Study Title: Preventing Hospital-Acquired Disability: An Intervention to Improve Older Adult Patient Ambulation

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Overall structure of study team:

The proposed project will be conducted by a multidisciplinary research team comprised of members from Nursing, Geriatric Medicine, Human Factors and Industrial Engineering, Statistics, and Nurse Informatics. Dr. King, a Nurse Scientist and Advance Practice Nurse in Geriatrics and Dr. Steege, a Human Factors and Industrial Engineer, both Associate Professors at the University of Wisconsin- Madison, School of Nursing, will serve as co-PIs. Dr. Jane Mahoney, MD in Geriatrics, University of Wisconsin, Madison, Dr. Roger Brown, Statistician, University of Wisconsin- Madison, School of Nursing, Dr. Jongwoon (Willie) Choi, Associate Profession, University of Wisconsin, Madison, and Dr. Mary Hook, Senior Research Scientist and Nurse Informatics specialist, [REDACTED], will serve as Co-Investigators. Two hospitals in south and southeast Wisconsin will participate as study sites; [Site details redacted]. Both hospitals have an established history of participating in and conducting clinical research, are Magnet designated, and are comparable in bed size. The study sites also have similar nurse to patient ratios, availability of physical therapy to assist with the psychomotor skills training of nurse volunteers and general medical units (where the intervention will be conducted). The Chief Nurse Executives demonstrate buy-in for this study by providing cost-sharing for hiring ambulation aides, providing paid work time for nurses to attend the psychomotor skills training, and providing in-kind support of physical therapy services. University of Wisconsin - Madison (UW) is a world class research institution with over $1,195 million in extramural grant and gift awards for research.

Protocol Synopsis

The overarching hypothesis of this study is that a systems-based intervention to increase older adult patient ambulation will improve functional and healthcare utilization outcomes. This study will use a multi-component intervention, **M**obilizing **O**lder adult patients **V**ia a systems-based **IN**tervention (*MOVIN*), to address numerous barriers that prevent nurses from ambulating older adult patients during a hospital stay. The Specific Aims for this proposal include:

Specific Aim 1: **To test the effectiveness of *MOVIN* to improve functional ability of older adult patients at discharge, and 1, 3, and 6 months post discharge.**

Specific Aim 2: **To test the effectiveness of *MOVIN* to reduce healthcare utilization of older adults at discharge, and 1, 3, and 6 months post discharge.**

2.A: To analyze a return on investment of *MOVIN* based on program costs and health utilization measures across different hospitals.

Specific Aim 3: **To measure change in nurse behaviors and unit culture and identify ongoing system barriers that impact translation of MOVIN across inpatient units and different hospitals**

This will be a multi-site study using an incomplete stepped wedge cluster randomization design across four medical units at two hospitals in different regions of Wisconsin. The primary outcome measure for patient outcomes (aim 1) are functional performance measured with gait speed and self-reported activities of daily living and extent of mobility in various locations. The primary outcome measures for healthcare utilization (aim 2) are length of stay, readmission rate, discharge destination and emergency room visits. Additionally, using billing data to understand use of PT services on the intervention units at pre/intervention/post data collection periods, the following outcome measures for all patients admitted to the study units during the study period will be tracked: admission dates, length of stay, discharge destination, physical therapy utilization.).

The primary outcome measures in aim 3 to evaluate nurse behavior are changes in self-efficacy, frequency and distance of patient ambulation, and characteristics (text verses numeric) of documentation of patient ambulation during pre/intervention/post data collection periods. Additionally, qualitative data will be collected post intervention from nursing staff to determine ongoing system barriers that may affect translation and dissemination of the intervention to other hospitals. Secondary measures that will be used as covariates in the analysis include patient sociodemographic data and the Charlson Comorbidity Index.

Study Design

This study will test the effectiveness of **M**obilizing **O**lder adult patients **V**ia a systems-based **IN**tervention (*MOVIN*) to improve functional ability and reduce healthcare utilization of older adults, measure change in nurse behavior and unit culture for patient ambulation and to identify persistent barriers that may affect translation and dissemination of *MOVIN* to other hospitals.

MOVIN is a multi-component intervention grounded in the PIs research and the literature. The Systems Engineering Initiative for Patient Safety (SEIPS) model and Social Cognitive Theory were used as theoretical frameworks for the intervention. *MOVIN* consists of five components: 1) psychomotor skills training; 2) resources; 3) communication tools; 4) ambulation pathways; and 5) unit culture. The five components of *MOVIN* will all be launched simultaneously. One week prior to launch, a 30-minute mandatory study orientation for all nursing staff will be provided by the PIs. During the orientation, nursing staff will be familiarized with each *MOVIN* component and with the roles of the ambulation aide and unit champion. The intervention will run 14 weeks to assure sufficient time to train all RNs and establish the role of the ambulation aide. The 5 components of *MOVIN* are stated below:

