**Research Strategy**

**Significance**
This project directly addresses federal priorities for improving health care for older Americans. Reducing the incidence of preventable hospitalizations of nursing home (NH) residents will play a critical role in achieving the “triple aim” articulated by the Center for Medicare & Medicaid Services (CMS) of improving care, improving health, and making care more affordable. The project also directly addresses the two major goals of the Department of Health and Human Services Partnership for Patients: improving patient safety and reducing hospital readmissions.

Hospitalizations of NH residents are frequent, and though often necessary they are associated with numerous complications that can cause morbidity in this population. Discomfort for the hospitalized NH resident, anxiety among family members, and hospital-acquired complications (such as delirium, de-conditioning, decline in functional status, falls, pressure ulcers, incontinence, hospital-related infections, polypharmacy and adverse drug effects) are common. Hospitalization and related complications may also result in excess health care costs. Close to 1 in 4 people admitted to a skilled nursing facility from acute care are re-hospitalized within 30 days, at a cost of $4.3 billion annually. Research also suggests that a substantial proportion of hospitalizations of NH residents may be avoidable. A study of 100 hospitalizations from 8 Los Angeles NHs found 45% to be inappropriate when assessed by a structured implicit record review. A more recent study using similar methodology suggests that as many as two-thirds may be avoidable (see below under Preliminary Studies). In 2004, 23% of the $972 million spent on hospitalizations of long-stay NH residents in the state of New York were for “Ambulatory Care Sensitive Diagnoses”, a proxy measure for potentially avoidable hospitalizations. This figure underestimates the frequency and costs of such hospitalizations, because short-stay residents on the Medicare Part A skilled benefit were excluded. Reducing potentially avoidable hospitalizations of NH residents therefore presents an opportunity to both improve care quality and avoid unnecessary health care expenditures.

Anticipated changes to the Medicare fee-for-service system as a result of the Affordable Care Act (ACA) will provide financial incentives to manage NH residents experiencing acute changes in status without hospital transfer, in contrast to the current financial incentives in the system. One such approach, recommended by the Medicare Payment Advisory Commission, is “bundling” of payments for episodes of care. Bundling would provide a global fee to a group of providers, potentially via an Accountable Care Organization (ACO) for a 30-day or longer episode of care for certain conditions that result in frequent re-hospitalizations. A second approach is pay-for-performance. CMS is currently conducting a three-state demonstration project that provides financial incentives to NHs based in part on potentially preventable hospital admissions. Similar to bundling, this pay-for-performance strategy provides incentives for NHs to avoid frequent hospitalizations. These changes in Medicare reimbursement will not be effective in improving care and reducing hospitalizations unless NH providers have adequate staffing, training, and tools they can use that will assist them in assessing and managing NH residents with acute changes in status, and effectively documenting and communicating their findings. In fact, providing financial incentives for reducing hospitalization without the necessary staff, training, and clinical practice tools could worsen care quality, if NHs are rewarded for managing sicker residents in the NH with inadequate capabilities to do so safely. The proposed project addresses this critical issue by testing, in a rigorous randomized controlled trial, the effectiveness of a quality improvement program that has shown promise in reducing hospitalization of NH residents. This program is based on previous research and clinical practice guidelines, and has been refined with input of both front-line NH staff and national experts in NH care. If proven effective, it can also become an integral component of the new CMS NH Quality Assessment and Performance Improvement program mandated in the ACA.

**Innovation**
This proposal directly addresses the critical need for innovative strategies to improve health care for the vulnerable elderly Medicare beneficiaries in NHs by: 1) integrating the multiple causes of preventable hospitalizations of NH residents within a single quality improvement framework which utilizes a parsimonious set of evidence-based and guideline-recommended tools that are feasible to implement in everyday clinical practice (Interventions to Reduce Acute Care Transfers (“INTERACT”); and 2) enhancing available resources within NHs rather than requiring additional personnel and increased costs. An overview of the INTERACT program and tools can be found at [http://interact2.net](http://interact2.net). INTERACT is specifically designed to improve care quality by enabling NH staff to identify, evaluate, and manage residents safely with acute changes in status in
the NH without acute hospital transfer when appropriate, and at the same time more rapidly and accurately identify those who should be considered for acute hospitalization. The proposed project also responds to key provisions in the ACA related to NH quality. The ACA has several provisions designed to improve care transitions and prevent unnecessary hospital admissions, and also mandates that NHs establish a formal quality assurance and performance improvement (QAPI) program. CMS is charged with assisting NHs with implementation of these programs through developing and promulgating best practices and evaluating and disseminating quality improvement tools. The proposed project responds to these CMS priorities.

The INTERACT program addresses many of the key clinical, health system, and person-centered factors that influence the decision to hospitalize NH residents (as shown in the adjacent figure). Previous research has not adequately addressed these multiple factors. The INTERACT program reinforces a culture of quality and safety, and enhances NH infrastructure and care delivery processes by providing clinical practice tools and training for their use in everyday practice. Specific INTERACT tools address advance care planning as well, which enhances person-centered care and respect for resident and family preferences related to hospitalization. INTERACT tools also enhance communication and documentation, which will be helpful for regulatory surveys and protection from legal liability related to adverse outcomes of acute conditions.

The proposed project is also innovative because it builds upon and complements other interventions that appear to reduce preventable hospitalizations of NH residents. A recent review concluded that one effective approach is the use of teams of primary care physicians and nurse practitioners (NPs) to provide primary care in the NH setting. Such teams are commonly used in managed care programs, and hospitalization rates are substantially lower in programs such as the Program for All-Inclusive Care of the Elderly (PACE), and Evercare. The vast majority of NH residents, however, remain in the Medicare fee-for-service system, and there are not enough NPs trained to provide care in all of America’s NHs.

