SUPPORTING STATEMENT

Part B

Using Nursing Home Antibiograms to Improve Antibiotic Prescribing and Delivery

January 4, 2011

Agency of Healthcare Research and Quality

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

This is a developmental study in which a draft nursing home (NH) antibiogram toolkit will be the developed. We will also collect preliminary pre- and post-implementation data from medical record reviews and provider and nurse questionnaires, as well as post-implementation administration interviews. In total, three NHs will participate in this project; one NH during the initial phase, and two additional NHs during the expansion phase (six-months later). The preliminary data will help to inform the draft toolkit and test the protocols for a future large-scale antibiogram study.

The settings will be selected using non-probabilistic convenience sampling. They will be recruited from among those NHs that provided letters of support for the proposal that was submitted to the Agency for Healthcare Research and Quality in response to the Request for Proposals for this work. Eligibility criteria for facilities will be that the executive director and medical director agree to participate in the project, and that they routinely transport residents to the Brigham and Women's Hospital Emergency Department (ED) for emergency treatment. In addition, the two sites recruited in the expansion phase will be of different size and type (e.g., corporate versus private) than the one recruited during the initial phase of the study. In addition to the three NH sites, one ED, Brigham and Women's Hospital will participate in the study. Brigham and Women's Hospital was selected as the ED for this study because Brigham and Women's Hospital and Abt Associates Inc. are research partners in this investigation.

NH recruitment adheres to the following procedures: The project Principal Investigator, Jeremiah Schuur, MD, will contact the medical director at each of the sites that expressed interest in the study during the proposal process. He will present the study and determine whether or not the medical director is still interested in having his/her NH serve as a study site. If the medical director is interested, he/she will discuss the project with the facility executive director. The Project Director, Rosanna Bertrand, PhD, and the Principal Investigator will then set up an in-person meeting with the medical director, executive director, and infection control nurse to describe the study and answer any questions about the intervention and/or evaluation that they might have.

Although we do not expect it, if the medical director or executive director at one of the original NHs is no longer interested in participating in the study, the Principal Investigator will use the Centers for Medicaid and Medicare Services web-site Nursing Home Compare, to determine additional NHs of appropriate size and type for recruitment. Again, a necessary criterion for selection is that the NH routinely transports residents to the Brigham and Women's Hospital ED for emergency treatment. He will then call the medical directors at these sites and follow the procedures described above.

Research subjects will include nurses from the three participating NHs as well as providers (i.e., physicians, nurse practitioners, and physician assistants) who provide care to residents in those facilities and in the Brigham and Women's Hospital ED. The initial phase, pre-implementation questionnaires will be administered while we are waiting for

OMB review and approval; therefore, respondent participation will be restricted to three NH nurses, three NH providers, and three ED providers. The initial phase post-implementation, and the entire expansion phase will occur after OMB review and approval has been obtained so all available NH nurses and NH and ED providers will be recruited for participation.

Participation of the nurses will be virtually assured by the facility's agreement to participate in the study so the response rate for these professionals is expected to be 75% percent. Although the literature indicates that the survey response rate for providers is low (estimated 30%), we expect a higher rate since the participation of NH providers will be facilitated by the facility medical director who will serve as a physician champion for the study. Once a facility has been recruited for participation, a letter will be sent to all facility providers signed by the facility executive director describing the project and requesting their participation. A high rate of ED provider participation is also expected since the project Principal Investigator, Jeremiah Schuur, MD is an emergency medicine physician in the Brigham and Women's Hospital and will serve as the physician champion in that facility. If necessary, Dr. Schuur, will contact NH and ED physicians directly to encourage participation. We are anticipating a 75 percent physician response rate.

One hundred percent of all residents for whom a record is entered in the infection control log will be included in the medical record review data collection activity. Since this is a project investigator data collection activity, all records will be reviewed.

2. Information Collection Procedures

Data collection procedures will consist of medical record reviews and administration of pre- and post-implementation questionnaires with NH and ED staff. These data collection procedures will occur in both the initial and expansion phases. As described in the previous section, the selection of the NHs will utilize convenience, purposive sampling procedures. The selection of residents for the medical record reviews and staff (i.e., providers, nurses, and administrators) will include one hundred percent of the population. That is all staff will be recruited to complete the questionnaire, and all residents for whom a record was entered into the infection control log will be included in the medical record review data collection activity. Probabilistic sampling is not utilized in this study because it is a developmental study in which a draft antibiogram toolkit will be created. The pre- and post-implementation data collection activities will help to inform the toolkit and also test protocols that can be used in a future full-scale antibiogram evaluation study.

Medical Record Review.

