/NORC worked with a multitude of non-Federal groups (including LTC associations, The Joint Commission, Institute for Healthcare Improvement, and others) to recruit LTC facilities within their networks. JHM/NORC also contacted health systems that had participated in the pilot program—Geisinger Health System, Lorien Health System, and Atrium Health—as well as other health systems that had not participated in the pilot (e.g., CommuniCare). In addition, JHM/NORC leveraged the Institute for Healthcare Improvement and JHM listservs and newsletters as dissemination channels.

EXHIBIT 6: LONG-TERM CARE RECRUITMENT EFFORTS



The National Program Team also

worked with the Society for Post-Acute and Long-Term Care Medicine (AMDA) to host a home page ad for the program and distribute e-blasts and Twitter posts to their community of over 5,000 medical directors, physicians, nurse practitioners, physician assistants, and other practitioners in long-term care settings. Additionally, the team conducted other social media outreach (e.g., via LinkedIn, Twitter, and Facebook).

Recruitment Role for Implementation Advisers

The Implementation Advisers were also an integral recruitment partner for the LTC cohort. As part of organizations that also function as Quality Improvement Network-Quality Improvement Organizations (QIN-QIOs) they are part of a larger network of QIN-QIOs that work with over 79 percent of U.S. long-term care facilities on quality improvement efforts. The IAs helped to disseminate program information advertised in the QIN-QIO National Coordinating Center newsletter, which supports a network of 14 QIN-QIOs nationally. In addition, the IAs also coordinated LTC cohort recruitment materials advertised in the Lake Superior QIN regional newsletter. QIN-QIO representatives recognize the value of the AHRQ Safety Program and were eager to inform LTC facilities they worked with about this free quality improvement program with many benefits.

As described earlier in this chapter under Recruitment Strategies, the JHM/NORC team leveraged numerous listservs and newsletters to promote the LTC cohort. These are summarized in **Exhibit 7** below.

Listservs/Newsletters for Recruitment	Reach/Contacts
AHRQ email list for long-term care	25,000
AHRQ patient safety email list	55,000
AMDA Listserv	5,000+
Armstrong Institute contact list	9,200
QIN-QIO National Coordinating Team listserv	2,000+
QIN Lake Superior newsletter (Michigan, Minnesota, and Wisconsin)	2,500+

EXHIBIT 7: LISTSERVS AND NEWSLETTERS FOR LONG-TERM CARE COHORT RECRUITMENT

AMDA = Society for Post-Acute and Long-Term Care Medicine; QIN-QIO = quality improvement network-quality improvement organization

Email Outreach

The program team conducted extensive email outreach, sharing program recruitment materials across local, regional, state, and national audiences. The JHM/NORC team leveraged additional contacts from the Safety Program's leads, TEP members, and Implementation Advisers.

One of the many recruitment efforts centered on outreach to the State health department health careassociated infections (HAI) committee and subcommittee participants, where antibiotic stewardship is a core component. The program team reached out to its network of contacts within these committees by state. Many of these State HAI contacts then shared program information within their respective State public health departments, as well as their HAI committee and subcommittee networks. The JHM/NORC team also reached out to participating sites from the AHRQ Safety Program Acute Care Cohort to inquire if they had an affiliated LTC facility that may be interested in LTC Cohort. See **Exhibit 8** for examples of organizations and other groups the program team included in this email outreach.

Organization Type	Organization Name
National and Regional Nonprofit Organizations	 American Health Care Association* Centra
	 Institute for Healthcare Improvement/National Patient Safety Foundation*
	The Joint Commission*
	New York Medical Directors Association
	Society for Infectious Diseases Pharmacists*
	Society for Post-Acute and Long-Term Care Medicine (AMDA)*

Organization Type	Organization Name
Nursing Home Chains	 CommuniCare* Genesis Healthcare* HCR ManorCare Leading Age
Healthcare Consulting Companies	 Infection Prevention Strategies LLC* Trivedi Consultants, LLC*
Public and Private Health Systems	 Atrium Health* Geisinger Health System*
University Health Systems	 Brown University* Case Western Reserve University, the University Center on Aging and Health Duke University, Duke Antimicrobial Stewardship Outreach Network* Johns Hopkins Health System* Ohio State University University of Maryland University of Michigan* University of Nebraska Medical Center* University of Rochester Medical Center
State and County Public Health Departments and Entities	 Alaska State Hospital and Nursing Home Association* Allegheny County Health Department* Arizona Department of Health Services* Montana Department of Public Health and Human Services Ohio Office of the State Long-Term Care Ombudsman* Oregon Health Authority, Public Health Division* Pennsylvania Department of Public Health* State health department HAI committee and subcommittee participants* Wisconsin Department of Health Services*
Individual LTC Facilities	 Via affiliated acute care hospitals that previously participated in the acute care program cohort

*Indicates followup recruitment outreach phone call and/or subsequent assistance with program recruitment efforts.

Recruitment Outreach Calls

Based on initial outreach emails, networking at conferences, informational webinars, and other recruitment outlets, the JHM/NORC team held recruitment calls with a number of organizations (**Exhibit 8**). During these calls the team provided an overview of the Safety Program, detailed eligibility and data collection requirements, and answered any questions about the program. These calls included both organizations to assist with recruitment efforts and organizations who may have had LTC sites interested in participating directly in the program.

Recruitment Followup Strategy

The National Project Team also employed a well-coordinated series of followup emails for interested sites at various points throughout the recruitment, application, and enrollment process, which culminated in a Letter of Commitment (LOC) from each LTC site (**Exhibit 9**).



EXHIBIT 9: TIMING OF COORDINATED FOLLOWUP EMAILS TO SITES INTERESTED IN PARTICIPATING

LOC = Letter of Commitment; LTC = Long-Term Care

These emails reminded interested parties of the multiple opportunities to learn more about the program, ask questions, or learn how to apply (**Exhibit 10**).

EXHIBIT 10: EXAMPLES OF FOLLOWUP EMAIL CONTENT

Email Example	Email Content
How to learn more about the program?	 Attend informational Webinar
	 Visit program Web site FAQs
	 Listen to online informational webinar recording
	 Contact the program (<u>antibioticsafety@norc.org</u>)
How to ask questions about the program?	 Attend informational webinar, which includes Q&A
	session
	 Contact the program (<u>antibioticsafety@norc.org</u>)
How to apply to participate in the program?	 Program Web site link provided to online application

FAQs = frequently asked questions; Q&A = question and answer

The National Program Team found that sending followup emails to sites that had submitted an application was a particularly successful strategy to enrolling LTC facilities into the program. Given the multiple demands of LTC facility executives, these prompts served as important reminders to directors of nursing, medical directors, and administrators. **Exhibit 11** details the number of followup emails the JHM/NORC team sent to LTC facilities that had applied for the Safety Program but not yet returned a signed letter of commitment, as well as the overall number of facilities that ending up enrolling in the

program. The National Project Team typically saw an increase in the number of submitted letters of commitments/enrollees in the days following one of these email reminders.





Program Web Site for Recruitment

JHM/NORC created a public facing Web site, <u>SafetyProgram4AntibioticStewardship.org</u>, to field requests to join the program, and developed a recruitment page to include frequently asked questions (FAQs), information about upcoming informational Webinars, an informational Webinar recording, and the program email address for interested facilities that had questions. The Web site FAQs covered a broad range of topics, including general LTC cohort questions (e.g., benefits of participation, timeline), eligibility, data collection requirements, and the Safety Program content.

Application for Program Enrollment

In addition, the Web site hosted the online application to begin enrollment into the LTC cohort. The application captured facility characteristics (e.g., size, type, and urbanicity), affiliation with a larger health system, EHR information, and facility contact information. Please refer to **Appendix A-5** for the online application. The application included separate instructions and pathways for both individual facilities applying and organizations that wanted to enroll multiple facilities. The online application instructed these larger nursing home chains or health systems to complete a Multiple Facility Contact Form. This form collected each facility name, NPI number, contact name, contact email, and contact phone number. The national program team sent a followup email to each facility contact from the Multiple Facility Contact Form with instructions on how to complete the individual facility online application. A total of 21 nursing home chains or health systems completed the Multiple Facility Contact Form; these organizations applied to enroll between 2 to 80 LTC facilities each.

Recruitment Informational Webinars

Instrumental to the LTC recruitment efforts, JHM/NORC held 13 informational Webinars, from early July through early November 2018, for facilities interested in joining the program. These informational Webinars provided an overview of the program and addressed questions and concerns of facilities considering joining the program. The JHM/NORC team arranged these Webinars to occur on different days of the week and at varying times to accommodate a broad range of schedules and time zones across the country. In addition, the program Web site provided a recording of an information webinar that could be viewed at any time. Informational webinar topics included:

- Program overview
- Benefits of participation
- Data submission requirements
- Program timeline
- Key points of contact for program staff at JHM/NORC
- How to learn more about the Safety Program

Exhibit 12 provides an overview of attendance at each of the informational Webinars. A total of 1,634 individuals attended one of the Webinars.



EXHIBIT 12: 2018 INFORMATIONAL WEBINAR ATTENDANCE BY DATE
After each informational Webinar, the JHM/NORC sent a thank-you email to participants for attending, along with a copy of the Webinar slides, a link to the online application to join the program, and a reminder to email the program team with any questions (<u>antibioticsafety@norc.org</u>).

Eligibility for Participation

Exhibit 13 below details the LTC facility eligibility for the cohort:

EXHIBIT 13: ELIGIBILITY CRITERIA FOR PARTICIPATING IN LONG-TERM CARE COHORT

LTC Facility Type	Inclusion Criteria	Exclusion Criteria
 Nursing homes Dementia care facilities Residential and continuing care facilities Skilled nursing facilities (SNF) Hospice facilities 	 Any location (rural, urban) Any electronic health record (EHR) (an EHR is not necessary to participate) Any size facility/number of beds Any nursing home rating SNF (with rehab beds or adjoining long-term acute-care hospital [LTACH] or ventilator unit) 	 Standalone LTACH Adult day care Home health Pediatric or developmentally disabled populations Rehabilitation facilities Assisted living facilities

Recruitment Materials

JHM/NORC developed recruitment and enrollment materials to provide to recruitment partners and LTC facilities:

General Recruitment Materials

- Outreach fliers
- Webinar outreach materials
- Email blasts for professional societies
- Posts on health care blogs
- Recruitment letters
- Recruitment FAQs
- Templates for email communications with LTC facilities/recruitment partners
- Pitch letter for partner communications
- Social media messaging

Enrollment and Post-Enrollment Materials

- Online enrollment application
- Commitment form
- "Next Steps" document

Enrollment Strategy

The LTC recruitment materials emphasized the benefits of program participation to eligible LTC facilities, including continuing education credits at no charge for participants. This free program also helped LTC facilities meet the CMS antibiotic stewardship requirements as well as The Joint Commission's Antimicrobial Stewardship Standard. Additional benefits of participating include:

- Monthly Webinars to review best practices in the management of common infectious syndromes, as well as approaches to improve teamwork and communication around antibiotic decision making
- Access to online presentations with facilitator guides that can be used to train frontline staff
- Assistance with developing and/or sustaining effective antibiotic stewardship programs
- Optional office-hours calls with experts to provide personalized guidance on antibiotic decision making or antibiotic stewardship activities
- Resident and family education materials, such as posters and handouts
- Certificates of Participation for facilities that completed the Safety Program

Help Desk for Recruitment Inquiries

The AHRQ Safety Program for Improving Antibiotic Use email address, <u>antibioticsafety@norc.org</u>, provided a centralized point of contact for recruitment questions, concerns, and requests for information from LTC facilities interested in participating in the Safety Program. Program enrollment or recruitment inquiries often related to specific actions to enroll (e.g., submitting an online application or a signed letter of commitment), data collection requirement, and/or questions related to the 13 informational recruitment Webinars offered. The Help Desk received 516 inquiries related to LTC recruitment between July 1, 2018 and November 30, 2018. The Help Desk continued to reply to recruitment inquiries through February 2019, during the program's implementation period. Refer to **Section 2.5** for more details regarding the Safety Program's dedicated Help Desk.

2.2.2. Retention Strategies

Early on during the recruitment period, the national program team began preparing for the higher staff turnover typically seen at LTC facilities. Anticipating program enrollment attrition due to staff turnover, the team employed a program waitlist, messaging to waitlisted facilities that an opening in the Safety Program could become available in the first few months of the program's implementation period. These waitlisted sites were able to join Safety Program webinars for the duration of the program so they were up to date if an opening became available. The national program team limited replacements from the waitlist to the first 1–3 months of the program for evaluation purposes. The waitlist protocol ensured the highest number of participating, engaged sites while accounting for attrition for the LTC cohort. **Exhibit 14** below summarizes recruitment and waitlist numbers. Refer to **Section 2.2.3** for more information on the site waitlist and withdrawal numbers for LTC.

EXHIBIT 14: SUMMARY OF RECRUITMENT STATISTICS

Recruitment	
Multiple Facility Contact form/applications received	21
Applications received	653
Waitlisted facilities at start of LTC cohort	
Letters of Commitment received	534
Total facility withdrawals	
Final enrollment at end of cohort	

The Implementation Advisers served as another key retention strategy, playing a principal role in keeping LTC facilities engaged in the Cohort. As detailed earlier, Implementation Advisers provided oneon-one support to participating LTC facilities, and were responsible for facility engagement and active participation. They served as the main facilitators for the program—offering continued support and guidance to facilities regarding data collection, accessing program resources, Webinar attendance, and other program requirements.

Implementation Adviser engagement activities included:

- 1. Initial onboarding call to discuss any LTC facility questions or concerns regarding participation
- 2. Monthly calls to discuss current issues and questions
- 3. Monthly and weekly prompting calls and email reminders of upcoming data submissions
- 4. Ad hoc calls and emails to discuss upcoming program activities, as well as questions regarding benchmarking reports, the waitlist, and other inquiries

The program also implemented numerous engagement strategies at the program level:

- Three antibiotic stewardship experts developed and led Webinars and office hours to provide consistency of messages, support continuity across the span of the program, and build the opportunity for ongoing relationships between the experts and the participants. These experts were all infectious disease physicians with experience in the caring for LTC residents.
- 2. Monthly office hours calls enabled facilities to engage regularly with stewardship experts on a broad range of topics.
- 3. Webinars and office hours were offered on several different dates and at several times of day to accommodate participants' schedules.
- 4. JHM/NORC staff worked with sites to facilitate data submission and allowed data submission via the program's online secure portal or via fax to better meet facilities' needs.
- 5. A JHM/NORC lead had email and/or phone contact with any facility considering withdrawal from the cohort.

2.2.3. Retention Challenges

From the initial recruitment stage on, JHM/NORC emphasized flexibility and the Safety Program's willingness to work with facilities to remain in the cohort. Implementation Advisers alerted JHM/NORC anytime their facilities had questions or concerns regarding their continued participation. Once Implementation Advisers contacted JHM/NORC when a LTC facility was considering withdrawing, one of the Safety Program principal investigators reached out directly to facility staff to answer any questions or concerns, and tried to work with the facility to remain in the cohort. A main challenge for the LTC cohort was site attrition due to high staff turnover.

The LTC Safety Program began with 500 enrolled facilities and 34 waitlisted facilities (**Exhibit 15**). Over the course of the LTC Safety Program, 78 of the original facilities withdrew and 6 of the waitlisted facilities who eventually joined the program withdrew, for a total of 84 withdrawals.



EXHIBIT 15: TOTAL RECRUITMENT NUMBERS AND WAITLISTED FACILITIES

LTC = long-term care

While the program waitlisted 34 facilities, within the first three months the National Project Team offered program enrollment to all but 3 of these facilities. **Exhibit 16** provides details about the outcomes of facilities initially on the waitlist.





Facilities that withdrew had similar LTC facility characteristics compared with facilities that remained for the duration of the program regarding facility type, urban/rural location, and being owned by a larger health system. Once a facility withdrew, the JHU/NORC team replaced it with a facility from the waitlist. The program began with 34 facilities on the waitlist, and 23 wait-listed facilities eventually enrolled in the program. Six of these 23 facilities ultimately withdrew from the program (included in the total number of facility withdrawals) and 17 completed the program. **Exhibit 17** summarizes the reasons LTC facilities provided for withdrawal.

EXHIBIT 17: REASONS FOR FACILITY WITHDRAWAL (N=84)



2.3. Webinars and Office Hours

This section highlights the process of engaging LTC facilities once they agreed to take part in the LTC Safety Program.

2.3.1 Onboarding of Long-Term Care Facilities

Once facilities agreed to participate in the program and returned a signed Letter of Commitment to JHM/NORC, onboarding activities began. During this period, facilities established their antibiotic stewardship team and started building the needed infrastructure for a successful ASP. Additional onboarding activities included:

- Introductory Webinar. JHM/NORC hosted the first Webinar, Introduction to the AHRQ Safety Program for Improving Antibiotic Use, which served as an onboarding Webinar for sites.
- Identifying a site lead. The JHM/NORC team encouraged the formation of an antibiotic stewardship team with a multidisciplinary background. Facilities identified a physician or pharmacist champion willing to be trained to become the antibiotic stewardship lead (if leads were not already present at participating sites). An AS team lead could also be an infection control nurse, infection preventionist, nurse, assistant director of nursing, or director of nursing.
- Speaking with Information Technology (IT) staff to establish the data submission process. Sites were encouraged to connect with their IT staff prior to the official start of the program to develop a process for data extraction and submission.

2.3.2. Content/Program Webinars

Over the 12-month LTC Cohort implementation period, participating facilities were invited to attend 15 educational Webinars. Each Webinar lasted for 30 minutes and there was generally 15–30 minutes after the end of each Webinar for questions and answers. The target audience for the Webinars was both ASP members and frontline staff. JHM developed content for the Webinars in close consultation with AHRQ; NORC provided operational support.

Webinars were offered three times on different days and times, to give participating facilities an opportunity to find a time that worked for their teams. The exception was the first Webinar, which was an onboarding webinar that occurred six times in November and December 2018 during the Cohort Implementation for LTC sites. This Webinar familiarized participants with the goals of the Safety Program and the components of the educational toolkit. It also informed sites about data collection and submission requirements.

The remaining 14 Webinars focused on changing the culture of antibiotic prescribing and best practices to improve antibiotic prescribing for infections common among LTC residents. **Exhibit 18** outlines the content and timing of the 15 Webinars.