Based on our preliminary studies of the factors underlying potentially avoidable hospitalizations of NH residents (described below), and the development and testing of the INTERACT program, we suggest there are at least three mechanisms by which this intervention can reduce hospitalizations (see adjacent figure). First, INTERACT tools enable front-line NH staff to identify acute conditions early in their course, thereby helping to prevent them from becoming severe enough to require acute hospitalization. Second, the tools provide communication and decision support tools that assist with the safe and effective management of certain conditions in the NH without transfer to the acute hospital. Third, INTERACT tools help NH staff in advance care planning and discussions about end-of-life and comfort care plans, and thus may increase the use of advance directives, comfort care measures, and palliative and hospice care. In the proposed project we will obtain and analyze data from the participating NHs that will enable us to determine which INTERACT tools and strategies were most commonly used, thereby allowing us to examine intervention fidelity and inform future implementation on a more widespread basis.

Preliminary Studies
The interdisciplinary project team has several decades of experience in conducting clinical, health services, and quality improvement research in NHs, and in working together. Joseph Ouslander, MD, project Co-PI, is a geriatrician who has been practicing clinical geriatrics, teaching, serving as a medical administrator, and conducting research in NHs for the past 30 years. He has co-authored a textbook on NH care, and collaborated with members of the project team on several multi-site studies of incontinence, exercise, sleep, falls. Most recently he led the development and early testing of the INTERACT program. Ruth Tappen, EdD, RN, FAAN, project Co-PI, is an experienced gerontological nurse with expertise in NH and transitional care.
research, who was a key collaborator on the development and initial evaluation of the INTERACT intervention. Robert Kane, MD, project Co-I, is an internationally recognized expert in NH care, health services research, and health policy at the University of Minnesota (UM). He has conducted numerous federally funded evaluations of health services interventions in NHs, and has extensive experience in acquiring and analyzing Medicare claims data. This team will be enhanced by three key consultants. David Grabowski, PhD is a health economist and expert on federal health care funding who has conducted seminal research on the incidence and costs of potentially avoidable hospitalizations of NH residents. Gerri Lamb, PhD, RN, FAAN is a gerontological nurse with expertise in transitional care and qualitative health services research, who served as a key collaborator on the development and initial evaluation of the INTERACT program. John Schnelle, PhD is a behavioral psychologist and internationally recognized authority on NH quality. He has collaborated with Co-PI Ouslander on several NIH funded multi-NH projects, and developed and tested the distance learning training strategy for NHs that will employed in the proposed project.

The INTERACT intervention was initially developed by an interdisciplinary team led by Drs. Ouslander and Lamb at the Georgia Medicare Quality Improvement Organization under a CMS special study contract. The objectives of the contract were to examine the frequency and factors related to potentially avoidable hospitalizations of NH residents, and to develop and pilot test tools and strategies to reduce these hospitalizations in 2-4 NHs with high hospitalization rates. Relevant findings from the CMS project include: 1) of 200 hospitalizations of NH residents reviewed by an expert panel, two-thirds were rated as potentially avoidable; 2) the expert panel recommended the development of evidence and consensus-based tools that guide care of common conditions resulting in acute care transfers; tools to enhance communication among health care providers in the NH and between the NH and the hospital; and tools to enhance the effectiveness of advance care planning in NHs; which led to the development of the first set of INTERACT tools; and 3) a 6-month pilot test of the implementation of the INTERACT tools in 3 NHs with high hospitalizations rates, was associated with a close to 50% reduction in hospitalizations, and a 47% reduction in hospitalizations rated as potentially avoidable by the expert panel. Refinements to the INTERACT program were also informed by the results of a recent project examining hospital readmissions from NHs. Among 10,777 discharges of patients age 75 and older from a community hospital, 3,254 (30%) were discharged to a NH, and of these, 584 (18%) were readmitted to the hospital within 30 days; 191 (33%) of the readmissions occurred within 7 days. The most common diagnoses associated with readmissions were congestive heart failure, pneumonia and other infections, gastrointestinal disorders, and acute renal failure (probably secondary to dehydration). These conditions are directly addressed by the INTERACT tools (see http://interact2.net).

The promising initial results led to a project supported by The Commonwealth Fund in which the INTERACT program was refined based on input from a broad range of front-line NH providers as well as national experts in long-term care. INTERACT was implemented for 6 months in 30 NHs in three states (10 in Florida, 10 in New York, and 10 in Massachusetts). Implementation included: in-person meetings with corporate and facility leadership to obtain their buy-in; appointment of on-site champions; provision of all the tools free of charge; on-site half-day training on the tools by a member of the project team; every two-week phone calls conducted by an experienced NP to discuss challenges and experiences in implementing the tools; availability of the NP for phone or email consultation; completion of the INTERACT Quality Improvement Tool on selected acute care transfers; assessment of the time taken to implement the tools in each facility; and pre and post data on the number of hospital transfers. The table summarizes the main outcomes. Among the 25 NHs that completed the 6-month project, there was a 17% reduction in hospitalizations compared to the same six-
month period in the previous year; the 17 NHs that were rated as engaged in the project had a 24% reduction, the 8 NHs that were rated as minimally engaged had a 6% reduction, and 11 matched comparison NHs had a 3% reduction during. Engaged NHs rated 26% of hospital transfers as avoidable or possibly avoidable in their retrospective review using the INTERACT QI Review tool, compared to 12% for minimally engaged NHs. The facility costs of the 6-month intervention were estimated to be $7,700 per NH; the projected savings to Medicare of reduced hospital admissions from a 100-bed NH were $125,000/year.6.

