SUPPORTING STATEMENT

Part A

Standardizing Antibiotic Use in Long-Term Care Settings (SAUL) Study

October 22, 2010

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see Attachment A), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. Research that develops and presents scientific evidence regarding all aspects of health care.

2. The synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators.

3. Initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

Inappropriate antibiotic prescribing practices by primary care clinicians caring for residents in long-term care (LTC) communities is becoming a major public health concern as it is a risk factor for morbidity and mortality among LTC residents. Antibiotics are among the most commonly prescribed pharmaceuticals in LTC settings, yet reports indicate that a high proportion of antibiotic prescriptions are inappropriate.[1] The adverse consequences of inappropriate prescribing practices are serious and include drug reactions/interactions, secondary complications, and the emergence of multi-drug resistant organisms.

In an effort to reduce antibiotic overprescribing, Loeb and colleagues developed minimum criteria for the initiation of antibiotics in LTC setting[2]. The criteria have been tested in several studies, but their implementation and tests of validity have been limited. In particular, though Loeb and colleagues developed distinct minimum criteria for several types of infection (skin and soft-tissue, respiratory, urinary tract, and unexplained fever), a rigorous evaluation has been conducted only for urinary tract infections[3].

Twelve nursing homes (NH) will participate in this project; six NHs will be recruited to serve as treatment sites and six to serve as control sites. Once a nursing home community has been selected and randomly assigned to the treatment or control group, a facility recruitment letter (see Attachment B) will be sent to the facility Administrator. The letter will include a description of the study and inform the

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[1] Zimmer JG, Bentley DW, et al. 1986. Systemic antibiotic use in nursing homes: A quality assessment. *Journal of .American Geriatric Society*, 34(10): 703-710

[2] Loeb, M., Bendey, D.W., Bradley, S., et al. (2001). Development of minimum criteria for the initiation of antibiotics in residents of long-term care facilities: results of a consensus conference. Infect Control Hosp .Epidemiol 22, 120-124

[3] Loeb, M. Brazil, K. Lohfeld, L. et al (2005) Effect of a multifaceted intervention on number of antimicrobial prescriptions for suspected urinary tract infections in residents of nursing homes: cluster randomized controlled trial. .BMJ BMJ, dol:10.1136/bmj.38602.586343.55.*British Medical Journal*, 331, 669

Administrator that the project manager will be calling in the near future to further discuss the project and answers any questions that he/she might have regarding the program.

The objectives of the study are to:

1. Implement a QI intervention program to optimize antibiotic prescribing practices;

2. Evaluate the effect of the QI intervention on antibiotic prescribing practices including validation of the Loeb minimum criteria; and

3. Develop and execute a dissemination plan to ensure wide dissemination of the findings and recommendations for improving antibiotic prescribing behaviors in LTC settings.

To address the first study objective, the research team will conduct a six-month QI intervention program in the six treatment sites to improve antibiotic prescribing practices. The intervention incorporates investigative evidence including the Loeb algorithms. QI program procedures are documented in the draft intervention manual (see Attachment C, SAUL QI Program Guide for LTC Facilities), including the Loeb algorithms. The protocol recognizes that not all factors will need attention in all instances, as (for example) some NHs may already be vigilant to advance directive completion. The QI program is intended for facilities to self-implement and monitor with guidance provided from the research team upon request.

In order to validate the Loeb Criteria and to test the efficacy of the QI intervention, recruited facilities will be matched in pairs with respect to bedsize, profit status and location (urban, suburban, rural) and within each pair, one facility will be randomized to each study arm (treatment and control). Appropriate statistical methods will be used to determine the effect of the intervention; see the Supporting Statement Part B for a description of these methods.

The following data collection activities and trainings will be implemented to achieve the first two objectives of this project:

1) Pre-implementation semi-structured interviews will be conducted separately with physicians, facility administrators and with the director of nursing (DON) or nurse educators (see Attachment D for each type of pre-implementation interview) from the six treatment sites. The purpose of these interviews is to generate ideas on how best to implement the new procedures and what approaches work best across facilities. Related risk factors and remedial strategies also will be identified. These interviews will take place during the three month baseline period and feedback will be used to modify the intervention materials as appropriate.

