PROTOCOL TITLE: *Nursing Home Prevention of Injury in Dementia (NH PRIDE)*

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2. SUMMARY AND BACKGROUND

2.1. SUMMARY

We propose to develop and test the implementation of a centralized **Injury Liaison Service (ILS)** to prevent injurious falls in four NH facilities. We will engage stakeholder groups (including NH staff, families, and administrators) and implementation scientists to refine and test the ILS. The ILS will combine successful elements of a Fracture Liaison Service (FLS) and a virtual case based staff education program with the goal of decreasing injurious falls in nursing home residents. ***This service delivers guideline-recommended fall prevention and osteoporosis care consistent with quality improvement initiatives; study activities are limited to data collection to evaluate this program.*** Our central hypothesis is that the ILS model will reduce *injurious falls* by changing care delivery in 2 areas: deprescribing psychoactive and cardiometabolic drugs to reduce falls, and increasing osteoporosis treatment to prevent injury in the setting of a fall.

2.2. Background and Significance

Burden of injurious falls in the NH: The incidence of falls in U.S. NHs is extraordinary: 150 falls/100 bed years.[1] Consequently, falls are the leading cause of hospitalization and ED visits among NH residents.[2] Five to eleven percent of falls in the NH result in major injury, defined as a fracture, joint dislocation, laceration requiring sutures, or serious hemorrhage.[1,3] Approximately one-half of injurious falls are fractures.[3]

Injurious falls are costly: the annual direct cost of managing hip fractures alone in U.S. NH residents exceeds $665 million.[4] For a single, average sized NH, the annual direct cost of injurious falls may equal $284,000.[5] In addition, injurious falls lead to pain[6], functional decline,[7,8] diminished quality of life,[8] and frequent litigation. CMS has determined that the proportion of NH residents experiencing an injurious fall is an important quality metric,[9] yet no standardized approach to prevent injury exists.

Efficiently target the intervention: A practical approach to preventing injury in the resource-constrained NH environment requires identification of residents at greatest risk for targeted interventions. Previously, our group published a model that estimates the two-year risk of hip fracture in NH residents: Fracture Risk Assessment in Long term care (FRAiL).[10] This model is derived entirely from data collected for the validated[11-16] and routinely collected in all nursing homes through the Minimum Data Set (MDS). The model identified a unique pattern of risk factors for hip fracture not seen in community dwellers: the strongest predictors of fracture were related to falls, rather than bone mineral density (e.g., falls history, wandering). In the derivation sample, the concordance index (C-index) was 0.71 in women and 0.69 in men. We have validated the model to predict the two-year incidence of non-vertebral fracture and hospitalized injurious falls, and model performance is similar (C-index for non-vertebral fracture=0.66; for hospitalized injurious falls=0.65).

Medication management prevents injurious falls: In order to prevent injurious falls it is necessary to 1) remove modifiable risk factors for falls, and 2) manage osteoporosis such that a fracture is less likely to occur in the setting of a fall. Medications are one of the most common and modifiable risk factors for falls and osteoporosis in the NH.

Deprescribing: Strong evidence from clinical trials supports deprescribing (i.e., discontinuing or reducing the dose of) psychoactive[17,18] and probably cardiometabolic drugs[19,20] as an effective strategy to prevent injurious falls in NH residents. In one study, seven pairs of NH facilities were randomized to receive individualized assessments from an external, multidisciplinary team.[18] Recommendations included psychoactive deprescribing. The authors achieved 46% adherence with deprescribing recommendations, and a 19.1% reduction in recurrent fallers. The intervention reduced the rate of injurious falls by 31.2%. Among older community dwellers,

reduction of psychoactive drugs resulted in a 39-66% reduction in recurrent falls.[17,21] Two observational studies have demonstrated a reduction in falls and orthostasis after deprescribing cardiometabolic medications in older adults attending falls clinics, and systematic reviews provide moderate evidence of benefit in a lower risk community population. [22] This benefit is likely greater in a NH population, who are at higher risk for hypotension, hypoglycemia, and orthostasis.