Order	Month	Webinar Title	Туре
1	Nov-Dec 2018	Introduction to the AHRQ Safety Program for Improving Antibiotic Use	Onboarding
2	Dec 2018	Developing an Antibiotic Stewardship Program	Technical
3	Jan 2019	Partnering With a Senior Executive	Adaptive
4	Jan 2019	Improving Antibiotic Use Is a Patient Safety Issue	Adaptive
5	Feb 2019	Improving Teamwork and Communication	Adaptive
6	Feb 2019	Identifying Targets To Improve Antibiotic Use	Adaptive
7	Mar 2019	Changing the System To Improve Patient Safety	Adaptive
8	Apr 2019	Appropriate Collection of Microbiologic Specimens	Technical
9	May 2019	Assessment of the Resident With a Suspected Urinary Tract Infection	Technical
10	Jun 2019	Treatment of the Resident With a Suspected Urinary Tract Infection	Technical
11	July 2019	Assessment of the Resident With a Suspected Respiratory Tract Infection	Technical
12	Aug 2019	Treatment of the Resident With a Suspected Respiratory Tract Infection	Technical
13	Sep 2019	Communicating Infectious Concerns With Antibiotic Prescribers	Adaptive
14	Oct 2019	Discussing Infectious Concerns About Residents With Family Members and	Adaptive
	0002013	Caregivers	
15	Nov 2019	Sustaining Your Antibiotic Stewardship Program	Adaptive

EXHIBIT 18: OVERVIEW OF LONG-TERM CARE COHORT WEBINAR TOPICS

*The final publicly available educational toolkit will separate out hospital-acquired and ventilator-acquired pneumonia into two separate presentations.

The Webinars were well attended throughout the Safety Program, averaging 230 attendees per topic (**Exhibit 19**). In some facilities staff members gathered in a room together to view the Webinars as a team; to capture this, the Webinars were set up so that participants were able to indicate how many attendees from their location were in attendance as they logged in to the Webinar. The attendance numbers in **Exhibit 19** reflect the total attendance of individuals, rather than simply the number of telephone lines used.



EXHIBIT 19: WEBINAR ATTENDANCE BY TOPIC

Overall, participants found the Webinars to be helpful based on feedback requested after each Webinar (Exhibit 20).



EXHIBIT 20: PARTICIPANT RATINGS OF USEFULNESS OF WEBINARS

CME and CEUs for nurses were offered for the Webinars through the Postgraduate Institute for Medicine. Physicians at enrolled LTC Facilities who attended the Webinars live were able to claim 0.5 AMA PRA Category 1 Credit(s)[™] and nurses were able to claim 0.5 contact hours. By the end of the program, participants claimed 1,361 credits. **Exhibit 21** shows the number of participants who claimed credits, by topic.

EXHIBIT 21: CREDITS CLAIMED, BY TOPIC



2.3.3. Office Hours

In addition to participation on Webinars, sites were encouraged to participate in optional office hours sessions led by JHM/NORC. The main goal of these calls was to give sites a venue for informal discussion on how program implementation was progressing at their sites. Along with discussions on implementation of ASPs, changing behavior, guideline development, and general medical management questions, these calls also facilitated peer-to-peer sharing. Participants could learn about: (1) other sites that were struggling with the same issues and also (2) strategies other sites developed to address barriers. The JHM/NORC also prepared discussion topics with questions and answers, if needed, to facilitate further conversation during office hours.

Office hours sessions were held 1 to 2 weeks following each Webinar, with 24 office hours sessions held over the course of the long-term care cohort year. Attendance averaged 51 participants per session (Exhibit 22).

EXHIBIT 22: OFFICE HOURS ATTENDANCE BY DATE



2.3.4. Other Implementation Activities

- In addition to attending Webinars and office hours, health care workers in participating facilities were encouraged to do the following:
- Incorporate antibiotic time outs into their daily practice

AHRQ Safety Program for Improving Antibiotic Use: Long-Term Care Cohort Final Report

- Meet at least weekly to complete Team Antibiotic Review Forms as a collaborative effort between frontline providers and the ASP team
- During regular team meetings, identify areas for improvement and develop solutions with input from a multidisciplinary group of health care workers
- Review antibiotic use over time and identify areas for improvement

During the Safety Program registration, each enrolled facility was asked to identify an ASP lead and/or data coordinator, to facilitate the data collection and communicate with their Implementation Adviser regarding any data collection issues or updates. Each site received access to the *AHRQ Safety Program for Antibiotic Use Data Collection and Submission Guide*, which was posted on the program Web site. The guide contained information on the purpose of the data collection, types of data to be collected and submitted, data collection and submission timeline for each data element, and step-by-step instructions for completing the data collection forms online and submitting the forms on the Web site portal.

As part of their participation in the LTC Safety Program, each facility received quarterly benchmarking reports to compare their facility's progress to similar facilities. These reports contained individualized results for all the data submitted by the facility (**Appendix A-6** illustrates a sample quarterly benchmarking report):

- Baseline and endline structural assessment
- Baseline and endline Nursing Home Survey on Patient Safety Culture
- Q1, Q2, Q3, and Q4 antibiotic days of therapy per 1,000 resident-days (overall) and by antibiotic subclass
- Q1, Q2, Q3, and Q4 antibiotic starts per 1,000 resident days (overall) and by antibiotic subclass
- Q1, Q2, Q3, and Q4 C. difficile laboratory-identifiable events per 10,000 resident-days
- Q1, Q2, Q3, and Q4 urine cultures collected per 10,000 resident-days

The reports also included aggregate data results from similar facilities (Benchmark). The quarterly benchmarking reports enabled sites to compare their progress with that of similar facilities, and to see their progress over the course of the Safety Program. ASPs were encouraged to share and discuss these reports, both within their team and with the frontline staff members and administrators.

2.4. Program Web Site

To ensure all participants had 24/7 access to the long-term care educational toolkit, NORC developed a Program Web site (<u>SafetyProgram4AntibioticStewardship.org</u>). The Web site included both a public-facing component with general information on the program, and a secure log-in component that served as a repository for content developed for the Safety Program as well as a data submission platform. Within each participating facility, staff members involved in the Safety Program were given log-in credentials for the user side of the program Web site. By the end of the cohort, the Web site had 1,879 users. **Exhibit 23** outlines the structure of the program Web site.

EXHIBIT 23: STRUCTURE OF THE PROGRAM WEB SITE



FAQs = frequently asked questions

JHM/NORC continued to add content over the course of the LTC Safety Program. By the end of the 1year period, the Web site contained the following resources shown in **Exhibit 24**:

EXHIBIT 24: AVAILABLE RESOURCES IN PROGRAM WEB SITE

Resource Type	Resource Name		
Educational webinars	 Webinar and office hours schedule, Webinar recordings, Webinar slides with facilitator guides 		
Data collection information	 Data collection-related templates and instructions, copies of data collection tools, program Web site and data collection Webinar recording and slide set, Team Antibiotic Review Form and completion guide 		
Implementation Resources	 Gather a Team Guide Timeline and Tasks Checkpoint Tool Informational Flier Intervention worksheet Template for an Antibiotic Stewardship Policy for Post-Acute and Long-Term Care Settings LTC Commitment Poster Four Moments Poster Staff Safety Assessment LTC Learning From Antibiotic- Associated Adverse Events Sustainability Plan Urinalysis and UTIs Improve Care Training Modules Sustainability Plan Sustainabilit		
Narrated presentations	 Assessment of the Resident With a Suspected UTI Approaching the Resident With a Penicillin Allergy Management of the Resident With a Suspected UTI Communicating Infectious Concerns With Antibiotic Prescribers Discussing Infectious Concerns About Residents With Family Members and Caregivers RTI = respiratory tract infection; SBAR = Situation, Background, Assessment, and Request; UTI = urinary tract infection 		

Participants appeared to be regularly accessing Safety Program Web site content. By the end of the LTC cohort, the 20 most popular materials on the Web site had just over 4,000 unique downloads (averaging 200 downloads per material). **Exhibit 25** shows the 20 most frequently downloaded materials from the Safety Program Web site.

EXHIBIT 25: TOP 20 MOST DOWNLOADED AHRQ SAFETY PROGRAM FOR IMPROVING ANTIBIOTIC USE MATERIALS DURING THE LONG-TERM CARE COHORT



RTIs = respiratory tract infections; SBAR = Situation, Background, Assessment, and Request; UTIs = urinary tract infections

In addition to program resources, the Safety Program lead at each site had access to the data portal section to submit data for their facilities.

2.5. Help Desk for Implementation Inquiries

NORC established the AHRQ Safety Program for Improving Antibiotic Use email address <u>antibioticsafety@norc.org</u> as a centralized resource for information and technical assistance for participating facilities and Implementation Advisers. The Help Desk provided a point of contact for questions, concerns, and requests for information from participants. The Help Desk developed a central repository for issues, concerns, suggestions, and most importantly, resolutions that came through the Help Desk. JHM/NORC monitored all requests in a systematic and thorough manner and assigned questions to the appropriate subject matter expert or team member (e.g., infectious diseases physicians answered clinical questions, Safety Program staff answered questions about Web site log-in details, etc.) Upon contacting the Help Desk, inquirers received an automated response confirming that the Safety Program had received their email and would respond in full as soon as possible. NORC staff monitored the emails daily, and typically responded to all inquiries within one to two business days. For calendar year 2019, the Help Desk received a total of 2,889 initial inquiries, of which 79 percent (n=2,273) related to the LTC Cohort and the remaining 21 percent (n=616) to inquiries about the Ambulatory Care Cohort recruitment, which overlapped the LTC Cohort implementation period.

JHM/NORC received implementation inquiries via the Help Desk either directly from staff at participating sites or through their Implementation Advisers (Section 1.2.2). If Implementation Advisers did not have adequate information to address any issues, they forwarded these issues to the Help Desk. NORC followed up with contacting the appropriate person to answer the question, so the Implementation Adviser could return the correct guidance to the LTC facility.

When the Help Desk staff noticed frequently recurring inquiries, these became part of the internal FAQs document for Help Desk staff, and/or part of a weekly Implementation Adviser question and answer resource available throughout the implementation period. **Exhibit 26** provides a summary of Help Desk inquiries communicated through the Implementation Adviser question and answer resource document. Note that this resource guide did not include clinical questions. The Help Desk forwarded them to the LTC subject matter experts, who wrote responses that were shared via email with the LTC sites that submitted the query.



EXHIBIT 26: SUMMARY OF KEY INQUIRIES FOR IMPLEMENTATION ADVISERS

KEY	Examples
Administrative Inquiries – 3%	Data use agreements; processes for disseminating resources
National Educational Webinars – 14%	Access to past webinars and resources mentioned in webinars
Office Hours – 5%	Attendance questions, followup questions; additional resources
CME/CEU – 16%	Process for obtaining credits; credit receipt timeline
Data Collection Tools – 33%	NHSOPS data collection and use; TARF data collection process
Other Data Collection Inquiries – 19%	Monthly data collection template; resubmitting data
General Inquiries – 10%	Web site access; availability of program materials

CME/CEU = continuing medical education/continuing education units; NHSOPS = Nursing Home Survey on Patient Safety Culture; TARF = Team Antibiotic Review Form

CHAPTER 3: PROGRAM IMPACT

Chapter Summary

In this chapter, we describe the goals of the Long Term Care (LTC) cohort evaluation, including the data collection timeline, primary and secondary data sources, data analysis methods, and key findings.

Evaluation Goals

The evaluation of the LTC cohort sought to answer three major questions:

- 1. What is the extent to which the Safety Program has been adopted by LTC cohort participating units?
- 2. What impact did the Safety Program have on changes in safety culture, antibiotic usage, *Clostridioides difficile* (*C. difficile*)rates, and urine cultures?
- 3. Is there any variation in the effectiveness of the Safety Program by facility characteristics (e.g., facility size, ownership, type, and geographic location)?

Data Collection

To evaluate the adoption, effectiveness, and variation of the Safety Program, we collected monthly facility-level data on antibiotic usage, *C. difficile* LabID events, and urine culture obtained for January-December 2019, along with facility-level Structural Assessment and provider/staff perspective on safety culture using AHRQ Nursing Home Survey on Patient Safety Culture (NHSOPS) at baseline and endline. **Exhibit 27** summarizes the data sources including data collection tools, target population, and frequency of data collection.

Evaluation Domain	Data Source/Measurement	Person(s) Responsible for Collection	Frequency of Data Collection
Adoption	Structural Assessment	A member of the antibiotic stewardship program (ASP) at participating sites	Baseline and endline
Effectiveness	Nursing Home Survey on Patient Safety Culture (NHSOPS)	All eligible staff from participating facilities	Baseline and endline
	Electronic health record (her) extracts for antibiotic starts per 1,000 resident-days by facility	ASP in conjunction with information technology department	Monthly from January to December 2019
EHR extracts for days of antibiotic therapy per 1,000 resident-days by facility			
	EHR extracts for <i>C. difficile</i> LabID events per 10,000 resident-days by facility		
	EHR extracts for number of urine cultures collected per 1,000 resident-days by facility		
Variation	EHR extracts antibiotic use and other outcomes data along with Structural Assessment and program registration data	See above	See above

EXHIBIT 27: LONG-TERM CARE COHORT EVALUATION DOMAIN AND DATA SOURCE

Participating facilities completed the baseline structural assessment during program application from July to December 2018. After completing the enrollment process, facilities began collecting and submitting relevant data elements in December 2018, beginning with the baseline NHSOPS surveys completed by eligible staff. The endline structural assessment and NHSOPS were completed at the end of the program from November 2019 to January 2020.

Participating facilities were asked to extract antibiotic usage, *C. difficile* events, and urine culture data via electronic health record (EHR) extraction or hand collection and submit them to the Safety Program Web site on a monthly basis for January-December 2019, by downloading the template from the Safety Program Web site and uploading the completed template to the same Web site. Data for each month were to be submitted by the end of the following month (e.g., March 2019 data submitted by April 30, 2019). The submission for data for the LTC cohort lasted until February 2020. **Exhibit 34** displays the percentage of units that completed the Safety Program that submitted monthly *C. difficile* LabID events and antibiotic use data.

Analytic Methods

The program evaluation used a pre-post longitudinal study design. Study population included 439 LTC facilities nationwide. The unit of analysis is participating facility.

Adoption of AHRQ Safety Program

We looked at descriptive statistics for antibiotic stewardship—related infrastructure collected from the structural assessment form and used the Chi-square test to compare the difference between baseline and end-of-intervention.

Patient safety culture as measured using NHSOPS

We collected NHSOPS data among participating facilities at baseline and end-of-intervention to measure the change in patient safety culture and assess the effectiveness of the Safety Program. We used linear mixed model with random intercept for LTC facility to examine the change in composite scores for each of the twelve NHSOPS domains from baseline to the end-of-intervention.

Antibiotic use, C. difficile LabID events, and urine culture collected

In addition to NHSOPS data, we also collected four monthly outcome measures, including antibiotic starts per 1,000 resident-days, antibiotic days of therapy per 1,000 resident-days, *C. difficile* LabID events per 10,000 resident-days, and urine cultures collected per 1,000 resident-days, in order to assess the effectiveness of the Safety Program.

For monthly tracked measures, generalized linear model with random intercept for LTC facility was used to assess the change from baseline (i.e., January-February 2019) to each of the bimonth intervention periods (i.e., March-December 2019) for each of the four measurements. The difference between January-February and November-December also represented the change from baseline to end-of-intervention. For antibiotic use, in addition to total antibiotic starts and total DOT, we also examined antibiotic starts and DOT per 1,000 resident-days for 11 antibiotic classes using the same method.

To assess the variation in effectiveness, a stratified analysis was used to examine bimonth changes in total antibiotic starts, antibiotic DOT, *C. difficile* LabID events, and urine cultures collected over time by selected facility characteristics, including number of beds (size), ownership, short-stay, and geographic location. The stratified variable and its interaction with time (i.e. bi-month indicator) were included in the generalized linear mixed model as independent variables in addition to bi-monthly period indicators.

Results

Below is a summary of key findings for the LTC cohort:

Characteristics of participating facilities

A total of 439 facilities completed the Safety Program LTC cohort. The number of certified beds averaged 124 in participating facilities, with a range from 18 to 874. About 70 percent of the facilities were either hospital based or owned by a larger health organization. Over 50 percent of facilities provided residential stay primarily (i.e., less than 25 percent short-stay residents). About 40 percent of facilities reported their location as rural.

Adoption of AHRQ Safety Program

All LTC facilities enrolled in the Safety Program completed the baseline assessment. Eighty-four percent of facilities (367 out of 439) also responded to the endline assessment. In these assessments, we evaluated the local stewardship and quality improvement infrastructure. All but one item improved significantly. Among all assessed actions to improve antibiotic use, post-prescription review with feedback of select antibiotics had the largest improvement, from 38 percent at baseline to 61 percent at the end of the Safety Program.

Patient safety culture as measured using NHSOPS

Among all 12 domains in the NHSOPS, only 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 percent, 95% CI: +12.2 percent to +17.2 percent, p<0.001).

Antibiotic Use

For the entire cohort, antibiotic starts per 1,000 resident-days decreased significantly by 0.41 (95% CI: - 0.76 to -0.07, p=0.020) from 7.89 at baseline to 7.48 at the end of intervention. The reduction was also significant for other bimonth intervention periods except for March-April. Antibiotic starts per 1,000 resident-days decreased significantly among mid-sized facilities, hospital-based facilities, and facilities with at least 75 percent short-stay beds. Similarly to DOT, fluoroquinolone starts per 1,000 resident-days decreased significantly; compared with baseline, fluoroquinolone use decreased by 0.21 starts per 1,000 resident-days (95% CI: -0.35 to -0.08, p=0.002) at the end of intervention.

Antibiotic DOT per 1,000 resident-days was 64.1 at baseline (i.e., January-February 2019), and 61.0 at the end of intervention (i.e., November-December 2019), reflecting a reduction of 3.1 DOT per 1,000 resident-days (95% CI: -6.34 to 0.23, p=0.068). For fluoroquinolones, DOT per 1,000 resident-days decreased significantly; compared with baseline, fluoroquinolone use decreased by 1.2 DOT per 1,000 resident-days (95% CI: -2.1 to -0.2, p=0.014) at the end of intervention.

