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COVER PAGE

PROTOCOL: REDUCING VETERAN'S HOSPITALIZATIONS FROM CLCS

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Reducing Veteran's Hospitalizations from Community Living Centers (CLCs)

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Protocol Title: Reducing Veteran's Hospitalizations from Community Living Centers (CLCs)

A. ABSTRACT

Although numerous interventions have aimed to reduce re-hospitalizations of community-dwelling older frail patients, fewer systematically developed interventions have aimed to reduce hospitalizations from nursing homes (NHs). One such program, the Interventions to Reduce Acute Care Transfers (INTERACT) program was designed by Dr. Joseph Ouslander and his colleagues. INTERACT is a comprehensive, multi-level nursing staff training and quality improvement program designed to: help staff identify common clinical signs that are precursors of conditions that frequently cause hospitalization; communicate residents' clinical conditions concisely and accurately to the physician; and examine potentially avoidable hospitalizations. A multi-state evaluation of 25 community NHs that implemented INTERACT found an overall 17% reduction in hospitalization rates and a 24% reduction among the 17 facilities rated as fully engaged in implementation. INTERACT has been adopted by CMS Quality Improvement Organizations and now has extensive on-line training and implementation documentation materials.

Despite the promise of the INTERACT program for reducing avoidable hospitalizations, it has not been adapted to or tested in VA Community Living Centers (CLCs). Such a program is ripe for implementation in the VHA because it is an integrated delivery system without conflicting payment incentives across providers. The goal of this study is to implement and evaluate an intervention in VHA CLCs that is designed to improve the care of Veterans using CLCs who experience acute changes in their condition and at the same time reduce their rate of hospitalization. We are guided by the evidence based hypothesis that engagement in the INTERACT program will identify Veterans' clinical problems earlier, help evaluate and safely initiate management of acute conditions in the CLC, communicate more effectively with physicians about Veterans' conditions and thereby avoid the need for hospitalization. To test these hypotheses, the following specific aims will be undertaken:

1. To characterize VHA CLCs in terms of alternate measures of hospitalization for long stay and post-acute care Veterans, including Medicare hospitalizations, and to examine regional variations in these rates over the period 2007 thru 2012;
2. (a) To modify, for VHA implementation, and pilot the INTERACT quality improvement program training materials; and (b) To implement the INTERACT quality improvement program as the intervention in 8-15 randomly selected, pair matched CLCs for a 6 month intensive training period and an additional 24 month implementation and data collection period.
3. To conduct a quantitative and qualitative evaluation of the implementation of the INTERACT quality improvement program in order to characterize the fidelity with which CLCs in the intervention pairs participated in training, engaged in regular conference calls, undertook root cause analyses identifying why hospitalizations occurred and used the tools in which they were trained;
4. To test the effect of the implementation of INTERACT as an intervention on the rate of reduction in hospitalizations from CLCs in the intervention as compared to the matched control facilities and to determine via a formalized "structured implicit review" whether the intervention was associated with a reduction in "avoidable" hospitalizations and did not lead to negative outcomes like mortality and ADL decline;
5. To conduct a Budget Impact Analysis of the cost of the intervention relative to the "savings" associated with fewer hospitalizations

B. INTRODUCATION/ BACKGROUND

Elderly individuals with long-term care (LTC) needs are at particular risk for hospitalization; more than 25% of long-stay nursing home residents are hospitalized in any given 6-month period.[12] Reducing hospitalizations from LTC settings is likely to have implications for health as well as health care costs. A clinical practice to transfer when indications are unclear is not optimal because the stress of transfer and the risk of nosocomial infection and other iatrogenic complications are not trivial for frail LTC recipients and can outweigh the health benefits from hospital treatment. A number of studies suggest that many hospitalizations for pneumonia could and should be avoided, as outcomes among those hospitalized can be worse than those treated without transfer.[13-15] While financial incentives across providers may vary, the cost to society of inpatient treatment is almost always more expensive than treatment elsewhere. Reducing potentially avoidable hospitalizations from LTC settings has the potential to improve health outcomes while simultaneously reducing overall costs for an important segment of the population.

While reasons for hospitalization vary widely across diagnoses, there is compelling evidence that interventions based on readily available clinical practice guidelines and care paths could have a large impact on overall re-hospitalization rates. For example, a majority of hospitalizations in the population are associated with infections, cardiac and pulmonary conditions and acute renal failure or dehydration.[11, 16, 17] Not surprisingly, many interventions designed to reduce hospitalizations target these conditions, but some components of these interventions have potentially wider applicability across diagnoses.

Hospitalizations can be loosely classified into those that are potentially avoidable versus unavoidable.[5, 18, 19] Some hospitalizations may be seen as avoidable because the underlying event is avoidable with proper care of a chronic condition. For example, hospitalizations related to diabetes, heart failure (HF), and chronic obstructive pulmonary disease (COPD) could be avoided if proper diet, exercise, and medication management are maintained. A separate but related distinction can be made between hospitalizations that are discretionary versus nondiscretionary, once an adverse health event has occurred.[5, 18] While hospitalization is seen as always necessary for some acute conditions such as hip fracture, transfer to a hospital is discretionary for other conditions such as pneumonia and dehydration. In the discretionary cases, the decision to hospitalize may depend on resources available in the LTC setting and family preferences as well as patients' clinical status.[20] Reducing hospitalizations is most feasible among avoidable and/or discretionary events.

A recent report from the Research Triangle Institute examined the dually eligible (Medicare and Medicaid) population in community NHs and found that more than one-third of these dually eligible beneficiaries were hospitalized at least once, totaling almost 1 million hospitalizations per year.[21] Of these, 382,846, or 39%, may have been avoidable, either because the condition might have been prevented or because the condition might have been treated in a lower level of care setting than a hospital. These potentially avoidable hospitalizations include 241,000 hospitalizations (63%) originating from a Medicaid-covered NH stay, 73,000 (19%) from a Medicare-covered SNF stay. In both Medicare covered SNF stays and Medicaid covered nursing facility stays, pneumonia accounted for over 30% of potentially avoidable hospitalizations.

To our knowledge no comparable hospitalization data exist on Veterans receiving post-acute care (PAC), approximately ½ of the CLC population. In community NHs, re-hospitalization of short stay, PAC patients is increasingly recognized as a major issue; however, these rates may differ between community NHs

and VA CLCs. Case-mix adjusted regional and facility variation in the rate of re-hospitalization among PAC Medicare SNF patients has been shown to relate to states' policies, facility resources and medical staff engagement.[7] VHA CLCs have medical and administrative staff that are under central control and therefore, at least theoretically, have the same organizational incentives as does the hospital director. These aligned incentives could mean that efforts to reduce re-hospitalizations in the VHA should be successful.

One systematic review of interventions to reduce hospitalizations from NHs classified interventions into those that increased staffing, altered provider incentives, identified high risk patients and introduced changes into the system of care.[22] Although changing the financial incentives could decrease avoidable transfers, it can also result in inadequate care if the infrastructure to manage residents with acute changes doesn't exist. Disseminating and implementing interventions that can assist NH staff manage acute changes in resident clinical status are critical to reducing avoidable hospitalizations of NH residents.

Interventions to Reduce Acute Care Transfers (INTERACT) is a quality improvement program involving a set of evidence-based clinical practice tools and strategies initially developed under a Centers for Medicare & Medicaid Services (CMS) contract to Georgia's Medicare Quality Improvement Organization. The original INTERACT tools were developed with input from a panel of expert NH clinicians and pilot tested in three Georgia NHs with high hospitalization rates. More recently, INTERACT II was evaluated in 25 NHs in three states in a 6-month quality improvement initiative that provided tools, on-site education, and teleconferences every 2 weeks by an experienced nurse practitioner. There was a 17% reduction in hospital admissions in these 25 NHs from the same 6-month period in the previous year. The group of 17 NHs rated as engaged in the initiative had a 24% reduction, compared with 6% in the group of eight NHs rated as not engaged and 3% in a comparison group of 11 NHs. The average cost of the 6-month implementation was $7,700 per NH while the projected savings to Medicare in a 100-bed NH were approximately $125,000 per year.[11]

Significance to the VHA: In conjunction with our GEC partners, this project is being proposed as one component of a general effort to improve care and enhance the medical capacity of CLC nursing and medical staff. If the INTERACT training program is effective, GEC anticipates expanding investment in the on-line training system and identifying local champions at CLCs across the country and implementing INTERACT. The training of CLC nursing and medical staff in INTERACT is completely compatible with, but expands upon, VHA "culture transformation" efforts. Reducing hospitalizations from CLCs has immediate positive benefits on the experience of Veterans since they would be spared the trauma of unnecessary transfer to hospital. In addition, INTERACT training advances several principles central to culture transformation by promoting Veteran-directed advance care planning and training staff to understand Veteran patterns of daily activities to better identify early warning signs and symptoms of decline.

Impact of Findings on the VHA: We expect that, compared to control-CLCs, intervention -CLCs which fully implement INTERACT will reduce hospitalizations by 20%, identifying avoidable hospitalizations. This figure is lower than the 25% reduction in hospitalization among facilities that were engaged in the INTERACT intervention.[11] Consistent with findings from community NHs, these reductions in hospitalizations will be achieved without increasing mortality or accelerating functional decline. From the VAMC perspective, this means hospital beds will be available for more emergent cases without major increases in VHA costs.

C. STUDY PROCEDURES Overview:

The INTERACT program, training curriculum and tools will be refined to be appropriate for implementation in a VA setting both in relation to standard CLC operating procedures and VHA language and policies.

Based upon merged VIReC and Medicare inpatient and outpatient data and CLC nurse staffing and other organizational data, we will match CLCs in terms of hospitalization rate, proximity to their VAMC hospital, admissions per bed and the mix of short and long stay CLC Veterans they serve. Up to 15 pairs of CLCs will be identified and from each pair one CLC will be randomly selected and approached about implementing the INTERACT program. We expect a minimum of 8 of the facilities approached to accept, adopt and implement the program over the 6 month training period and the additional 24 month implementation and data collection period (encompassing: a 12 month monitoring and data collection period to review the results of the intervention, followed by 12 months of indirect data monitoring). Both members of the CLC matched pairs will be dropped from the study if the CLC that is randomly selected to be offered the INTERACT program declines to participate. During the 6 month training period and the 12 month active monitoring and data collection period, extensive process measures, such as CLC staff participation in online training and support conference calls, will be gathered for use in both the implementation analyses as well as the Budget Impact Analysis (BIA). Additionally, quality improvement tools applied by staff to examine the characteristics and "avoidability" of hospitalizations during the 6 month training and 12 month active monitoring period will be assembled and coded. There will be no contact with pair matched control CLC since outcome data on their hospitalization rates will come exclusively from existing data. Changes in the case-mix composition and seasonally adjusted hospitalization rates for both the intervention and control CLC in each pair will be examined by comparing data from the two years prior to the introduction of INTERACT with data from the two years after the introduction of INTERACT.

Data Sources: To estimate the impact of the INTERACT on the rate of hospitalization from CLCs a variety of administrative data will be used. Our strategy for merging data is described below.

***VHA Utilization and Costs*:** VA utilization will be obtained from the national automated datasets maintained at the Austin Automation Center. The VHA Medical SAS Datasets are national administrative data for VHA-provided health care utilized primarily by Veterans. The datasets are provided in SAS format by fiscal year (Oct. 1 - Sept. 30). These data are extracted from the National Patient Care Database (NPCD). Two particular datasets will be used: the "Bed Section" dataset for acute and extended (nursing home) utilization. The "Bed Section" files (as opposed to the Main files) will allow us to differentiate between acute hospitalizations and inpatient rehabilitation, which is necessary for the creation of the Residential History File (see below) as well. These datasets will be used to obtain specific dates of admission and discharge that will enable us to define study outcomes. They also contain variables describing patient demographics, primary/secondary diagnosis, length-of-stay and up to 10 diagnostic code variables per admission. In conjunction with Dr. Phibbs and staff at HERC (Health Economic & Resource Center) we will use HERC cost data based upon standardized cost accounting rules.

Medicare Claims: Medicare data for Veterans are available to VA researchers with approved projects. The VA Information Resource Center, VIReC, prepares the data and attaches it to VA's Scrambled Social Security Numbers, which allows researchers to link VA and Medicare healthcare utilization data. The data are distributed to VA researchers as SAS datasets. The VIReC cohort, first

constructed for 1999, included a total of 6.4 million Veterans. Of these, there were approximately 6.1 million Veterans who were alive as of January 1, 1999. This cohort definition is updated annually to include the most recent source files to produce a cumulative finder file. Currently, files include claims from 1999 through 2011, and are updated continually.

Medicare's routine administrative databases include detailed demographic, financial and clinical data. The enrollment files include demographic data (birthdate, age, gender, race, and place of residence), eligibility information (Medicare Part A and B eligibility and periods of HMO enrollment) and vital status (date of death). Claims files are maintained for all beneficiaries not enrolled in HMOs. The hospital claims files include a record for each hospitalization (including DRG, multiple diagnoses, procedures, ICU days and reimbursements by revenue center). Other part A standard analytic files (SAF) include Skilled Nursing Facility, Home Health, and Hospice Files which contain claims with dates of service, charges, and the Outpatient file containing data on outpatient hospital procedures and reimbursements. Physician claims are part B claims and include dates, diagnoses, procedures and payments. All records in the claims and enrollment files include unique identifiers for Medicare enrollees that allow longitudinal linkage. Medicare claims are not available for beneficiaries, including Veterans, who enroll in a Managed Care plan, now constituting 25% of all Medicare beneficiaries. We are very conscious of the incomplete data resulting from this, but the proportion of long term care users who are covered by Medicare Managed Care is considerably lower than for the general population; whether this is true for the VA is not known at present.