2) Administrator interviews will be conducted at the time of facility enrollment to collect facility-level data in order to describe the sample and to explore linkages to prescribing practices. General facility-level descriptors including size (number of beds), profit status, location (urban, suburban, rural), and staffing levels (number of full and part-time registered nurses, licensed practical nurses, and nurse aides) will be collected. Additionally, simple summary (facility-level) information regarding resident demographics will be collected (e.g. age, gender, race/ethnicity, proportion long-stay vs. post-acute/rehab). Facility data will be collected through interviews with the Administrator at all twelve facilities. The Facility Information Form is included in Attachment E.

3) Train-the-trainer training will be conducted during the baseline period (prior to the implementation of the intervention). Research staff will present information about the Antibiotic Use QI and Monitoring Program at one, two-hour in-person meeting held at each treatment site. The research team will work

with physicians (the physician champion at each facility), administrators, directors of nursing and nurse educators using a train-the-trainer model to offer guidance on educating intervention site staff on how to implement the Antibiotic Use QI Program that is based on the Loeb criteria. Intervention and training materials include those products and strategies used in other successful projects (e.g., written Loeb algorithms; see intervention manual included in Attachment C).

4) Train-the-nurses training will be conducted by the nurse educator at each of the six treatment sites following the train-the-trainer training. The nurse educator will introduce the facility nurses to the Antibiotic Use QI and Monitoring Program materials and train them on the use of the Loeb minimum criteria (see Attachment C). This training will be offered two times at regularly scheduled in-service meetings; however each nurse will be required to attend only one session.

5) Train-the-physicians training will be conducted by the physician champion at each of the six treatment sites following the train-the-trainer training. The project team will be present to address any questions regarding the study. The physician champion will introduce the facility physicians to the Antibiotic Use QI and Monitoring Program materials (see Attachment C) and discuss with them the use of the Loeb minimum criteria. An average of five physicians at each facility will be individually contacted by the physician champion to discuss the use of the Loeb criteria. Each physician will have received a letter with the study description and the Loeb criteria prior to contact by the physician champion.

6) Medical record reviews (MMR) will be conducted by research staff to collect primary outcome data to determine antibiotic prescribing. Primary outcomes will be obtained by monthly chart review for a period of nine months: three months preceding the initiation of the QI intervention (for which the charts of all residents will be abstracted), and each month for six months following the inception of the program (for which the charts of all residents will be abstracted, regardless of whether or not they are discharged from the setting or die) at all 12 facilities (treatment and control) by trained research staff from current (not archival) records. The data collection manual and the MRR data extraction forms are included in Attachment F.

7) Final semi-structured interviews with QI team members including physicians, facility administrators, and other key facility staff will be conducted at the completion of the intervention to determine their perceptions regarding facilitators and barriers to successful program implementation. The discussion guides for the post-intervention interviews are included in Attachment G.

8) Nurse survey will be administered to nurses in all twelve facilities in the month prior to program implementation, and again in the final month of implementation. The purpose of this survey is to collect secondary outcome data regarding the antibiotic prescribing decision-making process and to collect basic information about each nurse, such as their title, type of degree and years worked in a LTC facility (see Attachment H for the Provider Protocol and Attachment I for the Nurse Survey).

9) Physician survey will be administered in all twelve facilities in the month prior to program implementation, and again in the final month of implementation. Similar to the nurse survey, the purpose of this survey is to collect secondary outcome data regarding the antibiotic prescribing decision-making process and to collect basic information about each physician (see Attachment H for the Provider Protocol and Attachment J for the Physician Telephone Interview and Web-based Survey).

In response to the third study objective, AHRQ and the CDC will draw upon their extensive experience of successfully disseminating information through varying strategies. To assist in designing a plan that has

"real world" impact, AHRQ's Dissemination Planning Tool will be utilized. For a detailed description of the dissemination plan, please see Section 16.

During the baseline period (prior to the implementation of the intervention), information about the Antibiotic Use QI and Monitoring Program will be shared with residents, their families and their primary care physicians via mailings from the nursing home administrator. The letter to residents and their families will include an invitation asking them to attend an information session to be held at the nursing home. The letter sent to residents' physicians will advise them of the project, provide the Loeb criteria and the site's intervention plan, and encourage their responsiveness. The resident-family and physician letters are included as part of the draft SAUL QI Program Guide in Attachment C.