Osteoporosis Treatment: Osteoporosis treatment rates are extremely low in NH residents, even among patients at high risk for fracture.[23] This is concerning given evidence to suggest that treatment is probably cost effective in persons with life expectancies as low as 2 years.[24] In a large sample of NH residents, we compared the incidence of hip fracture in new bisphosphonate users as compared with new calcitonin users, matched 1:1 with propensity scores (n=10,418). New users of bisphosphonates had a 17% reduced risk of hip fracture (95% CI, 0.71, 0.98) over mean follow-up 2.5 years *(under review).* These findings are consistent with small trials that suggest bisphosphonates may reduce the risk of clinical fracture[25] or vertebral fracture[26] in NH residents. Further, calcium and vitamin D supplementation has been shown to decrease the risk of non-vertebral fracture by 32% over 18-months in a large RCT of ambulatory NH residents.[27]

Overcoming implementation barriers: One of the biggest barriers to implementing clinical guidelines in the NH setting is lack of staff knowledge.[28] Our team has experience using a case-based video-consultation program designed to provide geriatric expertise in the care of dementia residents to community-based NHs.[29] Among the 11 facilities that received the video-consultation program (ECHO-AGE), staff reported improved knowledge of non-pharmacologic strategies to manage behaviors with dementia. Further, facilities receiving ECHO-AGE were less likely to use physical restraints (OR= 0.25, 95% CI 0.06, 1.04) and antipsychotic drug prescriptions (OR= 0.83, 95% CI 0.68–1.02) as compared with residents in the 22 matched facilities with usual care.[30] We propose to incorporate a virtual case based staff education program to improve education regarding medication management and falls prevention in residents with Alzheimer's Disease and Related Dementias (ADRD).

Ineffective communication between front-line providers and interdisciplinary staff is another major barrier in implementing individualized, multifactorial injury prevention strategies.[28] Successful intervention programs in the NH must change care philosophy,[31] which requires strong communication among all members of the interdisciplinary NH team. We have previously conducted a number of trials to optimize medication prescribing and prevent falls in the NH setting.[32-34] Our proposed model will use a centralized Injury Prevention (IP) Nurse and the virtual case based staff education program to develop an Injury Prevention Plan which reflects staff/resident/family and provider input. The Injury Prevention Plan uses a standard template, but it is individualized to each resident. This template will allow the physician or nurse practitioner to easily review, modify, accept or reject the proposed recommendations. As part of Aim 1, we will interview patients or their proxies, nursing assistants, nurses, and medical providers in order to identify key barriers to communication, and a human factors expert will help work with our team, including implementation scientists, to enhance communication during implementation.

In the current proposal, we will refine and test the implementation of a *centralized Injury Liaison Service (ILS*) to prevent injurious falls in the NH. Key features of the ILS are depicted in **Figure 1**. The FRAiL model will be used to automate identification of residents at highest risk for injurious falls. The ILS will include a nurse who

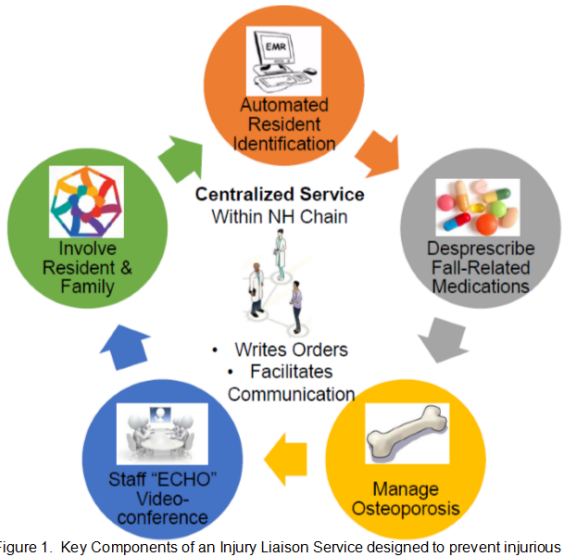

Figure 1. Key Components of an Injury Liaison Service designed to prevent injurious falls in Nursing Home Residents

works remotely across multiple facilities with support from a part-time Interdisciplinary Team in order to make medication recommendations to prevent injury. Among high risk residents, the IP nurse will coordinate deprescribing of fall-related medications, osteoporosis management, staff support of behavior management using video case conferencing, and shared decision making with residents and/or families.