Nursing Home Assessments: Minimum Data Set (MDS): The MDS resident assessment instrument (RAI) is a required clinical assessment done upon admission and periodically thereafter. In this study we will use the data elements included in the MDS as independent variables designed to adjust CLC hospitalization rates and as dependent variables to insure that reductions in hospitalization don't adversely affect patient functioning. Repeated evaluations of the reliability of the MDS reveal that with proper training, 92% of the identification and background items are reliable with an average reliability estimate of 0.71, and all diagnoses in the MDS are reliable with an average reliability of 0.74. [24] Inter-rater reliability data on over 6000 residents drawn from 209 facilities in 10 states were assembled on 100 different MDS data elements, average Kappa values exceeded .7 in over 90% of the items. The validity and reliability of summary scales measuring dependence in physical and cognitive functioning, mood, etc. have been documented in comparison with research instruments and other criteria. [25-34]

As of January 1st, 2012 VA CLCs began using the MDS 3.0 as the required resident assessment instrument. Psychometric analyses done as part of the developmental work and field testing of the MDS 3.0 reveal excellent inter-rater reliability for the new item definitions and many of those measuring function were not changed from the MDS 2.0. Dr. Saliba, one of the investigators in this project, was the architect of the MDS 3.0 so we are confident that we'll be in a position to work effectively with these data.[35, 36]

Facility Level Data: Facility information on CLCs is constructed by aggregating MDS and VA as well as Medicare claims and utilization data based upon Veterans' location. Specifically, we will create facility level aggregate measures of hospitalizations from a CLC as well as the proportion of short and long stay residents in the facility and the proportion or residents with primary psychiatric diagnoses. Finally, geographic proximity to the VAMC inpatient unit will be obtained from GEC as part of the CLC matching process.

Data on staffing in the CLCs will be obtained from VA's Corporate Data Warehouse (CDW) accessed through VINCI and stored locally on the secure research server in the designated restricted study drives through an existing DART request. This will be used to characterize the intervention and control CLCs in terms of the level of skilled and unskilled staffing at each CLC. This will help us to interpret the results of the comparison of hospitalization rates from the CLCs.

Residential History File (RHF): Intrator and colleagues have constructed algorithms that concatenate the MDS and Medicare Claims files into individual patient histories able to document trajectories as patients move in and out of hospital and other settings. Continuous days of health care utilization at the same health care location are assigned in calendar time. In the case of overlapping dates, a hierarchy (inpatient claims, SNF, hospice, and home health) is used to assign location of care. Prior experience has found that very few claims have overlapping dates of service (less than 0.05%), reflecting the ongoing error checking CMS does. More recently, under a current VA IIR, Intrator has applied the RHF to the combined VA-Medicare data, making it possible to track daily health care utilization of Veterans. This algorithm makes it possible to count the number of patient days at risk of hospital admission amongst residents in a CLC during any period of time. It is this feature of the RHF that makes it possible for us to precisely measure hospitalization rates in this study.

Implicit Review of Potentially Avoidable Hospitalizations: To estimate whether the rates of avoidable and inappropriate transfers changed with implementation of INTERACT, we will conduct a Structured Implicit Review (SIR) of the appropriateness of a sample of hospitalizations drawn from the CLCs participating in the intervention. To account for the heterogeneity and complexity of the CLC populations between sites, as well as the wide variety of factors that may influence the transfer decision, we will use SIR methodology to measure the appropriateness of transfer. SIR specifies key data sources for review and guides reviewers to consider specific domains in evaluating care. SIR has been shown to have acceptable reliability where data elements have not been specified in a manner that fully supports explicit reviews and where consideration of care elements requires clinical synthesis.[5]

Dr. Shay will assist the research team in recruiting up to 17 reviewers experienced with CLC care from VA GRECC clinical staff and from VA CLC Medical Directors not working at CLCs involved in the implementation of INTERACT. We will use VA reviewers to facilitate credentialing and access to records. VA staff are more familiar with the VA population and the VA electronic health record. The expert reviewers will be carefully trained in the use of the SIR. Dr. Saliba has experience in training clinical reviewers in performing SIR. Training will include reviewers independently completing a SIR on standardized practice charts. This will be followed by face-to-face meetings among reviewers to discuss their judgments and to clarify definitions and the information sources necessary to support a particular position viz. the potential "avoidability" of a hospitalization. Practice charts will be reviewed with the group discussion continuing until sources of disagreement have been resolved.

Reviewers will return to their facility where they will be assigned records to review from a nested random sample of the records of 163 residents transferred from the intervention facilities prior to the intervention compared to a nested random sample 163 residents transferred during the supported routine care phase (i.e. after the 6 month training period has been completed). Each reviewer will be asked to review up to30 charts, each requiring between 45 and 75 minutes. During the initial review period, 25 charts will have a second review to determine inter-rater agreement in the current sample. We will conduct monthly calls with the reviewers to encourage completion of reviews and to clarify questions or issues arising during reviews.

CLC Selection, Matching and Random Assignment: We will match up to 15 pairs of CLCs to ensure at least 8 implement the INTERACT program. Prior to undertaking the facility matching process and in consultation with GEC officials, we may exclude facilities experiencing challenges or management problems that would make them poor intervention candidates. We may also exclude from the matching process CLCs that are atypical or have very high proportions of long stay Veterans with histories of psychiatric conditions, since this population of Veterans has a different profile than our target population and are likely to be hospitalized in an inpatient setting for drastically different reasons.

The following criteria will be considered in creating the matched CLCs for this project. We will match CLCs based upon historical rates of hospitalization from CLC, the proportion of their Veterans who are short, post-acute care patients and the geographic proximity of the CLC to the VAMC inpatient unit. Additionally we will rely on two main types of characteristics: the monthly count of patient days alive in a CLC and the monthly re-hospitalization rate for each CLC. We restricted the analysis to 64 VA CLCs that had at least 50 beds, and were in operation during 2012. In addition, to calculate the matches we will only use data from 12/2007 to 12/2012.

The matching was accomplished in two stages. In the first stage, we partitioned CLCs into 10 groups using k-means clustering, based on the pattern of the monthly number of patient days alive in each CLC. The number of clusters (10) was chosen based on a change in the sum of squared error (SSE) of the scree plot. This step ensured that all of the CLCs within a cluster will have similar number of patient days alive which also corresponds to the size of the CLC. In the second stage CLCs were matched within each of the clusters defined in step 1, based on the monthly re-hospitalization rates per days alive. The matching algorithm within each cluster is of the greedy type that searches for the pair of CLCs with the smallest Euclidean distance, which is calculated based on the re-hospitalization rates in the last five years. Once two of these CLCs are declared to be a "match", they are removed from further consideration. The algorithm continues to find the closest pair remaining, and removes from consideration once identified. The process continues until all possible CLCs are matched. This two stage process ensures that matched CLCs have relatively similar sizes as well as other characteristics including relatively similar historical re-hospitalization rates.

Once CLCs are matched, the randomly selected CLC will be approached to solicit their participation with the strong endorsement of GEC leadership. We will approach the randomly selected experimental CLCs until up to 15 have agreed. If a CLC declines to participate, both members of the pair of matched CLCs will be dropped from consideration. The matched "control" case of those CLCs that agree to participate in the INTERACT program will not be approached. The "control" status of a CLC will be known to no one outside of the project research team and will not be divulged in any project description or publication.

Patient Selection: We do not anticipate excluding any Veterans in CLCs from the population to be included in the outcome analyses. The CLC is the unit of random assignment, meaning the intervention changes the skills of CLC staff. For each CLC agreeing to adopt the INTERACT program, it will be as if the CLC is introducing a focused quality improvement program to their staff. As such, no individual patient consent will be requested. We will separately examine hospitalization rates of Veterans classified as long stay or short stay based upon the pattern of recent admission and discharge data, but this will be regardless of their clinical condition or diagnoses.

Outcome Measures: The primary outcome (on which our statistical power estimates were based) will be the ***overall hospitalization rate*** calculated as the number of admissions to hospital from

the CLC in a month per person year at risk of hospitalization in that month. This measure has been constructed per CLC using VHA-Medicare merged data from 2004 and afterwards obtained under Dr. Intrator's current HSR&D IIR. The measure will be constructed covering the period from at least the 24 months preceding the introduction of the INTERACT program until 24 months after the introduction of the INTERACT program. Since hospitalization rates vary substantially during flu season, we have fit an ARIMA model to reduce the heterogeneity of variance in this monthly measure of hospitalization, thereby reducing the heterogeneity of residual variance. An ARIMA model will be fit for each CLC in the study, then using the monthly difference between the observed to the expected value to compare between any two matched CLCs over time. The dependent measure is a facility aggregate which we will risk adjust using indirect standardization by stratifying the per CLC month measure separately for long stay and short stay person months at risk of hospitalization. [See the Statistical Considerations section below for a detailed presentation of the ARIMA model.]

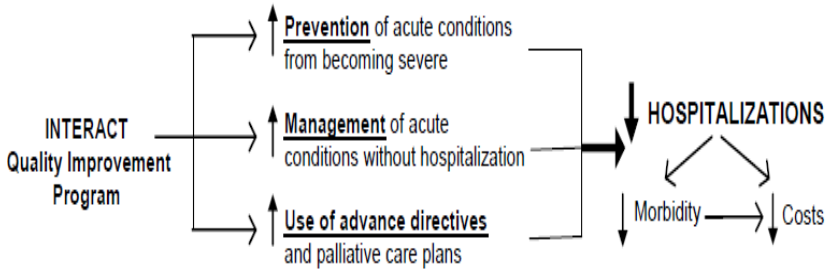
An alternate version of the outcome is a ***per-person, risk adjusted, probability of hospitalization*** variable which will be calculated and compared across intervention and control CLC pairs. In 2007, 32% of Veteran's were hospitalized at any time during the course of the year, ranging from under 10% per CLC to nearly 50%. However, since each Veteran had a different number of person months of observation, something that varies across CLCs, these individual probabilities will be examined separately for short and long stay patients. For short stay patients, we'll calculate the proportion with a 30 day re-hospitalization, adjusting for patient characteristics on the admission MDS and the originating hospital diagnosis and length of stay. For long stay residents (those who are residents of a CLC for at least 100 days), we will calculate the likelihood of hospitalization over a 6 month period, adjusting for MDS measured clinical and functional characteristics relying upon the MDS assessment closest to the beginning of the 6 month period. Both of these measures have been extensively used in the literature using Medicare fee for service claims and have been used by Dr. Mor and his colleagues at Brown in preparing these measures for use in the Commonwealth Scorecard system to rate states' health care system.[2][[37]]

The underlying intent of the intervention is to decrease transfers by avoiding decline, appropriately managing acute change or decline in the CLC, and improving the use of advance care plans. Transfer rates alone do not tell us whether these kinds of changes occurred in association with the focused intention of the intervention, i.e. to reduce the rate of potentially avoidable hospitalizations. We will therefore also examine the overall rates of ***potentially avoidable and inappropriate transfers*** prior to the intervention compared to these rates during the consolidation phase of the intervention (among only the CLCs exposed to the INTERACT program), using a tested and reliable structured implicit review process. The Structured Implicit Review (SIR) yields numerous judgments about the need for transferring the Veteran to the hospital and attributes this decision to whether identifiable clinical care problems had been missed and the expected benefits of hospitalization. The final outcome variable is an ordinal variable ranking the hospitalization in terms of the degree of "avoidability".

To ensure that adoption of the INTERACT intervention does not result in an excessive reduction in hospitalizations to the possible detriment of Veterans, we will adhere to the Data Safety Monitoring plan approved by the Data Safety Monitoring Board (DSMB). See Data Safety Monitoring Section, on page 35 for full details.

The INTERACT Intervention:

Overview: INTERACT is a quality improvement program that includes extensive training, clinical practice, quality improvement tools, and strategies to implement and sustain the program. An overview of the program and tools can be viewed at http://interact.fau.edu. The program's effect is based on three core strategies enabling front-line CLC staff to (see adjacent Figure): 1.) identify acute conditions early in their course, thereby helping to prevent them from becoming severe enough to require acute hospitalization; 2.) provide communication and decision support tools that assist with the safe and effective management of certain conditions in the CLC without transfer to the acute hospital; and 3) educate CLC staff in advance care planning and discussions about end-of-life and comfort care plans, thus increasing the use of advance directives, comfort care measures, and palliative and hospice care as an alternative to hospitalization when appropriate.



INTERACT will be implemented as a quality improvement initiative in each participating CLC. Completion of Quality Improvement tools, Communication Tools and tracking hospitalizations (including those which may have been avoided) are critical components of the INTERACT program. The Quality Improvement Tool guides the CLC staff in a review of the acute change in Veterans' condition. This is documented by the use of Communication Tools (Stop & Watch and SBAR Progress Note), what was done in the CLC to evaluate and manage the resident and decision making around transfer to the acute hospital when it occurs.