1) *Psychomotor skills training*: The goal of the psychomotor skills training is to increase RN patient ambulation self-efficacy, skill and knowledge. Patient ambulation, is a care task that is designed to enhance registered nurse (RN) knowledge and self-efficacy in falls under RN domain of clinical practice. The psychomotor skills training program is based on Self-Efficacy Theory (Performance Accomplishment, Vicarious Experience, Verbal Persuasion and Physiological Information) and Psychomotor Skill Acquisition (use of observation, physical practice, and proprioceptive and instruction feedback). The psychomotor skills training will consists of two components; 1) a 4 hour didactic session lead by an advanced practice nurse and 2) two separate 6 hour hands on training sessions on inpatients units led by a physical therapist (PT). RNs subjects will receive paid work time to participate in the psychomotor skill training. Ambulation Aides hired by each hospital for the intervention will also participate in the psychomotor skills training session.
2) *Resources:* To maximize the opportunity for patient ambulation additional resources will be placed on each study unit when the unit steps into the intervention cycle. Resources for *MOVIN* include a 1) 1.0 FTE ambulation aide for each study unit/hospital- hired by the hospital; 2) four wheeled walkers will be ordered from central supply at each hospital and kept on the study units for immediate patient/nurse use for patient ambulation and 3) gait belts (standard for all units) located in each patient room. Wheeled walkers will be labeled with unit name and stored in a convenient location on the unit for staff access. The Unit Champion will check the storage location daily to ensure that walkers are present and available for staff use.
3) Communication: The goal of the communication component is to improve and promote unit staff, patient and other healthcare provider communication on patient ambulation. Five mechanisms will be used to enhance communication and provide feedback loops to nursing staff: 1) ambulation whiteboards mounted in each patient room that is visible to nursing staff, other healthcare providers and patients and family members. The ambulation white boards will contain information on types of equipment needed for ambulation, patient level of independence, walking distance and times, patients determined walking goal and plan for the day. 2) standardized shift to shift report protocol

for reporting patient ambulation performance and progression to other registered nurses (RNs), certified nursing assistants (CNAs) and during interdisciplinary rounds (if applicable on the unit). 3) ambulation fields will be built into the Epic electronic medical record system at each hospital. Ambulation fields need to be filled with numeric entries. All nursing staff (RNs, CNAs) document in the ambulation fields. 4) *MOVIN* bulletin board in the nursing staff breakroom used to display unit ambulation goals and total distances patients have walked on the unit during the intervention. The Unit Champion will be responsible for maintaining the bulletin board and for posting achievement of unit ambulation goals and total distances that patients have walked. Distances will be updated weekly on the bulletin board. 5) a weekly newsletter will be sent to all nursing staff and nurse administrators weekly. The newsletter will contain information on ambulation goals and benchmarks achieved for each on the 5 components of *MOVIN*. No patient identifiable information will be present on the flyer. The newsletter will be created and distributed by the Unit Champion.

4) Ambulation Pathways: The goal of have a standardized ambulation pathway is to increase accuracy of documentation of distance patients walk and to have a measure to judge individual patient ambulation progression. The PIs will meet with facilities management for each hospital and discuss installing 10 foot distance markers that are highly visible in the hallways of each unit. The PIs will also request that distance from the patient bed to the bathroom and from the patient bed to the exiting doorway of the room is measured out and mapped onto a unit map for each of the study units. The unit map will be laminated and placed in key locations for each staff access on the study units. Distance markers will be installed on each study unit by facilities management one week prior to launching *MOVIN* on the unit.

5) Unit Culture: The goal of unit culture is to establish patient ambulation as a standard of care and to increase nursing staff accountability for patient ambulation. Establish a unit culture of ambulation will occur by the following mechanisms:

a. Clinical Nurse Specialist on each study unit will serve as Unit Champion. Each hospital has prior experience with using Unit Champions for targeted nursing practice. The Unit Champion along with the Nurse Manager will meet with the PIs weekly for a 6 month time period prior to launching *MOVIN* on the unit to assist with preparing the site. Preparing the site consists of:
    i. Discuss recruitment (patient and nursing staff) schedule and plan for the unit
    ii. Establishing unit ambulation goals
    iii. Establishing weekly incentives for unit staff
    iv. Discussion of best mechanisms for communicating to unit nursing staff whether they are meeting ambulation goals.
    v. Discussion of creating and displaying *MOVIN* Communication Board in unit breakroom
    vi. Discussion of Roles and Responsibility of Unit Champion
    vii. Discussion of process for Unit Orientation to *MOVIN*
    viii. Discussion of location of ambulation equipment (wheeled walkers, distance wheel) on the unit.
    ix. Discussion of policy and procedure for integration patient ambulation content into shift to shift report
    x. Discussion of protocol for standard shift to shift report for patient ambulation

xi. Facilities management updates on placing distance markers in hallways
xii. Discussion on role of ambulation aide and integrating ambulation aide into staffing for the unit. Ambulation aide will be hired 3 months prior to launching MOVIN on the study units and complete all employment requirements for orientation.
xiii. Discussion of process for scheduling RNs who volunteer for psychomotor skills training.

