SUPPORTING STATEMENT

Part A

Standardizing Antibiotic Use in Long-term Care Setting (AIR's Study)

Version: April 12, 2011

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; and
2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and
3. initiatives to advance private and public efforts to improve health care quality.

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

This project seeks to contribute to AHRQ's mission by optimizing antibiotic prescribing practices in nursing homes. Nursing homes serve as one of our most fertile breeding grounds for antibiotic-resistant strains of bacteria. Nursing home residents, with their combination of the effects of normal aging and multiple chronic diseases, have relatively high rates of infection. With high rates of respiratory, urinary, skin, and other infection comes a very high rate of antibiotic use that gives rise to Methicillin-resistant *Staphylococcus aureus* (MRSA), Vancomycin-resistant *Enterococci* (VRE), fluoroquinolone-resistant strains of a variety of bacteria, and multi-drug resistant organisms (MDROs). Inappropriate antibiotic prescribing practices by primary care clinicians caring for residents in long-term care (LTC) communities is becoming a major public health concern. Antibiotics are among the most commonly prescribed pharmaceuticals in LTC settings, yet reports indicate that a high proportion of antibiotic prescriptions are inappropriate.[1]

In general, determining "appropriateness" of antibiotic use in healthcare settings is challenging to standardize. This becomes even more complicated in the long term care setting because most antibiotic courses are started empirically due to the limited diagnostics available to many facilities. Many studies report that inappropriate antibiotics use occurs quite frequently in nursing homes. Katz and colleagues[2] found that in almost 17 percent of cases, a clinician prescribed and used antibiotics as a prophylaxis. In a retrospective chart review of post-acute

[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] Katz, P. R., Beam, T. R., Frank, B., & Boyce, K. (1990). Antibiotic uuse in the nursing home. *Archives of Internal Medicine, 150*, 1465-1468.

care residents, Richards et al[3] found that the source of infection was absent in 44 percent of antimicrobial prescriptions. Similarly, Loeb et al.[4] described that up to one-third of prescriptions for suspected urinary tract infections in nursing home residents are for asymptomatic patients who are bacteriuric. In another study, researchers found that between 25 to 75 percent of systemic antimicrobials and up to 60 percent topical antimicrobials were prescribed inappropriately[5]. Loeb et al. reported a similar percentage of inappropriate use, classifying between 22 percent and 89 percent of antibiotics prescribed to nursing home residents as inappropriate[6].

In an effort to address the need for optimizing antibiotic use (initiating antibiotics appropriately) in the long term care setting, Loeb and colleagues developed a set of minimum criteria for the initiation of antibiotics for long term care residents[6]. 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[7].These minimum criteria have formed the basis for other guidelines regarding evaluation and management of infections in long term care facilities, however, their implementation and validation has been limited. More recent guidelines that focused on what tests to perform were developed by the Infectious Disease Society of America[8] and supported the criteria overall, thus the Loeb criteria represented—at the time and continues to do so—the most current and best practices of antibiotic stewardship.

The AIR Team created it to build seamlessly on the current system of recording infection information required by federal regulations thus it demands minimal change in nursing home procedures. Yet, because it is a form that is integrated into current nursing home practices, it holds the promise of high fidelity to the planned intervention and important changes to care processes and to resident outcomes related to antibiotic use.

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[3] Richards, C. R. (2006). Preventing antimicrobial -resistant bacterial infections among older adults in long-term care facilities. *Journal of the American Medical Directors Association*, *7 Supplement*, S89-S96.

[4] Loeb, M., Simor, A. E., Landry, L., Walter, S., McArthur, M., Duffy, J. et al. (2001). Antibiotic use in Ontario facilities that provide chronic care. *Journal of General Internal Medicine*, *16*, 376-383

[5] Nicolle, L. E., Strausbaugh, L. J., & Garibaldi, R. A. (1996). Infections and antibiotic resistance in nursing homes. *Clinical Microbiology Review*, *9*, 1-17.

[6] Loeb, M., Bentley, D. W., Bradley, S., Crossley, K., Garibaldi, R., Gantz, N. et al. (2001a). Development of minimum criteria for the initiation of antibiotics in residents of long-term-care facilities: Results of a consensus conference. *Infection Congrol and Hospital Epidemiology*, *22*, 120-124.