2.3. Study Design

This protocol describes refinement and pilot testing activities for the Injury Liaison Service outlined above. The following study designs will be employed:

1. **Qualitative interviews** will be conducted with approximately 10 NH staff (i.e., nurse, certified nurse aide (CNA), physician, and nurse practitioner who have been employed in a nursing facility for at least 3 months) to gain a better understanding of effective and non-effective injury prevention strategies. Information from these interviews will be used to refine the program during co-design meetings with key stakeholders
2. **A non-randomized pilot program in four nursing home facilities** will provide data on the implementation of the ILS Program. This includes cross-sectional measures of acceptability, demand, practicality, and feasibility obtained from the electronic medical record (EMR), the IP nurse, and a **post intervention survey** with approximately 60 staff across the four facilities. A **pre-post study design** will be employed in order to measure the safety and efficacy of the ILS Program. Safety and efficacy outcomes will be measured at the resident level.

2.4. Outcome measures. The list of measures, data source, and targets are summarized in Table 1 and described in detail below.

Table 1. Proposed Measures of Implementation, Efficacy, Safety, and Validity with Data Source and Target/Goal

Type	Outcomes	Data Source	Target/Goal
Implementation			
Acceptability	Family acceptance of recommendations	IP Nurse Tracking, staff survey	≥ 50%
	Provider acceptance of recommendations		≥50%
	Provider satisfaction		≥80%
	Staff participation in virtual case based education program		10 staff/NH/mo.
Demand	Proportion eligible for intervention	IP Nurse Tracking	20%
	Proportion of high risk residents with deprescribing recommendations		50%
	Referral rates to virtual cased based education program		15%
Fidelity	Proportion of targeted staff completing intervention checklists	IP Nurse Tracking	90%
	Cost of IP Nurse per resident		$225

Practicality	NH staff time	IP Nurse Tracking, staff survey, EMR	<2 hour/mo.
	High-risk Resident 6-mo attrition (death, leave NH)		<40%
Fidelity/Safety			
Fidelity	No. of deprescribed medications at 3-6 months	EMR	≥1
	Osteoporosis medication initiation		70%
Safety	Behaviors	MDS	<10% increase
	Functional Decline		
	Unscheduled medical visits	EMR	≤2/facility
Validation			
Outcome Measure	Injurious falls	MDS and Chart Review	>90% sensitive, >95% specific

Acceptability: **(Primary)** Number of families that accepted one or more medication recommendation/ number of families offered a recommendation; Number of patients where the provider accepted one or more recommendations / number of patients with a medication recommendation; % of staff that indicated they were satisfied or very satisfied with the ILS; proportion of staff that attended one or more virtual case based education sessions **(Secondary)** number of total medication recommendations accepted/ total number of medication recommendations; proportion of staff that attended two or more virtual cased based education sessions.

Demand: We will use the FRAiL model to identify residents at greatest risk of injurious falls who are eligible for the ILS Program. Residents with an estimated 2-year risk of hip fracture of ≥5%, or similar target, will be considered high risk and eligible for the program. The facility staff will also be able to refer other at risk patients for participation in the program. Other demand outcomes include the proportion of high risk residents with one or more deprescribing recommendations or with a recommendation for osteoporosis treatment, AND referral rates to virtual case based education sessions, defined as the proportion of high risk residents discussed in these sessions.

