SUPPORTING STATEMENT

Part A

Using Nursing Home Antibiograms to Improve Antibiotic Prescribing and Delivery

September 26th, 2011

Agency of Healthcare Research and Quality

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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 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. The Agency for Healthcare Research and Quality 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, the Agency for Healthcare Research and Quality 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.

Overuse and inappropriate use of antibiotics, particularly broad-spectrum antibiotics, is recognized as a serious problem in nursing homes (NHs). The adverse consequences of inappropriate prescribing practices including drug reactions/interactions, secondary complications, and the emergency of multi-drug resistant organisms have become more common. For example, in one point-prevalence survey of 117 NH residents, 43 percent were culture-positive for one or more antimicrobial-resistant pathogens, including methicillin-resistant staphylococcus aureas (24 percent), extended-spectrum β-lactamase-producing klebsiella pneumoniae (18 percent) or Escherichia coli (15 percent), and vancomycin-resistant enterococci. Inappropriate overprescribing and overuse of broad-spectrum antibiotics, when narrower spectrum drugs would suffice, are believed to be important contributors to this problem.

Physicians typically begin antibiotics for suspected infections in NH residents without waiting for bacteriology laboratory culture results. If there is a clinical failure (e.g., patient does not improve), the physician may request a bacteriology laboratory test, but will often try a second antibiotic without waiting for culture confirmation. If a NH resident is deteriorating, many NHs do not try a second antibiotic but will instead transfer the patient to a hospital emergency department (ED). In the ED, physicians must make quick decisions about whether to continue the first antibiotic prescribed in the NH or start another, again often without culture results.

NH patients are transferred to EDs for all sorts of medical reasons, including but not limited to infections. When NH patients arrive at an ED, physicians may identify a urinary tract, respiratory, or other infection that was not the primary reason for the ED visit. Thus, patients may not leave the NH with a suspected bacterial infection or taking any antibiotics, but an infection is suspected in the ED and the first antibiotic is prescribed there.

As a result of the above complexities, NHs are increasingly recognized as reservoirs of antibiotic-resistant bacteria. Antibiograms aggregate information for an entire institution over a period of several months or a

year. They display the organisms present in clinical specimens sent for laboratory testing, and the susceptibility of each organisms to an array of antibiotics. Antibiograms are routinely prepared by hospital laboratories but are not routinely prepared in the NH setting. The culmination of this project will be a NH antibiogram toolkit that will contain the tools necessary for a NH to create a facility-specific antibiogram to assist physicians who must make antibiotic prescription decisions without bacteriology laboratory test results for patients in NHs as well as for those patients transferred from the NH to the ED. Outcomes of interest for antibiogram use include reduced reliance on broad-spectrum antibiotics as initial therapy and fewer clinical failures of antibiotics that are first prescribed. The development of a toolkit will be the first step in this process; future studies will be required to test the toolkit and, subsequently, the effectiveness of NH antibiograms.

There are many challenges to developing NH antibiograms, and in getting them into the hands of prescribing physicians when an antibiotic is being considered. First, NHs and the clinical laboratories with which they contract do not routinely generate antibiograms; this will be a new activity although it will likely not incur significant added costs since the option for this report is included in most computer programs utilized by labs. Second, once antibiograms are created they must be shared with prescribing physicians while they consider antibiotics for patients with suspected bacterial infections. A NH with 100 long-term patients may have three to eight physicians responsible for these patients; each of whom would need to receive an appropriate antibiogram before writing an antibiotic prescription. Third, when a patient with a suspected bacterial infection is transferred to a hospital ED, the appropriate antibiogram must accompany the patient to provide information to the ED physicians. Finally, these processes for creating and transmitting antibiograms may differ for different types and sizes of NHs.

The overall goal of this project is to develop a toolkit that will assist NHs to develop and use antibiograms. This project will be conducted in three phases. The first phase, currently underway, involves working with a single NH to develop the antibiogram and a draft toolkit. This has included working with a liaison from the nursing staff, medical director, and vendor laboratory to develop the antibiogram and developing a process for implementation. An outline for the draft toolkit has been developed based on the experiences of creating the antibiogram and the process of implementation for this first NH. This draft will be used as the basis for the next phase of the project and will be further refined based on the experiences with the next two NHs.
The second phase of the project, for which we are seeking OMB clearance, involves the recruitment of two additional NHs to further refine the toolkit. This phase will build on what was learned in the first phase by expanding the study to include NHs of different sizes, locations, ownership, and population from the first NH. We will use qualitative research methods to evaluate the feasibility and usability of antibiograms at these two nursing homes. We will also perform a post-implementation evaluation at all three NHs (initial NH from phase one and the two NHs in this second phase). We will use the experiences and information from this qualitative research to ensure that the draft toolkit has the necessary pieces for a nursing home to create, use, and maintain their own antibiogram. These items may include an assessment of organizational readiness, instruction on how to create and use an antibiogram, training materials, communication of antibiogram information to hospitals and emergency departments, and maintaining and monitoring the program.