[7] 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, dol:10.1136/bmj.38602.586343.55.*British Medical Journal*, 331, 669

[8] High, K. P., Bradley, S. F., Gravenstein, S., Mehr, D. R., Quagliarello, V. J., Richards, C., Yoshikawa, T.T. (2009). Clinical practice guideline for the evaluation of fever and infection older adult residents of long-term care facilities: 2008 update by the Infectious Disease Society of American. *Journal of the American Geriatrics Society, 57:* 375-394.

This project will assess an approach to using the Loeb criteria that requires minimal changes in facility procedures and, therefore, is likely to be widely adopted by nursing homes. The intervention makes use of a Communication and Order Form (COF), which has been designed by the researchers and will be used by the nurses and clinicians to guide their decision-making about whether to order an antibiotic for a specific resident experiencing a specific infection. Twelve nursing homes will participate in this project with eight assigned to the intervention and four serving as controls. The eight intervention sites will be divided into two groups of four sites each, with one group receiving an additional follow-up training 2 months after the intervention.

The objectives of the study are to:

1. Implement a quality improvement (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.

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

1. Loeb Criteria Communication and Order Form – This form will be completed by staff in the eight intervention nursing homes to determine if the Loeb criteria have been met (see Attachment B). The COF provides a logical decision model for determining the need for an antibiotic. Facility staff will complete the paper form and the data from the forms will be entered into a database by the project researchers. Based on a preliminary review of the infection logs at 4 nursing homes, we estimate that staff nurses will complete an average of 17 COFs per month per nursing home at the 8 nursing homes that will use the COF during the 6-month intervention period.
2. Medical record reviews (MMR) -- To be conducted by research staff to collect outcome data to determine antibiotic prescribing practices and their effects (see Attachment C) and to assess the resident's health and functional status, which are potentially important control variables. Outcome and control variables will be obtained by monthly chart review and review of the Nursing Home Minimum Data Set (MDS) for a period of nine months: three months preceding the initiation of the QI intervention (for which the charts of all eligible residents will be abstracted for a 3-month period at one time), and every other month during a 6-month period following the inception of the intervention (for which the charts of all eligible residents will be abstracted for the preceding two months. AHRQ's contractor will conduct the data abstraction at all 12 facilities (treatment and control). Since this data collection will not impose a burden on the facility staff, OMB clearance is not required.
3. Staff training – Prior to implementation, the staff (administrators, nurses, and clinicians) at all eight intervention sites will be trained in the proper use of the Loeb Criteria COF. Staff at four of the intervention sites will be trained a second time 2 months after the initial training. The reason for conducting this second training is because information from the TEP and the TMF's experience is that nursing homes have tremendous turnover. This second training would train new staff and retrain any staff who need reinforcement. We estimate that an

average of 24 nurses and 2 clinicians will be trained at each nursing home. See Attachment D for the training guide.

4. Pre-implementation semi-structured interview – The purpose of this interview is to gain an understanding of (1) how the staff and the department(s) and/or wider facility perceive quality improvement, in general; (2) the amount of experience the site has in QI and its processes for handling infections; (3) why the facility decided to adopt the Loeb Criteria COF; and (4) the reasons the facility decided to participate in the study and their expectations in doing so. It will help us understand why and how other facilities would choose to implement the COF/Loeb criteria. This information will be used in the implementation tool kit to be developed at the end of the project. Four staff members will interviewed at each nursing home: two champions (likely the administrator, director of nursing, and/or the assistant director of nursing), one line nurse, and one staff clinician. Questions vary by respondent type (see Attachment E).
5. Post-training semi-structured interview – The purpose of this interview is to measure the staff's (1) perceived adequacy of the training; (2) their reactions to the training; and (3) their plans for implementation. The same four persons at each nursing home who were interviewed for the pre-implementation semi-structured interviews will participate in this interview. Questions vary by respondent type (see Attachment F).
6. Post-implementation semi-structured interview – The purpose of this interview is to identify (1) facilitators and barriers to implementation; (2) how barriers were overcome; (3) what barriers remain; (4) perceived impacts of the Loeb Criteria COF on the use of antibiotics within the facility; and (5) the facility's view on the business case for Loeb Criteria COF. The same four persons at each nursing home who participated in the previous semi-structured interviews will participate in this interview. Questions do not vary by respondent type (see Attachment G).