C. difficile LabID events

For the entire cohort, *C. difficile* LabID events per 10,000 resident-days decreased by 0.16 from 1.66 at baseline to 1.50 at the end of intervention (95% CI -0.64 to 0.33, p=0.524), which did not attain statistical significance.

Urine cultures collected

For the entire cohort, urine cultures collected per 1,000 resident-days decreased significantly by 0.38 (95% CI: -0.61 to -0.15, p=0.001) from 3.01 at baseline to 2.63 at the end of intervention. The reduction was also significant for other bimonth intervention periods. Urine culture collected per 1,000 resident-days decreased significantly among midsized facilities, facilities that are not hospital based but part of a larger system, facilities with at least 75 percent short-stay beds, and facilities in suburban areas.

3.1. Evaluation Goals

The evaluation of the LTC Cohort sought to answer three major questions:

- 1. What is the extent to which the Safety Program has been adopted by LTC cohort participating units?
- 2. What impact did the Safety Program have on changes in safety culture, antibiotic usage, *C. difficile* rates, and urine cultures?
- 3. Is there any variation in the effectiveness of the Safety Program by facility characteristics (e.g., facility size, ownership, type, and geographic location)?

To address these questions, the three major data sources the evaluation used were a structural assessment, patient safety culture surveys, and a monthly template collecting facility-level antibiotic use, *C. difficile* LabID events, and the number of urine cultures collected.

The evaluation used a pre-post longitudinal design to evaluate:

- 1) The effectiveness of the intervention, with monthly facility-level antibiotic starts per 1,000 resident-days and days of antibiotic therapy per 1,000 resident-days as the primary outcomes.
- 2) Changes in the antibiotic stewardship (AS) infrastructure among the participating sites, assessed by responses to AHRQ NHSOPS before and after implementation of the Safety Program.
- 3) Program impact by changes in the number of *C. difficile* laboratory-identified (LabID) events per 10,000 resident-days and the number urine cultures collected per 1,000 resident-days.

Exhibit 28 presents the evaluation goals, research questions, data sources, and analytic methods used to evaluate the LTC Safety Program.

Evaluation Goals	Research Questions	Data Sources and Measures	Analytic Methods
Goal 1: Implementation of AHRQ Safety Program for Improving Antibiotic Use	What is the extent to which the AHRQ Safety Program for Improving Antibiotic Use has been adopted by sites participating in the long-term care (LTC) cohort?	Structural Assessment: The AHRQ Safety Program lead at each facility participating in the LTC Cohort completed a five to seven question form to collect information on each facility's infrastructure to conduct the program, as well as prior involvement in quality improvement programs.	Descriptive statistics and Chi-squared test to assess change in AS infrastructure from baseline to end-of- intervention
GOAL 2: Effectiveness of the AHRQ Safety Program for Improving Antibiotic Use	 (1) What is the effectiveness of the Safety Program for Improving Antibiotic Use in the LTC context? (2) What changes in safety culture, antibiotic usage, and/or clinical outcomes have resulted from the LTC Cohort? 	 Patient Safety Culture Surveys: composite scores for each of the 12 domains in AHRQ Nursing Home Survey on Patient Safety Culture (NHSOPS) Electronic health record (her) extracts for antibiotic usage and other outcome data for each participating facility (monthly for January-December 2019): Antibiotic starts per 1,000 resident-days Days of antibiotic therapy per 1,000 resident-days Number of <i>Clostridioides difficile</i> LabID events per 10,000 resident-days Number of urine cultures collected per 1,000 resident-days 	Linear mixed model to assess facility-level change in each of the 12 NHSOPS composite scores from baseline to end-of-intervention Generalized linear mixed models to assess facility-level change in antibiotic usage and other outcome data over time
GOAL 3: Variation in effectiveness of the AHRQ Safety Program for Improving Antibiotic Use	What is the variation in the change in antibiotic usage and other outcomes by selected facility characteristics?	 EHR extracts for antibiotic usage and other outcome data Facility characteristics from registration information and baseline structural assessment 	Generalized linear mixed models to assess facility-level change in antibiotic use and other outcomes over time by facility characteristics

EXHIBIT 28: AHRQ SAFETY PROGRAM FOR IMPROVING ANTIBIOTIC USE IN THE LONG-TERM CARE CONTEXT: EVALUATION GOALS/DOMAINS, RESEARCH QUESTIONS, DATA SOURCES, AND ANALYTIC METHODS

3.2. Data Collection Plan and Timeline

Participating facilities completed the baseline Structural Assessment during program application from July to December 2018. After completing the enrollment process, facilities began collecting and submitting relevant data elements in December 2018, beginning with the baseline NHSOPS surveys completed by eligible staff. The endline Structural Assessment and NHSOPS were completed at the end of the program, beginning in November 2019, and through January 2020.^b Facilities also began collecting monthly antibiotic usage and other outcomes in January 2019. **Exhibits 29 and 30** show the data collection and submission timelines for the data elements collected during the LTC Cohort.

EXHIBIT 29: STRUCTURAL ASSESSMENT AND NHSOPS DATA COLLECTION AND SUBMISSION TIMELINES



^b The official deadline for data collection was January 31, 2020, but we still accepted late submission and resubmissions for certain data in February 2020.

EXHIBIT 30: TIMELINE FOR COLLECTION AND SUBMISSION OF MONTHLY ANTIBIOTIC USAGE, C. DIFFICILE LABID EVENTS, AND URINE CULTURES COLLECTED



C. difficile = Clostridioides difficile; Q = quarter

3.3. Data Collection Elements

The evaluation employed primary data collection and secondary data sources to meet the research goals. **Exhibit 31** details the evaluation domains, data collection tools, target population, and frequency of data collection. Further details of the data collection tools and data sources are described in the subsections.

EXHIBIT 31: LONG-TERM CARE COHORT EVALUATION DOMAINS, DATA SOURCE, TARGET POPULATION, AND FREQUENCY OF DATA COLLECTION

Evaluation Domain	Data Source/Measurement	Person(s) Responsible for Collection	Frequency of Data Collection
Adoption	Structural Assessment	A member of the ASP at participating sites	Baseline and endline
Effectiveness	Nursing Home Survey on Patient Safety Culture	All eligible staff from participating facilities	Baseline and endline
	EHR extracts for days of antibiotic therapy per 1,000 resident-days by facility		Monthly from January to December 2019
EHR extracts for antibiotic starts per 1,000 resident-days by facility		ASP in conjunction with IT	Monthly from January to December 2019
	EHR extracts for <i>C. difficile</i> LabID events per 10,000 resident-days by facility	ASP in conjunction with IT	Monthly from January to December 2019
	EHR extracts for number of urine cultures collected per 1,000 resident-days by facility	ASP in conjunction with IT	Monthly from January to December 2019
Variation	EHR extracts for antibiotic use and other outcomes data along with Structural Assessment and program registration data	See above	See above

ASP = antibiotic stewardship program; *C. difficile* = *Clostridioides difficile*; HER = electronic health record; IT = information technology

3.3.1. Structural Assessment

The LTC Structural Assessment form consisted of seven questions to understand the facility's infrastructure and capacity to carry out the AHRQ Safety Program for Improving Antibiotic Use. The forms were completed online, via the AHRQ Safety Program Web site. The Structural Assessment form is illustrated in **Appendix A-7**.

The Structural Assessment was administered twice—at baseline and again at the endline—to measure the extent to which the program was adopted by the participating facilities. The baseline Structural Assessment forms were completed between July and December 2018; the endline forms were completed between November 13, 2019, and January 31, 2020. Of the participating facilities that completed the program, 100 percent completed the baseline Structural Assessment form and 84 percent of those facilities submitted the endline Structural Assessment form.

3.3.2. NHSOPS

The AHRQ NHSOPS is a widely used, validated survey to assess provider and staff perspectives on safety culture. It contains 42 survey items grouped into 12 composite measures, examining organizational perceptions of 12 domains of safety culture (ranging from communication openness to training and skills). The NHSOPS survey asks questions about staff perceptions of resident safety, communication, leadership commitment, staffing, and teamwork. The NHSOPS survey was sent to facility providers and

staff twice during the year, once at baseline and again at the endline, to measure changes in safety culture and assess the effectiveness of the program. The baseline NHSOPS was collected between December 27, 2019, and February 28, 2019, and the endline between November 1, 2019, and January 31, 2020.

To accommodate the varying capabilities of the participating facilities to administer the NHSOPS within their facilities, NHSOPS data for the LTC cohort were collected using two different methods. Each participating facility had two options for NHSOPS data for both baseline and endline NHSOPS:

- **Option A**: Participating facilities that had recently administered the NHSOPS survey for other purposes within a 6-month period before the start of the intervention (August 2018–February 2019 for the baseline survey), or within the last three months of the cohort (October–December 2019 for the endline survey), submitted their NHSOPS data file. The previously administered NHSOPS data were accepted if the nursing home could: (1) provide facility-level summary data with calculated composite scores, or (2) submit the respondent-level data in accordance with the AHRQ NHSOPS Data File Specifications (AHRQ NHSOPS data file specifications). Participating facilities were provided with step-by-step instructions for submitting the NHSOPS data files to the program Web site.
- **Option B:** Participating facilities that had not administered the NHSOPS within a 6-month period before the start of the cohort, or who preferred to administer the NHSOPS specifically for the cohort, were given the option to distribute the NHSOPS survey link directly to their eligible staff. The survey link, which was distributed by one point of contact at the facility, enabled providers and staff members to easily complete the NHSOPS survey on the program Web site.

For the baseline NHSOPS, 4.6 percent of facilities selected Option A, and 69.9 percent selected Option B. The remaining facilities (25.5 percent) did not select an option or responded that they were unable to administer the baseline NHSOPS at their facilities using either option. For the endline NHSOPS, 5.7 percent of facilities selected Option A, and 59.5 percent selected Option B. The remaining facilities (34.8 percent) did not select an option or responded that they were unable to administer the endline NHSOPS at their facilities using either options. **Exhibit 32** displays the responses for each baseline and endline NHSOPS for those facilities that completed the Safety Program. The overall proportion of facilities that either uploaded NHSOPS data via Option A tool or had at least one response via Option B tool was 62 percent at baseline and 46 percent at endline.

NHSOPS Options	Number (%) of Facilities Selected for Baseline Survey	Number (%) of Facilities Submitted Baseline Data	Number (%) of Facilities Selected for Endline Survey	Number (%) of Facilities Submitted Endline Data
Option A	20 (4.6%)	13 (65.0%) [*]	25 (5.7%)	8 (32.0%)*
Option B	307 (69.9%)	230 (74.9%) ⁺	261 (59.5%)	154 (59.0%) ⁺
Did not select an option	44 (15.5%)	23 (33.8%) [‡]	142 (32.3%)	40 (28.2%) [‡]
Unable to administer NHSOPS	68 (10.0%)	4 (9.1%) [¶]	11 (2.5%)	0
Total	439 (100%)	270 (61.5%) [§]	100%	202 (46.0%) [§]

EXHIBIT 32: BASELINE AND ENDLINE NHSOPS SELECTIONS BY FACILITIES AND RESPONSE RATES

NHSOPS = Nursing Home Survey on Patient Safety Culture

* Calculated as number of facilities that submitted NHSOPS data (either uploaded data file via option A tool or had at least 1 response via option B tool) divided by number that selected Option A.

⁺ Calculated as number of facilities that submitted NHSOPS data divided by number that selected Option B.

‡ Calculated as number of facilities that submitted NHSOPS data divided by number that did not select an option.

¶ Calculated as number of facilities that submitted NHSOPS data divided by number that stated unable to administer the survey.

§ Calculated as number of facilities that submitted NHSOPS data by total number of facilities that completed the program.

3.3.3. Antibiotic Use, C. difficile LabID Events, and Urine Cultures Collected

To evaluate the effectiveness of the Safety Program to change antibiotic use, participating facilities were asked to extract, compile, and submit antibiotic usage data, including measures for antibiotic starts and days of antibiotic therapy. The impact of the Safety Program on facility-onset *C. difficile* events and urine cultures collected were also evaluated. Data were extracted from EHR systems or through clinical chart review and entered into standardized Excel-based templates developed by the program, which were then uploaded onto the Safety Program Web site. The template for the monthly antibiotic use, *C. difficile* LabID events, and urine cultures collected is contained in **Appendix A-8**. To facilitate accurate and in-time data extraction, the program provided participating sites the template and instructions for their EHR extracts (e.g., National Drug Codes for selected antibiotics). **Exhibit 33** details the measurements and their definition that were collected in the monthly template.

EXHIBIT 33: MONTHLY EHR DATA ELEMENTS

Data	Description
Antibiotic starts per 1,000 resident-days	An antibiotic start is defined as initiation of an antibiotic for a resident, including resident transferred into the facility while receiving antibiotics. Each drug is counted independently. Resident-days are defined as aggregate number of days residents were living in the facility.
Days of antibiotic therapy per 1,000 resident-days	A day of antibiotic therapy is defined as any amount of an antibiotic administered to a resident on a single calendar day. Each drug is counted independently. Resident-days are defined as aggregate number of days residents were living in the facility. (i.e., sum of daily census for the entire reporting month).
Clostridioides difficile laboratory-identified events per 10,000 resident-days	<i>C. difficile</i> laboratory event is defined as number of all nonduplicate <i>C. difficile</i> toxin-positive laboratory results. Resident-days are defined as the aggregate number of days residents were living in the facility.
Urine cultures collected per 1,000 resident-days	One urine culture collection is defined as the obtaining of urine culture from a housed resident. Resident-days are defined as aggregate number of days residents were living in the facility.

Participating facilities were asked to submit data to the program Web site on a monthly basis during the cohort, by downloading the template from the program Web site and uploading the completed template to the Safety Program Web site. Facilities were also given the option to submit their monthly collected data via facsimile, to be tracked and entered by the project team upon receipt. Data for each month were to be submitted by the last day of following month, e.g., April 30, 2019, for March 2019 data.

We used multiple strategies to mitigate data collection burden and increase response rates (i.e., reduce missing responses).

- 1. For the NHSOPS we allowed facilities who already collected NHSOPS data within the eligible time frame to submit the same data for the Safety Program.
- 2. Data submission templates for monthly antibiotic use were simplified to ensure that we collected only the minimum necessary data.
- 3. Participating facilities were allowed multiple options to submit data. For the monthly antibiotic use data participating facilities could submit data via the online submission portal or by faxing completed forms.
- 4. Throughout the implementation we proactively monitored data quality issues and quickly identified participating facilities with outstanding data issues. In collaboration with the Implementation Advisers the JHM/NORC team reached out to those facilities and corrected data issues in a timely manner.
- 5. Participating sites were encouraged to communicate any questions regarding data collection to the Safety Program, and we developed and regularly updated data collection FAQs to answer those questions.

3.4 Analytic Methods

3.4.1. Summary of Analysis

Data submissions were assessed for quality and usability in our analysis. **Exhibit 34** summarizes the number of facilities with any data submissions and the number of facilities that contributed to the final analytic dataset for each tool/measurement. **Appendix B-1** presents the restrictions applied to antibiotic usage, *C. difficile* LabID events, and urine culture collected data in order to obtain the final sample that contributed to the analysis.

Data Submission Type	Number of Facilities With Data Submissions	% of Facilities With Data Submissions	Number of Facilities That Contributed to Final Analysis	% of Facilities That Contributed to Final Analysis
Total cohort	439	100%	-	-
Structural Assessment, both baseline & endline	368	83.8%	367	83.6%
Structural Assessment, baseline	439	100%	439	100%
Structural Assessment, endline	368	83.8%	367	83.6%
NHSOPS, both baseline & endline	172	39.2%	118	26.9%
NHSOPS, baseline	272	62.0%	227	51.7%
NHSOPS, endline	212	48.3%	142	32.3%
Antibiotic starts data, any month	437	99.5%	410	93.4%
Antibiotic days of therapy data, any month	437	99.5%	410	93.4%
C. difficile LabID events data, any month	437	99.5%	411	93.6%
Urine culture data, any month	437	99.5%	411	93.6%
All data elements	166	37.8%	-	-

EXHIBIT 34: SUMMARY OF FACILITIES WITH DATA SUBMISSIONS AND CONTRIBUTING TO FINAL ANALYTIC DATASET

C. difficile LabID = Clostridioides difficile laboratory identified; NHSOPS = Nursing Home Survey on Patient Safety Culture

The program evaluation used a pre-post longitudinal study design. Characteristics of participating facilities, including the number of beds, ownership, percent of short-stay, and geographic location was described. To evaluate the adoption of the program among participating units, facility AS infrastructure change was assessed from the baseline period to the endline as measured by the Structural Assessment.

To evaluate the effectiveness of the Safety Program, linear mixed models were used to assess the change in composite scores for patient safety culture from NHSOPS and generalized linear mixed models were employed to examine change over time for outcomes collected from EHR extracts including antibiotic use, *C. difficile* events, and number of urine cultures. Antibiotic use over time for select antibiotic classes were examined for the entire cohort as well. We also performed sensitivity analyses for each outcome by limiting the sample to facilities with all twelve months of within-range valid data.

AHRQ Safety Program for Improving Antibiotic Use: Long-Term Care Cohort Final Report The modified Park test⁷ and histograms were used to decide the distribution assumption for each outcome,^c and assumed negative binomial distribution for all EHR-based outcomes, unless the convergence was not achieved in model estimation, in which case a Poisson distribution was assumed instead.^d A generalized linear mixed model was specified as:

$$g(E(Y_{it})) = X\beta = \beta_0 + r_{0i} + \beta_1 Time_{it}$$

In the specification, *i* indexes the facility, *t* indexes the time for the measurement, Y_{it} is the outcome for the facility *i* at time *t*—for example, NHSOPS composite score at baseline, or total DOT per 1,000 resident-days in a given bi-month period. In addition, β_0 represents the expected value of *Y* when time is zero (i.e., baseline). β_1 is a vector and represents the average rate at which $X\beta$ changes from baseline to follow-up time point in the population. r_{0i} is the random intercept, which captures facility differences in the level of $X\beta$ at baseline. In a generalized linear model for all EHR-based outcomes, the outcome E(Y) is linked with the linear predictor $X\beta$ by: $E(Y) = g^{-1}(X\beta)$, where g(.) is the log link function.

We did not impute missing data. Instead, we excluded facilities from our analysis if they presented too many missing values for a certain outcome. For the rest of the unbalanced data, we assumed a missing at random pattern,^e which would not bias the results in mixed models.⁸ Another advantage of mixed models is that they incorporate heterogeneity across facilities via facility-level random effects.^f A two-sided p-value of less than 0.05 was considered a statistically significant finding.