Fidelity: At each facility, we will identify targeted staff including nurses and medical providers (physicians, nurse practitioners, or physician assistants) who will be asked to complete the program checklists. Our primary measure of fidelity will be the proportion of staff that complete ≥ 75% of requested checklists. As a secondary fidelity measure we will examine the proportion of resident checklists completed by a provider.

Practicality: We will estimate cost by monitoring the amount of time the IP nurse spends on each eligible resident. Other outcomes include the estimated amount of time the staff spend on the ILS service by self-reported survey AND the six-month attrition of eligible residents from the NH facility due to transfer, discharge to community, or death, as determined by the IP nurse from chart review.

Fidelity: Fidelity will be measured as the average number of medications that were deprescribed at 1 and 4 months among high risk residents, as well as the proportion of high risk residents with a prescription for an osteoporosis medication at 1 and 4-months. The IP nurse will review the EMR to determine medications at 1 and 4 months after medication recommendations are finalized.

Safety: Detailed resident-level data collection includes the following potential adverse events related to medication changes: 1) escalating behaviors, worsening depression, or functional decline following psychoactive deprescribing; 2) unplanned medical visits for hypertension,

tachycardia, or hyperglycemia for cardiometabolic deprescribing; 3) new gastroesophageal reflux disease or esophagitis following bisphosphonate prescription.

Each facility will provide two Minimum Data Set (MDS) assessments following baseline in order to characterize the occurrence of these adverse events. Behaviors and depression will be measured using validated scales from the MDS.35,36 Any worsening of behavior (any category) as assessed by nursing will be considered. Worsening depression will be defined as a 1-point increase in the PHQ-9 or PHQ-9-OV. This corresponds with meaningful change in depression severity.37 Any increase in the frequency of reported verbal, physical, or other behaviors will be considered. Functional decline will be defined as a 3-point increase in the MDS Activities of Daily Living Scale. A 3-point increase corresponds with complete loss of a single ADL or incremental loss of 2 ADLs.[38,39] Change in depression, behaviors, and functional status will be measured using the MDS assessment closest to and preceding implementation and the subsequent MDS assessment.

Lastly The IP nurse will enter all targeted adverse events into the RedCap database. At the next study team meeting, or within 14 days, the IP nurse will review the event with the team for a determination of an adverse event using the validated Drug Withdrawal Probability Scale[40,41] to determine if there is a probable, possible, or doubtful relationship between the medication change and the adverse event. Discordance will be adjudicated by a third investigator (physician).

2.5. ILS Program Description

All four facilities will receive the same ILS Program. Each facility will participate for a total of 18 months, including a 6-month start-up/planning period, a 6 month implementation period, and a 6 month data collection period. Residents eligible for the ILS Program will be identified during the 6-month implementation period, and each resident will be followed for up to 6 months.

The ILS Program has three main components (**Section 6** provides additional detail):

1. Automated identification of NH residents at high risk for injurious falls. Our IT personnel will work with the IT Departments at each of the 4 NH facilities in order to program the automated calculation of the FRAiL model from the EMR/MDS repository. Residents with an estimated FRAiL score ≥5% are eligible for the medication review via the IP nurse and videoconferencing. The facility staff may also suggest other residents for participation.
2. The IP nurse will provide recommendations to manage medications. The IP nurse will be supported by an interdisciplinary team including geriatricians, bone health experts, ADRD behavior management experts, nursing, and pharmacist. The IP nurse will develop an Injury Prevention Plan (IPP) with recommendations for medication changes including deprescribing medications association with falls and a prescription for osteoporosis medications. Recommendations will be left for the primary providers to review and co-sign.
3. Virtual case based education sessions to educate staff. We will hold regularly scheduled (up to monthly) virtual case based education with our interdisciplinary team and staff (nurses, CNAs, and providers) from the 4 NH facilities. During the conferences we may review some of the residents from each facility who are at high risk for injurious falls. These sessions could also include educational material on non-pharmacologic strategies to manage dementia with behaviors, falls prevention, deprescribing, and osteoporosis management. Frequency of meetings and content of the meetings will be individualized to each facility needs regarding case review,

education, or other implementation support needs.