We have strengthened the INTERACT program implementation by enhancing our training based on the distance learning strategy developed by project consultant Schnelle.29 Distance learning training represents a more systematic approach than the training strategy used in our preliminary research on INTERACT, and offers advantages over traditional training that is held in a single location, including reduced cost, improved communication, flexibility, and resources. It also benefits intervention implementation by providing consistency, reinforcement of key principles across training modules, evaluation of knowledge, and the ability to track curriculum completion. With the support of the Retirement Research Foundation, our team has developed a distance learning curriculum for training multidisciplinary NH staff on INTERACT implementation. It includes 8 teleconference sessions with PowerPoint presentations enhanced by audio for online review, short video clips illustrating key points, pre and post quizzes, and an evaluation. The curriculum is now approved by the Ohio Nurses’ Association for up to 12 continuing education credits. With limited dissemination, we received over 250 inquiries and 140 facilities volunteered to complete the curriculum and provide us feedback, suggesting that recruitment of participant NHs will not be a problem in the proposed study. Feedback from this evaluation will be used to further refine the curriculum prior to use in the proposed project.

In summary, our project team is highly experienced in NH research and practice, has collaborated on many projects, and has conducted extensive preliminary research that supports the importance and feasibility of improving care and reducing hospitalizations of NH residents, and at the same time reducing unnecessary health care costs. We will improve on our prior research in several critical ways. First, we will employ a randomized trial design, which will improve our ability to test the effectiveness of the INTERACT intervention and mitigate some of the weaknesses of the quality improvement approach used in our previous research.30-34 Second, in response to reviewers’ concerns about a Hawthorne effect, we will utilize a three-group design (INTERACT, usual care control, monitoring hospitalization rates only). This design will enable us to compare INTERACT to usual care, as well as determine the magnitude of any potential effect of simply paying attention to and monitoring hospitalization rates compared to the effect of INTERACT. Third, we will measure hospitalizations with Medicare data rather than relying only on self-reported data from participating NHs, which may be subject to inaccuracies. Fourth, we will use Medicare data to examine differential effects of INTERACT on hospitalizations for short-stay (Medicare Part A skilled) vs. long-stay NH residents (as recommended in reviewers’ comments), as well as examine emergency room visits that do not result in hospitalization, which we did not do in our previous study. Fifth, we will employ the refined training strategy described above. Finally, we will more systematically and quantitatively examine intervention fidelity than in our previous studies of the INTERACT program, as recommended in reviewers’ comments.

**Approach**

**Overview of Methods**
The revised study design and the project timeline are illustrated in the figures below. The effectiveness of implementing the INTERACT quality improvement program in reducing hospital admissions and their costs will be tested in a randomized controlled trial. NHs will be recruited from both not-for-profit and for-profit organizations that have agreed to assist in identifying facilities interested in participating, as well as by contacting individual NHs. After careful screening for the ability to safely manage acute changes in condition (see criteria below) and written assurance of leadership support, NHs that meet inclusion criteria will be randomized to one of three.
groups: 1) INTERACT implementation; 2) a usual care control group, and 3) a group that will self-monitor their hospitalization rates only. The purpose of the latter group is to respond to reviewers’ concerns about a Hawthorne effect by determining any effect of paying attention to and monitoring hospitalization rates compared to the effect of full INTERACT implementation. The primary outcome measure will be hospitalization rates per 1000 resident days measured using Medicare claims data and the cost savings to Medicare resulting from reducing hospitalizations in relation to the estimated costs of the intervention. The figure illustrates the project timeline in 3-month blocks. Baseline measures will be calculated from Medicare data obtained for a 12-month period before project initiation. Outcome measures will be calculated from Medicare data obtained for the 12-month INTERACT implementation period. We are proposing a 12-month implementation period to account for potential seasonality of hospitalizations, and to build upon our previous work by examining the effects of INTERACT over a longer period of time.

Recruitment and Enrollment of Nursing Homes

Sample Size Calculation: Two sample size calculations were conducted to address the primary hypothesis. The first focused on NHs as intact units and utilized a Generalized Linear Mixed Models approach to test the primary outcome of hospitalization rates per 1000 resident days. Based on the data from our Commonwealth Fund study described in the Preliminary Studies section, with an effect size of $f^2=0.21$, we need 28 NHs in each of the 3 groups for a total sample of 84 for power = 0.80 and alpha of .05. With the addition of 20% for potential dropouts (the attrition rate in the Commonwealth study was 17%) the required sample size is 102. This power analysis allows for nine organizational level linear dependent variables, including the three treatment groups and six covariates. The covariates were selected based on previous research and include factors that could influence hospitalization rates, including NH infrastructure (RN/resident ratios, proprietary vs. not-for-profit status), NH quality (number of survey deficiencies and CMS NH Compare Five-Star ratings), NH resident characteristics (mean Hierarchical Condition Category (HCC) score, a measure of co-morbidity and service utilization commonly used for risk adjustment in the Medicare population 35), and a composite measure of treatment fidelity (see below under Measures). The second sample size calculation focused on the individual as a unit of analysis utilizing a nested structure and including the nine organizational level (NH) covariates and four individual level covariates (age, gender, long vs. short stay, and individual HCC score). Again using the Commonwealth-funded study’s effect size of $f^2=0.21$, a total of 84 nursing homes are required at the organizational level and a minimum of 840 individual residents which will be far exceeded in this study. Thus, we plan to enroll a total of 102 NHs which will meet these requirements and account for a 20% dropout rate. These calculations were derived using G*power 3.1.2 36.

Inclusion and Exclusion Criteria: In order to participate NHs must be willing to be randomized, and have the following: 1) strong support for participation from the facility administrator, director of nursing, and medical director, as well as corporate leadership (for NHs that are part of a corporate chain), as evidenced by a signed letter of agreement before enrollment; 2) capability to manage acute changes in condition effectively and safely, as evidenced by the availability of: on-site medical or NP coverage at least once per week; lab and x-ray services with results available in no longer than 8 hours; urgent medications available within 4 hours; and nursing staff ability to administer parenteral medications, initiate intravenous fluids, provide respiratory treatments (i.e. bronchodilators, continuous oxygen), and assess oxygenation status by pulse oximetry; and 3) availability of computers and related technical support for online staff training and data submission. NHs will be excluded if they are 1) a hospital-based skilled nursing facility; 2) participating in a project designed specifically to reduce acute care transfers or hospitalization rates which might contaminate the intervention or control
conditions (including federal demonstrations); or 3) conducting more than one other major quality improvement or research project during the project period which would threaten their ability to fully participate in the trial.