Prior to program implementation information sessions will be offered to residents and their families at each treatment facility. One session at each site will be offered during the day and the other session at each site will be offered in the evening to accommodate family members who work. The focus of these meetings will be on the importance of reducing inappropriate antibiotic prescribing and on what they can do to help. A description of the resident and family information sessions is included in Attachment C as part of the draft SAUL QI Program Guide.

For six months each of the six facilities in the treatment group will implement and monitor the QI program. The Antibiotic Use Intervention was designed to be self-implemented and monitored as a standard NH QI program. The development of this initiative is intended to assist facilities in an area that has demonstrated need for improvement. In fact, developing QI plans is a federal regulation for long-term care facilities (483.75(o) Quality Assurance and Assessment). Research staff will be available for assistance only upon request.

This study is funded under Accelerating Change and Transformation in Organizations and Networks (ACTION), the successor to the Integrated Delivery System Research Network (IDSRN), a 5-year implementation initiative specifically developed by AHRQ to capitalize on the research capacity of, and research opportunities in, integrated delivery systems. ACTION is a model of field-based research that fosters public-private collaboration in rapid-cycle, applied research. It links many of the Nation's largest health care systems with its top health services researchers.

ACTION promotes innovation in health care delivery by accelerating the development, implementation, diffusion and uptake of demand-driven and evidence-based products, tools, strategies and findings. ACTION develops and diffuses scientific evidence about what does and does not work to improve health care delivery systems. It provides an impressive cadre of delivery-affiliated researchers and sites with a means of testing the application and uptake of research knowledge.

This study is being conducted by AHRQ through its contractors, Abt Associates and the University of North Carolina, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

2. Purpose and Use of Information

The purpose of this project is to implement and evaluate the Antibiotic Use QI and Monitoring Program, a highly innovative intervention program designed to reduce antibiotic over prescribing practices in NHs. The intervention incorporates an evidence-based conceptual model including the Loeb minimum criteria and is carried out using a quality improvement (QI) approach. Upper level facility staff (i.e., Administrators; DON; nurse educators; physician champions), at six randomly assigned treatment

facilities, will be provided with a standardized QI program to reduce antibiotic prescribing practices (see Attachment C for a draft intervention manual) and offered guidance throughout implementation of the program as requested.

3. Use of Improved Information Technology

This study will use a combination of paper and electronic forms to collect data. Primary data collected from the Administrator interviews and the MR reviews will be recorded on paper-based data extraction forms, regardless of whether or not the facility uses an electronic MR process. Similarly, informal feedback interviews with physicians and facility staff will be recorded using paper-based forms.

The secondary data collected via surveys with physicians will be administered primarily through a web-based tool, ***Checkbox*** software from Prezza Technologies. For respondents who do not have access to the web, we will administer the survey telephonically and enter the responses into a secure electronic data base (see item Section 10). The survey will be designed to collect information on signs/symptoms that factor into the prescribing decision. Surveys of nurses will be collected via paper hard copy.

4. Efforts to Identify Duplication

A comprehensive literature review was conducted and found no studies with a similar combination of objectives, design, setting and study participants. Hence, the proposed study is not duplicative.

5. Involvement of Small Entities

This project does not involve small entities.

6. Consequences if Information Collected Less Frequently

The facility-level data will be collected only one time from facility Administrators. These data can not be extracted from public web-sites such as Nursing Home Compare because we want to ensure that the facility-level data are current with the intervention program. The MRRs will occur monthly, but this data extraction activity will not place burden on facilities as MR abstractors will be UNC staff, rather than facility staff. In addition, less frequent MR data collection would require research staff to be at the facilities for longer periods of time to sort through months of MR information. The data requiring the involvement of physicians and nurses will be restricted to pre- and post-intervention (a span of approximately seven months). To determine the effectiveness of the intervention, pre- and post-intervention is the minimal frequency necessary for data collection.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice
As required by 5 CFR 1320.8(d), notice was published in the Federal Register on *(date and page number of 60 day notice)* for 60 days (see Attachment K). *If comments on the notice were received, state that and include the comments and describe actions taken by the agency in response to these comments. If lengthy put in an attachment. If the comments can be summarized include that here with the full comments in an*

attachment. Specifically address comments received on cost and hour burden. If no comments were received simply state that.