2.6. Sample Size and Population

We anticipate enrolling approximately 10 NH staff and 10 patient/families for an interview on injury prevention.

We anticipate approximately 20% of long-stay residents at the 4 facilities will be eligible for the medication management program (n=80). See **Section 10, Statistical Considerations** for a full explanation of sample size.

We anticipate conducting interviews to assess the acceptability and practicality of the ILS Program on 60 staff members across the four facilities.

3. STUDY TEAM ROSTER

3.1 Co-Principal Investigators

Sarah D. Berry, MD, MPH
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Role: Together with Dr. Colón-Emeric, Dr. Berry will be responsible for all aspects of the trial. Specifically she will take responsibility for overseeing the programming of the FRAiL model in the four NH facilities, development of the database used in the trial, and overseeing the virtual cased based education session component of the ILS Program. She will be responsible for budget management of the HSL site and the subcontract to Brown University. She will be responsible for annual project reports to the NIH and IRB approval. Dr. Berry's involvement as both a clinician and investigator is essential to the success of this project.

Cathleen Colón-Emeric, MD MHS

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Role: Together with Dr. Berry, Dr. Colón-Emeric will be responsible for all aspects of the trial. Specifically she will take responsibility for overseeing the qualitative interviews conducted at two NH facilities, and the recruitment, education and oversight of the ILS nurse. Dr. Colón-Emeric will be responsible for the development and refinement of a future embedded pragmatic clinical trial to test the efficacy of the ILS Program.

3.2 Co-Investigators:

Tom Travison, PhD:
Research Scientist, Hinda and Arthur Marcus Institute for Aging Research, Hebrew SeniorLife,
Assistant Professor of Medicine, Harvard Medical School
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Role: Dr. Travison is a senior statistician at the Institute for Aging Research, Hebrew SeniorLife and the co-Director of the Interventional Studies in Aging Center (ISAC). Dr. Travison has more than a decade of experience with clinical trials in frail, older populations. For the proposed project, Dr. Travison will be instrumental in overseeing the data entry process, and in developing the analytic approach. He will participate in the development of a study protocol for a future pragmatic RCT.

Susan Mitchell, MD MPH:
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Professor of Medicine, Harvard Medical School
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Role: Dr. Mitchell is a senior investigator at the Institute for Aging Research, Hebrew SeniorLife and the co-Director of the Interventional Studies in Aging Center (ISAC). Dr. Mitchell has considerable experience in the design and implementation of pragmatic clinical trials in the nursing home setting. She is an expert in the delivery of care to NH residents with ADRD. During year one, Dr. Mitchell will help with the recruitment of facilities and advise on the qualitative data as part of Aim 1. During the remaining years of the grant, she will advise on the implementation and analysis of the ILS Program and she will be instrumental in planning the protocol for a future pragmatic RCT.

Lew Lipsitz, MD:
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Professor of Medicine, Harvard Medical School
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Role: Dr. Lipsitz is the Chief of Gerontology at Beth Israel Deaconess Medical Center and the Director of the Marcus Institute for Aging Research, Hebrew SeniorLife. Dr. Lipsitz has previously served as the PI of two successful telemedicine programs. During years 2-3, Dr. Lipsitz will be instrumental as an advisor to the virtual case based education session component of the intervention. He will be involved in the interpretation of the results, as well as planning for a future pragmatic RCT.

Eleanor McConnell, PhD, RN:
Assistant Research Professor, Duke University School of Nursing
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Role**:** Dr. McConnell will serve as a human factors expert and facilitator of the stakeholder groups and refinement of the intervention during the qualitative study. She will assist in the generation of the resident fall ethnography and flow mapping. Further, she will assist with ILS nurse training and participate in the virtual case based education sessions as a dementia behavioral care expert.