This study is being conducted by AHRQ through its contractor, the American Institutes for Research (AIR), 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

This study is a one-time field test of a process intervention (the Loeb Criteria COF) designed to reduce inappropriate use of antibiotics in nursing homes. This research is not required by regulation and will not be used by AHRQ to regulate or sanction its customers. Participation will be voluntary, and the confidentiality of resident information will be preserved to the extent permitted by law. No personally identifiable information on nursing home residents will leave the nursing home or be entered into the project database.

Regarding burden on the facility staff, the research team will directly search the infection log and the medical records of residents listed in the evidence log without assistance from the nursing home staff. TMF staff routinely extract data from nursing home medical records as part of their Medicare QIO responsibilities, so they are familiar with the nursing home records systems. Nursing home staff will place the COFs, as they do with other forms, in the residents' medical

records, so the research nurses will abstract the COF at the same time that other data are abstracted from the record.

The information collected will be used to test and revise the intervention described in Section 1. The end result will be an effective process by which to improve and optimize the use of antibiotics and improved quality of health care.

3. Use of Improved Information Technology

The Loeb Criteria COF will be developed as a hard copy, printed document. Previous experience with Texas nursing homes and the advice of the Technical Expert Panel indicate that fax is by far the most common method of communication about residents' infections between nursing home staff and attending clinicians. Few nursing homes have electronic records or provide nursing staff with regular access to the Internet at work. In addition, the COFs, when kept at the nursing home, are stored in the medical record which is predominately paper based. Therefore, although it would be more efficient to use an electronic format, it would not be feasible. Our approach will use a fax or phone based method. The nurses will complete the paper COF, fax it to the clinicians, and then file it. The research team will abstract data from the COFs and nursing home records using an electronic format, programmed in MS Access, and enter the data into an electronic database, which will be used for analysis.

4. Efforts to Identify Duplication

AHRQ met with both teams (Abt Associates and AIR) who are conducting similar studies using the Loeb criteria to standardize and optimize the use of antibiotics in nursing homes. Abt is conducting a study in nursing homes that uses a more qualitative and participatory action approach that will eventually determine the nature of Abt's intervention. AIR's approach modifies an existing protocol (the use of a clinician fax or treatment order form) to incorporate the Loeb criteria. AHRQ contacted the developer of the Loeb criteria, Dr. Mark Loeb at the beginning of the project. While some of the Loeb criteria were used in a small number of nursing homes, the full range of criteria have not been used or tested for effectiveness. AIR also conducted a literature review to identify and understand issues with healthcare associated infections and the use of the Loeb criteria and found no duplicative projects.

5. Involvement of Small Entities

The sample for this pilot field test will come from CMS-certified nursing homes in Texas. The average nursing home has about 108 beds. We will recruit some facilities that are part of larger chains and others that are independent. Thus, some participants may have few beds and be independently owned, but there is no specific intention to study small businesses, other than to assure that there is some representation from small nursing homes in the study. With only 12 nursing homes participating, we would expect no more than two or three that would be considered small businesses. Our methods will be tailored to the existing communication models used by each participating nursing home, so the needs of small participants will be accommodated.

6. Consequences if Information Collected Less Frequently

This is a one-time data collection effort.

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 November 15th, 2010 for 60 days (see Attachment H). One comment was received and is shown below, followed by AHRQ's response.

Comment from the Gerontological Advanced Practice Nurses Association:

The Geriatric Advanced Practice Nurses Association (GAPNA) has reviewed the study criteria for "Standardizing Antibiotic Use in the Long Term Care Setting" and feel this is an important study as a starting point to support the goal of limiting clinically unnecessary antibiotic use in long term care to prevent antibiotic resistance. It also includes as a research question, whether the intervention will improve quality of care as measured by a reduction in the potential negative sequelae in frail LTC residents when using the study criteria. This will be very crucial data. The one area that seems deficient is the inclusion of the Nurse Practitioner in any point of the study. Since NPs provide a significant amount of care in LTC settings as prescribers, consideration should be given to including at least one in the study or process. At minimum, provider neutral language such as provider or practitioner rather than MD or physician would be preferable. A final area of concern is the limited geographical area in Texas. Hopefully this study can be reproduced in other areas of the country at a later date.