The third phase, which is beyond the scope of this project, will be to take the final form of the toolkit and test it in a broad range of nursing homes.

The specific objectives of the first two phases of the project are to:

1. Develop a standardized method for determining antibiotic susceptibility patterns and developing NH-specific antibiograms;

2. Extract preliminary data from NH facilities of various sizes and types to guide the development of the draft toolkit; and

3. Develop a draft toolkit to guide a wide variety of sizes and types of NHs in developing and sharing antibiogram information with prescribing providers (i.e., physicians and physician extenders) and EDs.

Three NHs and one ED will participate in this study.in the first two phases of the project . The first phase will include one small NH and one ED and is intended to test the data collection instruments and to draft the initial toolkit, including the creation of a NH specific antibiogram. The second phase will expand the study by adding two larger NHs, while retaining the same NH and ED as in the first phase and is intended to further test the data collection instruments and refine the draft toolkit. Each phase will use the same methods and data collections.

Working with these NHs and their vendor laboratory(s), the research team will develop facility-specific antibiograms. The antibiograms will be used by providers within the NH to help them make decisions regarding antibiotic orders, and will travel with NH residents when they are transferred to the ED to help ED providers make antibiotic decisions.

This small-scale pilot study will examine trends in the pattern of change in antibiotic prescribing practices and transfers to the ED for infections before, during and after the implementation of the antibiogram program in the target NHs. In addition, beyond studying whether antibiograms change prescribing practices and the use of the ED, we wish to understand how antibiograms change the way providers prescribe antibiotics for NH patients, and identify potential barriers to antibiogram use from the NH and ED prospective. Understanding these variables in the NH and ED setting, the draft toolkit can be created taking these variables into account. Given the small sample and lack of control facilities, we recognize that the study may not be sufficient to detect statistically significant change, or to attribute any change to the intervention. However, the methods used here are sufficient to create a draft toolkit which will be subjected to further testing before being publicly released.

The draft toolkit will be developed for the purpose of providing guidance to NHs on various ways to create antibiograms. We know of several possible ways to create the antibiograms – either working through the laboratory vendor to use data on file at the laboratory or using NH data - either paper or electronic - to create the antibiogram. In addition to information on creating antibiograms, the draft toolkit will include methods for identifying and addressing provider and nurse attitude challenges and biases; methods for sharing antibiograms with NH prescribing providers and ED physicians and methods for evaluating the impact of antibiograms with suggestions for data collection forms, instructions for straightforward impact calculations, and suggested displays of results.

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

1) Medical Records Extraction. Medical record data related to antibiotic use will be extracted by the research team at the three participating NHs and one ED. The team will extract the necessary data from the infection control log and request access to additional records (e.g., medication log and/or patient medical record) as needed to collect relevant data. Two months of retrospective NH and ED medical records will be reviewed prior the implementation period, on a monthly basis during implementation, and for one month post-implementation. In the ED medical records will be extracted for only those NH residents who have been transferred to the ED from one of the participating NHs. The pre-implementation data will be compared to the data collected during implementation and post-

implementation to see if the use of the antibiogram report had an effect on antibiotic use at the participating facilities. It is unlikely, but possible that NH staff may be asked to assist the research team with this task in the two larger, Expansion Phase Two sites, however ED staff will not. See Attachments B: NH Data Extraction Tool and Attachment C: ED Data Extraction Tool.

2) Provider Pre-Implementation and Post-Implementation Questionnaires. These questionnaires will be completed by providers at both the NHs and ED one month prior to implementation and again in the final month of implementation. NH and ED questions differ somewhat, as do pre- and post-implementation surveys. In addition to basic background questions such as the providers' title, type of residency and length of practice, questions related to their use and opinion of antibiograms are included. The post-implementation questionnaire contains three additional questions related to the use of antibiograms as well as a series of vignettes administered before and after the presentation of an antibiogram report. These questionnaires will assess change in the providers use and opinion of antibiograms. See Attachments D: NH Providers Pre-Implementation Questionnaire; Attachment E: ED Providers Pre-implementation Questionnaire; Attachment F: NH Providers Post-Implementation Questionnaire; and, Attachment G: ED Providers Post-implementation Questionnaire.