NH Recruitment, Enrollment, and Randomization: NHs will be recruited through contacts with not-for-profit and for-profit corporations and individual NHs, and by working with national organizations. We currently have letters of support from five corporations that own and/or operate close to 830 NHs in multiple states. We will work with Leading Age (formerly the American Association of Homes and Services for the Aging, the major national non-profit long-term care organization representing over 5,000 NHs, and with Advancing Excellence in America's Nursing Homes, a coalition which now involves over 6,600 NHs (see Letters of support). In addition, we have a list of over 100 NHs that expressed interest in participating in our INTERACT curriculum evaluation, but who could not meet the enrollment deadline and indicated they would be interested in future projects. In order to enhance recruitment, NHs that are not randomized to the INTERACT implementation group will be offered training and technical assistance so that they can implement INTERACT after the 12-month project implementation period. Based on our experience in previous research, recruitment of NHs to participate in this trial would be extremely difficult without this offer.

Randomization: After identification of potential NHs, the project Co-PIs will speak with NH leadership in order to explain participation, and to verify their interest, eligibility, and understanding they could be randomized to the control or self-monitoring groups and not implement INTERACT until after the 12-month study period is completed. The NH administrator, director of nursing, and medical director will then be asked to sign a letter of agreement which outlines the requirements for participation. After each NH has signed the letter of agreement they will be randomized, using computer-generated random numbers, to one of the three groups: INTERACT implementation, usual care control, and self-monitoring of hospitalizations only.

INTERACT Implementation

Overview: The INTERACT program will be implemented as a quality improvement initiative in the NHs randomized to implementation. The unit of intervention will be the NH. The Co-PIs will meet by teleconference with facility-based leadership and the project champion and co-champion of each NH in order to review the objectives of the program and mutual expectations. Our experience in several previous multi-NH quality improvement and research projects suggests that such meetings are critical to successfully launch and sustain these types of projects.

Facility-Based Project Champions and Co-Champions: In addition to strong support by corporate (if applicable) and facility-based leadership, our prior studies highlight the importance of selecting enthusiastic, experienced, respected, and stable individuals as project champions. We also learned that implementing INTERACT with one champion is challenging. Loss of the project champion was associated with NHs becoming less engaged in, or in some cases dropping out of the project. Thus, in this project, facility-based project champions and co-champions will be responsible for involvement of NH staff in the training and for leading the implementation of INTERACT in their facilities. The co-champion will assist the champion and assume the project champion role should that become necessary. Champions and co-champions will be selected by the NHs and be responsible for implementing the INTERACT intervention, including ensuring participation of NH staff in the INTERACT training; engaging the medical director, attending physicians, nurse practitioners, and physician assistants in the INTERACT program; meeting with emergency room and other key staff from each local hospital to which residents are transferred in order to educate them on INTERACT; participating on regular (every 2-4 week) multi-site conference calls during the 12-month implementation period, and ensuring that required data are sent to the project team in a timely manner.

Training: Training will occur during the 3-months immediately preceding the 12-month INTERACT implementation period. The training is based on the approaches described in the Preliminary Studies section using the INTERACT curriculum, which is housed on a sign-in section of the INTERACT website. We have shortened the training period to 3 months in response to reviewers’ comments and our experience thus far evaluating the curriculum. Because of the complex and multi-faceted nature of the intervention, as well as our experience implementing other NH Interventions, we believe that three months is the minimum necessary for effective program initiation. The project champions and co-champions, as well as key NH staff, including certified nursing assistants (CNAs), licensed nursing staff, administrative nurses, the medical director, and medical providers will be expected to participate and satisfactorily complete the training. Night and weekend
nursing staff will also be expected to complete the curriculum because these staff members are critical, as many acute care transfers occur at night and on weekends.

The curriculum includes a combination of online resources and teleconference review facilitated by one or more of the INTERACT project staff. Online resources include eight annotated Power Point presentations (see Table) with voice over and video clips of case examples to illustrate the rationale and goals for the program and how the INTERACT tools can be incorporated effectively into every day practice, and a post-session quiz and evaluation. Between session implementation assignments include practicing the use of the tools, and tracking acute care transfer and hospitalization rates. Teleconferences will be held weekly and include opportunities for participating NHs to ask questions, discuss implementation challenges, and share successes with other facilities. In addition to the eight sessions outlined in the table, four teleconferences will be devoted specifically to individual NHs reporting on progress and challenges, and discussing implementation strategies to address the challenges. Completion of the curriculum will be monitored via the INTERACT website. Each NH staff member will be assigned a unique username and password linked to their job title and will be expected to complete each session post-quiz and evaluation. Completion will be tracked and reports fed back to facility champions in order to ensure that all key staff members complete the curriculum during the 3-month training period.