To evaluate the variation of the effectiveness, stratified analyses were performed to examine the change in antibiotic use, *C. difficile* events, and urine cultures collected over time for subgroups defined by selected facility characteristics. **Exhibit 35** details the subgroup variables used in stratified analysis.

^c When modified Park test indicated Poisson distribution, we further examined the dispersion parameter to choose between Poisson and negative binomial distributions.

^d Poisson distribution was applied for antibiotic starts per 1,000 resident-days for these subclasses: penicillins (Non-

Antipseudomonal), Penicillins (Antipseudomonal), sulfamethoxazole / trimethoprim, and tetracyclines.

^e Missing at random (MAR) denotes units with missing data that are not a random subset of the sample, but their missingness is unrelated to the specific missing values that should have been observed. Compared with missing completely at random (MCAR, which assumes that missing data is a completely random subset of the sample), we think MAR is a more tenable assumption because more facilities had missing data in later months than earlier months.

^f Specifically, in addition to the population-averaged (or fixed) intercept, we allowed each facility to have its own random intercept, where this random component follows a normal distribution. The slope coefficients, however, are fixed (i.e., not random), so facilities can start from different baseline levels but will have parallel outcome trajectories over the intervention period.

EXHIBIT 35: SUBGROUP VARIABLES IN STRATIFIED ANALYSIS

Characteristics	Group	Data Source and Original Question	Note
Number of beds	 0–74 75–149 150 or more 	Structural assessment: "How many certified beds are in your facility?"	For missing answers, we reached to the facility or crosschecked external reference including facility's Web site and CMS Provider of Service database.
Ownership	 Hospital-based Non-hospital-based but part of a larger organization system Neither 	Program application: (1) "Is your facility part of a hospital/hospital-based, free-standing or neither?" (2) "Is your facility part of a nursing home chain or larger health system?"	Facilities who selected "part of a hospital/hospital-based" in the first question were coded as "hospital- based." For the rest of facilities who selected "free-standing" or "neither" in the first question, we further divided them based on whether they were "part of a nursing home chain or larger health system" as reported in the second question.
Proportion of residents in short-stay bed	 Less than 25% At least 25%, but less than 50% At least 50%, but less than 75% 75% or more 	Structural assessment: (1) "What is the average number of residents per day in skilled beds?" (2) "What is the average number of residents per day in residential beds?"	The proportion of residents in short-stay bed was calculated as number of residents in skilled beds divided by the sum of number of residents in skilled beds and number of residents in residential beds.
Geographic location	UrbanSuburbanRural	Program application: "What is your facility location?"	Facilities were provided with three options: "urban," "suburban," and "rural." In scenarios where the facilities did not check an option, we imputed the value based on the facility's zip code.

CMS = Centers for Medicare & Medicaid Services

Finally, sensitivity analyses that included facilities that submitted usable data for all 12 months for all four outcomes (i.e. antibiotic starts, antibiotic DOT, *C. difficile* LabID events, and urine culture collected) were performed for the entire cohort and by subgroups, using same modeling approach as the base analyses.

3.4.2. Structural Assessment

The antibiotic stewardship infrastructure among participating facilities at baseline and end of intervention was compared, and then conducted a Chi-squared test to examine the differences in selected items between baseline and endline.

3.4.3. NHSOPS

NHSOPS data were collected at baseline (or within a 6-month period prior to program implementation) and endline to measure average provider and staff perspectives of patient safety culture in the facility. For facilities that submitted previously collected NHSOPS data, we excluded LTC facilities whose data were collected prior to six months of the program baseline (i.e., allowable date period was from August 2018 to February 2019) for baseline NHSOPS, or prior to 3 months of the program endline (i.e., allowable date period was from October to December 2019) for endline NHSOPS. For facilities whose staff completed the online NHSOPS survey, when there were at least five respondents for the unit, responses were rolled up to the unit level to create composite scores.⁹

Facility characteristics between respondents and nonrespondents for both baseline and endline NHSOPS were compared. Linear mixed models were used to examine the change of each composite score from baseline to endline. A sensitivity analysis was performed that tested the results of the model only for facilities that submitted data for both time points.

3.4.4. Antibiotic Use

JHM/NORC reviewed a comprehensive list of antibiotics currently available in the National Healthcare Safety Network Antimicrobial Use module and selected 41 antibiotics that were likely to be administered to nursing home residents. The team selected all antibiotics anticipated to be administered orally, intravenously or intramuscularly to nursing home residents in the United States. Monthly antibiotic use data was requested for the 41 selected agents from all participating sites. Monthly resident days, antibiotic starts, and days of antibiotic therapy for each of the antibiotics were extracted and reported by participating facilities on a monthly basis.

The primary outcomes measured were: change in antibiotic starts per 1,000 resident-days, and change in antibiotic DOT per 1,000 resident-days between January-February 2019 and each of the subsequent 2-month intervals from March 2019 to December 2019. The webinars that targeted specific clinical syndromes (urinary tract infection and respiratory tract infection) were grouped into bimonthly intervals, which informed the strategy for outcomes measurement. This also enabled a brief evaluation of sustainability during September-October 2019 and November-December 2019, because the best practices webinars were completed in August 2019.

The change in DOT or antibiotic starts per 1,000 resident-days from January-February to November-December among facilities reflected changes in antibiotic use from the beginning to the end of the Safety Program. The comparison between the first and last bimonthly periods is of particular interest for two major reasons. The primary reason is that these time periods allow for comparison of the beginning and end of the formal Safety Program. Another reason is that comparing the November-December period to the January-February baseline (all winter months) holds seasonality in antibiotic use roughly constant. Data with out-of-range values (>100 for antibiotic starts per 1,000 resident-days or >1,000 for DOT per 1,000 resident-days) were excluded. Facilities were excluded if they missed January-February (i.e., baseline) data, and/or missed all data from July to December (i.e., second half of the program period), and/or submitted less than 6 months of data in total (i.e., less than half of the data points). **Appendix Exhibit B-1** presents the flowchart for facility inclusion in the analysis.

Generalized linear mixed models assuming negative binomial distribution with random facility effect were used to examine changes in total antibiotic use over time. For total antibiotic use, we also performed analysis stratified by number of beds, facility ownership, percent of short-stay, and geographic location (**Exhibit 37**), and then estimated the change over time for each stratum as well.

In addition to total antibiotic use, changes in antibiotic use for eleven antibiotic classes over time were also examined for the entire cohort using same modeling approach. **Exhibit 36** details the list of antibiotics for the antibiotic classes.

Antibiotic Class	Antibiotics	
Fluoroquinolones	Ciprofloxacin, ofloxacin, levofloxacin, moxifloxacin	
Penicillins (non-antipseudomonal)	Ampicillin/sulbactam, amoxicillin or ampicillin, amoxicillin/clavulanate	
Penicillins (antipseudomonal)	Piperacillin/tazobactam	
Cephalosporins (first generation)	Cephalexin, cefazolin	
Cephalosporins (third generation)	Cefdinir, ceftriaxone, cefotaxime	
Cephalosporins (antipseudomonal)	Cefepime, ceftazidime	
Glycopeptides	Intravenous vancomycin	
Macrolides	Azithromycin	
Trimethoprim/sulfamethoxazole	Trimethoprim/sulfamethoxazole	
Nitrofurantoin	Nitrofurantoin	
Tetracyclines	Doxycycline, oral tetracycline, minocycline	

EXHIBIT 36: SELECTED ANTIBIOTIC CLASSES

3.4.5. C. difficile LabID Events

Every month, facility-onset *C. difficile* LabID events data for each participating facility were collected. Change in *C. difficile* LabID events per 10,000 resident-days from January-February 2019 to each of the subsequent 2-month intervals from March to December 2019 were assessed. Data with out-of-range values for *C. difficile* LabID events per 10,000 resident-days (>20) were excluded. Facilities were excluded if they missed baseline data, and/or missed all data from July to December, and/or submitted less than 6 months of data in total.

Similarly to antibiotic use outcomes, we used generalized linear mixed models with negative binomial distribution and random intercepts for facilities to assess the change in *C. difficile* LabID events per

10,000 resident-days over time. Stratified analyses were performed to evaluate the variation of change in *C. difficile* LabID events across facility characteristics.

3.4.6. Urine Cultures Collected

Similarly to antibiotic use and *C. difficile* LabID events data, the number of urine cultures collected was also reported monthly by each participating facility. Change in number of urine cultures collected per 1,000 resident-days from January-February 2019 to each of the subsequent 2-month intervals from March to December 2019 were assessed. Data with out-of-range values for urine cultures collected (>50 per 1,000 resident-days) were excluded. Facilities were excluded if they missed data for baseline, and/or all data from July to December, and/or submitted less than 6 months of data in total.

Similar to measurements for antibiotic use data, we used generalized linear mixed models with negative binomial distribution and random facility effects to assess the change in urine cultures collected per 1,000 resident-days over time, for the entire cohort and by subgroups.

3.5 Results

The sections below describe findings in evaluating the adoption and effectiveness of the Safety Program in the context of the LTC cohort beginning with characteristics of participating facilities, followed by a structural assessment to assess adoption of the program, NHSOPS to assess the change in staff perspectives of safety culture, antibiotic starts and antibiotic days of therapy to assess changes in antibiotic use, *C. difficile* LabID events to assess changes in *C. difficile* events, and urine cultures collected to assess changes in the collection of urine cultures.

3.5.1. Characteristics of Participating Facilities

Of the 439 participating facilities that completed the Safety Program, the number of certified beds owned by the facilities was 124 on average, ranging from 18 to 874. Fifty-six percent of the participating facilities were not hospital-based but owned by a larger organization. Sixty-nine percent of the participating facilities were focused on residential care (i.e., with less than short-stay 50 percent beds). One quarter of facilities were in urban areas and 40 percent were in rural areas. **Exhibit 37** shows selected characteristics for these facilities. **Appendix B-2** presents the distribution of participating LTC facilities across the country.

Characteristics	Category	# Participating facilities (%)
Number of Beds	# certified beds in facility: mean (standard deviation), range	124.3 (96.0), 18–874
	0–74 beds	106 (24.1%)
	75–149 beds	229 (52.2%)
	150 or more beds	104 (23.7%)
Ownership	Hospital-based	60 (13.7%)
	Non-hospital-based and owned by a larger system	246 (56.0%)
	Non-hospital-based and not owned by a larger system	133 (30.3%)
Proportion of	Less than 25%	233 (53.1%)
residents in	At least 25% and less than 50%	70 (15.9%)
short-stay bed	At least 50% and less than 75%	45 (10.3%)
	At least 75%	91 (20.7%)
Geographic	Urban	108 (24.6%)
location	Suburban	156 (35.5%)
	Rural	175 (39.9%)

EXHIBIT 37: FACILITY CHARACTERISTICS FOR PARTICIPATING FACILITIES (TOTAL N=439)

3.5.2. Structural Assessment

The Structural Assessment consisted of seven questions to understand the general infrastructure, local stewardship practices (if any), and experience with quality improvement initiatives at each participating facility, and how responses changed over the course of the Safety Program.

All 439 participating facilities that completed the Safety program responded to the baseline assessment, but only 367 (83.6%) responded to the endline assessment. Compared with other groups for hospital ownership and short-stay, facilities who were neither hospital-based nor part of a larger system (p<0.001) and facilities with fewer than 25% short-stays (p=0.009) were more likely to complete the endline assessment.

At the beginning of the Safety Program, the infection prevention nurse or practitioner and Medical Directors were involved in running existing ASPs in 83 percent and 62 percent of participating facilities, respectively. Those percentages increased to 93 percent and 70 percent, respectively, at the end of intervention. At baseline, in-service training to nurses on appropriate antibiotic use was the most implemented antibiotic stewardship activity (75%), followed by developing protocols for the diagnosis and treatment of common infection syndromes (65%). The least implemented activity was formulary restriction of some antibiotics, reported by only 15 percent facilities. The percent of facilities that had any antibiotic stewardship activity in place increased significantly from baseline to end of intervention. Post-prescription review with feedback for select antibiotics had the most improvement, from 38 percent to 61 percent. At baseline, 87 percent of facilities tracked antibiotic use (at least one measure among antibiotic starts, DOT, and defined daily doses), which increased to 98 percent at the end of intervention.
Exhibit 38 presents infrastructure characteristics related to antibiotic stewardship for participating facilities at baseline and endline.

Assessed Domains	Assessed Items	Baseline (N=439)	Endline (N=367)	p-value
Accountability	Infection prevention and control nurse or involved with antibiotic stewardship program	363 (82.7%)	341 (92.9%)	<0.001
	Medical director involved with the antibiotic stewardship program	273 (62.2%)	257 (70.0%)	0.019
	Have a consultant pharmacist working at the facility	420 (95.7%)	353 (96.2%)	0.71
Actions To Improve	Giving in-service training to nurses on topics related to antibiotic use	328 (74.7%)	331 (90.2%)	<0.001
Antibiotic Use	Developing protocols for diagnosis and treatment of common infection syndromes	287 (65.4%)	279 (76.0%)	0.001
	Developing antibiotic prescribing recommendations for your facility	213 (48.5%)	205 (55.9%)	0.038
	Working with the contracted laboratory to develop an antibiogram	194 (44.2%)	191 (52.0%)	0.026
	Post-prescription review with feedback of select antibiotics	166 (37.8%)	223 (60.8%)	<0.001
	Formulary restriction of some antibiotics	66 (15.0%)	77 (21.0%)	0.028
	At least one of the above actions	402 (91.6%)	362 (98.6%)	<0.001
	All activities above	28 (6.4%)	41 (11.2%)	0.015
Antibiotic Use	Antibiotic starts	296 (67.4%)	327 (89.1%)	<0.001
Tracking	Antibiotic days of therapy per 1,000 resident-days	176 (40.1%)	269 (73.3%)	<0.001
	Defined daily doses per 1,000 resident-days	40 (9.1%)	89 (24.3%)	<0.001
	At least one of the above tracking methods	384 (87.5%)	358 (97.5%)	<0.001

EXHIBIT 38: INFRASTRUCTURE CHARACTERISTICS FOR PARTICIPATING LONG-TERM CARE FACILITIES AT BASELINE AND ENDLINE

3.5.3. Nursing Home Survey on Patient Safety Culture (NHSOPS)

Our analysis included NHSOPS data from participating facilities, unless these facilities: (1) previously collected NHSOPS data were not collected during the designated time period for this project (i.e., August 2018–February 2019 for the baseline survey, and October–December 2019 for the endline survey); and (2) had fewer than five individuals responding to the survey.

The analysis included 227 facilities for baseline NHSOPS and 142 facilities for endline NHSOPS with usable data. Among them, 118 facilities responded to both baseline and endline NHSOPS. At baseline, facilities in rural area had a higher rate of submitting usable data compared with facilities in urban and suburban areas (urban: 41.7 percent, suburban: 48.1 percent, rural: 61.1 percent, p=0.003). Among the 227 facilities that submitted usable NHSOPS data, larger facilities (0–149 beds: 47.8 percent, 150+: 67.4

percent, p=0.015) and free-standing facilities (hospital-based or part of a larger system: 43.0 percent, free-standing: 69.2 percent, p<0.001) were more likely to submit usable endline data compared with their counterparts.

At baseline, feedback and communication about incidents received the highest composite score (92 percent), followed by overall perceptions of resident safety (91%), and supervisor expectations and actions promoting resident safety (85%). The dimension that received the lowest composite score was staffing (44%). Other dimensions received composite scores between 63 percent and 76 percent. After program implementation, staffing dimension improved by 14.7 percentage points (95% CI: 12.2–17.2%, p<0.001) with an endline score of 59 percent. Composite scores for other domains did not change significantly from baseline to endline. **Exhibit 39** displays the NHSOPS composite scores for each domain at baseline and endline.



EXHIBIT 39: NHSOPS COMPOSITE SCORES FOR PARTICIPATING FACILITIES BEFORE AND AFTER THE PROGRAM

NHSOPS = Nursing Home Survey on Patient Safety Culture

Sensitivity analysis including only LTC sites that submitted both usable baseline and endline data (n=118) showed a similar pattern of NHSOPS composite scores before and after the program. Staffing was still the only domain with a significant increase from baseline to endline (14.5%, 95% CI: 11.7–17.3%, p<0.001).

3.5.4. Antibiotic Use

Antibiotic Starts

We included 410 facilities that submitted adequate and valid data for antibiotic starts analysis. We examined the changes in total antibiotic starts per 1,000 resident-days from baseline to each of the intervention bimonth periods for the entire LTC cohort and subgroups for selected facility characteristics. Antibiotic starts for specific classes were also assessed for the entire cohort.

Change in total antibiotic starts per 1,000 resident-days over time for the entire LTC cohort. For the entire LTC cohort, antibiotic starts per 1,000 resident-days decreased by 0.41 (95% CI: -0.76 to -0.07, p=0.020) from 7.89 in Jan-Feb to 7.48 in Nov-Dec (**Exhibit 40**).



EXHIBIT 40: BIMONTHLY ANTIBIOTIC STARTS PER 1,000 RESIDENT-DAYS

Change in total antibiotic starts per 1,000 resident-days over time by facility characteristics. In

addition to decreasing from across the entire cohort during the 1-year LTC Safety Program, antibiotic starts decreased significantly from Jan-Feb to Nov-Dec among some specific subgroups including mid-sized facilities (Nov-Dec vs Jan-Feb: -0.63, 95% CI: -1.11 to -0.14, p=0.011), hospital-based facilities (Nov-Dec vs Jan-Feb: -0.82, 95% CI: -1.64 to -0.01, p=0.048), and facilities with at least 75 percent short-stays (Nov-Dec vs Jan-Feb: -0.97, 95% CI: -1.72 to -0.21, p=0.012). **Exhibit 41** summarizes the change in total antibiotic starts per 1,000 resident-days from baseline to each bimonth period during the intervention for each facility characteristics.

