Supporting Statement Part B

for

Improving Quality of Care in Long-Term Care Preventing Falls in Assisted Living

Sponsored by

The Agency for Healthcare Research and Quality

HHSA290200600001I Task Order # 2

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B. Collection of Information Employing Statistical Methods

1. <u>Potential Respondent Universe and Sample Selection Method</u>

As mentioned earlier, because constraints required the study's sample size to be modest, we chose to limit the study sample to larger (>16 bed) facilities, a reasonable strategy given that larger facilities represent over 80% of resident beds (Zimmerman, et al., 2001). The four participating facilities are within the same geographic area of North Carolina and are from two national provider chains that have participated with our team in other projects. Consistent with the participatory based nature of quality improvement projects, staff from these facilities will be involved in decisions related to the actual implementation of the program in their facility, to assure that it is consistent with their policies and procedures.

It is anticipated that 270 residents will agree to participate in the intervention, one half of whom will be randomized to treatment, and one-half to placebo control. Facility administrators at each of the four participating facilities will be interviewed,

2. Information Collection Procedures

In this section, we describe how RTI and UNC will identify participants and collect data for this project. All information collections will be conducted in a manner that is consistent with the following guidelines:

- Participation will be fully voluntary, and non-participation will have no effect on eligibility for, or receipt of, future AHRQ-sponsored health services research.
- Information collection will be limited to that needed to implement and evaluate the intervention.
- Given the voluntary nature of the information collections from residents of participating facilities, efforts will be made to obtain the highest possible response rates.
- Each respondent will be assigned a study identification number and any names collected will be destroyed after the identification number has been verified.
- All data will be kept in a secure file and will be kept confidential. Data collected as part of the project will only be shared with staff involved in the project.

Data will be collected from participants using the data collection instruments included in Appendix A. Consent to participate in the project will be obtained from each individual using an informed consent process approved by both RTI International and UNC IRBs and will be consistent with HIPAA regulations. Consent forms will be signed by the participant and copies provided to each participant. (See consent forms included in Appendix B).

Facility administrators at each of the four participating facilities will be asked to participate in an interview. Each administrator will have an informed consent administered to them prior to the conduct of the interview.

Direct care staff who provide care to residents who consent to participate in the project will also be asked to report on matters related to falls risk. Direct care staff will provide information on residents' functional status using the Minimum Data Set Activity of Daily Living (MDS-ADL), and on cognitive status using the Minimum Dataset Cognition Scale (MDS-COGS).

All potential resident participants will be 65 years or older, English speaking, not bed bound, and not hospice patients. Non-English speaking residents will be excluded from the project because we do not have the capacity to provide translators and all research staff are English speakers. Because bed bound residents will not be ambulatory, they will not be at risk for falls. Residents in hospice will be excluded because it is expected that they will not live through the yearlong study or be able to participate fully in the assessments. Consent to participate will be obtained from each resident who is willing to participate.

Family members of residents with cognitive impairment will be contacted to provide consent for their family member to participate in the project, including HIPAA consent to release protected health information. These residents will be identified by facility staff or through the administration of the Mini-Mental Status Exam.

Physicians who provide care to residents participating in the intervention will be contacted by a member of the project team, who will explain the project in detail, and, if the physician consents to participate, arrange a time to conduct a 30 minute in-person interview base-line interview. Physicians who consent to participate will also be recontacted in 12 months to participate in a follow-up interview.

As described earlier, RTI International staff will also conduct semi-structured interviews with up to 10 individuals at each site participating in the study. Each of these individuals (facility administrators, medication staff, exercise staff, and residents) will be consented prior to the interview and will be reminded that participation is voluntary.

Finally, facility staff will be asked to nominate residents who are cognitively able and may be willing to participate in the semi-structured interviews. Staff will be asked to consider residents for nomination based on levels of participation in the intervention project so the team hears varied views of about the project.

As mentioned earlier, all measures related to falls risk will be collected by interview, chart review, and performance assessment at baseline, 6 and 12 months by research staff. Interviews administered to physicians will be done in person, at baseline and 12 months. The qualitative implementation evaluation interviews will be collected in person once at the end of the study.

Describe methods to maximize response rates.

We expect to recruit 270 subjects from the four facilities. This figure is based on the facility's bed size, occupancy rate, and UNC's similar projects that have achieved participation rates of 73–92%. If fewer than 200 residents agree to participate, we will allow for ongoing recruitment during the year of the study, until we reach a target of 200 subjects. In addition, if any facility is uncertain about its ability to commit the necessary staff resources, for example to participate in ongoing medication management, it will be replaced. UNC belongs to a long-term care consortium that includes more than 350 facilities, thus there is little concern that other facilities could be recruited to ensure an adequate sample size. However, in all cases, we will restrict the number of total facilities to four, as costs would increase exponentially if we were to add additional facilities.

Describe any tests of procedures or methods.

The individuals who will be involved in the statistical design and analysis of this project are Sheryl Zimmerman, PhD, Edith Walsh, PhD, and Phillip Sloane, MD.

Provide name and telephone number of individuals consulted on statistical aspects.

RTI International and its subcontractor, UNC Chapel Hill Scheps Center, will provide input and oversight on design planning and analytic issues.

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