Local adoption of new practices such as INTERACT requires a stable management team. Pair matched facilities will be initially reviewed by GEC leadership who would know of management challenges that would make the CLC a poor candidate for adopting INTERACT as a quality improvement program. The leadership at the pair matched CLC randomly selected to be offered INTERACT will be sent introductory material and will be called shortly thereafter by study team members who will explain the program and what adopting it could mean to the CLC and their affiliated medical center. We have made provisions for the possibility that up to 4 CLCs will decline the opportunity to participate which is why we have constructed 17 matched pairs; both members of the pair are dropped from consideration if the one randomly selected intervention site declines to participate. Site visits may be conducted (depending on project timing, enrollment uptake and geographic proximity to study staff) to some or all CLCs agreeing to participate in order to meet and orient facility-based leadership and the project Champions. CLCs will be asked to sign a research agreement enumerating the expectations of the facility and facility Champions prior to participating in this project. This research agreement can be found in Appendix 3. During the recruitment period Nancy Henry, GNP, PhD, or Maria Carolina Rojido, MHA, (Senior Project Coordinators) will review the objectives of the program and mutual expectations, including demonstrating the online training materials and the various forms used to document the implementation of the intervention. Experience from previous community Nursing Homes quality improvement research projects suggests that such meetings are helpful to successfully initiate and sustain research and quality improvement projects. CLC project Champions will be responsible for involvement of CLC staff in the training and for leading the implementation of INTERACT at their CLC.

The INTERACT program will be implemented in up to 15 CLCs that agree to participate involving various stipulations including: 1) identifying and appointing "Champions" who will be responsible for program implementation; 2) agreeing to incorporate the INTERACT program as a "quality improvement" project that will be evaluated on an ongoing basis; 3) agreeing to encourage relevant staff to engage in the web based training and regular conference calls to review the conditions surrounding each hospitalization; and 4) sustain engagement in the INTERACT program throughout the 6 month training and a 12-18month monitoring and data collection period to review the results of the intervention.

CLC-Based Project Champions: In addition to strong support by GEC and VAMC leadership, prior studies highlight the importance of selecting enthusiastic, experienced, respected leaders as project Champions. Implementing INTERACT with only one Champion is risky since loss of the project Champion was associated with a reduction in engagement, non-adherence or drop-out. Thus, at each CLC Champions will share responsibility for implementing the INTERACT program. They will ensure participation of CLC staff in the INTERACT training, and engage the medical director, attending physicians, nurse practitioners, and physician assistants in the INTERACT program, participate in regular conference calls and organize event briefings to review the conditions under which hospitalizations occurred and what the precipitating factors were.

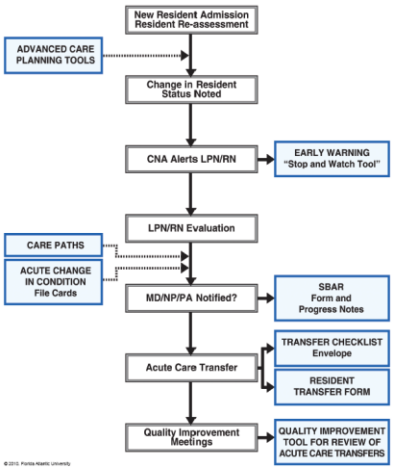
Training: Training and roll-out will occur over the course of a 6 month period followed by a 12-18 month monitoring and data collection period to review the results of the intervention. The training program is divided into two broad periods:

1.) 6 months to complete the training and to participate in the application of the INTERACT Program. The 6 month initial training and roll-out period is in line with our experience implementing the program at non-VA nursing homes. This timeframe has proven to be effective for program initiation. (See Appendix # 5, Webinars & Staff Modules);

INTERACT Training Curriculum
Webinar/Staff Module: *VA-INTERACT Introduction*
Webinar /Staff Module: *VA-INTERACT Decision Support Tools*
Webinar /Staff Module*: VA-INTERACT Stop & Watch Early Warning Tool*
Webinar /Staff Module: *VA-INTERACT SBAR Change in Condition Progress Note*
Webinar /Staff Module: *VA-INTERACT Advance Care Planning (ACP) Tools*
Webinar /Staff Module: *VA-INTERACT Quality Improvement Tools*
Webinar /Staff Module: *VA-INTERACT Interacting with your Hospital*
Webinar /Staff Module: *VA-INTERACT sustainability*

2.) A 12-18 month monitoring and data collection period to review the results of the intervention following the 6 month training period. In this second phase of the intervention, research staff will continue to host conference calls and participate in more of an observational and advisory role. The research team may host occasional refresher trainings and other web-based modules for new or existing staff interested in participating.

During the 6 month training period, the project Champions, as well as key CLC staff, including certified nursing assistants (CNAs), licensed nursing staff, ancillary staff, therapists, social workers, administrative nurses, the medical director, and medical providers (MDs, NPs, and PAs) will be expected to participate in the online training curriculum. Night and weekend staff will also be expected to complete the curriculum, as many acute care transfers occur at night and on weekends. These types of staff members successfully completed training in community-based trials of INTERACT.



The 6 month training curriculum includes a combination of online resources and teleconference calls facilitated by one or more of the VA-INTERACT research staff. Online resources include eight annotated Power Point presentations 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 feedback assessment. Individual CLC staff will be encouraged to take part in the designated staff modules hosted through the study SharePoint. Staff will be able to anonymously complete the modules and feedback assessment identifying only their job category within the CLC. Completion of individual webinars will be tracked and aggregate level reports generated for facility Champions in order to ensure that key staff members complete the curriculum during the training period. Completion of the modules will be tracked through the project specific SharePoint. Training sessions will not be linked to individual CLC staff.

Between sessions, suggested implementation activities will include practicing the use of the tools and tracking acute care transfer and hospitalization rates using existing information systems in the CLC, either paper or electronic formats. Teleconferences will be held every other week and include opportunities for participating CLCs to ask questions, discuss implementation challenges, and share successes with other CLCs. Individual CLC calls as well as calls with multiple intervention CLCs (Cohort calls) implementing INTERACT at the same time will be held. The calls will include the Champions and key leadership staff at the CLC.

The subsequent 12-18 month period will be characterized by every other week conference calls. The goal is to keep Champions and CLC staff engaged in the ongoing quality improvement process designed to reduce hospitalizations. Calls will be with the Champions and will focus on CLC staff experiences using the INTERACT tools, particularly those related to documenting the reasons for hospitalization.

The INTERACT Tools: The INTERACT tools were developed and refined with extensive input from national experts in nursing home 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.[40-43]

There are four types of tools within the INTERACT QI program, illustrated in the figure above:
1. Communication tools: structured to document communication between nursing assistants and licensed nurses (RNs/LPNs/LVNs), between nurses and medical providers (MD, NP, PA), and between CLCs and hospitals. These tools include an Early Warning Tool ("Stop and Watch"), Situation **B**ackground **A**ssessment **R**equest ("SBAR") Communication Form and Progress Note, Acute Care Transfer Checklist, CLC to Hospital Transfer Data List, Hospital to CLC Transfer Data List, and CLC Capabilities List.

2. Decisions Support Tools: including change in condition file cards and care paths for ten conditions that are common causes of potentially avoidable hospitalization of Veterans in CLCs including acute mental status change, change in behavior with new or worsening behavioral symptoms, dehydration, falls, fever, GI symptoms such a nausea, vomiting and diarrhea, shortness of breath, symptoms of CHF, lower respiratory illness and symptoms of UTI.
3. Advance Care Planning tools (ACP): including 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, a template for "comfort care" orders, and educational handouts for staff (Identifying Veterans Appropriate for Palliative or Comfort Care) and Veterans and their families (Education on CPR for residents and families, Education on Tube feeding for residents and families, Deciding about going to the hospital) .
4. Quality Improvement tools: include a structured review of acute changes in condition and acute care transfers, a form to track transfers and hospitalizations, and a quality improvement summary tool

The version of tools designed specifically for the VA CLCs can be found in Appendix 2, INTERACT VA CLC Version 1.0 Tools. The INTERACT VA CLC tools are designed to be integrated into the everyday care process in CLCs, as illustrated in the figure above. The *Advance Care Planning Tools* are helpful in promoting the use of advance directives and palliative care plans with appropriate residents at or within a short time after admission, as well as throughout their stay. When direct care staff notices an acute change in a Veteran, they can document and communicate the change using the *Stop & Watch 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 CLC *Transfer Data List*. The *Quality Improvement tools* include a structured review using a root cause analysis approach to assist CLC 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.

A potential barrier to using the INTERACT tools within the CLC setting is that they are not integrated into CPRS as electronic templates where CLC clinical staff document encounters and communication. To address the feedback from the pilot (Aim 2A) in Tampa for records to be maintained electronically, the SBAR Communication Form and Progress Note used by clinical staff to document a change in condition will be available for use electronically at CLCs that obtain approval through their local Medical Record Committee (MRC). All forms will not be created electronically at this time due to considerable time and resources and required to make changes to existing VHA systems before we have the evidence that the intervention is effective in the CLC setting.

Support by a Senior Research Project Coordinators: During the 6 month training period, the Research Project Coordinators will facilitate multi-site conference calls to foster cross pollination of ideas between CLCs about implementation, successes, and challenges to implementing INTERACT in the VA CLC. These cohort calls will be held periodically during the 6 month period. The Champions from each facility will be participants on these calls. Dependent upon progress in the implementation of the INTERACT program the audience on these calls may be expanded to include others in the CLC clinical and/or administrative leadership. The calls will be used to: review and reinforce the use of specific INTERACT tools and implementation strategies; share challenges and successes in implementing the intervention; review cases in which the INTERACT tools assisted in preventing a transfer and/or in managing residents without transfer; and review cases in which a resident was initially managed in the facility, but required transfer to the acute hospital.

Documenting Intervention Fidelity: The process of implementing and remaining true to the fidelity of INTERACT will be documented in a uniform manner across all intervention CLCs using the web based training, documentation of attendance on conference calls, qualitative notes from site visits, and from fielding trouble shooting calls. Specific items of interest that will be examined and reported will include: a change in the Champions; the proportion of staff who complete the web-based training; the number of Stop and Watch Early Warning Tools used; the number of SBAR Progress Notes completed relative to the number of hospitalizations per month; and any increase in the number of CLC residents with advance care directives. Variation between CLCs participating in the INTERACT intervention will be one of the foci of an implementation report. We will also document the association between a global assessment of "adherence" to the INTERACT intervention and the degree of reduction in the actual rate of hospitalization from CLC by CLC Veteran. Counts of contacts, calls and numbers of forms filed will be differentiated between the first 6 month period and the second 12 month monitoring and data collection period.

In order to evaluate intervention fidelity, we will use data on the number of CLC staff who complete INTERACT training, participate on teleconferences, and obtain information from project Champions during regularly scheduled calls on the use of specific INTERACT tools (Stop and Watch Early Warning Tool, SBAR, Quality Improvement Tools, and Advance Care Planning Tracking). The Project Coordinator will track receipt of data and will contact project Champions with reminders and follow-ups if data is not submitted.

Aim #1: *To characterize VHA CLCs in terms of alternate measures of hospitalization for long stay and post-acute care residents, including Medicare hospitalizations, and to examine regional variations in these rates over the period 2007 thru 2012*. Using data from the merged VA SAS data system and Medicare claims, we will construct several different measures of hospitalization from CLCs that are applicable to both short and long stay residents. A facility level measure with limited risk adjustment will be calculated as the number of CLC patient days in the year divided by the number of unique admissions from CLC. This measure can be calculated per calendar year, per quarter or per month. Using 2007 and 2008 data, we've calculated this for all VHA CLCs, although some outliers suggest that there are likely inconsistencies in how unit transfers are coded which we will correct under the proposed study. Since hospitalizations vary by season, we'll adjust for each CLC's own seasonal variation (due to latitude) and characterize regional variation as well as variation attributable to the mix of short and long stay residents in the CLC and the proximity of the CLC to the VAMC. Of particular interest will be tracking changes over time in the rates of hospitalization since in the Medicare FFS system we have documented large increases over the last decade.[2] We will undertake the same analyses using the risk adjusted, per patient level hospitalization measures, estimating the proportion of short and long stay residents, respectively, that were hospitalized between 2007 and 2012 and to test whether the patient level, risk adjusted rate of hospitalization increased, given changes in the acuity of individual entering and residing in CLCs.

Aim #2A: *To modify, for VHA implementation, and pilot the on-line INTERACT quality improvement program intervention training materials.*

The INTERACT quality improvement program was initially developed under a grant from the Commonwealth Fund and has since been modified extensively through interventions implemented under the auspices of CMS-sponsored quality improvement programs and select state-based efforts designed to reduce hospitalizations from nursing homes.[3, 44] INTERACT's web-based training

materials, forms for documenting hospitalizations, and avoidable hospitalization reviews include communication tools, quality improvement tools, and decision support tools, with care paths and advanced care planning education materials. These will all be modified to use appropriate VA Veteran centered language and practices.

Activities related to modifying and updating the INTERACT training tools to be VA-centric will involve six on-site focus group sessions at the Tampa VA CLC. Focus group sessions will be conducted by Nancy Henry, PhD (Senior Project Coordinator), under the supervision of Joseph Ouslander, MD, who is based at Florida Atlantic University, in close proximity to the Tampa site. Dr. Mor will serve as director for the pilot phase. The focus groups will not involve data collection, metrics, or any contact with CLC residents. The CLC personnel will be asked only to avail themselves of their professional expertise to make suggestions and/or feedback on the practical use of INTERACT.