Facility Subgroup	Each Intervention Bimonth Compared With Baseline (Jan-Feb 2019)	Mar-Apr	May-June	July-Aug	Sept-Oct	Nov-Dec
Entire cohort	Overall (n=410)	-0.22	-0.46**	-0.51**	-0.35*	-0.41*
	0-74 certified beds (n=99)	-0.48	-0.48	-0.36	-0.44	-0.46
Facility size	75-149 certified beds (n=209)	-0.19	-0.72**	-0.87***	-0.64**	-0.63*
	150 or more certified beds (n=102)	0.01	0.07	0.04	0.32	0.08
	Hospital-based (n=57)	-1.02**	-1.27**	-0.78*	-0.88*	-0.82*
Affiliation	Non-hospital–based and owned by a larger system (n=227)	-0.13	-0.30	-0.48	-0.35	-0.11
	Non-hospital–based and not owned by a larger system (n=126)	-0.01	-0.39	-0.44	-0.12	-0.70*
	Less than 25% (n=221)	0.02	-0.19	-0.24	-0.01	-0.16
Chart stoy	At least 25% and less than 50% (n=62)	-0.09	-0.59	-0.40	-0.89	-0.35
Short stay	At least 50% and less than 75% (n=41)	-0.77	-1.60**	-0.83	-0.68	-0.50
	At least 75% (n=86)	-0.60*	-0.50	-1.05**	-0.66	-0.97*
	Urban (n=100)	0.04	-0.38	-0.24	-0.12	-0.22
Location	Suburban (n=146)	-0.51*	-0.59*	-0.83**	-0.45	-0.48
	Rural (n=164)	-0.11	-0.41	-0.39	-0.41	-0.46

EXHIBIT 41: CHANGE IN TOTAL ANTIBIOTIC STARTS PER 1,000 RESIDENT-DAYS

Note: 410 facilities with 4,688 facility-months contributed to this analysis. A generalized linear mixed model with random intercept of facility was used to generate the estimate. The entire cohort model includes bimonth as the independent variable; each stratified model includes bimonth variable, stratified variable, and their interaction terms as the independent variables. * denotes p-value<0.05; ** denotes p-value<0.01; *** denotes p-value<0.01.

The sensitivity analysis of total antibiotic starts per 1,000 resident-days (**Appendix Exhibit B-3.2**) showed similar findings for the entire cohort (Nov-Dec vs Jan-Feb: -0.52, p=0.007), mid-sized facilities (Nov-Dec vs Jan-Feb: -0.76, p=0.005), and facilities with at least 75 percent short-stays (Nov-Dec vs Jan-Feb: -1.14, p=0.007). Facilities in suburban area also showed significant reductions in total antibiotic starts per 1,000 resident-days (Nov-Dec vs Jan-Feb: -0.72, p=0.041).

Change in antibiotic starts per 1,000 resident-days over time for selected antibiotic classes. Starts of fluoroquinolones per 1,000 resident-days decreased significantly from Jan-Feb to Nov-Dec (-0.21; p<0.01) **Exhibit 42** summarizes the change in antibiotic starts over time by select antibiotic classes.

Antibiotics	Mar-Apr	May-June	July-Aug	Sept-Oct	Nov-Dec
Fluoroquinolones	-0.068	-0.140 **	-0.198 **	-0.169 **	-0.214 **
Penicillins (non-antipseudomonal)	-0.011	-0.027	-0.068	-0.004	-0.037
Piperacillin/tazobactam	-0.008	0.019	0.006	0.025	0.018
Cephalosporins (first generation)	0.071	0.019	0.056	0.057	-0.011
Cephalosporins (third generation)	-0.004	-0.075	-0.061	-0.066	-0.060
Ceftazidime/cefepime	-0.002	0.009	0.009	0.023	0.037
Vancomycin	-0.028	-0.055 **	-0.019	-0.042 *	-0.021
Macrolides	-0.065 *	-0.140 ***	-0.198 ***	-0.085 *	-0.055
Trimethoprim/sulfamethoxazole	-0.033	-0.042	-0.034	-0.021	-0.008
Nitrofurantoin	-0.007	0.038	-0.013	-0.021	-0.022
Tetracyclines	-0.053	-0.030	-0.023	-0.023	0.006

EXHIBIT 42: CHANGE IN ANTIBIOTIC STARTS PER 1,000 RESIDENT-DAYS BY ANTIBIOTIC OR ANTIBIOTIC CLASS

Note: 410 facilities with 4,688 facility-months contributed to the antibiotic class analysis. Generalized linear mixed model with random intercept of facility was used to generate the estimate; bimonth indicator was the independent variable.

* denotes p-value<0.05; ** denotes p-value<0.01; *** denotes p-value<0.001.

Antibiotic Days of Therapy

We included 410 facilities that submitted adequate and valid data for antibiotic days of therapy analysis. We examined the changes in total antibiotic DOT per 1,000 resident-days from baseline to each of the intervention bi-month periods for the entire LTC cohort and subgroups for selected facility characteristics. Antibiotic DOT for certain classes were also assessed for the entire cohort.

Change in total antibiotic DOT per 1,000 resident-days over time for the entire LTC cohort. For the entire cohort, DOT per 1,000 resident-days decreased by 3.1 (95% CI: -6.3 to 0.23, p=0.068) from 64.1 in Jan-Feb to 61.0 in Nov-Dec (**Exhibit 43**).



EXHIBIT 43: BIMONTHLY ANTIBIOTIC DAYS OF THERAPY PER 1,000 RESIDENT-DAYS

Change in total antibiotic DOT per 1,000 resident-days over time by facility characteristics. Facilities that were mid-sized (75-149 certified beds), hospital-based or with at least 50 percent stays as short-stay tended to have larger magnitude in reducing total antibiotic DOT per 1,000 resident-days. Among facilities with at least 75 percent short-stay residents, DOT per 1,000 resident-days decreased by 9.8 (95% CI: -16.5 to -3.0, p=0.005) from Jan-Feb to Nov-Dec. **Exhibit 44** summarizes the change in total antibiotic DOT per 1,000 resident-days from baseline (January-February 2019) by each bi-month period during the intervention (March-December 2019) for each facility characteristics.

Facility Subgroup	Each Intervention Bimonth Compared With Baseline (Jan-Feb 2019)	Mar-Apr	May-June	July-Aug	Sept-Oct	Nov-Dec
Entire cohort	Overall (n=410)	-0.93	-2.54	-1.87	-1.50	-3.05
	0–74 certified beds (n=99)	-2.03	-2.03	-0.04	-2.32	-4.09
Facility size	75–149 certified beds (n=209)	-1.36	-4.64 *	-3.79	-2.86	-3.75
	150 or more certified beds (n=102)	0.74	0.78	0.01	1.58	-0.91
	Hospital-based (n=57)	-4.92	-6.60	-2.56	-6.26	-6.35
Affiliation	Non-hospital-based and owned by a larger system (n=227)	-1.68	-1.20	-1.38	-0.62	-0.46
	Non-hospital-based and not owned by a larger system (n=126)	1.88	-2.95	-2.28	-0.89	-5.14
	Less than 25% (n=221)	0.91	-0.79	0.59	1.18	-0.10
	At least 25% and less than 50% (n=62)	4.32	0.41	2.56	-2.03	-2.36
Short stay	At least 50% and less than 75% (n=41)	-12.0 *	-14.1 *	-8.97	-8.84	-6.94
	At least 75% (n=86)	-4.21	-3.91	-8.02 *	-5.40	-9.77 **
	Urban (n=100)	0.49	-0.72	-0.75	0.33	-1.98
Location	Suburban (n=146)	0.47	-2.27	-2.40	0.02	-1.67
	Rural (n=164)	-3.00	-3.95	-2.17	-3.93	-4.84

EXHIBIT 44: CHANGE IN TOTAL ANTIBIOTIC DOT PER 1,000 RESIDENT-DAYS

Note: 410 facilities with 4,688 facility-months contributed to this analysis. A generalized linear mixed model with random intercept of facility was used to generate the estimate. The entire cohort model includes bi-month as the independent variable; each stratified model includes bimonth variable, stratified variable, and their interaction terms as the independent variables. * denotes p-value<0.05; ** denotes p-value<0.01

In the sensitivity analysis that included 335 facilities with all 12 months usable data (**Appendix Exhibit B-3.1**), total antibiotic DOT per 1,000 resident-days reduced by 3.59 (95% CI: -7.07 to -0.11, p=0.043). There was also stronger signal for facilities with greater proportion of short-stay residents—among facilities with at least 75 percent short-stays, the reduction in total DOT per 1,000 resident-days from Jan-Feb was 11.5 in July-Aug (p=0.003), 8.0 in Sept-Oct (p=0.040), and 12.2 in Nov-Dec (p<0.001).

Change in antibiotic DOT per 1,000 resident-days over time for selected antibiotic classes. For fluoroquinolones, the DOT per 1,000 resident-days decreased significantly for all of the intervention periods, relative to the pre-intervention baseline (change from Jan-Feb: -0.77 for Mar-Apr, -1.03 for May-June, -1.10 for July-Aug, -1.19 for Sept-Oct, and -1.20 for Nov-Dec). **Exhibit 45** summarizes the change in antibiotic DOT per 1,000 resident-days over time by select antibiotic classes.

Antibiotics	Mar-Apr	May-June	July-Aug	Sept-Oct	Nov-Dec
Fluoroquinolones	-0.765 *	-1.033 *	-1.107 *	-1.190 **	-1.195 *
Penicillins (non-antipseudomonal)	-0.006	0.051	-0.618	-0.360	-0.320
Penicillins ((piperacillin/tazobactam)	0.131	0.403	0.145	0.622	0.835
Cephalosporins (first generation)	0.487	0.759 *	0.704	0.740	-0.219
Cephalosporins (third generation)	-0.174	-0.536	-0.653	-0.439	-0.758 *
Ceftazidime/cefepime	0.022	0.133	0.332	0.406	0.780 *
Vancomycin	0.013	-0.710	-0.311	0.654	0.353
Macrolides	-0.415 *	-0.928 ***	-1.121 ***	-0.526 **	-0.330
Trimethoprim/sulfamethoxazole	0.097	-0.280	0.191	0.121	-0.022
Nitrofurantoin	0.063	-0.068	-0.382	-0.423	-0.533
Tetracyclines	-0.392	0.071	0.308	0.067	0.356

EXHIBIT 45: CHANGE IN ANTIBIOTIC DOT PER 1,000 RESIDENT-DAYS BY ANTIBIOTIC OF ANTIBIOTIC CLASS

Note: 410 facilities with 4,688 facility-months contributed to the antibiotic class analysis. Generalized linear mixed model with random intercept of facility was used to generate the estimate; bimonth indicator was the independent variable.

* denotes p-value<0.05; ** denotes p-value<0.01; *** denotes p-value<0.001.

3.5.5. C. difficile LabID Events

We included 411 facilities that submitted adequate and valid data for *C. difficile* LabID events analysis. We examined the changes in number of *C. difficile* LabID events per 10,000 resident-days from baseline to each of the intervention bimonth periods for the entire LTC cohort and subgroups for selected facility characteristics.

Change in *C. difficile* LabID events per 10,000 resident-days over time for the entire LTC cohort. *C. difficile* LabID events decreased by 0.16 per 10,000 resident-days from 1.66 in Jan-Feb to 1.50 in Nov-Dec (p=0.524), but this did not reach statistical significance; **Exhibit 46**.



EXHIBIT 46: BIMONTHLY C. DIFFICILE LABID EVENTS PER 10,000 RESIDENT-DAYS

C. difficile LabID = Clostridioides difficile laboratory identified

Change for total *C. difficile* **LabID events per 10,000 resident-days over time by facility characteristics.** Facilities in urban areas had significant reductions for most of the intervention periods compared with the baseline, except for Mar-Apr (Nov-Dec vs Jan-Feb: -1.16, p=0.009). **Exhibit 47** summarizes the change in *C. difficile* events from baseline to each of the bi-month period during intervention for each facility characteristics.

Facility Subgroup	Each Intervention Bimonth Compared With Baseline (Jan-Feb 2019)	Mar-Apr	May-June	July-Aug	Sept-Oct	Nov-Dec
Entire cohort	Overall (n=411)	-0.004	-0.57 **	-0.07	-0.37	-0.16
	0-74 certified beds (n=99)	-0.02	-0.54	0.72	-0.33	-0.42
Facility size	75-149 certified beds (n=210)	0.28	-0.50	-0.30	-0.41	-0.23
	150 or more certified beds (n=102)	-0.50	-0.71	-0.38	-0.37	0.36
	Hospital-based (n=57)	0.12	-0.03	0.78	0.48	0.28
Affiliation	Non-hospital–based and owned by a larger system (n=228)	-0.03	-0.69 *	-0.07	-0.42	0.06
	Non-hospital–based and not owned by a larger system (n=126)	-0.05	-0.63	-0.54	-0.71 *	-0.61

EXHIBIT 47: CHANGE IN C. DIFFICILE LABID EVENTS PER 10,000 RESIDENT-DAYS

Facility Subgroup	Each Intervention Bimonth Compared With Baseline (Jan-Feb 2019)	Mar-Apr	May-June	July-Aug	Sept-Oct	Nov-Dec
	Less than 25% (n=222)	0.19	-0.37 *	-0.20	-0.31	-0.13
Chart stor	At least 25% and less than 50% (n=62)	-1.18	-1.64 *	0.15	-1.40	-0.64
Short stay	At least 50% and less than 75% (n=41)	0.41	0.19	0.67	0.28	0.64
	At least 75% (n=86)	-0.11	-0.64	0.16	-0.06	-0.20
	Urban (n=101)	-0.34	-1.02 **	-1.10 *	-1.32 **	-1.16 **
Location	Suburban (n=146)	-0.24	-0.78 *	0.03	0.18	0.39
	Rural (n=164)	0.32	-0.16	0.45	-0.19	0.08

C. difficile LabID = Clostridioides difficile laboratory identified

Note: 411 facilities with 4,690 facility-months contributed to this analysis. A generalized linear mixed model with random intercept of facility was used to generate the estimate. The entire cohort model includes bimonth as the independent variable; each stratified model includes bimonth variable, stratified variable, and their interaction terms as the independent variables.

* denotes p-value <0.05; ** denotes p-value <0.01; *** denotes p-value <0.001.

There was no significant reduction in *C. difficile* LabID events per 10,000 resident-days (**Appendix Exhibit B-3.3**) across the cohort between Jan-Feb and Nov-Dec. On subgroup analysis, significant reductions in *C. difficile* LabID events were observed in the LTC facilities in urban areas (n=101) over the course of the one-year Safety Program

3.5.6. Urine Cultures Collected

We included 411 facilities that submitted adequate and valid data for urine culture analysis. We examined the changes in number of urine cultures collected per 1,000 resident-days from baseline to each of the intervention bi-month periods for the entire LTC cohort and subgroups for selected facility characteristics.

Change in urine cultures collected per 1,000 resident-days over time for the entire LTC cohort. For the entire cohort, urine cultures collected per 1,000 resident-days decreased by 0.38 from 3.01 in Jan-Feb to 2.63 in Nov-Dec (95% CI: -0.61 to -0.15, p=0.001). The changes were also significant from baseline to all other bi-month intervention periods (change from Jan-Feb: -0.28 for Mar-Apr, -0.27 for May-June, -0.27 for July-Aug, and -0.28 for Sept-Oct). **Exhibit 48** presents the estimated urine cultures collected per 1,000 resident-days over time throughout the program period.



EXHIBIT 48: BIMONTHLY NUMBER OF URINE CULTURES COLLECTED PER 1,000 RESIDENT-DAYS

Change in urine cultures collected per 1,000 resident-days over time by facility characteristics. Urine cultures collected per 1,000 resident-days also decreased significantly from Jan-Feb to at least three of intervention periods, including Nov-Dec among mid-sized facilities (Nov-Dec vs Jan-Feb: -0.48, 95% CI: -0.75 to -0.20, p<0.001), facilities that non-hospital based and owned by a larger system (Nov-Dec vs Jan-Feb: -0.35, 95% CI: -0.69 to -0.02, p=0.037), facilities with at least 75 percent short-stay beds (Nov-Dec vs Jan-Feb: -0.62, 95% CI: -0.92 to -0.31, p<0.001), and facilities in suburban areas (Nov-Dec vs Jan-Feb: -0.63, 95% CI: -1.00 to -0.27, p<0.001). **Exhibit 49** summarizes the change in the number of urine cultures collected at baseline compared to each bimonth period during intervention for each facility characteristics.

Facility Subgroup	Each Intervention Bimonth Compared With Baseline (Jan-Feb 2019)	Mar-Apr	May-June	July-Aug	Sept-Oct	Nov-Dec
Entire cohort	Overall (n=411)	-0.28 **	-0.27 ***	-0.21 *	-0.28 **	-0.38 **
Facility size	0-74 certified beds (n=99)	-0.49 *	-0.23	-0.35	-0.30	-0.51 *
	75-149 certified beds (n=210)	-0.23	-0.38 **	-0.20	-0.37 **	-0.48 ***
	150 or more certified beds (n=102)	-0.04	-0.11	-0.04	-0.09	-0.00
Affiliation	Hospital-based (n=57)	-0.30	-0.37	-0.48	-0.68 **	-0.62 **
	Non-hospital–based and owned by a larger system (n=228)	-0.31 *	-0.24 **	-0.18	-0.28 *	-0.35 *
	Non-hospital-based and not owned by a larger system (n=126)	-0.21	-0.30	-0.19	-0.13	-0.35
Short stay	Less than 25% (n=222)	-0.12	-0.24 *	-0.18	-0.14	-0.18
	At least 25% and less than 50% (n=62)	-0.14	-0.27	-0.14	-0.41	-0.25
	At least 50% and less than 75% (n=41)	-0.63	-0.33 *	-0.50	-0.44	-0.67
	At least 75% (n=86)	-0.43 **	-0.27	-0.17	-0.38 *	-0.62 ***
Location	Urban (n=101)	0.10	-0.02	-0.06	-0.22	-0.18
	Suburban (n=146)	-0.60 ***	-0.36 **	-0.34 *	-0.51 **	-0.63 ***
	Rural (n=164)	-0.10	-0.30 *	-0.15	-0.04	-0.19

EXHIBIT 49: CHANGE IN URINE CULTURE COLLECTED PER 1,000 RESIDENT-DAYS

Note: 411 facilities with 4,688 facility-months contributed to this analysis. A generalized linear mixed model with random intercept of facility was used to generate the estimate. The entire cohort model includes bimonth as the independent variable; each stratified model includes bimonth variable, stratified variable, and their interaction terms as the independent variables.

* denotes p-value<0.05; ** denotes p-value<0.01; *** denotes p-value<0.001.