- Pre-Implementation
    - NH pre-implementation medical record reviews will consist of the review of infection control logs for a two-month period prior to the introduction of the antibiogram. The infection control logs should contain all necessary information on resident infections, (date, organism, unit, culture and

sensitivity and treatment). Research staff will travel to the NH and abstract the information into an Excel spreadsheet.
    - ED pre-implementation medical record reviews will involve a retrospective review of two months of medical records of residents transferred from the target NHs to the ED. Similar to the NHs, information on infections and antibiotic treatment will be recorded by research staff in the ED and entered into an electronic spreadsheet.
- Ongoing – on a monthly basis, research staff will travel to the NHs to review the infection control logs and record the resident information. The ED research assistant will, on an ongoing basis, flag records for review that belong to residents from the target NHs and record the antibiotic-related information. Ongoing review will occur throughout the study (12 months for the initial phase and 6 months for the expansion facilities).

Pre- and Post-Implementation Questionnaires

NH nurses and NH and ED providers will be asked to complete a brief questionnaire prior to the introduction of the antibiogram and again at the end of the study. NH Leadersip will be asked to complete a brief questionnaire at the end of the study.

- ***NH Nurses*** will be asked to complete a paper and pencil version of the questionnaire. They will be provided with a stamped envelop pre-addressed to the project director in which to return the completed questionnaire. 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 questionnaire is expected to take no more than 5 minutes to complete.

- ***NH and ED providers*** will be invited to complete a web-based questionnaire. The NH and ED provider questionnaires vary only slightly. The questionnaire is expected to take no more than 15 minutes. If a provider prefers not to complete a web-based questionnaire, he/she will be given the option of completing the questionnaire in a paper and pencil format. The provider will be given a stamped envelop pre-addressed to the project director in which to mail the completed questionnaire. The content of the paper and pencil questionnaires will be identical to the web-based tool.

- ***NH Leadership*** **(**Administrators or Directors of Nursing) will be asked to complete a post-implementation paper and pencil version of the questionnaire. They will be provided with a stamped envelop pre-addressed to project director in which to return the completed questionnaire. The administrator questionnaire is estimated to take 10 minutes to complete and will be administered in the final month of the intervention period.

Medical record review data will be extracted manually and entered into password protected laptop computers by two independent research assistants. Paper and pencil versions of the questionnaires (e.g., administered to nurses) will also be double entered by two independent research assistants. All data will be quality checked against each other and the original records to mitigate errors.

All instruments used for data extraction, both from medical records and questionnaires, are included as an attachment to Part A.

3. Methods to Maximize Response Rates

We will engage several methods to maximize response rates: utilizing the medical director at each facility as a "physician champion" to encourage full staff participation, one-page fact sheets to inform and keep staff updated regarding the status of the project and email reminders to providers to submit completed surveys.

We will work to maximize response rates by engaging the medical director as a physician champion at each of the participating facilities. This physician will communicate information about the project to staff physicians encouraging their participation. Although the literature indicates that the survey response rate for providers is low (estimated 30%), we expect a higher rate since the participation of NH providers will be facilitated by the involvement of the facility medical director. Once a facility has been recruited for participation, a letter will be sent to all facility providers co-signed by the facility executive director and medical director describing the project and requesting their participation. A high rate of ED provider participation is also expected since the project Principal Investigator, Jeremiah Schuur, MD works in the Brigham and Women's Hospital and will serve as the physician champion in that facility. If necessary, Dr. Schuur, will contact NH and ED physicians directly to encourage participation. We are anticipating a 75 percent physician response rate.

In addition, we will have included the Director of Nursing in preliminary discussions aiming to inform and educate them to the value of this study. Their endorsement and support will maximize the completion of nurse and NH leadership questionnaires.

Also, we will develop one-page fact sheets that 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 and ED providers will also have access to fact sheets, but are expected to be familiar with antibiograms because of their introduction during residency. Lastly, administrators and directors of nursing at NHs will be asked to encourage nurses to use antibiograms when discussing patients with the NH or ED providers, as the use of antibiograms often hinges on nurses' introduction of the antibiograms to providers.

The survey software that we will be using will invite and remind providers to initiate and complete the questionnaire. The software includes a feature that will generate an automatic reminder when surveys have been started but not completed and submitted.

4. Tests of Procedures

This is a developmental study where we will use the data collected from participant questionnaires (pre- and post-implementation) to help inform the draft antibiogram toolkit that will be developed as a product of this study. This study is also designed to test the preliminary data (i.e., medical record reviews; participant questionnaires) for use in a future, full-scale antibiogram evaluation study. Procedures and data collection for antibiogram toolkit development will be tested at the initial phase NH and will be fine-tuned to improve utility in the expansion phase NHs, before creating the final draft toolkit. Because of the developmental nature of the project, the draft toolkit will need to be tested in a future study before dissemination. All information gleaned from the questionnaires and medical record review data will inform the development of the draft toolkit.

5. Statistical Consultants

We do not anticipate needing statistical consultants for this project.