8.b. Outside Consultations

Planning for data collection in this study has involved extensive consultation with the contractor responsible for development, implementation, and evaluation of the SAUL program, Abt Associates Inc. and their partner, UNC. The design of the data collection schedule and methodology was largely informed by UNCs understanding of standard clinical practice in long-term care settings, to minimize burden while providing the level of detail needed on antibiotic prescribing practices for the formal evaluation. In addition, CDC's Nimalie Stone, MD is serving as a technical advisor on this project.

9. Payments/Gifts to Respondents

This study does not include any payments or gifts to respondents.

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose.

Abt Associates is committed to research practices conforming to basic ethical principles and Federal regulatory requirements governing research involving human subjects. All research involving interactions or interventions with human subjects that pose no more than minimal risk to those subjects is within the purview of the Abt Associates IRB. Abt Associate's Federal-wide Assurance (FWA) with the Office for Human Research Protections of the U.S. Department of Health and Human Services provides that the company will assure compliance with the Terms of Assurance only for Federally-supported research. Most research reviewed by the Abt IRB involves social and behavioral research, but the Abt IRB will also review clinical research, epidemiological research, and repository research.

We will submit data collection protocols and data management plans to Abt's IRB for review for both the control and intervention sites. We have discussed the proposed project with the Chairperson of Abt's IRB, who believes that the project will require two types of IRB waivers: 1) a waiver of informed consent (for MR extraction) since we will be extracting only a small amount of targeted information that already exists (i.e., resident ID, age, sex, face page diagnoses, whether or not an antibiotic was prescribed, name of antibiotic, state and stop date, infection related to antibiotic order, and adverse events); and 2) a waiver of signed written consent for the facility-level interview and for the physician web-based and telephone surveys since they present no more than minimal risk of harm to subjects and involve no procedures for which written consent is normally required outside the research setting. No personal, private, or sensitive information will be obtained or accessed about the respondents or other living individuals during the survey. We do not anticipate any challenges to obtaining these waivers from our IRB. Physician (web-based and telephone) and nurse written statements of informed consent are included in Attachment L.

At UNC, all information obtained from MRRs as part of this project will be kept in strict confidence and stored in secure locations. Resident health and demographic data will be recorded on coded data collection forms without personal identifiers. These forms will be stored in a locked filing cabinet and/or office. A list of residents and their study identification numbers will be maintained during the 9-month chart audit period in order for the research staff to collect information about a given resident over time. This list will be stored in a locked filing cabinet in the project office between chart audits. Resident names will not be recorded in any other location, on paper or electronically. At the end of the chart audit data

collection, this list will be destroyed. Provider and staff lists will be entered in a password protected database on a secure server at UNC. All paper forms will be stored in locked filing cabinets and/or locked offices.

Data forms transferred to Abt Associates for processing will be sent via FedEx and will be tracked until delivered. No identifying information will be included on the forms. Names and contact information about providers and staff will be scanned and sent via email or may be retrieved on a secure password protected FTP server at UNC. As stated earlier, we do not plan to request any resident-level data that NHs do not already uniformly gather as part of routine clinical operations and do not routinely maintain for quality improvement purposes.

The on-line physician survey will be hosted by the vendor, Checkbox Survey Solutions. Checkbox does not have any ownership rights to the data collected. Once collected, the web-based survey data will be exported from Checkbox to a computer database at Abt. At this time, the data in Checkbox will be deleted. Checkbox keeps deleted data a period of one week before it is completely destroyed from their records. Data entered into the database at Abt will identify participants only by number; all data will be de-identified. Abt's computers are password protected and located in offices that are locked during non-working hours. The confidentiality of all data will be assured by use of a secure, encrypted file server for data submission. Electronic files will be maintained only on password-protected secure network. Hardcopy of the on-line survey data will not be produced. Abt's IT department manages access to the company's internal data drives via password-protected authentication, and protects sensitive data through regular tape backups stored at a secure off-site facility. In addition, they support external data sharing through the encryption-compliant, Web-based Data Transfer Portal for sensitive data or the externally hosted Project Workspace for extended sharing of less confidential data. Since we will not be collecting sensitive, personal data in this study, we will use Project Workspace to share data. Only individuals who are granted access by Abt's PD, Rosanna Bertrand, will obtain a login and password to enter Project Workspace to access the survey data. The individuals who will have access to these data include: Abt's Rosanna Bertrand, PD, Donna Hurd, Christianna Williams, and Bethany Bradshaw; the UNC team Sheryl Zimmerman, PI, Philip Sloane, Co-PI, and Madeline Mitchell, PM.