All data related to nursing staff will only be accessed by the PIs and members of their research team. Only aggregated weekly distances that patients have walked on individual units will be provided to the Unit Champion and Nurse Manager for the purposes of updating *MOVIN* Communication Board and for weekly Unit Newsletter.

Design: The study will use an incomplete stepped wedge cluster randomization design which allows for a controlled stepped introduction of the intervention across the four general adult medical units in two hospitals (Hospital 1, 2 units and Hospital 2, 2 units). In the incomplete stepped wedge design, inpatient units are randomly sequenced into the intervention. Only baseline (control period) and 2 follow up data collection periods (intervention and post intervention period) occur for each unit. Incomplete stepped wedge cluster randomized trials are novel study designs that are particularly beneficial for evaluating service delivery interventions, trials using a pragmatic design, when evaluations need to be completed at a system or population level, or it is impractical or cost prohibitive to roll out an intervention across multiple units simultaneously. For this study units are randomly assigned to different starts (6-months apart). Time periods for control, intervention and post intervention are balanced. The risk of contamination is limited because the waiting period between launch on subsequent units is minimal (6 months), the two study units within each participating hospital are located on different floors, and do not share an employee base. Further, introduction and implementation of the program will be unit specific, minimizing any possible treatment spillover to other units.

A simple randomization process (flip of a coin) was used to determine that [Site 1 redacted] will launch first. An additional simple randomization process will be used to select: 1) two units out of the eligible units from each hospital to participate as study intervention units and 2) which of those two units at each hospital will launch the intervention first for that hospital. All eligible units are consistent in type of patient population and age distribution of patients and serve medical older adult patients with multiple co-morbid conditions. Mean LOS for the eligible units ranges from 4-6 days, consistent with a mean LOS of 5 days for non-profit community hospitals nationwide.

Recruitment: Both adult patients and nursing staff will be recruited to participate in the study.

Patient recruitment: Patients admitted to the inpatient units will be recruited seven days a week for physical performance measures, self-report of ADLs, sociodemographic information, medical record review, and follow up data collection post discharge. Consistent with UW- Madison, IRB standards, a nurse from the study unit will identify which patients meet inclusion criteria and approach patients to see if they are interested in hearing more about the study. A list of inclusion criteria will be provided by the PIs to nurses on the study units. Study staff with [Site redacted] electronic health record (Health Link) access may search patient list templates made

available to them as part of their research access to Health Link to help identify potential subjects for study enrollment evaluation. This initial screening activity will occur daily from a computer in the School of Nursing network in Cooper Hall. A list of potentially eligible patients will be shared with the unit charge nurse or manager at [Site redacted]. The research team will verify with the nurse that: The patient can consent- based on the Registered Nurse (RN) clinical judgement; can walk with or without assistance, in not in hospice, lives at home (not in a nursing home) and can speak and understand English. At [Site redacted], RNs perform a neurocognitive assessment each site. This includes determining the patient's level of consciousness, orientation, absence of confusion or altered mental status, appropriateness of speech and other neuro signs such as posturing, pupillary response to light and facial symmetry. If altered mental status or acute behavior change occurs, a Confusion Assessment Method (CAM) is used to determine if the patient is in delirium. Further, RNs conduct a symptomatic behavior evaluation each shift to assess for any agitated, physical, or verbal behaviors that may be an indication of cognitive change or impairment. The Neurocognitive assessment is used by RNs to determine if a patient is ability to consent to procedures and treatment. Once eligibility has been established a unit nurse will approach the patient to ask if they are interested in meeting with a member of the MOVIN research team. If the patient agrees, the research team member will meet with the patient, explain the study, provide a written consent for patient review, answer all questions, and obtain written consent. A copy of the consent form will be provided to patients who agree to participate in the study. Patient recruitment will occur within 36 hours of admission to the unit. All patients who consent to participate will receive a maximum $100 remuneration for participating. Distribution of the incentive will occur during the post intervention data collection period as follows: $25 at enrollment, $25 one-month visit; $25 three month visit; $25 sixth month visit.. In the rare case a patient admitted to the hospital, consents to participation, but then is unexpectedly discharged prior to being a one-day admission (defined by hospital census time), they will no longer be eligible for participation and will receive a form letter stating they are no longer eligible.

Nursing Staff Recruitment: Nursing staff will recruitment will occur through several means: 1) PIs King and Steege will attend unit staff meetings to discuss the study and answer questions. 2) Recruitment/Information flyers will be placed in each staff member's mailbox on the unit. RNs who wish to participate in psychomotor skills training will be instructed to contact PI King or Steege. 3) Nurse Managers from each study unit will provide the PIs with nursing staff email addresses for the purpose of sending an email for the Barriers to Ambulation Qualtric survey and for reminders to staff to complete the survey. Dillman's method for recruitment of surveys will be followed: 1) an initial email from the PIs will be sent out with a link to the Barriers to Ambulation survey, explaining the survey and length of time to complete; 2) one week after the initial email inviting staff to complete the survey and reminder email will be sent; 3) two weeks after the initial email, another reminder email with the link to the survey will be sent to all nursing staff members. All survey responses will be anonymous.