The INTERACT Tools: The INTERACT tools were developed and refined with extensive input from national experts in NH care, as well as from all levels of direct care NH staff and medical providers. The tools are consistent with evidence-based and expert recommended clinical practice guidelines 37-52. There are four types of tools illustrated in the figure: 1) Communication tools that structure and document communication between nursing assistants and licensed nurses (RNs/LPNs); between nurses and medical providers; and between NHs and hospitals. These tools include an Early Warning Tool (“Stop and Watch”), structured “SBAR” PCP Communication and Progress Note, Change in Condition File Cards, a Transfer Form, and Transfer Checklist; 2) Care Paths for six conditions that are common causes of potentially avoidable hospitalization of NH residents including altered mental status, fever, symptoms of common infections (lower respiratory and urinary tract), symptoms of congestive heart failure, and dehydration; 3) Advance Care Planning tools that include an Advanced Care Planning Tracking tool, communication guide with specific strategies and examples of quotes to use when discussing palliative and end-of-life care with NH residents and their families, and a template for “comfort care” orders; and 4) Quality Improvement tools, including a structured review of acute changes in condition and acute care transfers and a form to track transfers and hospitalizations. The most recent versions of the tools can be viewed at http://interact2.net. The INTERACT tools are designed to be integrated into the everyday care process in NHs, as illustrated in the figure. The Advance Care Planning Tools are helpful in promoting the use of advance directives and palliative care plans in appropriate residents at or within a short time after admission, as well as throughout the NH stay. When CNAs or other direct care staff notices an acute change in a resident, they can document and communicate the change using the Early Warning Tool. Licensed nursing staff can use the SBAR Form and Progress Note to document and
communicate their findings to medical providers, and can use the Care Paths and Acute Change in Condition File Cards as decision support tools. If the decision to transfer to the acute hospital is made, inter-facility communication is structured and facilitated by the Transfer Checklist and Envelope and the Resident Transfer Form. The Quality Improvement tools include a structured review using a root cause analysis approach to assist NH staff in reflecting on their experience in identifying, evaluating, and managing acute changes in condition, and a tracking form for acute care transfers and hospitalizations.

Telephonic Support by an Experienced GNP: Throughout the 12-month implementation period, the GNP will facilitate multi-site conference calls in two groups of 17 NHs each. The calls will be scheduled every 2 weeks during the first 6 months and then monthly for the second 6 months of the implementation period. The Co-PIs will participate on these calls, depending on the specific focus of the planned discussions. The calls will be used to: 1) review and reinforce the use of specific INTERACT tools and implementation strategies; 2) share challenges and successes in implementing the intervention; 3) review cases in which the INTERACT tools assisted in preventing a transfer and/or in managing residents without transfer; and 4) review cases in which a resident was initially managed in the facility, but required transfer to the acute hospital. The GNP will also provide telephonic and email support to project champions and co-champions on an as-needed basis during the intervention period. In addition, participating NHs will be able to have questions answered via a “Contact Us” section of the INTERACT website.

Completion of Quality Improvement Tools and Tracking Hospitalization Data: Since INTERACT will be implemented as a quality improvement initiative in each participating NH, completion of Quality Improvement tools and tracking hospitalization data will be critical components of the INTERACT program. The Quality Improvement tool guides the NH staff in a review of the acute change in resident condition, what was done in the facility to evaluate and manage the resident, and decision making around transfer to the acute hospital if it occurred. For those residents who were transferred, the tool asks whether, in retrospect, the transfer could have been prevented, and if so, to articulate a plan for improvement based on lessons learned. NHs will also complete an Acute Care Transfer Log on a continuous basis. This Log includes information on emergency room visits and hospitalizations for those residents who return to the facility (e.g. payer source at the time of transfer, hospital diagnoses), and will be used by NHs in the INTERACT implementation and self-monitoring groups to track hospitalization rates. With the support of the Retirement Research Foundation grant, we have developed a system for online submission of these data.

Nursing Homes Serving Usual Care Control and the Self-Monitoring Only Groups
NHs randomized to the usual care control group will only submit baseline and end-of-intervention surveys characterizing the facility and not be asked to submit any data during the implementation period. In order to address reviewers’ concerns about a potential Hawthorne effect, we have added a third group of NHs to the study design. This group will submit baseline and end-of-intervention surveys characterizing the facility, and also be asked to self-monitor acute care transfer and hospitalization rates during the 12-month project implementation period using the online Acute Care Transfer Log. They will not receive any training on or be asked to implement any other aspect of the INTERACT program. This group will therefore enable us to identify any potential effect of simply paying attention to and monitoring hospitalization rates compared to the effect of full implementation of the INTERACT program. Both of the monitoring and control groups will be offered the opportunity to take the INTERACT training curriculum and receive technical assistance for initiating the INTERACT program in their facilities after the 12-month project implementation period is completed.

Measures
Measures to be collected and the source(s) of data are illustrated in the Table below. All participating NHs will be characterized along the multiple dimensions listed using structured surveys completed by the NHs and CMS data files. NH administrators will be asked to complete a survey similar to that used in our Commonwealth Fund project that provides information on their resident census, payer mix, clinical capabilities and programs, and availability of medical providers, diagnostic testing, and pharmacy services. These data will include the number of short-stay vs. long-stay residents, with the former identified as those whose stay is supported by Medicare Part A (i.e. short-stay post-acute care). Data for key covariates will be obtained from CMS in order to characterize the resident case mix using the Minimum Data Set (MDS) and the Hierarchical Condition Category (HCC) system, and data on NH quality using the Online Survey, Certification, and Reporting data (OSCAR). Publicly reported quality data will also be obtained, including Five Star ratings and quality measures derived from MDS data which are available on the CMS website. These data will be used for
covariates in the analyses, as described above in the section on Sample Size, and below, under Analyses. The primary outcome measures will be hospitalization rates per 1000 resident days for all Medicare fee-for-service residents and costs of hospitalizations. Hospitalization rates will be calculated using Medicare claims data during a 12-month baseline period before the project is initiated, and compared to the rates during the 12-month implementation period. We will also analyze Emergency Room visits that did not result in hospital admission in a secondary analysis. MDS data will be used to identify residents of participating NHs and to calculate resident days in the facility. A Medicare denominator file that eliminates residents on Medicare managed care, private pay, and Medicaid only (i.e. those under 65 without Medicare) will be used to identify hospitalizations from each NH. In addition to Medicare Part A claims which will identify hospitalizations, Medicare Part B data will be used to determine the number of transfers to emergency rooms that do not result in hospitalization. Hospitalization rates will be risk-adjusted using the HCC system, which is a measure of co-morbidity and service utilization commonly used for risk adjustment, and other factors that can affect hospitalization rates will be accounted for in the analyses (see below). In response to reviewer suggestions, we also plan to examine hospitalization rates for short-stay residents (those on the Medicare Part A benefit), vs. long-stay residents separately, because the former is generally a more complex population among who are at greater risk of hospitalization.