Data collected through telephone interview and paper copies will be entered into a password protected database on a secure server. All paper forms will be stored in locked filing cabinets and locked offices.

11. Questions of a Sensitive Nature

This project includes no questions of a sensitive nature.

12. ***Estimates of Annualized Burden Hours and Costs***

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this research. Pre-implementation semi-structured interviews will be conducted with 3 staff members from each of the 6 intervention sites and will last about 1 hour. The administrator interviews will be completed with one administrator from each of the 12 participating NHs and will require 15 minutes. Train-the-trainer training will include 4 persons from each of the 6 intervention sites and will last 2 hours. Train-the-nurses training will be conducted with 24 nurses from each of the intervention sites; the number of responses per NH is 26 since the nurse trainer is an employee of the NH and will conduct the training twice, with about 12 nurses in each training. The nurse training will last about 1 hour. Train-the-physician training will be conducted with 5 physicians from each of the 6 intervention sites; the number of responses per NH is 6 since the physician trainer is affiliated with the NH. The physician training will last about 30 minutes.

Final semi-structured interviews will include 4 QI team members from each of the 6 intervention sites, at the completion of the intervention, and will last one hour. The nurse survey will be administered twice to 24 nurses from each of the 12 participating NHs and will take about 15 minutes to complete. The physician survey will be administered twice to 5 physicians from each of the 12 facilities and requires 15 minutes to complete. The total annualized burden hours are estimated to be 441 hours.

Exhibit 2 shows the estimated annual cost burden to the respondent, based on their time to participate in this research. The annual cost burden is estimated to be $25,204.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of nursing homes	Number of responses per nursing home	Hours per response	Total burden hours
Pre-implementation semi-structured interviews	6	3	1	18
Administrator Interviews	12	1	15/60	3
Train-the-trainer training	6	4	2	48
Train-the-nurses training	6	26	1	156
Train-the-physicians training	6	6	30/60	18
Final Semi-Structured Interview	6	4	1	24
Nurse survey	12	48	15/60	144
Physician survey	12	10	15/60	30
Total	66	na	na	441

Exhibit 2. Estimated annualized cost burden

Form Name	Number of nursing homes	Total burden hours	Average hourly wage rate*	Total cost burden
Pre-implementation semi-structured interviews	6	18	**51.68	$930
Administrator Interviews	12	3	***46.59	$140
Train-the-trainer training	6	48	31.31	$1,503
Train-the-nurses training	6	156	77.64	$12,112
Train-the-physicians training	6	18	31.31	$564
Final Semi-Structured Interview	6	24	77.64	$1,863
Nurse survey	12	144	***46.59	$6,709
Physician survey	12	30	46.10	$1,383
Total	66	441	n/a	$25,204

*Based upon the mean of the average wages, National Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics. May 2008. ** Average wages for one registered nurse ($31.31), one physician ($77.64), and one Administrator ($46.10); *** Average wages for two registered nurse ($31.31), one physician ($77.64), and one Administrator ($46.10).

13. Estimates of Annualized Respondent Capital and Maintenance Costs

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

14. Estimates of Annualized Cost to the Government

Exhibit 3 shows the total and annualized cost for conducting this research. The total budget for this three year study is $999,976. The administration task includes costs associated with the initial kick-off conference call with AHRQ and monthly progress reports and ongoing conference calls. The research plan task includes costs to finalize the research plan; conduct the literature search; prepare and submit the IRB applications and OMB package; recruit facilities; collect baseline and monthly data from medical record reviews and conduct pre- and post-intervention provider interviews; implement the intervention; and write the final report on the explanatory model. The dissemination costs include the writing of a dissemination plan and two manuscripts for publication as well as presentations at two national conferences. The final report costs include the writing of a draft and final report.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total	Annualized Cost
Administration	$24,474	$8,158
Research Plan	$591,788	$197,263
Dissemination Plan	$63,397	$21,132
Final Report	$46,501	$15,500
Overhead	$273,816	$91,272
Total	$999,976	$333,325

15. Changes in Hour Burden

This is a new data collection effort and does not build on a previous submission.