AHRQ's Response:

AHRQ appreciates GAPNA's thoughtful comments. One of the four nursing homes in the Small-Scale Trial was staffed with a Geriatric Nurse Practitioner. We expect to recruit additional nursing homes that utilize Nurse Practitioners for the field test portion of the study. We attempted to keep the provider language neutral, but we failed in some instances. Protocols and project materials have been reviewed again with that specific issue in mind and modified to use neutral language.

8.b. Outside Consultations

AHRQ's consultants for the design and conduct of this study include:

Nimalie Stone, MD, Centers for Disease Control and Prevention, an infectious disease clinician, who is serving as co-project officer.

Steven Garfinkel, PhD, MPH and Elizabeth Frentzel, MPH, of American Institutes for Research who serve as project director and project manager, respectively.

Charles Phillips, PhD, MPH of Texas A&M University's School of Rural and Public Health, who serves as Principal Investigator.

Kevin Warren, TMF Health Quality Institute. In addition,

Stephan Gravenstein, MD, of Quality Partners of Rhode Island, CMS' Quality Improvement Organization for Rhode Island and an expert on both infectious disease and nursing home care. He is also medical director of three nursing homes .

The Technical Expert Panel, which has already met once to advise on the study design and current communication models, includes representatives of the:

Texas Health Care Association

Texas Association of Homes and Services for the Aging

Texas Department of Aging and Disability Services

State Ombudsman Office

Texas Medical Directors Association

The Director of Nursing of a Texas nursing home

An administrator of a Texas nursing home.

9. Payments/Gifts to Respondents

No payments or gifts will be provided to respondents or nursing homes.

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their health care information 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. The nursing homes will be told the purposes for which the infection and antibiotic information will be collected and that identifiable information will not be used or disclosed for any other purpose. We will post a notice about study and data abstraction in the commons areas of the 12 participating nursing homes to inform residents and their family members about the study (see Attachment I). Staff and clinicians who agree to be interviewed will receive a consent form (see Attachment J) explaining that participation is voluntary and that they will not be identified in our reports.

Except for the resident's nursing home medical record number, information that can directly identify the respondent, such as resident name, and/or social security number will not be collected. The data from resident's medical record number in the nursing home will be collected so that we can link multiple episodes of infection for the same patient recorded in the infection log and so that we can merge data from the nursing home medical record and MDS record with the infection log and COF data for each resident with an infection log entry. The COFs themselves will reside at the nursing home. The medical record number will be destroyed and replaced by a project-generated ID as soon as all data are collected and merged so that the data will no longer be identifiable. We will seek a waiver of consent from the governing IRBs for record abstraction, because we will have no other reason to have any contact with the resident. In lieu of individual consent, we will propose to the IRB that we post an information sheet about the study in commons locations at each facility where residents and family members can readily see them (see Attachment I).

Until data collection is complete, the linkage between the medical record number for each resident and the project-generated unique identifier will be kept at the facility in a secured location. It will not leave the nursing home and will only be referenced by the data collectors to determine whether an infection log entry is for someone who is already a study participant and to identify the correct medical record and MDS record for data abstraction.

The data will be collected by clinically trained staff (nurses and therapists) employed by TMF Health Quality Institute, AIR's subcontractor. These individuals are experienced data collectors and regularly work with these nursing homes in their capacity as QIO employees. Data collection will be on-site at the nursing homes using a password-protected database on a password protected laptop computer owned by TMF. All data collectors have been trained in the protection of research subjects.

Researchers will keep all study records locked in a secure location. The COF forms will not leave the nursing homes and no resident names will be collected. Instead, Research records will be labeled with a code. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. Data that will be shared with others will be coded as described above to help protect identities. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and no one will be identified in any publications or presentations.