Andrew Zullo, PharmD, PhD:
Assistant Professor at Brown University
Clinical Pharmacist at Rhode Island Hospital
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Role: Pharmacy involvement will be key to the success of the proposed project. During Year 1, Dr. Zullo will participate as a stakeholder. In Years 2-3, he will be responsible for developing

standardized recommendations to deprescribe psychoactive and cardiometabolic drugs. He will work closely with Drs. Berry and Colón-Emeric in the development of a future pragmatic trial protocol, particularly as it relates to the integration of consultant pharmacists in the NH and he will serve as the pharmacist role as part of the interdisciplinary team providing medication recommendations.

3.3. Consultants

Sarah Sjostrom, R.N.:
Chief Nursing Officer, Hebrew SeniorLife,
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Role: Ms. Sjostrom is the Assistant Director of Nursing for Hebrew SeniorLife. During the qualitative portion of the study, Ms. Sjostrom will serve as a stakeholder representing nursing at the development meetings, and she will work in small groups to strategize an effective implementation plan. During subsequent years, she may be asked to review reports and provide feedback. She will also facilitate connections with nursing home chains that would be interested in participating in a larger pragmatic trial.

Joseph Ouslander, MD:
Chair, Department of Integrated Medical Science
Senior Associate Dean of Geriatric Programs Florida Atlantic University
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Role: Dr. Ouslander is a geriatrician and leader in improving the quality of care for older adults in skilled nursing facilities. He has recently worked with Dr. Colón-Emeric on a CMS-supported Institute for Healthcare Improvement Technical Expert Panel to improve patient safety in NHs. In the current proposal, Dr. Ouslander will serve as a consultant. He will participate in the qualitative study as a stakeholder. During the implementation study, he will review reports and provide feedback. He will also participate as an advisor in the planning of a subsequent pragmatic trial.

Heidi White, MD, MHS:
Professor of Medicine, Duke University School of Medicine
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Role: Dr. White is the former President of the American Medical Directors Association, and a certified Nursing Home Medical Director with over 25 years of experience in Long-Term Care. She will serve on the stakeholder panel representing NH medical professional perspective during the qualitative study. She will provide feedback into the ILS Program refinements and pragmatic trial protocol development during the subsequent clinical trial.

Lisa Gwyther, MSW:
Associate Professor in Psychiatry and Behavioral Sciences, Duke University School of Medicine
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Phone: 919-660-7510
Email: lisa.gwyther@duke.edu

Role: Ms. Gwyther is a nationally known expert in dementia caregiver support, and the founder of the Duke Family Support program with over 30 years of experience in dementia care. She will serve on the stakeholder panel representing family caregiver perspective during the qualitative study. She will provide feedback into the intervention refinements and pragmatic trial protocol development in subsequent years.

3.4. RESEARCH TEAM MEMBERS

Jason Rightmyer
Director of Informatics Core, Hinda and Arthur Marcus Institute for Aging Research
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Email: jasonrightmyer@hsl.harvard.edu
Role: Mr. Rightmyer will work with Mr. Resuke to oversee programming the calculation of the FRAiL risk score in the four facilities. He will meet with Dr. Berry and Mr. Rezuke at least monthly to ensure progress.

Margaret Bryan
Analyst, Hinda and Arthur Marcus Institute for Aging Research
Address: 1200 Centre Street, Roslindale, MA 02131
Phone: 617-971-5342
Email: marg@hsl.harvard.edu
Role: Ms. Bryan will receive the MDS files from the outside facilities. These MDS assessments will be used to validate the outcome injurious falls, to calculate the FRAiL score, and to assess the safety outcomes.

Tim Tsai
Analyst, Hinda and Arthur Marcus Institute for Aging Research
Address: 1200 Centre Street, Roslindale, MA 02131
Phone: 617-971-5342
Email: TimothyTsai@hsl.harvard.edu
Role: Mr. Tsai will assist with the creation of the Minimum Data Set Repository and the calculation of the FRAIL score.