Recruitment of nursing staff (RNs and CNAs) to participate in focus groups: All nursing staff (RNs and CNAs) on the study units will be recruited to participate in focus group interviews. A member of the research team or the PIs will meet with nursing staff during a unit meeting to describe the focus groups and answer questions. A recruitment flyer for the focus groups will be placed in all nursing staff mailboxes on the unit and a flyer will be posted in the staff lounge. PIs contact information will be posted on the flyer.

Recruitment of RNs for Psychomotor skills training (N=60): A member of the research team or the PIs will attend a unit staff meeting to describe the psychomotor skills training and component of *MOVIN* and answer questions. A recruitment flyer for participation in the psychomotor skills training will be placed in RN staff mailboxes and a flyer will be posted in the staff break room. PI contact information will be posted on the flyer. Enrollment in the psychomotor skills training will be based on the first 15 RNs/study that consent to participate in the training. RNs who participate in the psychomotor skills training will receive paid work time (normal hourly rate) to participate. Written consent will be obtained prior to participating in the training.

Incentives for Nursing Staff: All nursing staff will be eligible for unit weekly drawings. Nursing staff will be instructed during the orientation to *MOVIN* that every time they walk a patient, they should place their name on a paper shoe and place the shoe in the *MOVIN* drawing box located at the nursing station. Nurse staff members can place their name into the drawing as many times as they walk a patient. The Unit Champion will draw one name weekly from the box and award the person selected with a $10 gift card. After each weekly drawing the box will be emptied and entrant names will be placed in the document shredding box located on each unit. At the end of *MOVIN*, all nursing staff members names will be placed in a box and one name will be drawn for a FitBit. During focus group interviews light refreshments (beverages, vegetables and dip, fruit, bagels) will be served. All nursing staff on the study units will have to opportunity to participate in unit celebrations. A unit kick-off celebration, which includes a meal for the unit and *MOVIN* swag (lapel pins, pens), will be provided on launch day of *MOVIN* for each unit; four unit ambulation goal achievement celebrations will be held/study unit; and a final completion of *MOVIN* celebration at the end of the intervention phase will be provided. The PIs in coordination with the Unit Champions will plan for all unit celebrations and drawings for weekly prizes.

Sample: Two separate samples of patients for the pre- and post-test periods will be used for this study. Sample 1 represents pre-intervention/control groups at each unit. Sample 2 represents post-intervention patients at each unit. Data for each sample will be collected over a 6 month time period - including admission, discharge and post discharge at 1,3, and 6 months. A total of 400 patients will be recruited to participate in this study across 2 study sites. At site 1 N = 160 (combined units 1 and 2). At site 2 N = 240 (combined units 1 and 2).

60 RNs will be recruited to participate in the psychomotor skills training component of *MOVIN*. Another sample of 10 RNs and 5 CNAs/study unit for a total of 60 participants will be recruited for focus group interviews (some of these participants may have also participated in the psychomotor skills training.) Additionally, an 80% participation rate of RNs and CNAs on the study units will be targeted for completing 4 anonymous surveys: Barriers to Ambulation, Ambulation Culture, Nurse Fatigue, Professional Quality of Life surveys both pre and post intervention. Total number of potential survey responses is estimated as 527.

Power calculation for patient sample: This study will be powered to adequately assess primary outcomes used to measure patient ambulation performance and function for Aim 1 (gait speed, ADLs and Life Space). As the incomplete stepped wedge cluster design is a randomized trial with multiple time measures, a multilevel general linear mixed model may be adopted to describe the data. The Hemming and Girling program[58] was used to estimate power and sample size for our design. Based on published sample estimates,[12,28] anticipated effect sizes for ADL change were set at d = .52, and effect sizes for gait speed change were set at d =.53, requiring 240 patients (30 patients per unit per cohort (pre/post), 60 total per unit, providing a total number 1200

observations during the trial, to test the primary hypothesis that patients post-intervention phase will have faster gait speeds compared to patients during the control (pre-intervention) phase with power > 0.80 for two-tailed alpha < 0.05. Other studies with hospitalized older adults report a 20% dropout rates. [43,76] But in our prior studies to measure patient mobility performance on inpatient adult medical units we only experienced a 3-10% dropout rate. Due to the higher than expected mortality rates, due to underlying disease process and not the intervention, on Unit 1 at Site 2 we are adjusting our oversampling. We will recruit 60 patient participants per unit pre and post at site 2 only. This increases our total number of patient participants across both study sites to 400. Increasing the patient sample size will provide added insurance to maintaining a sufficient sample size for data calculation.