Interviews with staff. Trained, experienced qualitative interviewers from the AIR team will meet with staff at each of the nursing homes in offices or private settings to conduct the interviews or will conduct the interviews by phone. Potential participants will be told of the study purpose, the voluntary nature of the project, and be given assurances of confidentiality. All interview participants will be given a hardcopy of the consent form and one to sign and give back to the interviewer. For phone interviews, the consent form will be sent prior to the interview and we will obtain verbal consent. A staff member will take notes during the interviews. All interviews will be recorded for analysis. All recordings will be deleted within three years of the end date of the project. All notes will remove the name of the interviewee and the nursing home. All notes and recordings will be stored on password-protected computers. All interviewers have been trained in the protection of research subjects.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature in this data collection effort. Researchers will have no contact with residents and questions for nursing home staff and attending clinicians will only concern their job roles and activities, not their personal attitudes and behaviors except with respect to the COF.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the nursing home's time to participate in this project. All of the data collections and training in Exhibit 1 pertain only to the eight intervention nursing homes. The Loeb Criteria COF will be completed approximately 17 times a month for 6 months (102 total) by staff at each nursing home and will require about 5 minutes to complete. Staff training will be attended by all nursing and medical staff members at each nursing home (an average of 24 nurses and two clinicians per facility) and will last 1 hour. All

eight intervention facilities will receive training once at the start of the intervention and four of the eight facilities will receive a second training one month later to see if reinforcement results in improved performance. The pre-implementation, post training and post-implementation semi-structured interviews will be completed by the same four staff members at each nursing home consisting of two champions (likely the administrator, director of nursing, and/or the assistant director of nursing), one line nurse, and one staff clinician. Each interview will be scheduled for 1 hour. The total annual burden is estimated to be 476 hours.

Exhibit 2 shows the estimated annual cost burden associated with the respondent's time to participate in this project. The total annual cost burden is estimated to be $17,508.

Exhibit 1. Estimated annualized burden hours

Form name	Number of nursing homes	Number of responses per nursing home	Hours per response	Total burden hours
Loeb Criteria COF	8	102	5/60	68
Staff training				
Initial Training	8	26	1	208
Re-training	4	26	1	104
Pre-implementation semi-structured interview	8	4	1	32
Post training semi-structured interview	8	4	1	32
Post-implementation semi-structured interview	8	4	1	32
Total	44	na	na	476

Exhibit 2. Estimated annualized cost burden

Form Name	Number of nursing homes	Total burden hours	Average hourly wage rate*	Total cost burden
Loeb Criteria COF	8	68	$33	$2,244
Staff training				
Initial Training	8	208	$36	$7,488
Re-training	4	104	$36	$3,744
Pre-implementation semi-structured interview	8	32	$42	$1,344
Post training semi-structured interview	8	32	$42	$1,344
Post-implementation semi-structured interview	8	32	$42	$1,344

Total	44	476	na	$17,508

*Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States May 2009, "U.S. Department of Labor, Bureau of Labor Statistics." $33 is the average wage for nurses who will complete the COF. $36 is the weighted average wage of 24 nurses at $33 per hour and 2 clinicians at $70 per hour who will be trained. $42 is the weighted average wage of 3 nurses and administrators at $33 per hour and 1 clinician at $70 per hour who will be interviewed.

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 capital and maintenance costs for nursing homes, attending clinicians, or residents.

14. Estimates of Annualized Cost to the Government

Exhibit 3 shows the estimated total and annual cost to the government for funding this project. Although data collection will require less than one year, the entire project will span 2 years. The total cost of this research is estimated to be $999,554.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Development	$103,498	$51,749
Data Collection Activities	$361,178	$180,589
Data Processing and Analysis	$193,830	$96,915
Publication of Results	$48, 497	$24,249
Project Management	$65,334	$32,667
Overhead	$227, 217	$113,609
Total	$999,554	$499,777

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

Time Schedule

Field Test: begin as soon as approval is obtained from OMB and end 6 months later.

Analysis: 3 months following data collection

Reporting and Publications: 3 months following analysis

Publications

The plans for publishing the results of this pilot field test will be developed in year 2 or year 3 of the study. We anticipate one or two peer-reviewed journal articles.