The sensitivity analysis of urine culture obtained per 1,000 resident-days showed similar findings for the entire cohort (Nov-Dec vs Jan-Feb: -0.42, p<0.001) and among subgroups (**Appendix Exhibit B-3.4**).

3.6 Evaluation Limitations

The Safety Program for LTC cohort had several limitations:

We observed a reduction in all EHR-based outcomes from baseline to the intervention period. Particularly, the reductions were statistically significant for antibiotic starts and number of urine cultures collected per 1,000 resident-days throughout the intervention period. The reductions were also observed among several subgroups for facility characteristics, though most were not statistically significant. The small sample sizes in individual subgroups led to insufficient power to investigate differences in some of the subgroups.

Although we would like to fully attribute the decrease in antibiotic use and other outcomes to the success of the Safety Program, there are other possible explanations for this observation including the following: (a) the influence of seasonal trends, (b) expected secular trends, or (c) inaccuracies with submitted antibiotic use and other outcomes data, each of which is described in further detail below.

Seasonal trends have been shown to be an important determinant of rates of antibiotic prescribing. More specifically, antibiotic use increases in the winter months. Suda and colleagues investigated antibiotic prescriptions in the US over a 5-year period and found that they were almost 25 percent higher in winter months (defined as the first and last quarters of each year) compared with summer months.¹⁰ Similarly, an evaluation of antibiotic consumption in British Columbia over a 4-year period revealed that antibiotic use during quarters 1 and 4 were 22 percent greater than quarters 2 and 3.¹¹ Although seasonal trends may have influenced the high antibiotic prescribing rate observed in January-February in the Safety Program, as both the beginning (i.e., January-February) and the end (i.e., November-December) of the Safety Program occurred in winter months, seasonality was unlikely to have factored prominently into our findings. Moreover, we do not have evidence from the published literature suggesting that antibiotic use in January-February is expected to be higher than November-December.^{12, 13, 14, 15} Specifically for LTC settings, limited data indicates that rates of antibiotics are generally higher in March-April compared to January-February or November-December.^{16, 17}

Because of the ecological study design, it remains unknown if the significant decreases in overall antibiotic usage during the course of the Safety Program were reflective of secular trends. With a growing understanding of the need for judicious antibiotic prescribing due to public health campaigns emphasizing increasing rates of antibiotic resistance, an upsurge in both the lay and scientific literature focusing on antibiotic-associated harm, a broadening of the evidence base indicating shorter durations of therapy than historically prescribed are safe and effective and increased recommendations for judicious antibiotic prescribing for common indications, it is possible that antibiotic use would have naturally decreased in the participating long-term care facilities independent of implementation of the Safety Program. In October 2016, the Centers for Medicare and Medicaid Services (CMS) published its Reform of Requirements for long-term care which, among many changes, required long-term care facilities to have ASPs by November 2017³. There are not yet published reports describing rates of antibiotic use in US nursing homes. Using publicly available data describing citations issued by CMS to LTC facilities, we found that the number of citations related to ASPs was similar in 2018 and 2019 (674 and 717, respectively), suggesting that the deficiencies regarding ASPs were largely unchanged while the Safety Program was underway.¹⁸

We cannot discount the possibility of inaccuracies with antibiotic use and other outcomes data collected and submitted by participating sites. The number of facilities enrolled and our lack of access to protected health information precluded our ability to ensure the integrity of data submitted from facilities or to an evaluation of "appropriate" antibiotic use. Nonetheless, several rigorous steps were followed to maximize the likelihood of valid data submission. At the beginning of the Safety Program an informational webinar was held to assist sites with step by step instructions regarding data collection. Sites with electronic health records who were unfamiliar with how to extract antibiotic use data were connected to other sites enrolled in the Safety Program who had successfully navigated the same electronic health record system to access their antibiotic use data. Furthermore, a standardized template with detailed instructions was distributed to sites for collecting and uploading data. The

Implementation Adviser assigned to each facility worked closely with each site through at least monthly contact to trouble shoot any data collection issues. Finally, if sites reported antibiotic use and other outcomes that were much higher than expected, suggesting an error in the numerator or denominator, they were contacted to confirm that standardized practices were used to obtain data collection and sites were requested to re-extract data if necessary.

Other evaluation limitations include variation in the accuracy of self-assessments of antibiotic stewardship infrastructure and the representativeness of respondents to the NHSOPS surveys. A potential limitation of using generalized mixed models for antibiotic usage and other outcomes is that the conclusion depends in part on the distributional assumption for the outcome, which increases the risk in mis-specifying the model and hence introducing bias to the parameter estimates. We used the modified Park test and histograms to review all possible distributions and specify our model based on the most appropriate one for each outcome.

An additional limitation is that a reduction in antibiotic use does not necessarily indicate improved antibiotic use. Similarly, a reduction in the number of urine cultures ordered does not necessarily indicate a decrease in unnecessary antibiotic use for presumed urinary tract infections. Ideally, measures would either specifically assess for a reduction in inappropriate antibiotic use or demonstrate sustained or enhanced patient safety. Collection of this data would have been onerous and precluded conducting this quality improvement project. In general, ASPs reduce the incidence of infection and colonization with antibiotic resistant bacteria and of *C. difficile* infection among hospitalized patients (Baur¹⁹). In LTC settings, there is less data to evaluate the generally accepted premise that decreased antibiotic use correlates with increased patient safety (Wu²⁰, Katz²¹). For urine cultures, however, recent data supports that decreasing orders for urine cultures leads to a decrease in *C. difficile* infection rates (Trautner²², Nicolle²³, Salem-Schatz²⁴). Additionally, a quality improvement intervention designed to decrease treatment of asymptomatic bacteriuria found a decrease in *C. difficile* infection rates as well as no increases in the rate of in all-cause hospitalization or death (Nace²⁵).

CHAPTER 4: CONCLUSION

Chapter Summary

Policy changes announced by Centers for Medicare & Medicaid Services have driven mandatory implementation of antibiotic stewardship practices in long-term care (LTC) facilities, including a requirement for antibiotic stewardship programs (ASPs) by November 2017.³ Lack of knowledge and experience for ASPs in LTC has made implementation and effective change challenging.

The Safety Program demonstrated that establishing ASPs and training frontline staff can improve antibiotic use. We observed a reduction in antibiotic prescribing in LTC settings, with a notable and sustained decrease in the overall use of fluoroquinolones specifically, as noted by a decrease in the number of starts and DOT. These outcomes suggest that the LTC Safety Program contributed to improved antibiotic prescribing, potentially reduced patient harm. As the content from the Safety Program is publicly available, we believe that utilizing Safety Program resources provides exciting opportunities for LTC facilities across the United States seeking to establish or strengthen existing ASPs and to teach frontline staff to advocate for antibiotic stewardship and to communicate those values to their colleagues, prescribing clinicians, residents and their family members.

4.1. Sustainability

During the LTC cohort, Johns Hopkins Medicine/NORC at the University of Chicago developed a range of strategies to help participating sites develop plans to sustain the ASP they established beyond the formal 1-year Safety Program. The importance of sustainability and changing long-term practice was considered while creating all material and interventions for this program, and was guided from the initial literature review of interventions that lead to sustainable change. 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 health care 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.

The Safety Program materials remained available to the sites through the project Web site through June 2021; thereafter, the materials were posted and available to the public on the AHRQ Web site with release of the Toolkit to Improve Antibiotic Use in Long-Term Care.

4.2. Lessons Learned

The AHRQ Safety Program for Improving Antibiotic Use is a complex, national quality improvement collaborative. The goals for the LTC cohort were threefold. First, to develop or improve ASPs in long-term care facilities across the country. Second, to improve decision-making processes used by prescribing clinicians evaluating residents for a possible infection by ascertaining localizing signs and symptoms specific for bacterial infections, ordering appropriate microbiological cultures and diagnostic tests, encouraging narrow-spectrum antibiotic use when appropriate, choosing appropriate lengths of therapy, and regularly re-evaluating the need for antibiotic therapy. Third, to improve the knowledge, skills, and communication used by nursing staff caring for residents with a suspected infection by supporting their efforts to assess for localizing signs and symptoms, collect appropriate cultures if needed, communicate with family caregivers, follow up and communicate culture results, and collect and communicate information to prescribing clinicians with the goal of a team-based effort to reevaluate the need for antibiotics. The Four Moments of Antibiotic Decision Making for LTC helped encapsulate these goals for program participants as did the emphasis throughout the program on fostering teamwork and communication among the long-term care staff.

The LTC cohort demonstrated the ability of a large-scale, national program to successfully implement antibiotic stewardship programs and practices in LTC facilities. The AHRQ Safety Program for Improving Antibiotic Use provided LTC facilities with novel training opportunities and a platform to implement the Four Moments of Antibiotic Decision Making framework. The success of the Safety Program to lead to detectable changes was due in part to changes made to the implementation plan based on the experience of the preceding Acute Care Cohort. As with any large, complex initiative, implementation of the LTC Cohort yielded numerous lessons for the field. The Safety Program highlights the following challenges faced during the execution of the LTC cohort, and ways to mitigate these implementation issues going forward:

Retention – The LTC cohort was successful in meeting the target enrollment goals, with 500 facilities enrolled and an additional 34 facilities wait-listed, of which 23 joined the program within the first 3 months. During the program, 84 facilities chose to end their participation, resulting in 439 that completed the program. Reasons for leaving the program were often related to changes in staffing. Sometimes this involved the departure of a single individual, such as the infection control nurse or the director of nursing, which increased the responsibilities of other individuals. For some of the nursing homes, more sweeping changes in leadership, such as the nursing home being incorporated into a new management group, prompted the decision to withdraw. A mitigation strategy to help account for the high rate of turnover among LTC staff is to have more than one person can both continue to stay involved with the program as well as help involve other staff as needed.

- Participation The initial phases of the Safety Program had robust attendance for the Webinars
 as well as office hours. During the last 3 months, however, attendance decreased. Some of this
 was likely the normal attrition in enthusiasm for a program that lasted 1 year. Other reasons
 may have related to changes in priorities for the LTC facilities such that participants could not
 devote time to attend the Webinars. For the office hours specifically, we noted few questions
 from attendees following the initial sessions. In response, the infectious diseases and antibiotic
 stewardship experts developed questions and answers to help offer useful information during
 the call. When possible, these were questions submitted through the Implementation Advisers
 related to the recent Webinars, or were inspired by clinical situations faced by the infectious
 disease experts in their practices.
- Data collection burden Over 90% of LTC facilities were able to submit data describing antibiotic starts, antibiotic days of therapy, *C. difficile* LabID events and urine cultures collected, which surpassed our expectations in this setting. Coaching and support from the implementation Advisers, as well as the quarterly feedback reports, were likely strong contributors. Also, to ease the burden, the Safety Program requested data regarding only commonly used antibiotics. Most participating long-term care facilities (>80 percent) also completed the baseline and endline structural assessment. The Nursing Home Survey on Patient Safety Culture proved to be challenging, however, with just over 25 percent of participating long-term care facilities providing the requested information.

Despite those implementation challenges, the LTC Safety Program engaged facilities and demonstrated meaningful changes in safety culture. This strategy led in turn to promising outcomes in antibiotic use and rates of urine cultures collected, among other key outcomes.

APPENDIXES

Appendix A-1 Technical Expert Panel (TEP) Members

Name	Title	Affiliation	Representation
Elizabeth Dodds-Ashley, Pharm.D.	Antibiotic Stewardship Pharmacist	Duke Antimicrobial Stewardship Outreach Network	Acute Care Setting
Neil Fishman, M.D.	Associate Chief Medical Officer, Chief Patient Safety Officer	University of Pennsylvania	Acute Care Setting
Kristi Kuper, Pharm.D.	Antibiotic Stewardship Pharmacist	Vizient, Inc.	Acute Care Setting
Andrew Morris, M.D., SM(Epi), FRCPC	Medical Director, Antimicrobial Stewardship Program	Sinai Health System/University Health Network	Acute Care Setting
Jeffrey Gerber, M.D., Ph.D.	Assistant Professor of Pediatrics, Director of Antimicrobial Stewardship	Children's Hospital of Philadelphia	Ambulatory Care Setting
Daniella Meeker, Ph.D.	Assistant Professor of Preventative Medicine	University of Southern California	Ambulatory Care Setting
Julia Szymczak, Ph.D.	Medical Sociologist	Dept. of Epidemiology and Biostatistics, University of Pennsylvania	Ambulatory Care Setting
Marjory Cannon, M.D.	Medical Director, Quality Improvement Group Centers for Clinical Standards and Quality	Centers for Medicare & Medicaid Services	Ex-Officio
James Cleeman, M.D.	Director, Division of Healthcare-Associated Infections	AHRQ Center for Quality Improvement and Patient Safety	Ex-Officio
Shelly Coyle, R.N., M.S., M.B.A.	Nurse Consultant	CMS/Center for Clinical Standards and Quality (CCSQ)	Ex-Officio
Lauri Hicks, D.O.	Director, Office of Antibiotic Stewardship	Centers for Disease Control and Prevention	Ex-Officio
Melissa Miller, M.D., M.S.	Medical Officer	AH/RQ Center for Quality Improvement and Patient Safety	Ex-Officio
Arjun Srinivasan, M.D.	Associate Director of HAI Prevention Programs	Centers for Disease Control and Prevention	Ex-Officio

Name	Title	Affiliation	Representation
Nimalie Stone, M.D., M.S.	Medical Epidemiologist for Long-Term Care	Centers for Disease Control and Prevention	Ex-Officio
Anita Thomas, Pharm.D.	Medication Safety Expert	CMS/Center for Clinical Standards and Quality (CCSQ)	Ex-Officio
Whitney Buckel, Pharm.D.	Infectious Disease Specialist	Intermountain Healthcare	Integrated Healthcare Delivery Systems
Lisa Davidson, M.D.	Medical Director, Antimicrobial Stewardship Network	Atrium Health	Integrated Healthcare Delivery Systems
Stanley Martin, M.D.	Director of Infectious Diseases	Geisinger Health System	Integrated Healthcare Delivery Systems
Edward Septimus, M.D., FACP, FIDSA, FSHEA	Infectious Disease Specialist	Memorial Hermann Southwest Hospital	Integrated Healthcare Delivery Systems
Linda Behan, B.S.N., R.N., CWCN, CIC	Corporate Director of Infection Prevention and Control	Genesis Health	LTC Setting
Joseph Marek, R.Ph., CGP, FASCP	Director of Pharmacy Services	CommuniCare Health Services, American Society of Consultant Pharmacists	LTC Setting
David Nace, M.D., M.P.H.	Director, Long-Term Care Program	University of Pittsburgh Medical Center	LTC Setting
Rita Olans, D.N.P., R.N., CPNP, APRN-BC	Assistant Professor, School of Nursing	MGH Institute of Health Professions	Nursing/Nurse Practitioner
Christian Lillis	Patient Advocacy Group	Peggy Lillis Foundation	Patient Representative

Appendix A-2 Long-Term Care Cohort TEP Meeting Agenda Items

TEP Meeting Date	Agenda Items
September 7, 2018	Long-Term Care Facility Implementation and Recruitment Plan
	 Overview of program and timeline
	 Current recruitment partners
	 Progress to date
	 Questions and discussion
	 Additional strategies to increase recruitment? Retention?
	 Suggested modifications to the educational content or implementation plan?
	 Additional strategies that Implementation Advisers should consider for keeping sites engaged?
	Long-Term Care Cohort – Data Collection Plan
	 Relevant data submission requirements for participating sites
	Additional relevant data sites may already be collecting?
	 Questions and discussion
	 Suggestions on how to stratify data reports for sites?
	 Suggestions for pulling CDI lab-event data submitted to NHSN?
	 Are there additional data that sites may already have access to that should be collected? Or ways to ease data collection burden?
October 17, 2019	Long-Term Care Cohort
	 Overview of educational content
	 Webinars and Office Hours engagement
	 Data submission to date
	Points of discussion
	 Suggestions for promoting sustainability of stewardship programs in the long- term care setting
	 Suggestions for managing missing data

#	First Name	Last Name	Affiliation
1	Melissa	Miller	AHRQ
2	Tania	Caballero	Johns Hopkins Medicine
3	Sara	Cosgrove	Johns Hopkins Medicine
4	Sara	Keller	Johns Hopkins Medicine
5	Pranita	Tamma	Johns Hopkins Medicine
6	Jeffrey	Linder	Northwestern University
7	Sarah	Legare	Health Quality Innovators
8	Katie	Richards	Health Quality Innovators
9	Simi	Chabra	Health Services Advisory Group
10	Una	Fraser	Health Services Advisory Group
11	Emilie	Sundie*	Health Services Advisory Group
12	Jerri	Hiniker	Health Services Advisory Group
13	Betsy	Jeppesen*	Health Services Advisory Group
14	Kathie	Nichols*	Stratis Health
15	Marilyn	Reierson	Stratis Health
16	Roy	Ahn	NORC at the University of Chicago
17	Prashila	Dullabh	NORC at the University of Chicago
18	Julie	Gasparac	NORC at the University of Chicago
19	Laurie	Imhof	NORC at the University of Chicago
20	Gillian	Lawrence	NORC at the University of Chicago
21	Savyasachi	Shah	NORC at the University of Chicago
22	Patricia	Stauffer	NORC at the University of Chicago
23	Samantha	Martocci	NORC at the University of Chicago
24	Meagan	Robichaud*	NORC at the University of Chicago

Appendix A-3 Stakeholder/Train-the-Trainer Meeting Attendees

* Indicates remote attendees

Appendix A-4 10 HHS Regions and Number of Participating Facilities by Region



HHS Region	States & Territories	Total Number of Participating Facilities (after withdrawals)
1	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont	26
2	New Jersey, New York, Puerto Rico, and the Virgin Islands	28
3	Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia	92
4	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee	45
5	Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin	129
6	Arkansas, Louisiana, New Mexico, Oklahoma, and Texas	48
7	Iowa, Kansas, Missouri, and Nebraska	22
8	Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming	23
9	Arizona, California, Hawaii, Nevada, U.Saffiliated Pacific Islands (American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, and Republic of Palau)	14
10	Alaska, Idaho, Oregon, and Washington	12
	TOTAL	439

AHRQ Safety Program for Improving Antibiotic Use

The Agency for Healthcare Research and Quality (AHRQ) created the AHRQ Safety Program for Improving Antibiotic Use in conjunction with Johns Hopkins Medicine's Armstrong Institute for Patient Safety and Quality and NORC at The University of Chicago to develop and implement a bundle of technical and adaptive interventions designed to improve the use of antibiotics in long-term care facilities across the United States.