The Senior Project Coordinator (SPC) will coordinate with the Tampa Site Champion to identify those staff within the CLC who will volunteer to participate first in a *free* thirty minute discipline-specific introductory learning session about INTERACT. This will involve staff watching a 30 minute video provided via the Medline University website. Staff will be provided free access to the website and can schedule at their convenience prior to their involvement in the focus groups. Using a classroom setting in the CLC, the SPC (FAU) will facilitate (6) fifty minute focus groups which will build on the Medline University INTERACT introductory session. These focus groups will be facilitated by the SPC (FAU) along with the Site Champion to include scheduling at a convenient time for staff participation. During each focus group, CLC volunteer staff will be provided a Power Point presentation and paper versions of specific INTERACT education materials and tools**.** The SPC (FAU) will lead a discussion about the usability of the tools in the CLC practice setting. Staff will have the option to offer verbal feedback and/or write their feedback on the paper materials during the session. The last of the six focus groups will include a discussion of recommendations and/or consideration for use of select INTERACT tools in electronic template form for use in CPRS, the VA electronic medical record. Input from these VA CLC volunteer staff will provide essential feedback on how best to modify the program and tools to ensure delivery of the most effective and efficient version of the INTERACT Quality Improvement Program for VA CLC intervention sites. A focus group guide containing detailed procedures around the introduction of the INTERACT program tools and training materials can be found in Appendix 4. The Tampa VA CLC staff will make a substantial and valuable contribution towards enhancing the use of INTERACT in preparation of introducing the modified INTERACT Quality Improvement Program to the CLC intervention sites.

Interaction with the employees of the Tampa CLC is exclusively for engaging their voluntary participation in focus groups to gather feedback about improving the INTERACT tools and materials. Feedback from staff provided either verbally and/or in written format, will be summarized by the SPC (FAU) but no personal data will be collected from any staff or any resident in the Tampa CLC. Furthermore, no information gathered during the focus group process will involve topic areas beyond that of refining the INTERACT Quality Improvement tools nor any sensitive disclosures that might result from staff mix in attendance. This process will involve minimal risk: the voluntary participation and input sought from VA CLC employees does not increase the probability of harm or discomfort.

(Note: As we are not gathering any data or information related to the participants in the focus group sessions, we are requesting both a waiver of informed consent and will not maintain a master list of subjects).

Upon completion of the (6) focus groups, the SPC (FAU) will coordinate scheduling of thirty minute learning sessions for the day, evening and night staff of one CLC unit with the Tampa Site Champion and

CLC leadership, (3 learning sessions in total). During the learning sessions, staff will be provided an overview of the INTERACT program and instructions on the use of 1) the Stop and Watch Early Warning Tool, and 2) SBAR tools for use in everyday care of residents. The staff will be provided a supply of paper tools to complete as opportunities arise and submit them to their ward leader for a period of 30 days. The Data Handling Plan that the Site Champion will utilize is described in the next paragraph. The Site Champion will track the number of tools staff use during this period of testing and gather feedback about usability. The SPC will provide site visits and/or telephonic support during the 30-day usability testing. The Site Champion will share with the SPC (FAU) the verbal or written feedback about the staff's experience with the tools and the total number used. This thirty day period of feedback will add a substantial and valuable contribution towards understanding how best to revise the INTERACT tools in preparation for use in the CLC intervention sites. At the conclusion of the (6) focus groups and one month of tool usage in one CLC ward, the total sum of feedback and/or recommendations offered by staff will be used only to revise the INTERACT Quality Improvement Program prior to introducing it to the VA CLC interventions sites. This will conclude the activities at the Tampa VA CLC.

Data Handling Plan (Tampa pilot): The staff will fill out paper tools and hand them off to the unit leader, who will ultimately submit them to the Site Champion. The Site Champion will keep the tools in a locked cabinet in a secure room at the CLC until the completion of the 30 days. Once a count is completed and feedback is summarized, the sample education materials and tools will be disposed of securely by the Site Champion, utilizing acceptable VA protocol. Specific details regarding data security and permissions for the INTERACT tools that may potentially be used throughout the whole study intervention period can be found in Appendix 1, pages 2-4. However, please note that the SBAR and Stop and Watch tools are the only two tools that will be tested at the Tampa pilot, and that resident information collected by these two tools will only be seen by CLC personnel, not research staff. However, research staff will receive verbal or written feedback about the staff's experience with the tools and the total number of each tool used in the 30 day period. All feedback gathered in Tampa will be used to refine the INTERACT quality improvement program tools and the education materials in preparation for use as an intervention in 8-10 randomly selected VA CLCs.

The INTERACT training tools are grouped into four categories, Quality Improvement Tools, Communication Tools, Decision Support Tools, and Advanced Care Planning Tools and can be found in Appendix 2. These tools will be modified for use in the VA CLCs based on the feedback obtained from the focus groups and through a one month period of use of select INTERACT tools in one ward of the Tampa CLC. Dr. Christa Hojlo will review all the updated INTERACT tools and materials following the completion of the work at the Tampa VA CLC prior to the roll out of the INTERACT intervention for study aim 2B (see below).

Aim #2B: *To implement the INTERACT intervention in up to 15 randomly selected, pair matched CLCs for a 6 month intervention training period and an additional 12-18 month observation period.*

CLC agreement to participate: Up to 15 CLCs will be identified as potential participants in the INTERACT intervention program based on a pair matching system and random selection of one CLC from each pair. If the selected CLC does not agree to participate the pair will be dropped and we will go back to the remaining list of potential pair matches and select another site until up to 15 have agreed to participate or we have contacted all eligible sites.

The formal training at each CLC is scheduled to occur over a 6 month period followed by 12-18 additional months of observation. A minimum level of participation in the training is required to

ascertain that the intervention has been embraced by the CLC staff. The Providence research staff will monitor the CLCs' participation in the intervention. If a CLC is doing poorly and the Champions seem to be unable to engage and motivate the staff, we may drop the site or try to recruit an additional Champion(s). This is one of the reasons for matching extra pairs of CLCs. One of the strengths of the pair matched design is that if one of the intervention CLCs is dropped we can readily drop the matched control site without having to worry about unbalancing the design.

Each CLC will follow the procedure below to become an active participating CLC in the INTERACT intervention. Selected CLCs will be contacted with a letter from the PI, Vincent Mor, PhD, Co-PI Debra Saliba, MD, MPH, INTERACT Developer, Joseph Ouslander, MD, and GEC leadership containing introductory material, describing the INTERACT training program being proposed. After the letter, follow up contact will be made with each CLC to determine participation. Sites who agree to participate will be asked to sign a Research Study Agreement (See Appendix # 3, Research Study Agreement).

The intervention CLCs that agree to participate will agree to the following stipulations: identify appropriate candidates as Champions who will be responsible for program implementation (and replacing a Champion if identified Champion can no longer complete assigned duties during study timeframe); incorporate the INTERACT program as a "quality improvement" project that will be evaluated on an ongoing basis; encourage relevant staff to engage in the web based training, anonymous feedback and conference calls to review the conditions surrounding each hospitalization and provide information on the implementation of INTERACT; and sustain engagement in the INTERACT program throughout the training and 12-18 month monitoring of the INTERACT implementation at the CLC.

Implementation of INTERACT Training Curriculum*:* Site visits and/or calls will be conducted by a project coordinator to review the objectives of the program and mutual expectations. This includes gathering preliminary information regarding QI activities already existing within the CLC, demonstrating the online training materials and the various tools, and working with sites to introduce the use of INTERACT to hospital personnel as necessary. A resource handbook will be provided along with access to the secured VA-INTERACT CLC SharePoint providing all essential documentation and resources for the intervention. We will schedule training times and confirm with Champions to begin distributing information (electronic and paper materials will be used) about the upcoming INTERACT Intervention to personnel. Providence VAMC staff will assist sites with scheduling, material distribution and resources. *ALL training will be scheduled based on site and study staff availability*.

Eight (30-50 minute) webinars will be held (online or in-person) (at convenient times for the site champions, other staff and moderator/facilitators) (See Appendix # 5, INTERACT Webinars & Staff modules). Each live webinar will be recorded for the Champions to reference as well as for any Champion who is unable to attend the live webinar to listen after. The recorded (live Champion) webinars will be accessible through the individual secure CLC SharePoint or site-specific shared folder stored on the secure server at the Providence VAMC in building 4, room 201 for the sites participating in the cohort for each webinar series and only Champions of each CLC in the cohort will have access. No recordings will be shared across the cohorts of CLCs participating. At the beginning of each live webinar the Champions will be read a statement about the recording (See Appendix 7, Webinar Recording Statement) and given the opportunity to not participate in the live session if they do not want to be recorded. This statement will be posted on at the beginning of the each webinar before the recording begins for the Champions to read. Additionally it will be posted on each CLC site SharePoint as a reminder to Champions throughout the project. The recording will not begin until all questions are

answered about this and those who wish to decline participation in the recording have been given the opportunity to exit the webinar.

INTERACT VA CLC Version 1.0 tools will be introduced and suggested implementation will be provided. (See Appendix # 2, INTERACT VA CLC Version 1.0 Tools) Champions will be asked to engage key personnel in online training modules to assist personnel with implementation and get feedback on use of tools. The online modules will be available through a secured VA website portal for each site to have individual access. Individual employees will remain anonymous, identifying only their position in the CLC when completing the modules and post session quizzes. (Only Providence VAMC Research staff will have access to individual responses. Providence Research staff will quantify the results and share with clinicians so they can provide feedback to sites on their implementation status and evaluate process measures related to uptake of INTERACT implementation at a particular CLC (See Appendix # 5 , INTERACT Webinars & Staff modules). In between webinars personnel will be asked to use the tools and track acute care transfers and hospitalization rates using existing information systems within the CLC (paper or electronic). Conference calls with each CLC will be held between webinar sessions to assess and support the implementation of INTERACT from the Champions and leadership perspective. Cohort conference calls will be held periodically to get feedback across sites on the implementation process and INTERACT uptake, as well as an opportunity for sharing successes and challenges.

SBAR usage will be monitored regularly throughout the study timeframe for each CLC. (Appendix # 6, Interview Guide)Beginning after the introduction and use of SBAR (approximately 2 months into the 6 month training period), CLC Champions will review SBARs of all CLC Veterans for whom the form was completed during the timeframe of interest. (These forms are completed by CLC nursing staff when they notice a clinical change in a patients' condition that warrants a discussion with the physician regarding the need for changes in standing orders.)

CLC Champions or other identified personnel within the CLC (i.e. informatics or clinical applications coordinators CACs personnel, who would have access, as part of their regular job duties at their local site) will produce a list of Veterans with a SBAR in their record. This list will include Veterans names (including DOB or last 4 of SSN, only for reference when pulling the full SBAR data within the VistaWeb system and CPRS to confirm the correct record is being accessed) and the date the SBAR was used. The list will be securely transferred to an access-controlled and site-specific shared folder stored on the secure server at the Providence VAMC in building 4, room 201, sent through encrypted PKI email to the project coordinator or to their secured SharePoint designated specifically for each site with a secured folder only accessible to those who upload to it from the CLC, the site Champions, the Providence VAMC research staff and the Project clinicians who will conduct the review.

The Project Coordinator will be given access to VistaWeb for each local site participating in the study, to search by the 'INTERACT SBAR Note' title (named locally with specific naming conventions) created for the study locally and obtain the SBAR Note used for each Veteran listed. This will lessen the burden on the CLC personnel as well as provide more accurate and timely data for the study. The SBAR Note will be extracted from VistaWeb into PDF files including the Veterans name and DOB. These files will be stored on the secure access-controlled and site-specific shared folder stored on the secure server at the Providence VAMC in building 4, room 201. (See Data Assurances on page 30 for details on data security). An excel file will be populated as a key and include identifiable data from each SBAR completed. This key will include the code, linking collected SBARs to the limited data set, which will include dates but no other identifiable Veteran information. This allows for future analysis of the collected data. The key will be kept secure by the project coordinator in Providence, stored on the secure drive designated for SBAR collection.

The coded SBAR data (including a limited data set) and the SBAR review data collected for each case will be entered and stored in REDCap which will assist with future tracking, exporting and general analysis of the collected data.

REDCap is a secure data storage method. We will use this data storage option because it provides: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

This has been reviewed by the local privacy officer and ISO. All information being stored here is acceptable and cannot be readily or easily re-identified. There is no identifiable information stored here so it is acceptable to store the data here as well. REDCAP is approved for use within the VA as a secure data storage mechanism.

The SBARs collected will be shared with the Champions to gather further information on the outcome of each SBAR used. The name, DOB or last 4 of SSN is shared only for the purpose of making it easier for the Champions, who already have access to this information in a search of the VISTA system locally, to gather the additional details about the SBAR usage for each case without having to do an additional search. These PDF files will be share directly through the secured SharePoint designated specifically for site Champions, the Providence VAMC research staff and the Project clinicians who will conduct the review with the Champions.

This process will continue throughout the 12-18 month active monitoring and data collection period.