3) Nurse Pre/Post-Implementation Questionnaire. This questionnaire will be administered one month prior to implementation and again in the final month of implementation. In addition to basic background questions such as the nurses' title, position at the NH and length of employment, questions related to their use and opinion of antibiograms are included. The same set of questions are asked at each time period. This questionnaire will measure any change in the nurses' use and opinion of antibiograms. See Attachment H.

4) NH Leadership Post-Implementation Questionnaire. This questionnaire will be completed by the NH administrator or the director of nursing in the final month of the implementation. In addition to basic background questions such as their title, position at the NH and length of employment, questions are asked about the impact the antibiograms had in terms of antibiotic use, the cost associated with their use and whether they intend to continue using them once the study has been completed. See Attachment I.

Recruitment Letters and Statements of Informed Consent are included as Attachments J – L and M – Q, respectively. Prior to program implementation, one-page fact sheets (See Attachment R: Fact Sheet) will be distributed at the NH facilities to familiarize nurses with the purpose and functionality of antibiograms. Formal trainings will not be conducted, but nurses are directed to call the project director should they have any questions about the study or about antibiograms. NH providers and ED physicians will also have access to fact sheets, but are expected to be familiar with antibiograms because of their introduction during residency. Lastly, administrators at NHs will be asked to encourage nurses to use antibiograms when discussing patients with the NH providers or ED physicians, as the use of antibiograms often hinges on nurses' introduction of the antibiograms to providers.

This study is being conducted by the Agency for Healthcare Research and Quality through its contractors, Abt Associates and the Brigham and Women's Hospital ED, pursuant to the Agency for Healthcare Research and Quality'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 develop a daft NH Antibiogram Toolkit, and to generate preliminary results on whether NH antibiograms are cost-effective and helpful to who must make antibiotic prescription decisions without bacteriology laboratory test results, for patients in NHs and for patients who are transferred from NHs to EDs. Preliminary outcomes of interest include reduced reliance on broad-spectrum antibiotics as initial therapy, and fewer clinical failures of antibiotics than are first prescribed.

3. Use of Improved Information Technology

This study will use a combination of paper and electronic forms to collect data. Primary data collected from NH and ED medical record reviews will be recorded into an electronic data base such as excel, regardless of whether or not the facility uses an electronic medical record process. Questionnaires completed by NH nurses and administrators will be recorded using paper-based forms. Hard copy administration will be more convenient for this group of respondents as they do not typically have easy access to a computer for internet use.

The data collected from NH providers and ED physicians will be gathered primarily through a web-based tool, ***Checkbox*** software from Prezza Technologies. For respondents who do not have access to the web, we will offer a paper and pencil version of the tool. The providers will be given a stamped envelop pre-addressed to the project director in which to mail the completed paper questionnaire. The content of the paper and pencil questionnaire will be identical to the web-based version.

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 medical record reviews will occur monthly for 12 months. NH staff may assist the research staff with this activity. Less frequent medical record data collection would require research staff to be at the facilities for longer periods of time to sort through several months of medical record information. The data requiring the involvement of providers and nurses will be restricted to pre- and post-implementation (a span of approximately 12 months for the initial facility and seven months for the expansion facilities). To determine the effectiveness of the implementation, pre- and post-implementation 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 use of antibiograms in NHs, Abt Associates Inc. and their partner, Brigham and Women's Hospital. The design of the data collection schedule and methodology was largely informed by Abt's 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 preliminary evaluation. Jeremiah Schuure, MD, MHS as Principal Investigator and Director of Quality, Safety and Performance Improvement for the Department of Emergency Medicine at Brigham and Women's Hospital led the design of the ED-related data collection. In addition, Brigham and Women's Hospital's Gianna Zuccotti, MD, MPH is serving as a consultant on infectious diseases and hospital epidemiology for the 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 Institutional Review Board. Abt Associate's Federal-wide Assurance 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 Institutional Review Board involves social and behavioral research, but the Abt Institutional Review Board will also review clinical research, epidemiological research, and repository research.