Antibiotics are a precious resource and can be critical for improving the outcomes of residents with serious infections. However, antibiotics also have the potential to cause resident harm including allergic reactions, *Clostridium difficile* infections, and antibiotic resistance both at the individual resident level and for society as a whole. It is important that antibiotics are available and effective for future generations, and that is only possible through the judicious use of antibiotics.

Potential Benefits of Participation

The Agency for Healthcare Research and Quality (AHRQ) offers your long-term care facility an opportunity to participate in the AHRQ Safety Program for Improving Antibiotic Use. It will help your organization to—

- Develop and enhance antibiotic stewardship efforts
- Reduce inappropriate antibiotic use
- Reduce *Clostridium difficile* rates
- Improve teamwork and communication
- Improve resident and family satisfaction
- Improve compliance with the Centers for Medicare & Medicaid Services' antibiotic stewardship mandates

Expectations for Participating Facilities

Identify team leaders at participating facilities to assist with overseeing work. If there is no existing Antibiotic Stewardship Team, we ask that the participating facility select a clinician/leader who would like to be trained in becoming an antibiotic stewardship leader. At facilities with an existing Antibiotic Stewardship Team, the program will work with team members to enhance their antibiotic stewardship efforts.

Throughout the 12 months, the Antibiotic Stewardship Team and available frontline staff will participate in bimonthly or monthly calls that will include both content and coaching. These calls will include a formal discussion of technical or adaptive work to improve antibiotic prescribing and will also include open dialogue about successes and challenges related to improving antibiotic use.

During both the 3-month base period and the 9-month intervention period, we will use data submitted from your electronic health record to collect monthly data on days of antibiotic therapy per 1,000 days present and quarterly data on rates of *Clostridium difficile* lab-events per 10,000 resident-days. If your

facility does not have an electronic health record, we can discuss ways we can work with your organization to collect data.

If you are part of a nursing home chain or larger health system and would like to enroll multiple longterm care facilities the application will request contact information for a primary contact person. Upon reviewing your submitted application, the program will request a list of facility names that you would like to enroll in the program, as well as a contact name, phone number, email address, and fax number for each facility.

After completing the online application, please click on the "Submit Application" button. After you have successfully submitted your application, you will receive a confirmation message. You will then receive an email from <u>antibioticsafety@norc.org</u> within 5 business days of submission that will include additional information and a Letter of Commitment for your organization to review and sign.

[SECTION A].

Would you like to enroll multiple long-term care facilities for The AHRQ Safety Program?

-Yes -No [SKIP TO SECTION B.]

Please select below if you are part of a nursing home chain or larger health system, and include the name, if applicable.

-nursing home chain ______ -larger health system ______ -Not applicable [SKIP TO SECTION B.]

Organization Contact Information (mandatory):

Name: Title: Phone Number: Email: Fax Number:

Upon reviewing your submitted application, the program will request a list of long-term care facility names that you would like to enroll in the program, as well as a contact name, phone number, email address, and fax number for each facility.

SUBMIT APPLICATION

Submission Message Popup: Thank you for submitting your application for the AHRQ Safety Program for Improving Antibiotic Use. You will be contacted within 5 business days by <u>antibioticsafety@norc.org</u> with more information and, if eligible, a Letter of Commitment for your organization to complete and sign.

[SECTION B]

[For individual long-term care facilities to enroll in the program]

Please provide the following information about your facility (mandatory):

Legal Name of Long-Term Care Facility Street Address Line 1 Street Address Line 2 City State Zip Code Facility Web site URL address (optional): National Provider Identifier (NPI) (ten-digit) number (mandatory): *NPI is a unique ten-digit identification number CMS issues to U.S. health care providers. To find the NPI for your individual LTC facility, please visit https://npiregistry.cms.hhs.gov.*

In which Department of Health & Human Services region is your facility located:

Region 1 (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont)

Region 2 (New Jersey, New York, Puerto Rico, the Virgin Islands)

Region 3 (Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia)

_Region 4 (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee)

Region 5 (Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin)

Region 6 (Arkansas, Louisiana, New Mexico, Oklahoma, Texas)

Region 7 (Iowa, Kansas, Missouri, Nebraska)

Region 8 (Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming)

Region 9 (Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, Republic of Palau)

Region 10 (Alaska, Idaho, Oregon, Washington)

Facility Contact Information (mandatory): Primary Contact Name: Primary Contact Title: Primary Contact Phone Number: Primary Contact Email: Primary Contact Fax Number:

Secondary Contact Name: Secondary Contact Name: Secondary Contact Title: Secondary Contact Phone Number: Secondary Contact Email: Secondary Contact Fax Number:

Is your facility— (select all that apply) -Part of a hospital/hospital-based -Free-standing -Neither

Is your facility part of a nursing home chain or larger health system? Y/N [If yes]: What is the name of the nursing home chain/health system?

Is your facility (check all that apply)— -For-profit -Not-for-profit -Government owned -Religious affiliated -Other (please specify)

How many certified beds are in your facility?

What is the approximate proportion of residents in skilled beds (compared to residential beds)? ____

What is your facility location? -Rural -Suburban -Urban

Is your facility designated a(n) (check all that apply)— -Continuing Care Retirement Community (CCRC) -Dementia Care Facility -Hospice Facility -Intermediate Care Facility -Long-Term Care Hospital -Skilled Nursing Facility/Nursing Home

More information about eligible LTC facilities is available for reference in the FAQs, or please contact antibioticsafety@norc.org.

How many days does the consultant pharmacist spend at your facility each month? ____

What percent of their time at your facility is dedicated to antibiotic review? ____

What is the name and phone number of the pharmacy providing services to your long-term care facility?

Pharmacy name:	
Pharmacy phone:	

What is the name of the laboratory servicing your long-term care facility?

Do you have an electronic health record (EHR) in your facility? Y/N If your facility does not have an electronic health record, we are happy to discuss ways we can work with your organization to collect data.

[IF YES] Who is your electronic health records vendor?

- Allscripts
- American Data
- Answers on Demand
- Cerner
- -eHealth MedX
- Epic
- LINTECH
- Meditech
- Melyx
- Optimus
- PointClickCare
- Siemens
- Other (please specify)

[IF YES] How long have you been using this electronic health record?

Dropdown menu:

- < 6 months
- 6-12 months
- > 12 months

Are you measuring antibiotic use at your facility? Y/N

[IF YES] How are you measuring it?

- -Antibiotic starts
- -Antibiotic days of therapy per 1,000 resident-days
- -Defined daily doses per 1,000 resident-days

-Other measures, please describe:

Has your facility been actively involved in quality improvement projects or programs in the last two years? Y/N

[IF YES] Please briefly describe previous quality improvement programs.

Does your institution have an existing Antibiotic Stewardship Program (ASP)? Y/N

[IF YES] Does the Infection Prevention and Control nurse or practitioner help run the ASP? $\rm Y/N$

[IF YES] Does the Medical Director help run the ASP? Y/N

[IF YES] What percent FTE does the Medical Director receive for stewardship activities? ____

Are there any other members of your ASP? (Please describe)

What are the current antibiotic stewardship activities of your facility? (Check all that apply)

-Working with the contracted laboratory to develop an antibiogram

-Giving in-service training to nurses on topics related to antibiotic use

-Developing antibiotic prescribing recommendations for your facility

-Formulary restriction of some antibiotics

-Post-prescription review with feedback of select antibiotics

-Developing protocols for diagnosis and treatment of common infectious syndromes (i.e., urinary tract infection vs. asymptomatic bacteriuria)

-Other activities, please describe:

-Our nursing home does not have active initiatives to improve antibiotic use

How did you first learn about the AHRQ Safety Program for Improving Antibiotic Use?

- -AHRQ Patient Safety listserv
- -Armstrong Institute contact list

-Flier

-Infectious Disease Society of America listserv

-Institute for Healthcare Improvement listserv

-The Joint Commission Web site

-Johns Hopkins email

-Quality Improvement Network National Coordinating Center newsletter or listserv

-Other (please specify)

In a few words, please explain why you would like to participate in this program.

For more information on the AHRQ Safety Program for Improving Antibiotic Use, please visit: https://safetyprogram4antibioticstewardship.org

> If you have any questions about the program, please contact: antibioticsafety@norc.org https://safetyprogram4antibioticstewardship.org

SUBMIT APPLICATION

Submission Message Popup: Thank you for submitting your application for the AHRQ Safety Program for Improving Antibiotic Use. You will be contacted within 5 business days by <u>antibioticsafety@norc.org</u> with more information and a Letter of Commitment for your facility to complete and sign.

Appendix A-6 Sample Quarterly Benchmarking Report

Quarterly Benchmarking Report, January to December 2019 (Q1-Q4)

1. Introduction

Facility: FACILITY NAME Facility Type: Skilled Nursing Facility Benchmark: all participating facilities with less than 100 certified beds

As part of participation in the AHRQ Safety Program for Improving Antibiotic Use, your facility receives quarterly benchmarking reports to compare your facility's progress to those of similar facilities.

This report contains individualized results from all the data submitted by your facility for the 1st, 2nd, 3rd, & 4th quarters (January-December 2019). It includes the following results for your facility, where data are available at the time of production of this report.

- 1st, 2nd, 3rd, & 4th quarters antibiotic days of therapy (DOT)
- 1st, 2nd, 3rd, & 4th quarters antibiotic starts
- Ist, 2nd, 3rd, & 4th quarters *C. difficile* LabID events
- 1st, 2nd, 3rd, & 4th quarters urine culture events
- Baseline and Endline Structural Assessment Data
- Baseline and Endline NHSOPS

This report also includes aggregate results from similar participating facilities (benchmarking facilities). This benchmark is the average of results from all benchmark facilities whose data are available at the time of production of this report. In addition to directly comparing your facility's results with the benchmark, we provide your facility's rank among benchmarking facilities. For instance, if your facility's rank is 5/111 for DOT in April, that means only 4 out of 111 benchmarking facilities had a lower level of DOT than your facility in April.

If your facility submitted data that are reported using an older version of the data collection template and/or if your facility's data are out-of-range (high rates in comparison to the benchmark), your data is excluded from the benchmark calculation as they are not directly comparable to the benchmark. Usable newly submitted Q4 data and resubmitted data by 2/15/2020 are incorporated in the Q4 report. Please see the individual results below for more detail.

Please note that results from individual facilities are not shared with other participating facilities; the report only includes aggregate benchmark data from other facilities. We welcome your feedback on the report. If you have any questions about the report or your facility's results, please contact your Implementation Adviser.

2. Structural Assessment

Table 1 summarizes the data from the baseline and endline Structural Assessment forms completed by your facility at the time of program registration, and at the end of the program. It also includes comparative Structural Assessment data from all participating facilities with less than 100 certified beds.

Item	Your Facility (Baseline)	Benchmark (Baseline)	Your Facility (Endline)	Benchmark (Endline)
Number of certified beds in facility	90	67	74	66
Proportion of residents in skilled beds	40%	41%	9%	52%
Proportion of residents in residential beds	-	-	78%	82%
Actively involved in QI projects in past 2 years	No	100% Yes	Yes	89% Yes
Number of days consultant pharmacist spends at facility each month	1	2	1	2.9
Facility has existing Antibiotic Stewardship Program (ASP)	Yes	100% Yes	No	96% Yes
AS activity: developing an antibiogram	No	0% Yes	No	44% Yes
AS activity: in-service training to nurses on antibiotic use	No	100% Yes	Yes	87% Yes
AS activity: developing antibiotic prescribing recommendations	No	0% Yes	No	54% Yes
AS activity: formulary restriction of some antibiotics	No	0% Yes	No	22% Yes
AS activity: post-prescription review of select antibiotics	No	0% Yes	No	61% Yes
AS activity: developing protocols for treatment of common infectious syndromes	No	100% Yes	No	74% Yes
Antibiotic starts used to measured antibiotic use	Yes	100% Yes	Yes	87% Yes
Antibiotic days of therapy used to measured antibiotic use	No	0% Yes	No	75% Yes
Defined daily doses used to measured antibiotic use	No	0% Yes	No	23% Yes

TABLE 1. STRUCTURAL ASSESSMENT ITEMS FROM YOUR FACILITY AND BENCHMARK, BASELINE AND ENDLINE.

3. Nursing Home Survey on Patient Safety Culture (NHSOPS)

Please see Data Collection Information on the program website for a copy of the NHSOPS form.

Figure 1 compares your facility's baseline and endline NHSOPS composite scores to the composite scores from all participating facilities with less than 100 certified beds.

When both the baseline and endline data are available, the endline score is represented by a horizontal bar, while the baseline score is written as a percentage in parentheses inside the bar.

FIGURE 1. NURSING HOME SURVEY ON PATIENT SAFETY CULTURE COMPOSITES, BASELINE AND ENDLINE.



4. Antibiotic Days of Therapy

Figure 2 shows the trend of monthly antibiotic days of therapy per 1,000 patient-days in your facility. It includes data for all antibiotics reported by your facility. The benchmark rates represent an average across all participating facilities with less than 100 certified beds. Rates below the benchmark line indicate your facility's antibiotic days of therapy are lower than the benchmark. Rates above the benchmark line indicate your facility's antibiotic days of therapy are higher than the benchmark.





In addition, Table 2 shows how your facility ranks in this measure when compared with all facilities in the benchmark.

Label	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Total antibiotic days of therapy reported by your facility	233	234	204	278	273	259	134	254	261	196	148	187
Patient-days reported by your facility	2,119	1,895	2,030	2,037	2,092	2,042	2,017	1,885	1,778	1,868	1,741	1,787
Your facility's data are included in the benchmark	Yes											
Your facility's rank among benchmarking facilities	149	168	149	163	159	163	120	155	151	136	126	133
Total number of facilities in the benchmark	173	185	177	172	176	177	177	172	162	162	158	149

TABLE 2. ANTIBIOTIC DAYS OF THERAPY, YOUR FACILITY VS. BENCHMARK, THE	IROUGH 04 2019.

Antibiotic Days of Therapy, Antibiotic Subclasses

Figure 3 shows the monthly days of therapy per 1,000 patient-days for each of 11 drugs or drug classes. Data are shown for your facility (**indicated by bolded numbers** in graphs below) and the benchmark. Rates below the benchmark line indicate your facility's antibiotic days of therapy are lower than the benchmark. Rates above the benchmark line indicate your facility's antibiotic days of therapy are higher than the benchmark.






Penicillins (Non-Antipseudomonal)

Your Facility Benchmark





🔶 Your Facility 🔹 Benchmark



Cephalosporins (1st Generation)

🔶 Your Facility <table-cell-rows> Benchmark

Cephalosporins (Antipseudomonal)





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5. Antibiotic Starts

Figure 4 shows the trend of monthly antibiotic starts per 1,000 patient-days in your facility. It includes data for all antibiotics reported by your facility. The benchmark rates represent an average across all participating facilities with less than 100 certified beds. Rates below the benchmark line indicate your facility's antibiotic starts are lower than the benchmark. Rates above the benchmark line indicate your facility's antibiotic starts are higher than the benchmark.



FIGURE 4. ANTIBIOTIC STARTS PER 1,000 PATIENT-DAYS, THROUGH Q4 2019.

In addition, Table 3 shows how your facility ranks in this measure when compared with all facilities in the benchmark.

Label	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Total antibiotic starts reported by your facility	35	24	20	24	21	18	6	14	17	14	9	12
Patient-days reported by your facility	2,119	1,895	2,030	2,037	2,092	2,042	2,017	1,885	1,778	1,868	1,741	1,787
Your facility's data are included in the benchmark	Yes											
Your facility's rank among benchmarking facilities	158	165	134	144	139	134	39	108	127	103	69	81
Total number of facilities in the benchmark	173	185	177	172	176	177	177	171	162	162	158	149

TABLE 3. ANTIBIOTIC STARTS, YOUR FACILITY VS. BENCHMARK, THROUGH Q4 2019.

Antibiotic Starts, Antibiotic Subclasses

Figure 5 shows the monthly antibiotic starts per 1,000 patient-days for each of 11 drugs or drug classes. Data are shown for your facility (**indicated by bolded numbers** in graphs below) and the benchmark. Rates below the benchmark line indicate your facility's antibiotic starts are lower than the benchmark. Rates above the benchmark line indicate your facility's antibiotic starts are higher than the benchmark.







Penicillins (Non-Antipseudomonal)



Cephalosporins (3rd Generation)





Cephalosporins (1st Generation)



Cephalosporins (Antipseudomonal)



AHRQ Safety Program for Improving Antibiotic Use: Long-Term Care Cohort Final Report



6. C. difficile LabID Events

Figure 6 shows the trend of number of *C. difficile* LabID events per 10,000 patient-days in your facility. The benchmark rates represent average across all participating facilities with less than 100 certified beds. Rates below the benchmark line indicate your facility's *C. difficile* LabID events are lower than the benchmark. Rates above the benchmark line indicate your facility's *C. difficile* LabID events are higher than the benchmark.





In addition, Table 4 shows how your facility ranks in this measure when compared with all facilities in the benchmark.

Label	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Total c. difficile events reported by your facility	0	0	0	0	0	0	0	0	0	0	0	0
Patient-days reported by your facility	2,119	1,895	2,030	2,037	2,092	2,042	2,017	1,885	1,778	1,868	1,741	1,787
Your facility's data are included in the benchmark	Yes											
Your facility's rank among benchmarking facilities	1	1	1	1	1	1	1	1	1	1	1	1
Total number of facilities in the benchmark	180	185	181	177	175	179	177	173	169	164	160	157

TABLE 4. C. DIFFICILE LABID EVENTS, YOUR FACILITY VS. BENCHMARK, THROUGH Q4 2019.

7. Urine Cultures Collected

Figure 7 shows the trend of monthly urine cultures collected per 1,000 patient-days in your facility. The benchmark rates represent an average across all participating facilities with less than 100 certified beds. Rates below the benchmark line indicate your facility's urine cultures collected are lower than the benchmark. Rates above the benchmark line indicate your facility's urine cultures collected are higher than the benchmark.





In addition, Table 5 shows how your facility ranks in this measure when compared with all facilities in the benchmark.