Cost data will include Medicare expenditures on hospitalizations during the intervention period and the estimated costs of the intervention. Medicare Part A data will be used to determine expenditures for each hospitalization. The cost of the intervention will include the costs of providing the INTERACT tools to the NHs assigned to the implementation group, project staff time devoted to training, NH staff time participating in training (obtained from attendance on training calls and monitoring use of the INTERACT website), and estimated NH staff time involved in implementing the INTERACT program obtained through monthly surveys of project champions using questions employed for this purpose in our previous research. The cost of NH staff time will be calculated using national averages for wages of participating NH staff.

In response to reviewers’ concerns, additional data will be collected in order to examine intervention fidelity as well as process of care during the implementation period. In order to evaluate intervention fidelity, we will: 1) document the number of NH staff who complete INTERACT training; 2) quantify participation on teleconferences during the implementation period; 3) obtain data from project champions on the number of specific INTERACT tools used in the facility (Early Warning, SBAR, Advance Care Planning Tracking); and 4) track the number of Quality Review tools submitted online. Surveys of administrators before and at the end of the 12-month implementation period will be used to quantify advance directive use (i.e. care limiting orders such as do not resuscitate, do not hospitalize, palliative or comfort care plans), because one of the key INTERACT strategies is to enhance advance care planning. The project research assistants will track receipt of these data and will contact project champions when data are due.
Data Management

Co-Principal Investigator Dr. Tappen and the project statistician, Dr. Newman, have extensive experience and expertise in using SAS for data management and analysis. They will supervise the Florida Atlantic University (FAU) senior project coordinator and project research assistants who will be responsible for obtaining, tracking, cleaning, and entering data on NH descriptive measures from administrator surveys and publicly reported quality measures from all NHs; tracking online submission of transfer data and summarizing the trends for feedback to the implementation and self-monitoring NH groups, and obtaining data from INTERACT implementation NHs, including: 1) monthly census and acute care transfer data and QI Tool data (submitted online); 2) data on the costs of the intervention by tracking of project team and NH staff time for training (via attendance at training sessions and website usage), monthly surveys from intervention NH project champions on staff time for implementation; and 3) treatment fidelity data, including training session attendance, number of Stop and Watch, SBAR, Advance Care Planning Tracking and QI tools completed. The project research assistants will be responsible for tracking receipt of all data and contacting NH champions if data are not sent in a timely fashion. All data will be entered by the project research assistants and double checked on desktop computers using password protected access to a SAS data entry system, and backed-up daily on FAU servers. Field names and codebooks used for our previous project will be updated for these purposes. Files will be linked within the FAU data base as well as with the data from CMS being collected and managed by the University of Minnesota (UM) by a specific NH code number so that they can be merged for analyses.

The data collection procedure will result in the creation of two separate database tables that are linked on a key field of a unique NH identification number. The first database table will contain NH characteristics and their self-reported survey data outlined above. The second set of tables will contain the data obtained from CMS. These data will be acquired by co-investigator Kane, who has several decades of experience obtaining and analyzing CMS data and will work with other UM collaborators to obtain and manage Medicare claims, MDS, HCC, and OSCAR data for this project. These data will be obtained via a Data Use Agreement facilitated by the Research Data Assistance Center (ResDAC), which acquires CMS data for studies nationwide, and is located in close proximity to Dr. Kane’s office at UM. Residents of participating NHs will be identified through the MDS, and a finder file will be created. Residents on managed care or with no files in the Medicare denominator file will be eliminated. A revised finder file will then be submitted to obtain claims data for the year prior to the study and then for the study year. HCC scores will be obtained from the denominator files, and MDS and OSCAR files will be used for descriptive data on the NHs. The data will have the unique individual Medicare identification numbers removed and replaced so that it is not possible to identify individuals but it will be possible to track the same individual over time. The data will then be transferred to FAU for linkage with the NH database and for analysis.

Data screening programs will be developed to examine incoming data to ensure values are in predefined ranges for each variable. If correction is not possible, the values will be coded as missing. In addition, we will examine each statistical model for normality of the residuals and to look for any outliers and overly influential data points. Non-normal residuals will require modifications of the data analysis and techniques that will allow non-normal distributions will be used (described in Data Analysis section). Outliers will be examined to determine if they reflect errors in data entry. Errors will be corrected or changed to missing if not correctable. Outliers and influential data points that are not errors will be noted and discussed in the results. If appropriate, analyses will be run with and without such values to examine their effect on the results.

Data Analyses

General Analytic Strategy: Drs. Tappen, Newman, Kane, and Grabowski will collaborate closely on all data analyses. The general linear mixed model (GLMM) technique, also known as Hierarchical Linear Modeling (HLM), will be used for data analysis. GLMM is the most appropriate technique due to its flexibility in modeling data structures as compared to the more rigid repeated measures general linear model. GLMM can be used to examine change over time for organizational structures such as NHs using a polynomial function of time. Depending on the nature of the individual change function, parameter estimates for the intercept, slope, and, if necessary, curvature are estimated to create the best predictive model fit for the data. There are several advantages of using GLMM in this study. Of primary importance is that this technique allows for examination of change in a specific variable of interest. GLMM also provides unbiased estimates of the correlations among the parameters, thus eliminating the problem of artifactual negative correlations between initial status and any change that may occur. A more practical consideration is that it allows us to maximize our sample size,
because it does not rely on the stringent requirements of repeated measures ANOVA. As GLMM models the longitudinal changes as a function of time, the time variable will be centered at the baseline of this study. Thus, in the examination of model growth parameters, the intercept will represent the baseline data on hospitalizations. The slope will indicate the rate at which the level is changing. GLMM assumes multivariate normality of the dependent variables, but also allows maximum likelihood estimation for variables that follow a distribution that is other than the normal. If data are not normally distributed but approximately follow some exponential distribution, then a generalized estimating equation will be applied using a general nonlinear mixed model, SAS procedure, NLMIXED. This may be applied for binary variables using a logit link function or for positively skewed distributions using log functions with Poisson or gamma distributions. The same hypotheses can be tested with these methods as with the normal mixed model.