Analysis Plans

Data: Analyses will be carried out at the nursing home, resident, and infection levels. Information on an estimated 1,836 infections that received antibiotic treatment during the field test will be available for analysis.

The three main research questions are:

1. Did the intervention reduce the likelihood that residents received an antibiotic when their condition failed to meet the Loeb criteria for antibiotic use in nursing homes?
2. Did the intervention improve quality of care as measured by reductions in the likelihood of (1) a poor health outcome related to antibiotic use, (2) an adverse drug reaction related to antibiotic use, (3) hospitalization for the infection, and (4) mortality?
3. Did the intervention reduce the use of antibiotics as measured by the number of antibiotics prescribed per resident?

Dependent Variables: The research team's initial list of potential dependent variables contains both process and outcome quality measures. These are:

- Were the Loeb guidelines followed with the resident (yes/no)?
- Did the resident experience an adverse drug event (yes/no)?
- Was the resident hospitalized for an infection or antibiotic- related reason (yes/no)?
- Did the resident die of an infection or antibiotic-related cause (yes/no)?
- Did the resident receive an antibiotic?

Treatment Variable: The treatment variable will be an indicator of whether the resident resides in a nursing home that is classified in one of three groups—comparison, field test intervention, and field test intervention with follow-up training. If initial analyses show that follow-up re-training has no effect, the final formulation of the main treatment variable may simply be comparison vs. intervention.

Sub-group analyses: Through the use of interaction terms or subgroup analyses, the research will investigate differential impact of the intervention by several resident characteristics, including

- residents residing in different type of facilities
- residents with infections at different sites
- residents with different types of attending clinician (i.e., Medical Director or other)
- longer-stay or shorter-stay residents
- severely cognitively-impaired residents, or
- residents with a terminal prognosis

Analysis Strategy: The basic analysis plan involves the development of descriptive statistics for the dependent variables for the entire sample and for sub-groups, as well as visual displays for all

homes and for each home in each intervention type. This will be followed with fixed-effect logistic regression models using the dependent and independent variables noted above. The primary analysis will then use multilevel random intercept logistic regression models (Rabe-Hesketh & Skrondal 2008). The unit of analysis, each infection or resident, will be repeated measures (pre-intervention and post-intervention), nested within homes, which also accounts for the different mix of clinicians used by residents in each home.

The mixed-effects logistic regression method accounts for the lack of independence between the observations. A backwards elimination approach based on likelihood ratio testing will be used to create multivariate models for formal hypothesis testing. Significance testing for the coefficients will be set at alpha = 0.05 and the model parameter will be exponentiated so that they may be interpreted as odds-ratios. The SAS version 9.1 will be used for performing the analysis. Due to the complexity with multilevel models for binary outcomes, we will use different procedures (PROC GLIMMIX and PROC NLMIXED) to perform our analysis and determine the robustness of our results.

All interviews will be audiotaped and attended by a note taker. We use a variety of well-established techniques, including data reduction, generation of themes, and validation of themes and findings to draw conclusions from the qualitative data.[9,10]

17. Exemption for Display of Expiration Date

AHRQ does not request this exemption.

List of Attachments

Attachment A: The Healthcare Research and Quality Act of 1999

Attachment B: Loeb Criteria Communication and Order Form

Attachment C: Medical Record Data Abstraction Form

Attachment D: Staff Training Guide

Attachment E: Pre-Implementation Semi-Structured Interview Protocol

Attachment F: Post-Training Semi-Structured interview Protocol

Attachment G: Post-Implementation Semi-Structured Interview Protocol

Attachment H: Federal Register Notice

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[9] Devers, K.J. (1999). How Will We Know "Good" Qualitative Research When We See It?, *Health Services Research*,.34 (5): Part II, S1153-1188.

[10] Miles, M. B., & Huberman, A. M. (1994). *Qualitative data analysis: An expanded sourcebook* (2nd ed.). Thousand Oaks, CA: Sage.

Attachment I: Information sheet to be posted in the nursing home for residents and family members

Attachment J: Consent Form for Interviews