All study data collection protocols and data management plans have been approved by Partners Healthcare's (owner of Brigham and Women's Hospital) and Abt's Institutional Review Boards. The project received two types of Institutional Review Board waivers: 1) a waiver of informed consent (for medical record extraction) since we will be extracting only a small amount of targeted information that already exists (i.e., resident ID, age, sex, date of NH/ED admission, NH admission diagnoses, reason for ED transfer, name of antibiotic(s) prescribed, prescription date(s), date of first dose(s), culture information (if applicable); and 2) a waiver of signed written consent for the provider web-based questionnaire since they presents 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 questionnaire. Provider (paper and web-based) and nurse written statements of informed consent are attached (see Attachments M – Q); the NH leadership statement of informed consent is included at the beginning of the survey (see Attachment I).

All information obtained from medical record reviews as part of this project will be kept in strict confidence and stored in secure locations. Patient/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 12-month chart audit period in order for the research staff to access information about a given resident over time. This list will be stored in a separate locked filing cabinet in the project office. 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 Abt Associates. All paper forms will be stored in locked filing cabinets and/or locked offices.

Data collection forms completed by Brigham and Women's Hospital and transferred to Abt Associates for processing will be sent via a shared, password-protected Project Workspace. No identifying information will be included on the forms. 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 questionnaire will be hosted by the vendor, Checkbox Survey Solutions. Checkbox does not have any ownership rights to the data collected. Checkbox stores data on Amazon EC2, a secure location. Access to the Checkbox physical facility is by keycard only. Survey data are transferred from Checkbox via an encrypted SSL website and are destroyed after 90 days. Once collected, the web-based questionnaire data will be exported from Checkbox to a computer database at Abt. Data imported 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 questionnaire data will not be produced. Abt's Information Technology 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.

Data obtained from paper questionnaires 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. Although medical records extraction using the NH and ED Data Extraction Tools will occur at the NHs and ED only the NH staff may be burdened by it. Medical record data extraction will occur monthly for 7 months at the two Expansion Phase Two NHs and may require 15 minutes assistance from the NH staff.

The NH Provider Pre-Implementation Questionnaire will be completed by 10 providers at each of the two Expansion Phase Two NHs and will take about 10 minutes to complete. The NH Provider Post-Implementation Questionnaire will be completed by three providers in the Initial Phase One NH and 10 providers at each of the two Expansion Phase Two NHs (23 total or an average of 7.67 providers per NH as shown in Exhibit 1) and takes 15 minutes to complete. The ED Provider Post-Implementation Questionnaire will be completed by 30 providers in the ED and requires 15 minutes to complete. The

Nurse Pre/Post Implementation Questionnaire will be completed pre-implementation by approximately 25 nurses at each of the two Expansion Phase Two NHs and again post-implementation by 25 nurses at each of the 3 participating NHs (125 total or an average of 41.67 nurses per NH as shown in Exhibit 1). The Nurse Pre/Post-Implementation Questionnaire is estimated to take 5 minutes to complete. The NH Leadership Post-Implementation Questionnaire will be completed by one NH administrator or director of nursing at each of the three participating NHs and will require 10 minutes to complete. The total annualized burden hours are estimated to be 32 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 $1,921.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of facilities	Number of responses per facility	Hours per response	Total burden hours
Medical Records Extraction	2	7	15/60	4
NH Provider Pre-Implementation Questionnaire	2	10	10/60	3
NH Provider Post-Implementation Questionnaire	3	7.67	15/60	6
ED Physician Post-implementation Questionnaire	1	30	15/60	8
Nurse Pre/Post Implementation Questionnaire	3	41.67	5/60	10
NH Leadership Post-Implementation Questionnaire	3	1	10/60	1
Total	14	n/a	n/a	32

Exhibit 2. Estimated annualized cost burden

Form Name	Number of facilities	Total burden hours	Average hourly wage rate*	Total cost burden
Medical Records Extraction	2	4	$31.99	$128
NH Provider Pre-Implementation Questionnaire	2	3	$83.59	$251
NH Provider Post-Implementation Questionnaire	3	6	$83.59	$502
ED Physician Post-implementation Questionnaire	1	8	$83.59	$669
Nurse Pre/Post Implementation Questionnaire	5	10	$31.99	$320
NH Leadership Post-Implementation Questionnaire	3	1	$51.45	$51
Total	14	32	n/a	$1,921

*Based upon the mean of the average wages, National Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics. May 2009. Hourly mean wage for registered nurse ($31.99), physician ($83.59), and NH administrator ($51.45).

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 two year study is $458,812.

The administration task includes costs associated with the initial kick-off conference call, monthly progress reports, ongoing conference calls, and preparation of Institutional Review Board and OMB packages.