Sample size justification for qualitative data (focus group interviews): A sample of 60 is more than sufficient for discovery of categories and dimensions nursing staff perceptions of ongoing barriers and facilitators for patient ambulation within their hospital setting. In qualitative research reliance on a priori statistical power estimate are not appropriate. Further, a recent audit of sample sizes for qualitative studies determined a median of 36 subjects as sufficient.

Data Collection:
Patient level: Data collection for patients will occur during their hospital stay and post discharge at 1, 3, and 6 months. A trained research staff member will collect patient level data. The research staff members will be trained by PI King (also an Advance Practice Nurse). It will be impossible to blind the research staff members to the main outcome variables; however, he/she will not be involved in direct patient care and will have limited knowledge of patient's functional status during or after hospital stay, thereby decreasing the risk of potential bias in data collection. Patient data will consist of 1) Physical performance (gait speed measured by a 4 meter walk test), 2) Self report for Activities of Daily Living, Life Space Assessment, readmission to hospital or emergency room visits post-discharge, 3) Medical record review for patient socio-demographic data, Charlson comorbidity index, and discharge destination. In-person patient data will be collected during admission, discharge and at 3 month post discharge. Self-report data will be collected via phone by a research staff member at 1 and 6 month post discharge.

We will be requesting from each hospital study site their HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) raw survey data and the hospitals percentage on how patients responded to response options for individual survey questions. HCAHPS is a nationally publicly available survey that is standardized and validated. The HCAHPS measures patients' perception of care quality and reported quarterly. Patient responses are anonymous. We will ask each hospital to send their HCAHPS data for the time period 6 months prior to implementation of MOVIN, 14 weeks during the intervention, and for a 6-month period after completion of the intervention. HCAHPS Data results will be reported in aggregate form and not by individual hospital site. We will also be requesting for each study site their National Research Corporation (NRC) real-time survey data. NRC is a national survey on patient experiences during their hospital stay. NRC administers a patient experience survey that individuals complete during their hospital stay. NRC Questions are similar to those in the HCAHPS but vary slightly. Receiving data from both surveys (NRC and HCAHPS) will provide a comprehensive capture of the patient experience before, during, and after MOVIN was implemented on the inpatient units participating in the study. Similar to the HCAHPS, we will be requesting from each hospital study site their NRC raw survey data and the hospitals percentage on how patients responded to response options for individual survey questions. The NRC measures patient's perception of care quality and is reported quarterly. Patient responses are anonymous. We will ask each hospital to send their HCAHPS and NRC data for the time period 6 months prior to implementation of MOVIN, 14 weeks during the intervention and for a 6-month period after completion of the intervention.

HCAHPS and NRC data will be reported in publications in aggregate form and not by individual hospital site.

A request will be submitted to both [Sites redacted] to build a retrospective report of select nurse-sensitive patient satisfaction survey questions/responses for each study unit plus one additional unit where MOVIN was previously piloted at [Site redacted]. The patient satisfaction survey will include both the HCAHPS, a CMS required, standardized survey instrument and NRC survey data, a standardized national survey on patient experiences during their hospital stay. Only responses in their database (HCAHPS and NRC) from patients on study units during that unit's approximately 18-month study window (pre, intervention and post) will be provided to the study team. The reports will be deidentified. This data will be used for cost-benefit analysis (Aim 2A).

Nursing Staff Level: 4 anonymous surveys, Barriers to Ambulation, Ambulation Culture, Nurse Fatigue, Professional Quality of Life surveys will be distributed by email to all nursing staff on the intervention units pre and post intervention using Qualtrics. All responses to the survey will be anonymous. Completion of the surveys will be used for implied consent. Focus group interviews consisting of RNs and CNAs will be conducted post intervention in a private office space in the hospital. PIs King and Steege will lead all focus groups. Both PIs have extensive experience conducting qualitative research and leading focus groups. Focus groups will last 30-60 minutes and be audio recorded and transcribed verbatim. Semi structured interview questions based on the SEIPS model, Social Cognitive Theory and *MOVIN* will be used. Interview questions will be open to allow for broad exploration and become more focused to identify themes as the analysis proceeds. Nursing staff who volunteer to participate will be provided an information sheet to review and ask questions about the focus group prior to conducting the interview. Participants will be asked to provide a verbal consent.

Weekly unit-based reports that identify information present in ambulation fields (occurrence of ambulation activity and distance in feet) in the electronic medical record (EMR) will be generated for each study unit from each participating hospital during the pre-intervention, intervention and post intervention phase of the study. Nursing staff complete patient activity fields as part of routine patient care. Both hospitals use Epic's EMR system, which allows for consistency in generating the reports. Content related to use of textual data (up to bathroom or ambulating in hallway) versus use of actual distance (feet) patients ambulate will be collected and a % numeric documentation will be calculated. Frequency of ambulation occurrences per week and a total distance ambulated per week will also be calculated from weekly EMR reports throughout the control, intervention, and post intervention periods for each unit. The PIs used this mechanism to quantify changes in nursing practice and distances that patients ambulated in the pilot study of *MOVIN*. No staff identifiable data will be present on the weekly reports.