16. Time Schedule, Publication and Analysis Plans

Time Schedule

Assuming that we receive OMB approval by November 2010, we will adhere to the following schedule of project activities. Site recruitment and baseline data collection activities will begin as soon as OMB approval has been received. Although we have planned a six-month intervention, the timing of implementation will be staggered across sites so that it will last for approximately one-year, Primary and secondary data collection will extend two months beyond the intervention to complete data collection and data management activities. Work on the explanatory model (analytic plan) will begin October 2010 and be completed in final draft form in March 2011. The Abt/UNC team will develop a dissemination plan during the time from September 2011 to December 2011. A manuscript with study findings and abstracts for submission to two national conferences will be drafted between following data collection and analyses.

Publication Plan

To ensure that the approaches developed for optimizing antibiotic prescribing practices are utilized effectively and shared widely, the Abt team working closely with AHRQ and CDC, will draw upon our extensive experience of successfully disseminating information through varying strategies. To assist the team in designing a plan that has “real world” impact, we will utilize AHRQ’s Dissemination Planning Tool.

Published Manuscripts. Upon completion of the analyses of the pre- and post-intervention data, the Abt team will draft a minimum of two papers for peer-reviewed journal submission that report on research activities and findings. It is anticipated that this study will generate rich data that will support an empirical manuscript that addresses the evaluation findings, as well as a policy paper outlining the approaches for appropriate antibiotic prescribing practices. The manuscripts will be written in a style and format for a peer-reviewed health or medical journal that focuses on medical/pharmacology aspects of aging (e.g., Journal of Research in Gerontological Nursing; Journals of Gerontology, Medical Sciences; Journal of American Geriatrics Society).

Conference Presentations. The content of the manuscript will form the basis of abstracts for submission to four national conferences (e.g., American Geriatrics Society, Gerontological Society of America, AMDA). The Abt team is well known to these and other associations given their years of presentation experience. For example, in 2009 AMDA invited members of the Abt team to present data on medication in LTC.

AHRQ Health Care Innovations Exchange. As determined with input from the AHRQ and CDC, we will share findings with the AHRQ Health Care Innovations Exchange staff. If materials are deemed appropriate for sharing with the public, we will prepare materials in a 508-compliant format for posting on the public website (www.innovations.ahrq.gov).

Partnerships with Professional Organizations. Much of the project team's work has been widely disseminated to healthcare providers, policy-makers and other major stakeholders. We have a long-standing history of successfully partnering with professional organizations and members of the provider industry such as the American Association of Homes and Services for the Aging and the Massachusetts Extended Care Federation to disseminate findings related to QI in LTC settings. To ensure wide circulation across providers, we will continue to foster our relationships with these organizations since they offer a direct link to providers. Several members of the Abt team regularly attend and present at industry meetings; we will take advantage of this opportunity to disseminate findings and recommendations on optimizing antibiotic prescribing practices. We will also provide affiliates with informative electronic materials in the form of fact-sheets, and will share with key staff and family/patient groups, the manual, Antibiotic Quality Improvement and Monitoring Program, that will be developed from the intervention materials by the Abt team.

Analysis Plan

The evaluation of the intervention will compare changes from baseline (3 months of pre-intervention data) to follow-up (6 months of data) with respect to overall antibiotic prescribing and proportion of antibiotic prescribing that is in conformity with the Loeb criteria. Paired control sites will follow the same timeline as intervention sites, which will control for seasonal variation in infection rates and other possible secular trends in infection or prescribing practices to the extent possible. Baseline data collection will be completed in all sites before active intervention development occurs within the intervention sites to ensure that these data are truly pre-intervention.