Before testing the specific research hypotheses, a principal components analysis will be conducted to create a construct that reflects INTERACT implementation fidelity. This technique will use a Varimax orthogonal solution to help create a clear and interpretable linear construct of fidelity. The construct will be a linear combination of the numbers of training sessions completed and teleconferences attended, and the number of INTERACT tools completed (SBAR, Early Warning, Advance Care Planning Tracking and Quality Improvement – See Measures section). This construct will be added to the covariates as the implementation fidelity measure.

**Hypothesis 1**: The INTERACT implementation NHs will have a greater reduction in hospitalization rate than the control and monitoring only NHs during the 12-month implementation compared to a 12-month baseline period. This will be tested in two stages. Stage 1 will test if the rate of hospitalizations is significantly lower in the INTERACT NHs than in the control and monitoring only NHs during the 12-month implementation period. This will be tested using GLMM to investigate the pretest-posttest changes across groups while controlling for covariates that could influence hospitalization rates, including NH infrastructure (RN/resident ratios, proprietary vs. not-for-profit status), NH quality (number of survey deficiencies and CMS NH Compare Five-Star ratings), NH resident characteristics (mean HCC score, commonly used for risk adjustment in the Medicare population), and the composite measure of treatment fidelity described above. Stage 2 will use GLMM to test the hypothesis that there will be significantly lower hospitalization rates in the residents nested within INTERACT implementation NHs than in the control and monitoring only NH residents when testing growth trend differences over the 12-month implementation period, while controlling for NH level covariates listed above as well as individual covariates (including age, gender, individual HCC score, long or short stay status).

Secondary analyses will be conducted in order to investigate: 1) differential effects of the INTERACT program implementation on long vs. short term stay residents (as defined above); 2) rates of transfers that involve an Emergency Room visit without hospital admission; 3) relative proportions of hospital admissions for common “ambulatory care sensitive” diagnoses, including the five being used in the CMS NH value-based purchasing demonstration; 4) describe reasons for hospitalization from the NHs’ perspective and care processes during INTERACT implementation from data obtained from the Quality Improvement Tools using the same qualitative analytic strategy used in our Commonwealth project, and 5) advance directive and care-limiting order use during INTERACT implementation compared to the baseline facility survey.

**Hypothesis 2**: (Reductions in Medicare expenditures for hospitalizations in the INTERACT intervention NHs relative to the control NHs will exceed the estimated costs of implementing the intervention): Two analyses will be conducted to examine the cost benefits of INTERACT implementation. Both will use Medicare claims data to compare costs across the implementation, self-monitoring, and control group NHs. The initial analysis will use a traditional least squares regression approach and experiment with alternate specifications of the dependent variable (e.g., log transformation models). This facility-level model is specified as:

\[ Y = \beta T + \gamma X + \varepsilon \]  

where \( Y \) is the facility’s aggregate Medicare hospital expenditures per 1000 resident days, \( T \) is assignment to the INTERACT implementation group, and \( X \) is symbolic of vectors that represent multiple organizational and NH resident characteristics as described under Hypothesis 1. \( \beta \) will provide an estimate of the difference in hospitalization expenditures due to INTERACT program implementation. If this estimate is negative (i.e., INTERACT generated savings), we can compare it to the total cost of implementing the INTERACT program in order to address Hypothesis 2. For facility-based implementation costs (described in detail in the Measures section), we will average the time reported by project champions on monthly surveys for different levels of staff. The time in hours will be multiplied by the average hourly wages for each type of staff. The hourly wages used
for our Commonwealth Fund project will be updated for these calculations ($10.23 for nursing assistants, $18.46 for licensed practical nurses, $24.51 for registered nurses, $31.87 for directors of nurses, and $35.93 for administrators). In order to provide a more complete estimate of implementation costs, we will add costs of non-routine visits by medical providers to manage conditions in the NH using the average Medicare Part B reimbursement for acute visits. All implementation costs will be weighted to the facility-level and denominated by the number of resident days and then compared to the potential savings from equation 1 above. A separate analysis will be performed that includes emergency room visit expenditures that did not result in hospitalization using Medicare Part B claims data in addition to the costs of hospitalization. The second analysis will use Hierarchical Linear Modeling which will allow us to not only observe differences in expenditures from pre to post implementation, but also to assess the trends in monthly expenditures between INTERACT, self-monitoring, and control groups across time.