Physical Therapy Billing Data (aim 2): A request will be submitted to both [sites redacted] to build a retrospective report of select physical therapy orders and the resulting patient care/billing. This will be a limited data set including an alias for the hospital stay's unique contact serial number, admission dates, indicator whether this was an inpatient or observation stay, length of stay, pt billing codes, and discharge destination. Our existing data tells us on a weekly basis how many patients are admitted on each enrolled hospital unit. From this, we know that there are 14,735 possible hospital encounters during the study period (26 weeks prior to active intervention launch, 14-20 weeks of active intervention, 26 weeks post active intervention). A portion of patients have hospital stays of greater than one week or would have a single hospital stay that would overlap the end of one week and the beginning of another. Therefore, the actual number of encounters shared with us may be less than 14,735. Only data from patients on study units during the unit's approximately 18-month study window (pre, intervention and post) will be provided to the study

team. This will be a limited data set including an alias for the hospital stay's unique contact serial number, admission dates, indicator whether this was an inpatient or observation stay, length of stay, pt billing codes, and discharge destination. Names will not be included in the data set. Data from patients who opted out of the patient outcomes data collection will be removed from the limited data set by the research services staff before being sent to the study team.. The data will include physical therapy orders and billing in the following scenarios: Scenario #1: Physical Therapy (PT) consult ordered and later screened out by PT without a PT evaluation. Scenario #2: PT consult occurs with no PT treatment. This data will be used for cost-benefit analysis (Aim 2A).

NDNQI: A request will be submitted to both [sites redacted] to build a retrospective report of selected National Database of Nursing Quality Indicators (NDNQI) data. The data is aggregated by unit and reported on a quarterly basis. Staffing data includes information on hours of nursing care provided by agency staff, total nursing hours per patient day, and nursing hours by licensure. The data will be used to understand the context in which nursing units were operating during the pre-intervention through maintenance phases of the study.

NDNQI data on patient falls includes total number of patient falls per 1000 patient days and falls related injuries and severity. The data will be used to understand unit-level changes as a result of the intervention.

Data Analysis

Specific Aim 1: **To test the effectiveness of *MOVIN* to improve ambulation ability in older adult patients at discharge, and 1, 3, and 6 months post discharge.**

Introduction to Aim 1: The objective of this aim is to use a system-based intervention that directly addresses barriers to patient ambulation to maintain independent patient ambulation. We will attain this objective by testing *Hypothesis 1a Post-intervention (Sample 2) patients will have faster gait speed at discharge and 3 months post discharge compared to control (Sample 1) patients and Hypothesis 1b Post-intervention (Sample 2) will have a greater positive change in gait speed from admission to 3 months post discharge compared to control (Sample 1). Hypothesis 1c Post-intervention (Sample 2) patients will have higher levels of independence in self-report of ADLs and mobility at discharge and 1, 3, and 6 months post discharge compared to control (Sample 1) patients. Hypothesis 1d Post-intervention (Sample 2) will have a greater positive change in self report of ADLs and mobility between admission and discharge, 1, 3, and 6 months post discharge compared to control (Sample 1).* Upon completion of this study, we will be able to identify the impact of early and consistent ambulation on patient ability to maintain independent ambulation during hospitalization and after discharge

Aim 1 Analysis: Descriptives: Means and standard deviations or frequency distributions for all demographic and clinical variables will be reported as appropriate. Missing data: Initially, Little's test[69] for MCAR (missing completely at random) will be used along with Potthoff[70] and colleagues' assessment of MAR+ (missing at random). Contingent upon either MCAR or MAR missing data, imputation will be considered to respond to the level of missingness and to use the optimal amount of information in our model. In the case of participant withdrawal, all available data will be used (Chakraborty and Gu, 2009). To respond to hypotheses 1a – 1d, a series of general linear mixed models (GLMM) for repeated measures will allow us to assess time specific contrasts (discharge and 1, 3, and 6 months post-discharge) for our measures (Cnaan, Laird, and Slasor, 1997). The outcome measures will include measures of independence in ambulation measured longitudinally to provide a 360 degree view of patient function. *Gait speed* is the gold standard test for measuring functional performance in older adults.[71] Gait speed is a sensitive clinical indicator of health, mortality, healthcare utilization, and independence in ambulation,[72,73] and is feasible to test in hospitalized older adults.[28] A 4 meter walk test will be used to measure gait speed. The model will

also include *Katz ADL Index*, a self-report scale that measures five ADLs on three levels (independent, requiring assistance, and unable to do) and is sensitive to change in hospitals.[61-63] *Life Space* Assessment is a self-report scale of mobility that measures spaces patients move in, the frequency of moving into those spaces, and dependency in moving into those spaces. This scale has demonstrated reliability and predictive validity and sensitivity to change after hospital stay.[64]