Label	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Total urine cultures collected reported by your facility	4	2	1	3	1	3	1	3	4	1	2	4
Patient-days reported by your facility	2,119	1,895	2,030	2,037	2,092	2,042	2,017	1,885	1,778	1,868	1,741	1,787
Your facility's data are included in the benchmark	Yes											
Your facility's rank among benchmarking facilities	78	51	25	72	28	73	33	82	97	26	51	87
Total number of facilities in the benchmark	176	181	177	174	172	176	175	173	166	162	158	154

TABLE 5. URINE CULTURES COLLECTED, YOUR FACILITY VS. BENCHMARK, THROUGH Q4 2019.

Glossary for Clinical Measures

Number of patient-days of care - Sum of each daily patient census (number of residents in-house) for the reporting month. Other synonymous terms include "monthly resident-days", "monthly bed days of care", "monthly inpatient service days", "monthly occupied bed days", or "monthly census inpatient days of care".

Antibiotic days of therapy per 1,000 patient-days - Aggregate number of days residents were administered each antibiotic (as reported by your facility for that month), divided by the number of patient-days reported by your facility for that month, multiplied by 1,000.

Antibiotic starts per 1,000 patient-days - Aggregate number of starts for each antibiotic among all residents (as reported by your facility for that month), divided by the number of patient-days reported by your facility for that month, multiplied by 1,000.

C. difficile LabID events per 10,000 patient-days - Total number of non-duplicate *C. difficile* positive laboratory assays obtained while a resident is receiving care from your facility (as reported by your facility for that month), divided by the number of patient-days reported by your facility for that month, multiplied by 10,000.

Urine cultures collected per 1,000 patient-days - Total number of urine cultures obtained while a resident is receiving care from your nursing home (as reported by your facility for that month), divided by the number of patient-days reported by your facility for that month, multiplied by 1,000.

Appendix A-7 Structural Assessment

STRUCTURAL ASSESSMENT

Form Approved OMB No. 0935-0238 Exp. Date 08/31/2022

- 1. How many certified beds are in your facility?
- 2. What is the approximate proportion of residents in skilled beds (compared to residential beds)?
- 3. Has your facility been actively involved in quality improvement projects or programs in the last 2 years?

\cap

3a. If yes, please briefly describe previous quality improvement programs.

4. How many days does the consultant pharmacist spend at your facility each month?

4a. What percent of their time at your facility is dedicated to antibiotic review? _____

5. Does your institution have an existing Antibiotic Stewardship Program (ASP)?



5a. If yes, does the Infection Prevention and Control nurse or practitioner help run the ASP?



5b. If yes, does the Medical Director help run the ASP? \bigcirc Yes

• What percent FTE does the Medical Director receive for stewardship activities?

5c. Are there any other members of your ASP? (Please describe)

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6.	What are the current antibiotic stewardship	p activities of v	/our facility? (Check all that apply)

		Working with the contracted laborate	ory to develo	o an antibiogram
--	--	--------------------------------------	---------------	------------------

Giving in-service training to nurses on topics related to antibiotic use Developing antibiotic prescribing recommendations for your facility Formulary restriction of some antibiotics

- Post-prescription review with feedback of select antibiotics
- Developing protocols for diagnosis and treatment of common infectious syndromes (i.e. UTI vs. asymptomatic bacteriuria)
- Other activities, please describe
- □ Our nursing home does not have active initiatives to improve antibiotic use
- 7. Are you measuring antibiotic use at your facility?

	()
) Yes	

7a. If yes, how are you measuring it?

Antibiotic	starts

- Antibiotic days of therapy per 1000 resident-days Defined daily doses per 1000 residentdays
- Other measures, please describe

Public reporting burden for this collection of information is estimated to average 12 minutes per response, the estimated time required to complete the survey. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-0238) AHRQ, 540 Gaither Road, Room # 5036, Rockville, MD 20850.

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.

Appendix A-8 Monthly Data Collection Template

Form Approved OMB No. 0935-0238 Exp. Date 8/31/2022 **General Instructions:** * Each LTC facility participating in the AHRQ Safety Program for Improving Antibiotic Use should use this spreadsheet to submit monthly data for: * monthly days of antibiotic therapy * monthly antibiotic starts * monthly C. Difficile Laboratory-identifiable (LabID) events * monthly urine culture data. * Separate spreadsheets should be submitted for each reporting month * Please speak with your Implementation Advisor regarding the timeline for the monthly data submissions * Please DO NOT modify the structure of the spreadsheet such as adding, deleting, or altering rows or columns * Please fill in all non-colored cells. All numbers are expected to be whole numbers. * Please use the facility name that you used during website registration. Instructions for Reporting: Number of patient days of care: Sum of each daily patient census (number of residents in-house) for the reporting month. Other synonymous terms include "monthly resident-days", "monthly bed days of care", "monthly inpatient service days", "monthly occupied bed days", or "monthly census inpatient days of care". C. difficile LabID Events: Total number of non-duplicate C. difficile positive laboratory assay obtained while a resident is receiving care from your nursing home during the reporting month. C. difficile positive laboratory assay: An unformed/loose stool that tests positive for C. difficile toxin A and/or B, (includes molecular assays [PCR] and/or toxin assays) OR a toxin-producing C. difficile organism detected in an unformed/loose stool sample by culture or other laboratory means. Duplicate C. difficile positive laboratory assay: any C. difficile positive laboratory assay from the same resident following a previous C. difficile positive laboratory assay within the past two weeks [<15 days]. There should be at least 14 calendar days with no C. difficile positive laboratory assay for the resident before another C. difficile LabID Event is counted for the numerator. The date of specimen collection is considered Day 1. Please see Appendix 2 for C. difficile LabID events counting algorithm. Urine Cultures Collected: Total number of urine culture obtained while a resident is receiving care from your nursing home during the reporting month. Days of Antibiotic Therapy (DOT): Aggregate number of days residents were administered each of the antibiotics for the reporting month. For example, if your unit had 3 residents using Ciprofloxacin in January 2019 and they used it for 3, 5, & 7 days, respectively, then days of Ciprofloxacin in January 2019 should be counted as 3+5+7=15 days * Please see NDC codes for corresponding antibiotics in Appendix 1. * Please note that antibiotic brand names are listed only as examples. Not all brand names are listed. * If you anticipate difficulties in collecting antibiotic usage data for the antibiotics listed below, please contact your Implementation Advisor for assistance. Antibiotic Starts: Total number of antibiotic started among all housed residents for each antibiotic for the reporting month

* If a resident is transferred into your facility while on antibiotics, those antibiotics are also considered a 'start'.

* Please note that antibiotic brand names are listed only as examples. Not all brand names are listed.

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	Please upload completed form to the website portal using your log-in credentials or fax to: 410-500-4243; Attn: AHRQ Safety Program - LTCIf you are uploading completed form to the website portal, please be sure to save it with file name: [Facility name Reporting month],					
e.g. ABC Nursing Home_Jan 2019 (please use t						
NPI						
Long-Term Care Facility Name	[enter facility name here]					
Contact Name	[enter name here]					
Contact Email						
Contact Telephone Number						
Reporting Month	[enter reporting month] To enter report mont right.	·				
Number of Patient days of care	[the sum of each daily census (number resider reporting month]					
Number of C. difficile LabID events	[enter # C. difficile LabID events for the report					
Number of urine cultures collected	enter # urine cultures collected in the reporting month]					
	Days of Antibiotic Therapy (DOT): [enter aggregate # of days residents were administered each antibiotic below in the reporting month. If no resident was administered a particular antibiotic, enter "0" for that row]	# Antibiotic Starts: [enter # of antibiotic starts for each antibiotic below in the reporting month. If there were no antibiotic starts for a particular antibiotic, enter "0" for that row]				
AMIKACIN (Amikin)						
AMOXICILLIN (Amoxil), AMPICILLIN						
(Omnipen, Polycillin)						
AMOXICILLIN/CLAVULANATE (Augmentin)						
AMPICILLIN/SULBACTAM (Unasyn)						
AZITHROMYCIN (Zithromax)						
AZTREONAM (Azactam)						
CEFADROXIL (Duricef)						
CEFACLOR						
CEFAZOLIN (Ancef)						
CEFDINIR (Omnicef)						
CEFEPIME (Maxipime)						
CEFIXIME (Suprax)						
CEFPODOXIME (Vantin)						
CEFOTAXIME (Claforan)						
CEFTAROLINE (Cellorally						
CEFTAZIDIME (Fortaz, Tazicef)						
CEFTRIAXONE (Rocephin)						
CEFUROXIME (Ceftin), CEFPROZIL (Cefzil)						
CEPHALEXIN (Keflex)						
CIPROFLOXACIN (Cipro)						
CLINDAMYCIN (Cleocin)						
DAPTOMYCIN (Cleocin)						
DOXYCYCLINE (Vibramycin)						
ERTAPENEM (Invanz)						
FOSFOMYCIN (Monurol)						
GENTAMICIN						
IMIPENEM (Primaxin)						
LEVOFLOXACIN (Levaquin), OFLOXACIN (Floxin)						
LINEZOLID (Zyvox), TEDIZOLID (Sivextro)						
MEROPENEM (Merrem)						
METRONIDAZOLE (Flagyl)						
MINOCYCLINE						
MOXIFLOXACIN (Avelox)						
NITROFURANTOIN (Macrobid)						
PIPERACILLIN/TAZOBACTAM (Zosyn)						
SULFAMETHOXAZOLE/TRIMETHOPRIM						
(Bactrim, Septra)						
TETRACYCLINE (oral forms only)						
TOBRAMYCIN (Tobrex)						
TRIMETHOPRIM						
VANCOMYCIN Intravenous (Vancocin)						
VANCOMYCIN Oral (Vancocin)						
Public reporting burden for this collection of inf	ormation is estimated to average 60 minutes n	er response, the estimated time required to				
complete the survey. An agency may not condu						
	Conditional to a second to the based of the second second					

Public reporting burden for this collection of information is estimated to average 60 minutes per response, the estimated time required to complete the survey. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paper Reduction Project (0935-0238) AHRQ, 5600 Fishers Lane, #07W41A, Rockville, MD 20857.

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

Appendix B-1 Data Flowcharts

For antibiotic usage and other outcome data, we created final analytic datasets to include facilities with data in valid range for at least half year (i.e. three bimonth periods) including baseline. **Appendix Exhibit B-1** describes the data flow steps and number of facilities retained at each step for each outcome measure. The final analytic file included over 410 facilities for each outcome, with each facility contributing 11.4 months of data on average. A total of 335 facilities had all 12 months valid data for all four outcomes, which was the sample for sensitivity analysis as presented in **Appendix B-3**.

Data Flow Steps	Antibiotic Starts	Antibiotic Days of Therapy	<i>C. difficile</i> LabID Events	Urine Culture Collected
Facilities that submitted any data	437	437	437	437
Facilities with data in valid ranges	435	435	437	435
Facilities with both months data for a given bimonth period	431	431	433	432
Facilities with both Jan and Feb data (baseline) and at least one bimonth period data in the second half of the year (i.e., July–Dec)	420	420	422	421
Facilities with at least half year data	410	410	411	411

APPENDIX EXHIBIT B-1: NUMBER OF FACILITIES RETAINED IN THE ANALYSIS AT EACH STEP, BY OUTCOME

Appendix B-2 Participating Facilities Distribution in the Country



APPENDIX EXHIBIT B-2: DISTRIBUTION OF PARTICIPATING FACILITIES FOR LTC COHORT (TOTAL N=439)

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Appendix B-3 Sensitivity Analysis

Sensitivity analysis included 335 facilities who submitted usable data for all 12 months. Similar to the base analysis, generalized linear mixed models with random intercept of facility were used to examine the change from baseline to each of the bimonth periods during interventions. In exhibits, significant findings were denoted as * for p-value<0.05, ** for p-value<0.01, and *** for p-value<0.001.

Facility Subgroup	Each Intervention Bimonth Compared With Baseline (Jan-Feb 2019)	Mar-Apr	May-June	July-Aug	Sept-Oct	Nov-Dec
Entire cohort	Overall	-0.29	-0.55 **	-0.65 ***	-0.50 **	-0.52 **
Facility size	0-74 certified beds	-0.37	-0.32	-0.42	-0.47	-0.47
	75-149 certified beds	-0.32	-0.79 **	-0.98 ***	-0.85 **	-0.76 **
	150 or more certified beds	-0.13	-0.33	-0.23	0.21	-0.05
Affiliation	Hospital-based	-0.94 **	-1.15 **	-0.54	-0.75	-0.73
	Non-hospital based and owned by a larger system	-0.33	-0.51 *	-0.83 **	-0.62 *	-0.31
	Non-hospital based and not owned by a larger system	0.04	-0.36	-0.44	-0.21	-0.73 **
Short stay	Less than 25%	-0.10	-0.39	-0.29	-0.18	-0.28
	At least 25% and less than 50%	-0.02	-0.53	-0.63	-1.03	-0.49
	At least 50% and less than 75%	-0.94	-1.11 *	-0.75	-0.50	-0.39
	At least 75%	-0.63 *	-0.69	-1.46 ***	-0.89 *	-1.14 **
Location	Urban	0.11	-0.32	-0.23	-0.14	-0.16
	Suburban	-0.67 **	-0.80 **	-1.08 **	-0.67	-0.72 *
	Rural	-0.19	-0.46	-0.52	-0.55	-0.54

Appendix Exhibit B-3 1. CHANGE IN	TOTAL ANTIBIOTIC STARTS PER 1.000 RESIDENT-DAYS
	TOTAL ANTIDIOTIC STARTSTER 1,000 RESIDENT DATS

Facility Subgroup	Each Intervention Bimonth Compared With Baseline (Jan-Feb 2019)	Mar-Apr	May-June	July-Aug	Sept-Oct	Nov-Dec
Entire cohort	Overall	-1.32	-3.55 *	-2.59	-2.34	-3.59 *
Facility size	0–74 certified beds	-1.47	-1.27	1.33	-2.42	-3.08
	75–149 certified beds	-1.65	-5.53 *	-5.03 *	-4.17	-4.91
	150 or more certified beds	-0.57	-2.07	-1.79	1.01	-1.65
Affiliation	Hospital-based	-3.88	-4.89	-0.18	-4.47	-5.29
	Non-hospital–based and owned by a larger system	-3.18	-3.38	-2.57	-1.94	-1.15
	Non-hospital-based and not owned by a larger system	2.01	-3.20	-3.45	-2.00	-5.90 *
Short stay	Less than 25%	0.36	-2.21	-0.16	0.11	-1.02
	At least 25% and less than 50%	3.24	-0.48	2.43	-2.17	-0.89
	At least 50% and less than 75%	-10.01	-11.26	-4.75	-5.53	-3.94
	At least 75%	-4.93	-5.67	-11.46 **	-7.99 *	-12.2 ***
Location	Urban	0.87	-0.62	0.27	1.13	-0.99
	Suburban	-0.95	-4.49	-4.01	-1.12	-3.11
	Rural	-2.86	-4.52 *	-3.14	-5.25 *	-5.42

APPENDIX EXHIBIT B-3.2: CHANGE IN TOTAL ANTIBIOTIC DOT PER 1,000 RESIDENT-DAYS

APPENDIX EXHIBIT B-3.3: CHANGE IN C. DIFFICILE LABID EVENTS PER 10,000 RESIDENT-DAYS

Facility	Each Intervention Bimonth Compared					
Subgroup	With Baseline (Jan-Feb 2019)	Mar-Apr	May-June	July-Aug	Sept-Oct	Nov-Dec
Entire cohort	Overall	0.07	-0.62 **	-0.03	-0.43	-0.17
Facility size	0–74 certified beds	-0.19	-0.60	0.74	-0.34	-0.50
	75–149 certified beds	0.49	-0.67	-0.35	-0.55	-0.32
	150 or more certified beds	-0.30	-0.49	-0.19	-0.27	0.60
Affiliation	Hospital-based	0.31	-0.16	0.94	0.64	0.32
	Non-hospital–based and owned by a larger system	-0.00	-0.75 *	-0.03	-0.60	-0.01
	Non-hospital-based and not owned by a larger system	-0.03	-0.66	-0.62	-0.78	-0.68
Short stay	Less than 25%	0.33	-0.32	-0.07	-0.30	-0.08
	At least 25% and less than 50%	-1.25	-1.93 *	-0.10	-1.64	-0.98
	At least 50% and less than 75%	0.72	0.15	0.48	0.26	0.77
	At least 75%	-0.39	-0.94 *	0.04	-0.23	-0.37
Location	Urban	0.23	-0.98 *	-0.97 *	-1.05 *	-0.97 *
	Suburban	-0.37	-0.87 *	-0.02	-0.15	0.23
	Rural	0.24	-0.26	0.47	-0.25	0.01

Facility Subgroup	Each Intervention Bimonth Compared With Baseline (Jan-Feb 2019)	Mar-Apr	May-June	July-Aug	Sept-Oct	Nov-Dec
Entire cohort	Overall	-0.29 **	-0.33 ***	-0.22 *	-0.29 **	-0.42 ***
Facility size	0–74 certified beds	-0.54 **	-0.31 *	-0.33	-0.35	-0.54 *
	75–149 certified beds	-0.20	-0.39 **	-0.16	-0.36 *	-0.50 **
	150 or more certified beds	-0.01	-0.25	-0.14	-0.07	-0.05
Affiliation	Hospital-based	-0.32	-0.42	-0.47	-0.67 **	-0.64 *
	Non-hospital–based and owned by a larger system	-0.36 *	-0.33 ***	-0.19	-0.31 *	-0.43 *
	Non-hospital-based and not owned by a larger system	-0.17	-0.30	-0.17	-0.12	-0.34
Short stay	Less than 25%	-0.10	-0.28 *	-0.15	-0.09	-0.21
	At least 25% and less than 50%	-0.18	-0.37	-0.19	-0.50	-0.23
	At least 50% and less than 75%	-0.66	-0.37 *	-0.42	-0.37	-0.64
	At least 75%	-0.45 *	-0.36 *	-0.24	-0.48 **	-0.71 ***
Location	Urban	0.16	-0.04	-0.08	-0.17	-0.21
	Suburban	-0.62 **	-0.39 **	-0.32	-0.51 **	-0.66 **
	Rural	-0.12	-0.41 **	-0.17	-0.09	-0.24

APPENDIX EXHIBIT B-3.4: CHANGE IN URINE CULTURE COLLECTED PER 1,000 RESIDENT-DAYS

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