The initial antibiogram development phase includes the recruitment of the initial facility, development of the antibiogram for that NH, NH medical record review for residents treated with antibiotics during the two-month period prior to program implementation, ED medical record review for residents transferred to the ED from the first NH during the two months prior to program implementation, administration of pre-implementation questionnaires with NH nurses and NH and ED physicians, administration of post-implementation questionnaires with NH nurses, NH providers, and the administrator. (Post-implementation information from ED physicians will be obtained at the end of the Expansion Phase.)

The expansion of the antibiogram development includes the recruitment of two additional NHs, development of their corresponding antibiograms, dissemination of antibiograms to NH staff, monthly medical record reviews at the NH to collect data on antibiotic use, weekly medical record review at the ED to identify residents from the two study NHs and collect data on antibiotic use; administration of pre- and post-implementation questionnaires with NH nurses and NH providers, and administration of post-implementation questionnaires with ED physicians and NH administrators.

Development and refinement of the toolkit task includes methods for 1) creating antibiograms; 2) identifying and addressing physician and nurse attitudinal challenges/biases; 3) sharing antibiograms with NH prescribing physicians; 4) sharing antibiograms with ED physicians; and 5) evaluating the impact of antibiograms including suggestions for data collection forms, instructions for impact calculations and suggested displays of results.

The small-scale pilot evaluation includes the assembly of the analytic file and analysis of trends in the pattern of change in antibiotic prescribing practices and transfer to the ED for bacterial infections before and during/after the implementation of the antibiogram program in the target NHs.

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
Project Administration	$60, 511	$30,256
Initial Antibiogram Development and Implementation	$47,618	$23,809
Expansion of Antibiogram Development and Implementation	$36,948	$18,474
Toolkit – Development and Refinement	$92,688	$46,344
Evaluation	$153,978	$76,989
Final Report and Dissemination	$67,071	$33,536
Total	$458,812	$229,406

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
The NH component of the project will be conducted in two phases: an Initial Phase in which one NH is recruited for participation and an Expansion Phase in which two additional NHs are recruited for participation. Both the Initial and Expansion Phases incorporate a small-scale pilot pre- and post-implementation study design. Pre-implementation data collection for the NH Initial Phase will occur during the first two months of the project following Institutional Review Board approval and recruitment of the first facility (pre-OMB approval). Initial Phase post-implementation and Expansion Phase pre-and post-implementation data collection activities will occur after OMB approval.

The ED component of this project which also utilizes a small-scale pre- post-implementation study design has only one phase. The initiation of the ED component coincides with the beginning of the Initial NH Phase and the end of the ED component coincides with the termination of the Expansion Phase. It should be noted that given that the ED pre-implementation occurs prior to OMB approval, only three ED providers will participate in pre-implementation data collection activities. The post-implementation data collection will be administered after OMB approval, so all available ED providers will be recruited for participation.

Prior to OMB approval, as noted above, recruitment of one NH (Initial Phase) will occur along with collection of two months of baseline data on antibiotic use (conducted by research staff). Three NH nurses, three NH providers and three ED providers will be asked to complete questionnaires. Also during this pre-OMB period, the antibiogram for this initial NH will be developed by the research team (January 2011) and shared with the NH. The research staff will conduct monthly medical record reviews from February 2011 through December 2011, conducted by research staff.

The research team will integrate the information learned during the Initial Phase through developing, transmitting, and utilizing the antibiogram into a draft toolkit. It is anticipated that the toolkit will have several components including methods for sharing information between the NH and the affiliate laboratory to create antibiograms, methods for identifying attitudinal challenges that may be barriers to utilization, methods for sharing antibiograms with NH and ED providers, and methods for evaluating the impact of antibiograms. The draft toolkit will also include guidance on how to construct, update, and maintain NH-specific antibiograms. Based on information gained during the Expansion Phase, the Abt team will gather data to further refine the antibiogram toolkit.

Assuming that we receive OMB approval by August 2011, we will adhere to the following schedule of project activities. Recruitment of the two expansion NHs, baseline data collection, development of their respective antibiograms, and pre-implementation interviews with the NH nurses and NH providers will begin as soon as OMB approval has been received (August - September 2011). In September 2011, we will implement the antibiogram in the Expansion NHs. Monthly medical record reviews will continue (September – March 2012), and the draft toolkit will be refined. Administration of post-implementation questionnaires with NH nurses, NH and ED providers and NH leadership staff will take place in March 2012. Data analysis will commence in March 2012 with the final report delivered in June 2012.