Using the GLMM, we will assess the average treatment effect (ATE) of the *MOVIN* program on our model of patient outcomes at each time period using equation (1): ATE = $E(y_t - y_0)$. While we cannot directly apply equation (1), since there may be other factors that affect the treated patients due to the lack of patient randomization to treatment, we will consider matching patients to help resolve the assessment of equation (1). Matching patients on covariates can be difficult as the number of covariates increase. One solution is to use a similarity measure matching approach, which is a statistic that measures how "close" two observations are. Matching estimators are based on the idea of comparing the outcomes of patients that are as similar as possible with the sole exception of their treatment status. The two we will consider are the Nearest-neighbor (NNM) and Propensity-score matching (PSM). We will use Stata Version 13.0 to estimate the ATE in our models. Socio-demographic measures, the *Charlson Co-Morbidity Index*, and *LOS* will be included as covariates.

Specific Aim 2: **To test the effectiveness of *MOVIN* to reduce healthcare utilization of older adults at discharge, and 1, 3, and 6 months post discharge.**

Introduction to Aim 2: The objective of this aim is to determine if increasing patient ambulation impacts length of stay, discharge destination (home or nursing home), readmission and emergency room visits. Our working hypothesis is that *during the intervention phase (Sample 2), patients will have a shorter length of stay, fewer readmissions, emergency room visits and discharges to skilled nursing facilities compared to patients on the unit during the control phase (Sample 1).* Of the few studies conducted on ambulation of hospitalized older adults, only length of stay has been included as a healthcare utilization measure. We will include length of stay and other key measures of healthcare utilization; discharge destination, emergency room use and readmission. These measures will be accumulated over the 6-month pre and post-intervention periods per unit. Simple pre-post contrasts of means and proportions will be conducted. Findings from Aim 2 will provide a greater understanding of the importance of early and consistent ambulation for older adults on healthcare utilization rates.

Aim 2 Analysis: A variant of the above proposed general linear mixed model, the "generalized" linear mixed model will be used to assess unitization counts (e.g., ambulation occurrence) using the Poisson distribution. Proportion of documentation and proportion of discharge to long-term care facilities will be modeled using the Binomial distribution. Time specific between and within group pre and post assessments will be conducted.

Specific Aim 2a: To analyze a return on investment of MOVIN based on program costs and health utilization measures across different hospitals. Analysis: It is critical to demonstrate the cost-effectiveness of *MOVIN* to support adoption. Implementation costs of *MOVIN* will include upfront and maintenance costs. Upfront costs include: training costs (mean salary for nursing staff training and PT trainer time), alteration costs (distance markers) for unit environmental changes, intervention supplies (communication whiteboards), and incentive costs. Maintenance costs consist of annual salary for the ambulation assistant. We will conduct several analyses to assess the returns on investment of *MOVIN*. These returns include both estimated cost savings in terms

of reductions in length of stay and readmission rates. We will also explore cost savings associated with physical therapy utilization using physical therapy billing data. Analysis of returns also include differential analysis (incremental margin analysis) that compares realized benefits to benchmark benefits. For example, given our expectation that *MOVIN* will reduce readmission rates, one potential differential analysis includes a comparison of actual reimbursement amounts in the 30-day post-discharge period to expected reimbursement amounts in the 30-day post-discharge period assuming a patient is readmitted within 30-days of being discharged.

Specific Aim 3: **To measure change in nurse behaviors and unit culture and identify ongoing system barriers that impact translation of *MOVIN* across inpatient units and different hospitals.**

Introduction to Aim 3: The *objective* of this aim is to determine to what extent *MOVIN* influences nursing behavior related to patient ambulation. We will achieve this objective by testing our working hypothesis that *all units enrolled in the study will have higher rates of ambulation, increased ambulation distance, and increased documentation and communication of objective ambulation parameters during the post intervention phase compared to baseline.* A mixed methods approach will be used for this aim.

3.4.8.2 Quantitative Data Collection (3a): Survey and Weekly Reports will be used to collect quantitative measures (see Table 4).The 4 nursing staff surveys: Barriers to Ambulation, Ambulation Culture, Nurse Fatigue, Professional Quality of Life surveys, will be created in Qualtrics and sent via email to unit nursing staff. The RA will attend monthly staff meetings to describe the survey and inform staff as to when they can expect the survey to arrive via email. A unit-based incentive for 80% participation in completing the survey will be offered. The PIs have extensive experience using Qualtrics surveys and used this method in their pilot study of *MOVIN*. Weekly unit-based reports that identify information present in ambulation fields (occurrence of ambulation activity and distance in feet) in the EMR will be generated for each study unit from each participating hospital. Nursing staff complete patient activity fields as part of routine patient care. Both hospitals use [vendor redacted] EMR system, which allows for consistency in generating the reports. Content related to use of textual data (up to bathroom or ambulating in hallway) versus use of actual distance (feet) patients ambulate will be collected and a % numeric documentation will be calculated. Frequency of ambulation occurrences per week and a total distance ambulated per week will also be calculated from weekly EMR reports throughout the control, intervention, and post intervention periods for each unit. The PIs successfully used this mechanism to quantify changes in nursing practice and distances that patients ambulated in the pilot study of *MOVIN*