**Potential Problems, Limitations, and Alternative Strategies**
We recognize several potential challenges in implementing this project and limitations in the design and data we plan to collect. We have tried to address each by incorporating strategies that will mitigate their effects on the interpretation of our results. First, we recognize the challenges of implementing research and quality improvement projects in the NH setting. In our Commonwealth Fund project, 4 of 30 NHs dropped out because of changes in key staff, and 8 additional NHs were rated as minimally engaged in the project, despite initial enthusiasm. Turnover of key staff in NHs is high, and NH leadership is understandably focused on many other issues, including maintaining the facility’s census, finances, and preparation and responses to surveys. We have incorporated several strategies to address these challenges, including: 1) obtaining buy-in from key NH leadership before enrollment in the project; 2) identifying a project co-champion, who can assist the project champion and take on the champion role if necessary; 3) obtaining a written agreement of participation from each NH signed by key facility leadership including the administrator, director of nursing, and medical director; 4) implementing the project as the facility’s major quality improvement initiative, and excluding facilities that are already conducting more than one other major project at the same time; 5) compensating participating NHs for time involved in completing paperwork for data reporting (but not for implementing the intervention); and 6) allowing for a 20% dropout rate in our sample size calculation based on our experience in implementing INTERACT and other interventions in the NH setting. Second, we recognize the possibility of a “Hawthorne effect” in the control NHs. In order to address reviewers’ concerns about this issue, we have modified the study design to include a third group of NHs that will only monitor hospitalization rates and not implement the INTERACT program. This group will allow us to examine the potential for a Hawthorne effect clearly and quantitatively, comparing the effects of paying attention to hospitalization rates vs. full INTERACT implementation. Third, we understand the limitations of different methods of collecting and analyzing hospitalization data, and the challenges of risk-adjustment among NHs that might have substantial differences in case-mix. We have developed alternative strategies to deal with both of these issues. With regard to hospitalization data, our strategy is to use Medicare claims data for the primary outcome measure. Although we know that it may take approximately 12 months to obtain these data, collaborators on this project, Drs. Kane and Grabowski have extensive experience in obtaining, managing, and analyzing these data. We will only use self-reported data on transfers and hospitalizations submitted online from NHs randomized to INTERACT and self-monitoring groups as back-up and comparison for the Medicare data. With regard to risk-adjustment, there is no well validated methodology in relation to the outcome of hospitalization rates. We will use HCC scores, a commonly used risk-adjustment method for Medicare patients, in our analyses comparing hospitalization rates, as well as several other covariates (listed in the Data Analysis section) that have been cited in previous research that may affect hospitalization rates. We will also perform separate analyses of hospitalization rates among short-stay vs. long-stay NH residents, since the former tend to be more clinically complex and have a higher rate of hospitalizations. In addition, in response to reviewers’ suggestions, we have increased our sample size to account for facility effects in the analyses. Fourth, we will not be able to evaluate the fidelity INTERACT implementation by on-site monitoring because it would be prohibitively expensive. In response to reviewer concerns about evaluating the fidelity of INTERACT implementation, we plan to enhance the assessment of “engagement” and fidelity used in our previous work by tracking several additional quantitative measures of implementation as outlined in the Measures section.

Despite these limitations, we believe that this project is perfectly aligned with new federal health care priorities, and will provide data and experience critical for improving the care of older Americans who spend time in NHs, reduce unnecessary hospital transfers and related complications, and result in cost savings to the Medicare program that can be used to further support improvements in care quality for this vulnerable population.
Specific Aims

Hospitalizations of nursing home (NH) residents are frequent and associated with numerous complications that cause morbidity and increase health care costs. As many as two-thirds of these hospitalizations may be avoidable. Anticipated changes in the Medicare fee-for-service system that will affect payments for NH care, such as pay-for-performance and bundling of payments for episodes of care, have the potential to mitigate current financial incentives that favor hospitalization. Changing the financial incentives could, however, result in reduced care quality if NH staff does not have the training and clinical practice tools to manage residents in the NH when acute changes in condition occur. Such training and tools are critical to safely reducing avoidable hospitalizations of NH residents and their attendant morbidity and costs. The proposed project can play a critical role in both the new Center for Medicare & Medicaid Services (CMS) NH Quality Assessment and Performance Improvement requirement and the “triple aim” of improved care, improved health, and more affordable care. It also directly addresses the two major goals of the Department of Health and Human Services Partnership for Patients: patient safety and hospital readmissions.

INTERACT (Interventions to Reduce Acute Care Transfers) is a quality improvement program that includes clinical practice tools developed under a CMS contract. The INTERACT tools are based on established practice guidelines, and target three key strategies to reduce potentially avoidable hospitalizations of NH residents: 1) preventing conditions from becoming severe enough to require acute hospital care; 2) managing selected acute conditions in the NH; and 3) improving advance care planning for residents for whom a palliative or comfort care plan, rather than acute hospitalization, may be appropriate. The INTERACT tools can be viewed at http://interact2.net. A pilot test of the INTERACT tools in three Georgia NHs resulted in a significant reduction in hospitalizations rated as potentially avoidable, as well as in overall hospitalization rates during a six-month period. Our project team has refined the tools and examined their effects in 30 NHs in a multi-state quality improvement project that included provision of the tools, on-site education of a project champion and NH staff, and regular multi-site conference calls with the champions facilitated by an experienced nurse practitioner. Among the 25 NHs that completed the six-month project and provided complete baseline and intervention data, there was a 17% reduction in hospitalizations compared to the same six-month period in the previous year. The 17 NHs that were rated as engaged in the project had a 24% reduction, the 8 NHs that were rated as minimally engaged had a 6% reduction, and 11 matched comparison NHs had a 3% reduction during the same time period. The cost of the six-month intervention was $7,700 per NH; projected savings to Medicare of reduced hospital admissions from a 100-bed NH were $125,000/year.

While these results are promising, the effectiveness of INTERACT in reducing hospitalizations remains to be tested in a controlled trial. We therefore propose a randomized controlled trial to test implementation of the INTERACT quality improvement program. NHs randomized to INTERACT implementation will participate in an online curriculum to train project champions and NH staff on the INTERACT program and use of the tools, receive guidance from an experienced nurse practitioner through regular multi-NH conference calls, and have access to as-needed telephonic or email support. The effects of implementing the INTERACT intervention on hospitalization rates will be compared to a randomly assigned group of usual care control NHs, and a group of NHs who will monitor their hospitalization rates but not implement the INTERACT program.

The specific aims of this project are to:

1. Determine the effectiveness of implementing the INTERACT quality improvement program in reducing hospitalization rates.
2. Calculate the differences in Medicare expenditures for hospitalizations between NHs implementing INTERACT, the usual care control group, and NHs in the monitoring hospitalization rates only group.

The primary hypotheses to be tested are:

Hypothesis 1: INTERACT implementation NHs will have a greater reduction in hospitalization rate than the control and monitoring only NHs during the 12-month implementation compared to a 12-month baseline period.

Hypothesis 2: Reductions in Medicare expenditures for hospitalizations in the INTERACT implementation NHs will be greater than the estimated costs of implementing the intervention.