After assembly of the analytic file, preliminary descriptive analyses will compare intervention and control facilities with respect to the facility descriptors (e.g., size, profit status, resident demographic mix). Comparability is expected on most of these factors because of the randomization strategy; however, any observed imbalance will be controlled statistically in the multivariate analyses. Baseline values for each of the three primary outcomes will also be compared: (1) overall rate of antibiotic prescribing (number of prescriptions per resident-month); (2) rate of antibiotic prescribing for a condition for which these drugs do not meet the Loeb criteria (number of prescriptions not meeting criteria per resident-month); and (3) a combined outcome for rates of adverse drug events, facility-associated *C. difficile colitis*, and infection-related transfers to the hospital (per resident-month). These baseline (pre-intervention) values will be

controlled for in the multivariable analyses. This strategy not only accounts for potential differences between control and intervention facilities, it also enhances the power of the analyses by eliminating this source of variability among facilities with respect to the post-intervention/follow-up values. This is because the baseline rates are likely to be among the strongest predictors of the follow-up values; and controlling for them enhances the likelihood of identifying an intervention effect. Preliminary analyses will also include bivariate month-by-month comparisons of the two groups of facilities and simple graphical methods (e.g. "spaghetti plots") of the primary outcomes over time to evaluate the distributions and examine time trends.

The unit of analysis for multivariable analyses will be the facility-month, which accounts for the clustering of resident outcomes within facilities. For each primary outcome, a repeated measures design will be used with three months of baseline data and six months of follow-up data. The six months of follow-up data (monthly rates) will serve as the dependent variables (six measures per facility) in the regression model. For each primary outcome, a single baseline (pre-intervention) value will be estimated as the average of the three months of baseline data for that measure. This will be included as an independent variable in the regression models, month of follow-up (1-6), and treatment group.

The distribution of the outcomes (rates) will be examined and an appropriate type of generalized linear model will be selected based on these distributions. A Poisson model is commonly applied for outcomes that are rates; alternatively, a negative binomial model may be appropriate if the Poisson model shows evidence of over-dispersion. For either a Poisson model or a negative binomial model, the regression coefficient for the treatment effect can be interpreted as the logarithm of the rate ratio between intervention and control facilities. Exponentiation yields the rate ratio.

A potential limitation in this evaluation is that our data collection method for the primary outcomes is based on prescriptions, rather than incidence of infections; hence, we will not be identifying instances when an antibiotic may have been indicated but was *not* prescribed. However, the proposed case-identification strategy is more efficient given the recognition that overprescribing is more common than under-prescribing and that the intervention targets minimum criteria for appropriate prescribing. Analyses of the secondary data will be primarily descriptive and will provide information regarding the decision making process, whether this changes over time, and whether different factors are considered most important between intervention and control facilities when making prescribing decisions.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Healthcare Research and Quality Act of 1999
Attachment B: Recruitment and Follow-up Emails and Letters
1. Facility Recruitment Letter
2. Nurse Recruitment Letter
3. Physician Email Invitation
4. Physician Email Reminder
5. Physician Survey Recruitment Letter
6. Physician Telephone Recruitment Script

Attachment C: SAUL QI Program Guide
Attachment D: Pre-Implementation Interview Discussion Guides
1. Pre-Implementation Discussion Guide, Administrators
2. Pre-Implementation Discussion Guide, Nurses
3. Pre-Implementation Discussion Guide, Physicians

Attachment E: Facility Information Form (Administrator Interview)
Attachment F: Medical Record Review Data Collection Manual and Forms
1. Data Collection Manual
2. Consensus Minimum Criteria Abstracting Form
3. Monthly Antibiotic Abstracting Form Audits
4. Residents Who Received An Antibiotic or Were Hospitalized

Attachment G: Final Interview Discussion Guides
1. Final Interview Discussion Guide, Administrator and DON
2. Final Interview Discussion Guide, Physician

Attachment H: Provider Survey Protocol
Attachment I: Nurse Survey
Attachment J: Physician Survey
Attachment K: 60 Day Federal Register Notice
Attachment L: Statements of Informed Consent
1. Nurse Statement of Informed Consent
2. Physician Telephone Statement of Informed Consent
3. Physician Web-based Statement of Informed Consent