A standardized set of questions will be asked of the Champions or other personnel identified to have insight into the SBARs for review. The calls will focus on reviewing the SBARs completed within the designated timeframe and look to ascertain whether a Veteran was transferred to the hospital or should have been transferred sooner, and information about the Veteran's advanced directives and end of life care wishes. (Appendix # 6, Interview Guide)

INTERACT active monitoring and data collection period: The CLCs will be followed for 12-18 months after completion of the training period to determine the uptake of INTERACT at the CLCs. The 12-18 months is an active monitoring and data collection period in which SBAR usage will continue to be monitored and the Champions and leadership will be asked to participate in monthly conference calls to ascertain that the intervention has been embraced by the CLC staff. The goal is to keep Champions engaged and involve CLC staff in the ongoing quality improvement process designed to reduce hospitalizations. Calls will focus on CLC staff experiences using the INTERACT tools, particularly those related to documenting the reasons for hospitalization. Champions and leadership will serve as representatives of the CLC staff on these monthly calls. If desired the call group could be expanded to include others in the CLC clinical and/or administrative leadership, depending upon progress in the implementation of the INTERACT program. The calls will be used to: review and reinforce the use of specific INTERACT tools and implementation strategies; share challenges and successes in implementing the intervention; review de-identified cases in which the INTERACT tools assisted in preventing a transfer and/or in managing residents without transfer; and review cases in which a Veteran was initially managed in the CLC, but required transfer to the acute hospital. (Appendix # 6, Interview Guide)

Additionally, during the 12-18 month active monitoring and data collection period following the 6 month training, CLC staff will be encouraged by the Champions to continue using their CLC SharePoint for resources on the implementation of INTERACT and foster continued interest via refresher webinars or

online trainings, and engaging newly hired clinical staff in the on line training. They will also be encouraged to complete the Quality Improvement Tools (i.e. Quality Improvement Tool for Review of Acute Care Transfers and Quality Improvement Summary Worksheet) using the electronic versions (fillable PDF version of the paper forms found in Appendix 2) on their secure SharePoint. The Champions can also complete these by paper and choose to scan and email them encrypted with PKI or fax paper copies to the Providence Research team for review as well.

The *Quality Improvement tools* include a structured review using a root cause analysis approach to assist CLC 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. The completed tools will be available for the research staff to review and identify areas to continue helping with implementation and improved outcomes.

Additional training sessions to assist with proper usage and reinforce the use of the INTERACT tools will be offered as necessary to the Champions. Also, the research team may host occasional refresher trainings and other web-based modules for new or existing staff interested in participating.

Exit Survey: To finalize the intervention and elicit feedback on the full intervention an exit survey (*See Appendix 8- VA-INTERACT Exit Survey*) will be conducted with CLC study Champions. The exit survey will gather specific information on how much of the VA-INTERACT QI program was utilized by each CLC, continued plans for use of VA-INTERACT within the CLCs, and in their opinion if the INTERACT QI program can be fully integrated into the daily care practices of CLC staff.

This information will be gathered by research team members who did not participate in study aim 2b and did not have any interaction with CLC staff or Champions. The individual champion responses will remain anonymous to all research staff except those who are responsible for collecting the exit survey.

The champions will be notified by the intervention staff about the exit survey. They will be contacted after completion of the intervention by other study staff members regarding this final survey. It is entirely voluntary and their individual responses will remain anonymous to all other study staff except those sending and collecting the exit survey by email.

The Exit Survey questions (See Appendix 8) will be emailed to all Champions within 30 days of the CLCs final contact with intervention research staff as part of the follow up and monitoring period. The intervention research staff will notify the exit survey staff when this last contact occurs. The exit survey research team will send an email message (See Appendix 8) with the attached interview questions to be completed at the Champions convenience and sent back to the exit survey research team by email. The exit survey team will send a reminder email to those champions who have not responded after one week and a second reminder after week two if no response received. The reminder will be the same scripted email originally sent with an additional line in each indicating *"This is a reminder we have not received your exit survey responses yet"*. The final email will say *"This is a reminder we have not received your exit survey response yet, this is our final attempt to collect this information. Please respond by returning the attached survey."* Those are the only reminders that will be sent.

A follow up phone call may be scheduled with any individual champion to clarify or expand on any specific content from the returned exit survey deemed important to further our understanding of the use of VA-INTERACT in the VA CLC setting. This will be scheduled with those champions at their earliest

convenience. Which champions receive a follow up phone call will be determined based on the following:

First, they must be willing to be contacted by checking yes to the final survey question regarding future phone contact (if left blank, we will consider them as having checked no and they will not be eligible for follow up phone contact). Additional criteria for determining who will receive a follow-up call includes: 1.) Any responses that includes a novel or unique challenge or success that further details could result in a better understanding of how VA-INTERACT could be integrated into the CLC setting or 2.) any incomplete or unclear narrative response that with further conversation could contribute to a better understanding of how VA-INTERACT can be integrated into the CLCs.

If determined a follow up call would provide valuable feedback on VA-INTERACT usage in the VA CLC setting based on the above criteria, the exit survey team will email the designated champion requesting a time to speak over the phone to expand or clarify some of their responses. Through email, the exit survey team member and champion will determine a time to schedule this call. The exit survey member will call the champion at the designated time. If they are unavailable at this time, a message will be left regarding a time to reschedule. Also an email requesting at time to reschedule will be sent, this email will remind the champion that their participation is voluntary. If they no longer wish to participate, they can reply to the email letting the exit survey member know and no future contact will be made. If no response is received from the champion a second email will be sent a week later to try to reschedule the call. This will be the final attempt and it will be noted in the email that this is the final contact. Only if a response from the champion occurs will any further contact be made to schedule this call.

The information gathered will be entered into their survey responses to those narrative questions being followed up on from that champion.

The exit survey research team will compile the completed interviews, stripping them of the CLC and Champion name, replacing with an ID. Only the exit survey research team will have access to connect the champion or CLC with their interview responses. The exit survey staff will keep the coded list of champions' names and IDs and their responses on a secure server within their local VA system. The local VA exit survey team will be responsible for analyzing and providing the outcomes from these interviews to the rest of the research team

Aim #3: *To conduct a quantitative and qualitative evaluation of the implementation of INTERACT in order to characterize the fidelity with which CLCs in the intervention participated in training, engaged in regular conference calls, undertook root cause analyses identifying why hospitalizations occurred and used the other tools in which they were trained.*

The proposed documentation of the implementation of the INTERACT intervention will have both a quantitative as well as a qualitative component. We will rely upon the data recorded as part of the documentation of the intervention process to characterize the extent of adherence to INTERACT over the course of the training period and across the participating CLC sites. Each site will be characterized in terms of the following: percentage of direct care staff who initiated and completed the on-line training; the percentage of training calls attended by the Champions; the proportion of hospitalizations for which a root cause analysis was completed by the nursing staff; and the number of SBAR and Stop & Watch tools reported on by the Champions per week. To document changes in the intervention from the beginning of the training period to the end of the monitoring period, we will calculate some metrics on a monthly basis to share with the CLC, allowing for the likelihood that the level of adherence of the intervention will change over time, presumably rising throughout the 6 month training period and

beginning to decline during the monitoring period.

The qualitative component of the intervention will be undertaken throughout the monitoring period during the numerous regularly scheduled calls with CLC representatives. An audit trail of anecdotal feedback derived during these calls will be kept in a restricted folder on the SharePoint which only Providence Research staff on this project will have access to.

We are aware the data may be impressionistic and may not accurately reflect the variation in how the intervention was implemented over the duration of the project. However, having information on the utility of the INTERACT tools, how they were used in practice, and how that use changed from the start of the active 6 month training period compared to the 12 month monitoring period will be very valuable in ascertaining fidelity to INTERACT protocols and uptake of intervention. This may help explain possible differential results between facilities.

Aim #4: *To test the effect of the INTERACT intervention on the rate of reduction in hospitalizations from intervention CLCs as compared to the matched control CLCs and to determine via a formalized structured implicit review (SIR) process whether the intervention was associated with a reduction in "avoidable" hospitalizations and that it did not lead to negative outcomes like mortality and ADL decline*.

We will test the effect of INTERACT on the rate of hospitalization from CLCs taking advantage of *both* the paired control CLCs as well as the differences in the hospitalization rates among intervention facilities before and after the implementation of the intervention. The primary outcome variable is the monthly rate of hospitalization, which, after adjusting for seasonality and trends in the rate over several years prior to the intervention, is compared to the rate of the paired comparison CLC. To allow for regional differences in seasonality, separate ARIMA models will be run for each CLC and then we will use the monthly difference between the observed to the expected CLC hospitalization rate value to compare between the two matched CLCs, aggregating these differences overall pairs. Technically, the average monthly rate of hospitalization before the intervention will be compared to the average monthly rate after and the difference between these two rates will be compared to the differences in the rates of the comparison facilities, using a standard *difference in difference* design.

A similar approach will be used with the person level, risk adjusted hospitalization rates for short and long stay residents calibrated as an annualized rate and there will be fewer facility years than were facility months under the approach described above. The unit of analysis will be the CLC resident but the standard errors will be clustered at the facility level.

Using the results of the Structured Implicit Review process, we will determine the percent of hospital transfers rated as avoidable through better quality of preventive care and early change recognition and the percent rated as inappropriate because the Veteran's condition could have been safely managed in an average VA CLC. We will compare the percentage hospitalized before the implementation to that after implementation. The sample size of 326 hospitalization records, 163 pre and 163 post-INTERACT, is based upon the assumption that the pre-intervention rate of potentially avoidable hospitalizations will be 40%. For the overall project, we are hypothesizing that there will be a 20% reduction in hospitalizations. Logically, the reductions in hospitalizations will come primarily from the "avoidable" type (otherwise we have a causal inconsistency). Thus, if 40 of 100 hospitalizations pre INTERACT are avoidable and all of the 20% reduction in hospitalizations (20 of 100) will come from among those that are avoidable, we expect a 50% reduction in the rate of avoidable hospitalizations. So, if the pre rate is 40% and the post rate is 20%, using a one tailed test at the alpha .05 level, we need about 100 records

before and 100 after to achieve a power of .90. In the event that some "unavoidable" hospitalizations are really avoided due to the intervention, we increase the sample size to 163 per time period.

Finally, we will test for unintended consequences by examining changes in the rates of overall mortality and in the rate of decline in the late loss ADLs, as measured by the MDS 3.0 nursing home resident assessment, which is done upon admission, periodically thereafter and upon discharge.[45]

Random selection of records with a transfer: A total of 326 medical records with a transfer to the hospital and across the eight intervention CLC sites will be reviewed, 163 pre-INTERACT intervention and 163 post-intervention.

The 163 pre-INTERACT records will be selected from a list of transfers that occurred during the 18 months prior to INTERACT being introduced to the CLCs. This list will be compiled by the study programmer/analysts who will pull it from current CDW data and MDS data. Once the list is generated, random selection will occur to obtain 163 records pre-intervention.

A second list of transfers will be generated across the intervention CLCs for the post-intervention period and a random selection of 163 of these transfers will also be selected for review.

Once each set of records is selected, the 326 records will be combined and randomized. The randomized list will be randomly divided amongst the reviewers (and include a randomized portion of the records to be used for training on how to complete the SIR).

Reviewer Recruitment and training: Up to 17 physicians or other clinical experts from within the VA and with a geriatric background will be recruited by Dr. Debra Saliba and her team from LAVAMC. These individuals will be added as study team members and will be required to complete a two-day training (in-person or web based), sign confidentiality and privacy agreement, be provided access through CAPRI (Compensation and Pension Record Interchange) /VistaWeb to the 8 intervention sites through an amendment to the DART DUA for this purpose, provided access to a secure restricted folder within the Providence VA Research Server and access to their secure SharePoint.

To avoid the use of INTERACT influencing the reviewers' structured implicit review we will NOT recruit anyone from our existing CLC intervention sites.

After the reviewers complete their assigned chart reviews they will participate in a debriefing with the LA team, notifying them about the use of INTERACT as the QI intervention and the impact their reviews will have on determining INTERACT's effectiveness at preventing 'avoidable' hospitalizations from occurring within the CLCs.

The reviewers will be trained to use CAPRI/VistaWeb to complete the chart reviews. CAPRI/VistaWeb provides a standardized, user-friendly method to access the charts for review within VA.

Structured Implicit Review (SIR) Procedure: Each reviewer will be randomly assigned an equal percent of the 326 charts to review based on the number of reviewers. The charts will be randomly assigned, from across the intervention sites to the reviewers. The reviewers will not be provided any specific information about the intervention conducted using INTERACT or any indication of whether it was a pre or post intervention chart.

The reviewers' will then complete their review of the charts using the SIR Instruction Manual and Guide (See Appendix 7, Structure Implicit Review Instructions and Guide). They will utilize access to a

restricted folder within the Providence VA Research Server and PKI encryption by email for this purpose throughout the process to do the reviews and share information with the research team, from Providence and LAVMC related to assistance with the SIR process.

The reviewers will complete each review using the SIR Instructions and Form (appendix 7). They will save each review to the secure designated restricted folder. If they choose to hand write their responses, they will scan the original review in and save on the secure restricted designated folder or send encrypted (PKI) to the project coordinator in Providence to be stored on the secure restricted folder within the Secure Providence VA Research Server. The original hand written copies will be stored locally in a designated locked location by the reviewer for the specified time frame noted in RSC-10.

While the reviewer will have access to complete medical records, only specific identifiable information from any medical record will be shared with the research staff (from Providence and LAVMC) to assist them in making sure they are accessing the correct record prior to their reviews. That information would include the Veterans name, Date of birth, last four of SSN, treatment dates being reviewed and the information contained in the Review Form (appendix 7).

REDCap may be used to input the reviews for analysis. The reviews would be input by Providence VA research team members, stripped of any identifying information and used to confirm the hypothesis that a reduction in avoidable hospitalizations was accomplished by the use of the INTERACT intervention, specifically the use of the SBAR change in condition progress note within CPRS. Review by the local privacy officer and local ISO confirms that the use of REDCap for the requested data is acceptable and within the guidelines of use.

REDCap is a secure data storage method. We will use this data storage option because it provides: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources**.**

Aim #5: *To conduct a Budget Impact Analysis (BIA) of the INTERACT program from a VA perspective, using the 2-year study follow-up period as the time horizon. Given the important public policy implications for Medicare, we will conduct a secondary BIA from the perspective of the entire Federal Government. The purpose of the BIA is to provide VA managers with the budget impact information they need to manage the start-up and implementation of the program if this project demonstrates that INTERACT works in VA.* Preliminary non-VA studies have found INTERACT to save more than 15 times the cost of the intervention. Thus, even if INTERACT is less effective in VA, it still should yield significant savings.