3.4.8.3 Quantitative Analysis: Regression discontinuity analysis will be used to identify functions and evaluate differences in nurse behaviors related to patient ambulation. Functional models will be estimated based on weekly data for ambulation occurrences, ambulation distance, and percentage numeric documentation across 14 weeks during pre-intervention, intervention and post-intervention phases for each unit. Significant differences in function intercepts and slopes across phases will be assessed from these models to address the research hypothesis for this aim.

Aim 3 Qualitative Analysis: Directed content analysis will be used to determine critical components within the work system of nurses that impact the effectiveness of *MOVIN* and persistent barriers to patient ambulation. We will perform content analysis by following five stages. 1) Transcripts will be read to achieve immersion, 2) transcripts will be read word by word to capture key thoughts and concepts, 3) labels for codes will be created, 4) themes will be developed and organized, and 5) a tree diagram or conceptual model that describes the

interaction among the components of *MOVIN* will be developed. Ongoing system barriers will be identified along with potential strategies to overcome these barriers.

Dissemination Plan: A manuscript from data collected for each Aim will be generated in years 1,2,3 based on data available. 2-3 manuscripts on final results of all data will be submitted for publication in year 4 and 5. We will also present our results at 2 national scientific conferences in years 3-5.To prepare for dissemination of MOVIN to other inpatients units and hospitals, we will create a *MOVIN* toolkit, which contains: 1) an operational manual that describes how to plan, prepare, and implement all *MOVIN* components; 2) evaluation tools to measure organizational readiness for implementation and the impact of *MOVIN*; 3) required templates (e.g., communication whiteboard, weekly flyers, unit newsletters); and 4) job descriptions and role responsibilities for key unit personnel. Given the ongoing emphasis on decreasing health care costs, it is critical to demonstrate the cost-effectiveness of *MOVIN* to support adoption. Implementation costs of *MOVIN* will include upfront and maintenance costs. Upfront costs include: training costs (mean salary for nursing staff training and PT trainer time), alteration costs (distance markers) for unit environmental changes, intervention supplies (communication whiteboards), and incentive costs. Maintenance costs consist of annual salary for the ambulation assistant. Cost offsets in terms of length of stay and 30-day readmission rates will be estimated and included in the toolkit. This toolkit will allow other hospitals to implement *MOVIN* and will be freely available online at UW-Madison HIPxchange. HIPxchange is an open access website dedicated to disseminating evidence-based programs, tools, and materials, and to accelerate the translation of new and existing knowledge into clinical practice to improve healthcare delivery and health outcomes.

We are seeking <$300,000 in direct costs in any given year of the grant period. Based on the NIH Data Sharing Policy and Implementation Guidance accessed at https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#inc we are not required to include a plan for sharing our final research data. The proposed research will include data from 320 patient subjects and 60 nurse subjects from 2 hospitals in Wisconsin. The final data set will include patient self-reported demographic information, physical functional performance measures and healthcare utilization measures. The data set will also include interview data from 60 nurses. How patients perform on the functional performance measures and length of stay along with nursing staff reports of barriers to getting patients up to walk, could be sensitive to the hospitals that are participating. Even though the final dataset will be stripped of identifiers prior to release for publication, we believe that there remains the possibility of deductive disclosure of hospitals that participated. However, if we receive a request for our data we will use the following: We will make the data available to users who are qualified researchers on a case by case bases and only under a data-sharing agreement that provides for 1) a commitment to using the data only for research purposes and to not identify the hospital participant; 2) a commitment to securing the data using appropriate secured servers; and 3) a commitment to destroying or returning the data after analyses are completed.

Following the Clinical Trials Registration and Results Information Submission policy found at: https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission, PI King will register the clinical trial and upload the protocol upon receipt of the award from AHRQ and once approval from the University of Wisconsin-Madison, Health Sciences IRB has been secured. Further in quarter 4 of year 5 PI King will

submit in tabular form, including participant flow, demographic and baseline subject information, statistical results of primary and secondary outcome measures and any adverse event information. Ongoing record requirements (study status updates) will be submitted by the Project Manager hired for this study.

We will also assure that the following language will appear on the written consent forms:

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most the Web site will include a summary of the results. You can search this website at any time

The University of Wisconsin (UW)- Madison, Research and Graduate Education division has an internal policy in place to guide and assure that UW- Madison researchers are compliant with Clinical Trials registration. This policy is available at https://kb.wisc.edu/gradsch/page.php?id=34044.