Publication Plan
To ensure that the approaches developed for the development and use of antibiograms are utilized effectively and shared widely, the Abt team working closely with the Agency for Healthcare Research and Quality, 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 the Agency for Healthcare Research and Quality’s Dissemination Planning Tool.

Published Manuscripts. Upon completion of the analyses of the pre- and post-implementation data, the Abt team will draft a final report. Given the length of the project, it is unlikely that findings will be generated in time to submit abstracts for scientific presentations or manuscripts during the contract period. It is anticipated that this study will generate data that will support a manuscript that addresses the preliminary evaluation findings, as well as a policy paper outlining the approaches for the use of antibiograms in NHs. 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, American Medical Directors Association). The Abt team is well known to these and other associations given their years of presentation experience. For example, in 2009 American Medical Directors Association invited members of the Abt team to present data on medication in long-term care.

Agency for Healthcare Research and Quality, Health Care Innovations Exchange. As determined with input from the Agency for Healthcare Research and Quality, we will share findings with the Agency for 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 quality improvement in long-term care 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 the development and use of antibiograms in NHs.

Analysis Plan

The intent of the small-scale evaluation is to serve as a pilot test of the study protocols and data collection tools. The results will be considered preliminary and not used to infer causality. Rather, we will examine trends in the pattern of change in antibiotic prescribing practices and transfer to the ED for bacterial infections before and during/after the implementation of the antibiogram program in the target NHs.

Evaluation of the intervention will compare changes from baseline (2 months of pre-implementation data) to follow-up (12 months of data for the Initial Phase NH and 6 months of data for the Expansion Phase NHs) with respect to antibiotic prescribing practices and transfer to the ED for bacterial infections.

Baseline data collection will be completed in each NH and the ED before introduction of the antibiograms to ensure that these data are truly pre-implementation.

After assembly of the analytic file, preliminary descriptive analyses will report on the three NHs with respect to the facility descriptors (e.g., size, profit status, resident demographic mix).

The following baseline/pre-implementation and post-implementation outcomes will be compared: 1) proportion of NH residents that were started on an antibiotic; 2) number of residents transferred to the ED with evidence of infection; 3) proportion of antibiotics that were broad-spectrum; 4) proportion of initial

empiric antibiotics for specific infections that are potentially inappropriate based on the NH antibiograms; 5) proportion of patients started on an antibiotic while in the NH who require a change in antibiotics for clinical or bacteriologic failure. Bacteriologic failure is microbiologic evidence of antibiotic resistant infection which will be calculated for NH residents by tracking antibiotics prescribed in the NH or at the ED.

Questionnaire data collected pre- and post-implementation from NH and ED providers, NH nurses and NH administrators will help to determine whether or not physicians' attitudes/opinions about antibiotic prescribing change with the availability of information from accessing antibiograms, as tested in this project. Questionnaires completed by NH nurses pre-implementation and at the end of the implementation phase of the study will help us understand what information NH nurses share with physicians when a resident has a suspected bacterial infection, how this information is conveyed to prescribing providers and how this interaction changes when antibiograms become available. Information from NH administrators will help us understand the start-up effort and costs and the steady and ongoing costs associated with creating and using NH antibiograms. We are also interested in staff burden and other factors that may affect their willingness to continue using antibiograms.

17. Exemption for Display of Expiration Date

The Agency for Healthcare Research and Quality does not seek this exemption.

List of Attachments:

Attachment A: Healthcare Research and Quality Act of 1999
Attachment B: Data Extraction Tool
Attachment C: ED Data Extraction Tool
Attachment D: NH Provider Pre-Implementation Questionnaire
Attachment E: ED Provider Pre-Implementation Questionnaire
Attachment F: NH Provider Post-Implementation Questionnaire
Attachment G: ED Provider Post-Implementation Questionnaire
Attachment H: Nurse Pre/Post-Implementation Questionnaire
Attachment I: NH Leadership Post-Implementation Questionnaire
Attachment J: NH Provider Recruitment Letter
Attachment K: ED Provider Recruitment Letter
Attachment L: Nurse Recruitment Letter
Attachment M: NH Provider Paper Statement of Informed Consent
Attachment N: NH Provider Web-Based Statement of Informed Consent
Attachment O: ED Provider Paper Statement of Informed Consent
Attachment P: ED Provider Web-Based Statement of Informed Consent
Attachment Q: Nurse Statement of Informed Consent
Attachment R: Fact Sheet