The BIA will be driven by the other Aims' estimates of the VA effectiveness of INTERACT. As part of the intervention, we will carefully track both the start-up and on-going labor associated with INTERACT. Actual VA labor costs will be used to value this time. The cost savings of the program are not directly observed as they are the hospitalizations that INTERACT prevents, and thus must be estimated. We will obtain data on all VA and Medicare hospitalizations and other types of care. VA costs will be obtained from the DSS fee-basis files, and the Medicare reimbursement will be used as the estimated costs of non-VA care. The first analysis will be to compare the hospitalization costs between the intervention and control sites, including looking for offset effects for other types of care (reduced hospitalizations being partially offset by higher costs for other types of care, including higher costs in the CLC).

We will conduct a full sensitivity analysis of the estimated savings, of how quickly they accrue, and of potential off-setting cost increases. The extent of the savings will be driven by how the intervention affects both the rate of hospitalization, and of the types of hospitalizations (costs vary significantly by the types of conditions treated). Another concern is that the DSS cost estimates include fully allocated overhead costs. The details in the DSS cost data will be used to provide information about how the potential cost savings are distributed across variable direct care costs (e.g., supplies and nursing labor), costs that can only be changed over time (e.g., reallocation of space to other types of care), and allocated overhead costs that will not change with the program.

Statistical Considerations:

We estimate our power to detect an expected decrease in hospitalization rate over a 24 month period using simulation analysis, over different scenarios with different sample sizes (# of CLCs), to predict the expected power of our pair matched experiment. Previous research reveals that a Auto-Regressive Moving Average (ARIMA) model characterizes hospitalization rate trends with high accuracy. In our simulations analysis we assume that each CLC's rate follows an ARMA(2,2) model of the following form:

$Y_t = c + \grave{o}_t + \sum_{i=1}^{2} \rho_i Y_{t-i} + \sum_{i=1}^{2} \theta_i \grave{o}_{t-i}$, where ρ_i the correlation of the current to the previous i months, θ_i is the parameter that describe the effect of the error at time t-1 on the current hospitalization rate, ε_t is normal random with mean zero and standard deviation of σ_ε and c is the overall expected hospitalization rate. The simulation analysis included 5 parameters: 1) the sample size in the treatment group; 2) an increase/decrease in the hospitalization rate variance σ_ε (F); 3) the size of the effect (c); 4) the accuracy of the decrease $\sigma_{c;}$.; and, 5) the variability of ρ_i, θ_i of the nursing home that received treatment from the matched nursing home that received control σ_d. For each configuration of the five parameters, the following algorithm was repeated for 100 times: 1. a sample of n yearly hospitalization rates was chosen from currently observed empirical hospitalization rates and assigned to treatment and control CLCs; 2. sample ρ_i's, θ_i's from the above ARMA(2,2) model randomly generated for each of n treatment CLCs; 3. for each i treated nursing home we perturbed the ρ_i's, θ_i's by a factor of σ_d, and assigned them to the pair matched control CLC; 4. generate 2n ARMA processes using the ρ_i's, θ_i's generated in step 2 and 3, and the variance σ_ε/F; 5. decrease the hospitalization rate in the treated group gradually by 5c% to 20c% over 24 months + random deviation of σ_c; 6. calculate the monthly differences between the treated nursing home hospitalization rate to its matched control, and average across 24 months (τ_j) and calculate the standard error σ_τ ; and finally, 7. use the average and variance calculated in 6 to obtain overall weighted average $\frac{\sum_{j=1}^{J} \frac{\tau_j}{\sigma_{\tau j}}}{\sum_{j=1}^{J} \frac{1}{\sigma_{\tau j}}}$ and its pooled variance $\left(\sum_{j=1}^{J} \frac{1}{\sigma_{\tau j}} \right)^{-1}$.

To find the factors with the largest effect on power, we calculated the MSE of all the main effects and their interactions. The F, n and c are factors that capture 93% of the variability in the data. Figure 1 shows how the # of CLCs and F (variance of hospitalization rate) affect the power of our analysis. . Even if the monthly reduction in hospital rate will be as low as 10%, using 8 treatment CLCs will result in .77% power.

Figure 4: Power Estimates, Number of CLC's by Effect Size and Variance in Monthly Hospitalization Rates

Effect	20% Reduction in Hosp. Rate	10% Reduction in Hosp. Rate

size										
# CLCs	6	7	8	9	10	6	7	8	9	10
.5	1	1	1	1	1	.99	1	1	1	1
1.0	.98	.99	.99	1	1	.7	.74	.77	.81	.84

Preliminary Studies:

The investigative team assembled to undertake this study is exceptionally strong and well suited to implementing the proposed study. Dr. Mor has been studying nursing home quality and the clinical, organizational and policy factors associated with the hospitalization and re-hospitalization of nursing homes for almost two decades in the Medicare and Medicaid environment.[2, 46-48] He has extensive experience managing large scale, multi-faceted and interdisciplinary research projects having had an NIA funded MERIT award and PI of an NIA Program Project grant making him well suited to direct this talented group of co-investigators on a complex intervention study. With funding from the VA HSR&D Center of Excellence for the Study of Healthcare Provider Behavior, Dr. Saliba developed the SIR instruction manual and form based on literature review, expert panel input into elements, a conceptual model for nursing home to hospital transfer and pilot testing. Reliability testing in 100 transfers from 8 nursing homes to 10 hospitals showed that SIR methods demonstrated high inter-rater reliability for judging whether transfer could have been avoided.[5] The SIR form was revised based on input and questions from participating reviewers and was used in the Georgia QIO test of IMPACT.[3] Additionally, Dr. Saliba was the author of the MDS 3.0, leading an interdisciplinary group of clinicians and scientists in testing and reviewing the evidence for reliable and valid assessment items in both community and VA facilities.[36] In addition to his extensive research outside of VA settings, Dr. Ouslander did his Geriatric Medicine Fellowship at the Sepulveda VAMC, and subsequently served as the medical director of that facility's CLC. He directed the Atlanta VAMC Rehabilitation Research and Development Center and served as an investigator in the Birmingham-Atlanta VA GRECC. During that time he successfully conducted a multi-CLC study of an exercise and incontinence intervention. Orna Intrator, Ph.D. is an applied mathematician, health services researcher who is a funded VA investigator studying use of long term care services by Veterans both within and outside of the VHA. She has been a long-time collaborator with Dr. Mor examining nursing home hospitalizations and developed of the Residential History File in both the Medicare and VHA environment.[12, 19, 49] Ciaran Phibbs is a health economist with a long time interest in estimating the cost of medical interventions, particularly for the chronically impaired.[50, 51] He has integrated multiple sorts of health care utilization records in characterizing the costs of mental illness and experienced by women Veterans.[52, 53] Dr. Dan Berlowitz is an experienced physician health services researcher who is one of the most experienced researchers in the long term care arena in the VA having done seminal research on the predictors of pressure ulcers, the measurement of nursing home quality indicators and the use of multiple pharmacologic agents by the frail elderly.[54, 55]

Examination of CLC Hospitalization Rates has been undertaken using the linked SAS and Medicare files for the year 2008. We accumulated all hospitalizations of Veterans directly from the CLC, both those occurring in VAMCs and those occurring in Medicare reimbursed hospitals. Given the relatively high use of Medicare hospital services in other VA populations, we were surprised to see that only 7% of all hospitalizations of Veterans in CLCs occurred outside of a VAMC. As expected, this varied from a high of nearly 50% in a small CLC to virtually no non-VAMC hospitalizations in many large CLCs. We calculated the number of acute events per Veteran and constructed the rate of hospitalization defined as the number of hospitalizations per person year. We did this by applying the Residential History File

algorithm initially developed using Medicare files and recently applied to VHA data by Dr. Intrator.[56] Across all CLCs, we found that there were .35 hospitalizations per Veteran but 23.5% of Veterans ever in the CLC in 2008 were hospitalized, suggesting that some individuals were hospitalized many times. Indeed, we find that the observed hospitalization rate is 1.3 per person year, ranging from a high of 1.1 to a low of .1! Both of these outliers had relatively few patient days suggesting that they house relatively few patients at any given time. In spite of these outliers, we should be able to effectively match CLCs with hospitalization rates in the mid-range.

Limitations:

Like all research studies, ours has various limitations. First, our design requires comparisons over time and between our intervention and control VAMCs under which we assume no other competing forces such as policy changes that might confound our interpretation. Secondly, we assume that reductions in hospitalization are desirable from the Veterans' perspective and that many of the current hospitalizations of Veterans from CLC are, indeed, avoidable. Third, we assume that CLCs offered the opportunity to introduce a new training program will be interested in doing so, which, given the strong interest in the private sector, we feel will actually occur. Fourth, we are explicitly treating the introduction of the INTERACT intervention as a quality improvement demonstration which CLCs and VAMC leadership can choose to adopt as an administrative practice rather than as research *per se*. Finally, as noted, it is likely that the intervention would be more smoothly implemented were its documentation features fully integrated into Veteran's medical record, but the complications and cost associated with such a significant local departure from the medical record system may be too great to be borne by a single research project.

Dissemination:

As part of the LTC CREATE, the INTERACT trial is embedded within a broader dissemination structure that has direct access to senior officials within the VHA who are committed to transforming the character of the VHA long term care system to be more Veteran centered and evidence based. This is described in detail in the accompanying CREATE overview. Our principle vehicle for dissemination is the Geriatric and Extended Care (GEC) service and the Office of Patient Centered Care and Cultural Transformation (OPCCCT). Every 6 months the LTC CREATE investigators will meet with GEC and, in consultation with them, determine which insight or finding from a LTC CREATE project will be highlighted and incorporated into a report that Planetree (currently a major contractor to OPCCCT helping to transform the VHA) prepares and which identifies examples of positive instances of transformation around the country. Thus, GEC leadership will be fully engaged in interpreting and then developing a practical implementation strategy for the findings of the INTERACT research program.

Another aspect of our dissemination plan is to publish study results via the academic and clinical journals and to present study results at clinical meetings such as the *American Geriatrics Society, the American Medical Directors Association* and VAHSR&D annual meetings. Since Drs. Saliba and Ouslander are leaders in the geriatrics and long term care communities and Dr. Berlowitz is a well-known figure in the VA HSR&D system, we are confident that presentations, including pre-conference workshops, will be well attended since they represent a great draw. As importantly, the whole issue of re-hospitalization and hospitalization from nursing home is increasingly recognized as a major issue in clinical and hospital practice meaning that the results of a trial revealing reductions in hospitalizations among either short or long stay residents would generate great interest among mainstream medical journals.

Management Plan:

Vincent Mor, Ph.D. will serve as Principal Investigator of the proposed project and will be responsible for all scientific and operational aspects of the study. Dr. Deb Saliba will serve as Co-PI and, in addition to being the senior clinical investigator, will be responsible for the implementation of the Structured Implicit Review (SIR) and all analyses related to estimating the impact of the INTERACT intervention on the level of avoidable hospitalizations. Dr. Dan Berlowitz will provide senior oversight to the evaluation design and Dr. Joseph Ouslander, and Nancy Henry, GNP, PhD under an IPA, will be responsible for revising and implementing the INTERACT intervention. Dr. Orna Intrator will direct all the data file and outcome variable construction and will collaborate with Dr. Ciaran Phibbs in creating the outcome and cost data analysis files necessary for the final hospitalization impact analyses and the budget impact analyses. Dr. Roee Gutman will serve as the statistician directing the monthly hospitalization reduction analyses and fitting the ARIMA seasonality models necessary to reduce the heterogeneity of variance in the CLC monthly hospitalization measures. Dr. Mor will lead monthly project status conference calls and speak bi-weekly with Drs. Ouslander, Henry, Berlowitz and Saliba while the INTERACT intervention is underway and bi-weekly with Drs. Intrator, Phibbs and Gutman about the data and analyses. Progress with respect to meeting project milestones will be monitored carefully and difficulties in recruiting CLCs will be discussed with the GEC leadership who are committed to this project.

Figure 5 below presents the GANNT chart for the 4 year project which begins in the second year of the LTC CREATE. The availability of up to date baseline data comes from the other CREATE projects.

FIGURE 5

TASK	**9/13-3/14**	**4/14-8/14**	**9/14-3/15**	**4/15-8/15**	**9/15-3/16**	**4/16-8/16**	**9-16-3/17**	**4/17-8/17**
Select CLCs		**XXXX**	**XXXX**					
RCT IRB		**XXX**	**XXX**					
Adapt INTERACT		**XXX**						
Train CLCs				**XXXX**				
Support CLCs					**XXXX**	**XXXX**		
Create Hosp. Data			**XXXX**	**XXXX**	**XXXX**	**XXXX**	**XXXX**	**XXXX**
Implicit Review							**XXXX**	
Implementation Analysis								**XXXX**
Avoidable Hospitalization								**XXXX**
Impact Analysis								
Budget Impact Analysis								

Personnel:

Vincent Mor, Ph.D. (37.5% Yrs. 1-3, 32.5% Yrs. 4-5): Vincent Mor, Ph.D. will serve as Principal Investigator of the proposed project, responsible for all scientific and managerial aspects of the project. Dr. Mor has managed numerous, large scale multi-site research studies, both observational and

intervention studies. He will coordinate the activities of the intervention teams (Drs. Saliba and Ouslander) as well as the research and data teams (Drs. Intrator, Guttman and Phibbs) via bi-weekly conference calls with monthly combined calls and quarterly calls that include our Geriatrics and Extended Care partners.

Orna Intrator, Ph.D. (15% Yrs. 1-5): Dr. Intrator is an applied mathematician and health services researcher who has specialized in the creation of complex, integrated, longitudinal and hierarchical research analysis files that merge Medicare and VA data together. Given the complexities of creating historical, contemporaneous overall, and risk adjusted rates of hospitalization from CLC, Dr. Intrator will directly supervise the programmer and coordinate carefully with Dr. Phibbs to insure that the files necessary to undertake the intervention impact analyses also meet the needs of the budget impact analyses.

Danielle Cote, Project Manager (50% - Yrs 1-5): Ms. Cote will facilitate all communication between the project sites; serve as a liaison between the intervention and the research groups, particularly the work being done under Dr. Saliba's direction of the Structured Implicit Review of "potentially avoidable" hospitalizations. Ms. Cote will file IRB requests; make modifications to these, run interference in the event that participating VAMC CLCs have difficulties with their individual IRB approval. She will be shared half time with the other LTC CREATE proposal emanating from the Providence VAMC for 3 years and in the last year will be 100% on the INTERACT study working primarily with Drs. Mor and Intrator preparing analysis tables, conducting literature reviews and facilitating communication among the investigators.

Amy Mochel, Project Coordinator (100% - Yrs 2-5): Ms. Mochel will serve as a liaison between intervention project sites, other project staff and clinicians. Ms. Mochel will focus on the work being done to implement the INTERACT intervention, assisting sites in adhering to the fidelity of the QI program. She will file IRB requests, make modifications, work with individual IRBs across sites, and produce and file other study related reports as necessary.

Health Research Scientist, TBN (50%; Yrs. 1-4): This individual will work directly with Dr. Intrator applying algorithms from the residential history file to create the Veteran level measures of hospitalization and then aggregating these up to the level of CLC specific aggregated measures of hospitalizations per Veteran day at risk in the CLC. The programmer will also create all the measures of adverse effects based upon the MDS assessments looking at functional decline and other complication rates. The programmer will create analysis files at both the individual and aggregated levels for Dr. Gutman, the statistician who'll be modeling the hospitalization rates and other outcome measures.

Analyst, TBN (12.5% Yr. 1, 25%- Yrs. 2-5): This individual will work directly with Dr. Intrator and the study Programmer to create the Veteran level measures of hospitalization and then aggregating these up to the level of CLC specific aggregated measures of hospitalizations per Veteran day at risk in the CLC. The analyst will assist Programmer in creating all the measures of adverse effects based upon the MDS assessments looking at functional decline and other complication rates.

Ciaran Phibbs, Ph.D. (12.5% Yrs.1-5): Dr. Phibbs is a health economist at HERC who has pioneered the application of Budget Impact Analysis to the world of health care operations and policy changes, moving beyond the world of drugs and devices where the techniques were developed. He will be responsible for conducting the Budget Impact Analysis and will engage the intervention team, relying upon the extensive process data collected and will work with Dr. Intrator to insure that the appropriate utilization

data are available to apply various cost adjustments to them. Most importantly, he will direct discussions with our GEC partners to best determine the appropriate budget assumptions that will be most helpful to them in making the case for broad scale implementation of the INTERACT program if it is found to be effective at an acceptable cost.

Brian Mittman, Ph.D. (5% Yrs.2-5): Dr. Mittman is an organizational and implementation researcher who is nationally recognized for his leadership in the field of implementation science. He serves as co-editor in chief of the journal Implementation Science and as Director of CIPRS (VA Center for Implementation Practice and Research Support) through which he provides technical assistance, consultation and support to the VA implementation research community to further develop and strengthen implementation science theory, methods and research practice. Dr. Mittman and Saliba have collaborated on projects, including an ongoing VA project to evaluate provider practices and Veteran and caregiver preferences surrounding goal setting for diabetes. Dr. Mittman will serve as co-investigator throughout all of the proposed project phases and assist Dr. Saliba in the design and interpretation of the qualitative interviews to improve the identification of barriers and facilitators to implementing INTERACT.

Debra Saliba, MD, MPH (project co-Principal Investigator; GLA site principal investigator (Yrs.1- 5, 5% In kind): Dr. Saliba is a geriatrician and a research physician in the VA Greater Los Angeles HSR&D Center of Excellence and the Geriatric Research, Education and Clinical Center (GRECC). She also holds the Anna and Harry Borun Endowed Chair in Geriatrics at UCLA and is a senior natural scientist at RAND. Dr. Saliba brings content expertise in assessing and improving care quality for persons with long term care needs, including developing and testing the structured implicit review (SIR) system that will be used as part of the outcome evaluation in the proposed project. Dr. Saliba will serve as co-PI on the overall research project and work closely with Dr. Mor to provide content and methodological expertise across all project phases and to interpret results and conduct dissemination activities. As site PI, she will be responsible for overall conduct of the SIR and the qualitative interviews with providers in participating facilities.

Deborah Riopelle, MS (project manager – 75% FTE years 3 and 4): Ms. Riopelle is a Supervisory Health Science Specialist in the GLA VA with over 17 years of experience managing research projects. She has managed several large intervention and evaluation projects during that time, participating in survey design and administration, IRB application and data safety management, subject recruitment, staff trainings and supervision. In the proposed project, Ms. Riopelle will organize training activities and reviewer recruitment, identify transfer records, maintain reviewer assignment algorithm, assign records for review, track reviews, abstract data from records, maintain communication with reviewers, and organize monthly review calls. She will manage data safety protocols and privacy protections. She will also work closely with Ms. Yosef to
organize staff recruitment for qualitative interviews and will alternate note-taking responsibilities with Ms. Yosef during provider discussions.

Barbara Simon, MA (survey/IRB SPA leader- 5% FTE year 3) Ms. Simon is the COE's expert in qualitative methods (both focus groups and semi-structured interviews) and survey development; her expertise builds on over 30 years' experience in VA, RAND's Survey Group and the National Opinion Research Center (NORC). She worked with Dr. Saliba in the development and testing of the preference and pain interviews for the MDS. For the proposed project, she will work directly with Dr. Saliba to design appropriate interviewer guides for qualitative assessment of INTERACT materials and program implementation and assist with appropriate set up of data security, review storage, and training activities.

Julia Yosef, RN, MS Psychology (survey expert - 30% FTE year 3) Ms. Yosef is a Survey Interviewer and Project Coordinator with the Greater Los Angeles VA HSR&D Center of Excellence who has led both qualitative and structured interviews on a variety of projects, including working in both the pilot and national study for the MDS 3.0 project in VA CLCs. She will work with the team in developing discussion probes, schedule and conduct interviews with providers in the VA CLCs that implemented INTERACT, alternating interviews and note taking with Ms. Riopelle, and will participate in analysis of interview results.

Alissa Simon, MA (survey expert - 4% FTE year 3) Ms. Simon has been working in survey design and development for over 13 years, both for the VA GLA HSR&D Center of Excellence and as a consultant for other entities (UCLA, RAND). She is an expert in survey content, field methods, logic, flow, format, consistency and web programming. Ms. Simon will be responsible for converting the Structured Implicit Review form into a web-based format for reviewer use that will be password access protected and housed on the COE's protected server, compliant with established VA data security protections.

Clinician Reviewers (TBD – 4% FTE) Up to 17 clinicians will be recruited to serve as reviewers.

These reviewers, as credentialed VA staff members, will donate their time for review activities. We will recruit and train up to 17. Although we plan to distribute charts among all recruited for review, we have intentionally recruited a number that could accommodate "drop out" because of changes in appointment status or availability of review... Our goal is to identify reviewers familiar with VA CLCs at non implementation sites and who have clinical experience in identifying change in condition and in making transfer decisions.

Ken Shay, DDS, MS who is Director of Geriatric Programs in the VA Office of Geriatrics and Extended Care will also assist Dr. Saliba in identifying GRECC individuals to serve as reviewers.

Off-Site Consultants

Joseph Ouslander, MD. (20% Yrs. 1-3; 5% Yrs. 4-5): Dr. Ouslander was the developer of the INTERACT quality improvement program. He will supervise Nancy Henry, GNP, PhD and direct his team to initially modify the existing program to be more appropriate for implementation in the VA CLCs by initially engaging the Tampa VA Medical Center CLC staff to offer feedback on best methods for modifying and adapting INTERACT for practical use in VA CLCs and then participate in recruiting and implementing the intervention and training in 8 sites across the country. He will be a participating author in all analyses emerging from this study and will be available to provide instruction in the optimal manner in which the intervention is to be generally rolled out across all VA CLCs.

IPAs

Nancy Henry, GNP, PhD, Senior Project Coordinator will lead the modification and adaptation of the existing INTERACT program for use in the VA CLCs in collaboration with Joseph Ouslander, MD. Before testing the effect of the INTERACT intervention it is essential to work with the Tampa VA Medical Center VA about the best methods for modifying and adapting the INTERACT program for use in VA CLCs. This will involve educating CLC leadership and clinical staff about INTERACT, its website, tools and related education materials to enhance practical use of INTERACT and how best to refine the program to make

it a vital part of improving care for Veteran's in the CLCs; and participate in implementing the intervention and training in 8 sites across the country.

Maria Carolina Rojido, MD, Research Coordinator will assist in the modification and adaptation of the existing INTERACT program for use in the VA CLCs in collaboration with Joseph Ouslander, MD. She will work collaboratively with Nancy Henry, GNP, PhD, Senior Project Coordinator to develop and implement the INTERACT QI program in the CLCs.

Roee Gutman, Ph.D. (10% Yrs.1-4 5% Yr 5): Dr. Gutman is a biostatistician who specializes in observational data analysis and propensity score modeling. He will be part of the data analysis team and will be responsible for undertaking the outcome analyses and specifically fitting an ARIMA model to the hospitalization rates from CLC over the entire study period in such a manner as it optimizes the statistical
power of our test of the INTERACT intervention. He will work closely with Dr. Intrator and Dr. Mor.

Project Team Members

First	Last	Project Role	Site	Access to secondary data (aim #1)	Participating in pilot as described in qualitative aim #2a	Participating in INTERACT Intervention as described in aim #2b
Vincent	Mor	Principal Investigator	Providence	Yes	No	Yes
Danielle	Cote	Project Manager	Providence	Yes	No	Yes
Rajesh	Makineni	Programmer	Providence	Yes	No	Yes
Roee	Gutman	Biostatistician	Providence	Yes	No	Yes
Rouba	Youssef	Analyst	Providence	Yes	No	Yes
Maxwell	Cutty	Research Assistant	Providence	Yes	No	Yes
Nancy	Henry	Senior Project Coordinator	Providence	No	Yes	Yes
Debra	Saliba	Co-Principal Investigator	Greater LA	Yes	No	No
Brian	Mittman	Co-Investigator	Greater LA	No	No	No
Deborah	Riopelle	Qualitative Analyst	Greater LA	No	No	No
Alissa	Simon	Qualitative Analyst	Greater LA	No	No	No
Barbara	Simon	Qualitative Analyst	Greater LA	No	No	No
Julia	Yosef	Sr. Qualitative Analyst	Greater LA	No	No	No
Kisa	Fulbright	Research Assistant	Greater LA	No	No	No

Ciaran	Phibbs	Co-Investigator	Palo Alto	Yes	No	No
Sonji	Blanks	Local Site Investigator	Tampa	No	Yes	No
Carol	Rueter	Local Site Investigator	Tampa	No	Yes	No
Orna	Intrator	Co-Investigator	Canandaigua	Yes	No	No
Dan	Berlowitz	Co-Investigator	Bedford	No	No	No
Maria Carolina	Rojido	Research Coordinator	Providence	No	No	Yes
Amy	Mochel	Project Coordinator	Providence	No	No	Yes
Kristen	Morgan	Research Assistant	Providence	No	No	Yes

Human Subjects:

Risks to Subjects: This proposed project has two different aspects of human subjects research: 1. Use of de-identified, sensitive health data which will be accessed for all Veterans receiving long term care over the period 2008 through 2017; and 2. CLC staff of the up to 15 intervention CLCs which participated in the implementation of the INTERACT staff training and quality improvement program. Our approach to addressing the risks and benefits of the proposed research for each of these two subject groups is described separately in the sections below.

Data Sources and Data Handling*:* There are two major types of data used in this project: Veteran specific data and organization level data. These data will be assembled from existing administrative data sources available either from the VA or from sources assembled by our study team in other studies. All individually identifiable datasets made available by the VHA have a unique identifier, the scrambled SSN, which is a formula-based encryption of the individual's Social Security Number. The identifier is consistent for a given patient across datasets and this project's fiscal years and will enable us to access and link data from all of the data sources required for this project.

All organization level data are identified by either a federal identification number (Medicare/ Medicaid certified community nursing homes), or by their VA site identifier (station). Organization level data include public available data from the Online Survey Certification and Reporting (OSCAR) of Medicare/ Medicaid certified nursing homes, the Area Resource File (ARF) obtained from the U.S. Department of Health and Human Services (http://arf.hrsa.gov/overview.htm).

VA data will be extracted from Austin Automated Center via VA intranet. Following a signed DUA with VIReC/CMS, VIReC will set up a secure share for us to transfer the finder file containing scrambled SSNs of Veterans residing in VA CLCs, as required for the project.

Data Assurances:

Adequacy of Protection against Risk: The procedures described in this section address our efforts to minimize the risk of breach of confidentiality. All research personnel involved in the project will have successfully completed the Collaborative IRB Training Initiative (CITI) at the VA and all other elements of human research protections education programs required by the Providence VAMC.

The primary risk for this study is the potential of loss of confidentiality resulting from a breach of data security. This risk is low. We will reduce this risk by storing the data in a protected location in the Providence VA Medical Center and by not removing the data from this VA location. All data analytic work will occur in the Providence VAMC on the secure cluster present there after VA and Medicare files are downloaded from the VA system in Austin. All personal identifiers are removed from the dataset prior to generating analytic files thus further minimizing the risk of loss of identifiable data.

The Providence COIN computing infrastructure consists of a Windows server (COIN server), accessed via remote desktop sessions and client Windows PCs. Network security is provided by a combination of VA firewalls, local network access controls, and continuous auditing and monitoring for security breaches. Access from systems external to the VA's intranet and COIN server is limited to encrypted channels, e.g. VPN. Access to the COIN server is independent from the general VA network to provide an extra layer of protection.

All VA data are stored on the COIN server, which is maintained and backed-up on a daily basis by IRM personnel. Personally-identified as well as partially-de-identified data housed on the COIN server are restricted to the system analyst at IRM and to the project's programmer and investigator. No data may be transferred to other computers (desktops or laptops) unless they are stripped of all identifiable information. COIN employees sign a VA privacy agreement to ensure confidentiality of all sensitive information, and its violation may result in criminal charges and a fine of from $5,000 to $20,000.

The COIN's computer system is highly secure, and accessible only to authorized users. Within the group of authorized users, access to project data is restricted to critical research support staff and INTERACT Study Facilitators, as well as CLC specific Champions (Champions only have access to PHI from their own CLC site).Data uploaded to the project SharePoint is stored in the VA environment on a secure VA server behind the VA firewall.

Data are de-identified before analytic files are created, providing an additional level of protection. Furthermore, COIN employees have signed an oath of confidentiality, and its violation is sufficient grounds for immediate termination. Finally, analysis results are always presented in aggregate form with minimum cell sizes restricted to greater than 10 in accordance with VHA and CMS Data Use Agreements and policies.

The project will use real time CDW data available from VINCI to provide CLCs with hospitalization rates and mortality data for the selected INTERACT CLCs on a regular basis. The Providence research staff will also track this data for the pair matched facilities and provide aggregate, de-identified data for the Data Safety Monitoring Board.

Data Safety Monitoring Plan:

To ensure the safety of Veterans in the CLC and confirm the intervention is not reducing hospitalizations to the detriment of Veterans' we have created a safety monitoring plan as described below which has been reviewed and signed off on by the Data Safety Monitoring Board (DSMB).

1. We will generate mortality data for all CLC residents in both INTERACT (experimental) and control facilities, charting changes in mortality rates relative to the historical and contemporary mortality rates of paired facilities;
2. The INTERACT (experimental) CLCs will complete SBAR Progress Notes regarding acute changes in conditions for Veterans. These forms are completed by CLC nursing staff when they notice a clinical change in a patients' condition that warrants a discussion with the physician regarding the need for changes in standing orders. There is considerable detail on patients' clinical condition at the time along with information on the disposition of the case;
3. Staff will transfer the names of cases for which an SBAR is completed to Providence VAMC research staff via a joint SharePoint and Providence staff will keep records of SBARs used.
4. The INTERACT (experimental) CLCs, during every other week calls with the site Champions will review the record of all CLC Veteran's for whom an SBAR form was completed during the previous timeframe.
5. During these qualitative interviews/calls with CLC site Champions intervention staff will review cases where a Veteran had an SBAR completed, but was <u>not</u> transferred to the hospital that subsequently dies and/or is hospitalized within seven days of the documented change in condition record. These cases will be further discussed based upon the content of the SBAR progress note. A standardized set of open ended questions will be asked focusing on whether the Veteran should have been transferred to the hospital sooner, based upon the SBAR progress

note, as well as information about the patients' advanced directives and end of life care wishes. (See Appendix # 6, Interview Guide)

These summarized data will be reported to the DSMB on a quarterly basis. The number of hospitalizations and deaths occurring in the Control group of CLCs will also be reported quarterly and cumulatively (See tables below). Additional aggregate data on outcomes will be provided as requested to confirm the intervention is safe for residents and staff.

Appendix 2: Quarterly monitoring report

Quarterly Monitoring Report
Quarter ____
Report Dates: _____ to _____

Experimental CLC Report

*Pair-matched #	(Experimental) Community Living Center ID #	Date enrolled as experimental site	# of hospitalizations	**# of SBAR Communication Tool & Change in Condition Progress Notes completed as part of the INTERACT QI program	# of hospitalizations occurred within 7 days of a SBAR Progress Note being completed	# of deaths	# of deaths occurred within 7 days of SBAR Progress Note being completed	# of unexpected deaths	***# unexpected deaths reported by CLC staff occurred within 7 days of a SBAR Progress Note	*Comment*
1[E]										
2[E]										
3[E]										
4[E]										
5[E]										
6[E]										
7[E]										
8[E]										
9[E]										
10[E]										

*Pair matched # identifies matched experimental [E] and control [C] CLC sites
** *SBAR Communication Tool & Change in Condition Progress Note* is used by VA CLC licensed nursing staff to evaluate and communicate acute changes in condition to MD, NP, and/or PA and document evaluations and communications
*** *Unexpected Death* defined as a death of a Veteran who did not have acute symptoms or signs such as increased fever, increased respiratory rate, decreased po intake and/or semi-comatose state.

Control CLC Report

*Pair-matched #	(Control) Community Living Center ID #	Quarter ____ # of hospitalizations	Quarter ____ # of deaths	Cumulative # of hospitalizations	Cumulative # of deaths
1[C]					
2[C]					
3[C]					
4[C]					
5[C]					
6[C]					
7[C]					
8[C]					
9[C]					
10[C]					

VA Informatics and Computing Infrastructure (VINCI):

As VA and VHA research progresses, large amounts of data are being collected into databases maintained by a variety of investigators, studies, and locations. Individual investigators and multiple databases may lack sufficient resources to ensure consistency and quality control, or a long-term commitment to data storage and access. Therefore, there are less consistent standards for the protection of Veterans data, data quality, and data access compared to a centralized repository. A centralized research data repository, such as the VA Informatics and Computing Infrastructure (VINCI), offers a number of important advantages: Consistent, defined, and transparent security and standards for access to data; a common point of entry for all investigators who use the data; tools for analysis and reporting; tighter and more consistent control over the standards and quality of the data included; and the ability to standardize and update terminology and format as technology and methodology improve. VINCI is a partnership between the VA Office of Information Technology (OI&T) and the Veterans' Health Administration Office of Research and Development (VHA ORD). VINCI provides the storage and server technologies to securely host suites of databases integrated from select national data. These servers reside at the Austin Information Technology Center (AITC), located in Austin, Texas. To ensure the protection of Veterans data, VINCI maintains compliance with the guidelines set forth by Veterans Health Administration (VHA) Handbook 1200.12, Use of Data and Data Repositories in VHA Research and all other applicable VA and VHA policies and regulations. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate (ATO). Access to VINCI resources will be approved in accordance with the requirements of National Data Systems (NDS), VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. Researchers and Operations staff will access the data along with the tools for analysis and reporting in the secure, virtual working environment through a certified VHA network computer using the VA INTRANET (NOTE: VINCI is not accessible through the INTERNET). If not working within a VA or VHA hosted office environment containing VA network access, researchers may access VINCI through an approved Virtual Private Network (VPN) and Remote Desktop application. The remote computing environment will enable data analysis to be done directly on VINCI-CDW servers located at the Austin Information Technology Center, thus keeping all data from being transmitted to local PC hard drives.

Data Collection

VA provides care to veterans at over 1,400 points of care. At the core of virtually all care processes is a broadly scoped and extensively used electronic health record system known as the Veterans Information System Technology Architecture (VistA). VistA provides a longitudinal view for patients receiving care nationwide including diagnosis, procedures, pharmacy, orders, labs, microbiology, physiologic measurements, and text documents. VA uses 128 VistA implementations to provide longitudinal electronic health record services nationwide for more than 25 million veterans historically. The aggregate content of these 128 VistA systems includes just over 1.03 Billion documents (e.g., Progress Notes, Discharge Summaries, Reports) accumulating at a rate of 638,000 each workday; 1.65 Billion orders (+955,000 each workday); 590 Million images (+884,000 each workday); 1.06 Billion vital sign measurements (+729,000 each workday) and 850 Million medication administrations (+607,000 each workday).

VA Informatics and Computing Infrastructure (VINCI) aggregates data sources from individual VistA systems, data from the Regional Data Warehouses for all 4 VA regions, the VA Corporate Data Warehouse, and the VA Health Data Repository and prepares them for research use. Other data published by the VHA Decision Support System (DSS) and Inpatient and Outpatient Medical SAS

(MedSAS) can be requested through VINCI. VA National Data Services and other data stewards regulate the right to use the data, but VINCI facilitates the process. VINCI servers for data, applications and virtual sessions are physically located in the VA Automation Center in Austin, Texas. This secure enclave with 20 racks of high-performance servers and 72 terabytes of high-speed data storage has multiple layers of security to prevent data loss. When study data requested through VINCI is approved for use, it is extracted from source databases and placed in SQL tables accessible only to the research team and VA Automation Center OI&T operations personnel.

The Communication tools and Quality Improvement Tools will be used to track Veterans changes in condition and hospitalizations. During calls with CLC Champions and study clinicians the tools will be referenced to determine if in retrospect, a transfer could have been prevented. A root cause analysis assessment will be performed to determine better practices for future instances of similar conditions. The research team will track data for the pair matched facilities and provide aggregate, de-identified data for the Data Safety Monitoring Board (See page 31).

Natural Language Processing (NLP):

The VINCI application library has a suite of Natural Language Processing (NLP) tools for extracting information from unstructured text. The ability to create textual reports offers flexibility to clinicians for describing symptoms, vital signs, behaviors, attitude, instructions, patient and family history, and much more; but free text is not a data format well suited to the analytical tools familiar to researchers. VINCI has an NLP "Pipeline", a collection of configurable NLP modules available as a Service Oriented Architecture (SOA) within the VINCI processing environment. This SOA pipeline, named V3NLP, is more easily configured than other NLP pipelines and it is easier to adapt existing GATE or UIMA NLP modules to the SOA environment. VINCI and their customers have adapted V3NLP to data patterns specific to the VA and V3NLP has been used for several clinical use cases.

Potential Benefits of the Proposed Research to the Subjects and Others:

Although there are no direct benefits to human subjects, this study would provide information that would assist policy makers and facility administrators. The minimal risks to subjects are reasonable for the importance of the information that will help understand the variation and outcomes of health care transitions. Reducing hospitalizations from CLCs has immediate positive benefits on the experience of Veterans since they would be spared the trauma of unnecessary transfer to hospital. In addition, INTERACT training advances several principles central to culture transformation by promoting Veteran-directed advance care planning and training staff to understand Veteran patterns of daily activities to better identify early warning signs and symptoms of decline.

Importance of the knowledge to be gained:

By assembling and analyzing the linked data it will be possible to perform analyses relating to how the health care system performs to meet the needs of its frail Veterans.

Women and Minority Representation:

The cohort selected for this study will be population based, thus ensuring adequate representation of minorities and women, as represented among the overall veteran population served in nursing homes. According to a recent report, among newly admitted veterans to VHA NHCU between June 1999 and

October 2004, 97% of the population were men, 82% were white, 13% were African American, and 5% were of other racial or ethnic background[25].

Since 2003, the VA has collected self-reported race in compliance with a new federal guideline from the Office of Management and Budget (OMB). In FY 2003 the variables RACE1 - RACE6 were added to the SAS Inpatient Datasets and in FY 2004 RACE1 - RACE7 were added to the SAS Outpatient Datasets to allow for multiple race reporting. These new variables are coded to incorporate both race and method of collection. Hispanic ethnicity is recorded as a separate variable under the new coding. The variable ETHNIC was added to the SAS Inpatient Datasets in FY 2003 and to the Outpatient Datasets in FY 2004. The RACE variable is only partially populated in the FY 2003 Medical SAS Inpatient Main Dataset and is entirely empty in the FY 2004 Inpatient Main Dataset. VIReC conducted a study examining issues related to the transition to the new race/ethnicity data collection standards in the VA [60]. Using Medical SAS Inpatient and Outpatient Datasets for FY 1997 through FY 2002 and FY 2004, the researchers found that the agreement between observer-recorded race before the transition and self-reported race/ethnicity in FY 2004 was high overall and among White and African American (AA) VHA users. This result suggests that observer-recorded and self-reported data for these groups can be used across years without creating serious bias. Observer-recorded race was less reliable for non-AA minorities. The investigators demonstrated that combining those groups to create a higher-level more inclusive group improved accuracy of observer-reported race/ethnicity and that the AA and non-AA distinction provided the greatest agreement between observer- and self-reported race/ethnicity. Consistent with VIREC's recommendation (http://www.virec.research.va.gov/DataSourcesCategory/DataQuality/HSRD_Data_Quality_Alert.pdf), we plan to use race/ethnicity as a 3 level categorical variable identifying Whites, African Americans, and other minorities. For veterans enrolled in Medicare, the Medicare denominator file is considered of good quality with few missing values, and will be preferred to the VHA recorded race/ ethnicity. Other veterans' not enrolled in Medicare who have missing race/ ethnicity information will be examined for evidence of race/ ethnicity in prior year's data.

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