Laurie Herndon, RN NP
Project Manager, Hinda and Arthur Marcus Institute for Aging Research
Role: Ms. Herndon will be responsible for engaging the four nursing home facilities, identifying a site champion and maintaining site engagement in the project. She will additionally be responsible for eliciting a full description of the facility processes (flow mapping) necessary to implement the intervention.

Ilean Isaza
Project Director, Program Manager, Hinda and Arthur Marcus Institute for Aging Research
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Role: Ms. Isaza will develop the REDCap database used to collect study information for Aim 2

Emily Hecker, RN, MSN
Injury Prevention Nurse, Duke University Medical School

Role: Ms. Hecker will be responsible for working with participating sites to identify eligible residents for the program. She will additionally be responsible for providing recommendations to manage medications and offer feedback on prescribing practices.

Michelle Tingzhong Xue

PhD Student, Duke University School of Nursing

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Role: Ms. Tingzhong Xue will assist with the qualitative analysis of the key informant interviews.

4. PARTICIPATING STUDY SITES

The study is being conducted at 4 NH facilities: two in the Durham, NC area and two in the Boston area. Eligible homes must have at least 80 long stay beds. Recruitment and study enrollment will be done in 2 waves, with each wave starting three months apart. In each wave, 2 NHs will begin the study.

For specific Aim 2c, the validation of the outcome measure injurious falls via the MDS v3.0, it will take place at one NC facility and Hebrew SeniorLife.

4.1. STUDY OBJECTIVES

Aim 1: *Develop an ILS care model designed to prevent injurious falls in NH residents using* 1) an automated risk calculator to identify high risk residents, 2) centralized care coordination by an Injury Prevention Nurse, and 3) videoconferencing with NH staff.

Aim 2*:* *Test implementation of the ILS in 4 NH facilities*. The intervention will target residents at high risk for injury as estimated by the risk calculator (~80 residents total). Results will be presented among all residents and in ADRD residents separately.

- **Aim 2a**: *Evaluate implementation* of the ILS including measures of acceptability, demand, fidelity, and practicality (e.g., provider and family acceptance of recommendations, staff participation and time.)
- **Aim 2b:** *Evaluate effectiveness and safety* of the ILS using change in process measures related to injurious falls (e.g., number of drugs prescribed, osteoporosis medication prescriptions, behaviors, and functional status). Process measures will be collected at baseline and 1 and 4 months post-intervention. Additional safety measures (e.g., unplanned medical visits due to hypertension or hyperglycemia) will be assessed at 1 and 4 months post-intervention by chart review.
- **Aim 2c**: *Validate the outcome measure for a future pragmatic clinical trial*. Injurious fall ascertainment from the MDS will be validated against chart review in the facilities.

5. SELECTION AND ENROLLMENT OF PARTICIPANTS

The ILS intervention will be rolled out facility-wide. Participation in the study will occur at 4 levels. Nursing homes will be recruited and enrolled into the study. Site administrators who agree to participate in the study will serve as gatekeepers within their facility. Eligible residents will be enrolled for ongoing chart reviews and minimum data set assessments in order to assess the program effect on injurious falls and safety outcomes. Providers (nurses, CNAs, midlevel providers, physicians) will be recruited to participate in the qualitative interviews, the virtual case based educational sessions, and to evaluate post-intervention acceptability and practicality. Proxies will be approached for qualitative interviews on their experience with preventing injurious falls.

5.1. Inclusion Criteria

5.1.1.Facility inclusion criteria

1) More than 80 long-stay beds
2) Within 30 miles of Boston or Durham, NC

5.1.2. Resident inclusion eligibility criteria

1) Age ≥ 60 years
2) NH length of stay ≥ 30 days
3) Estimated 2-year risk of hip fracture ≥ 5% using FRAiL model; OR
4) Staff referral of someone at high risk for injurious falls

5.1.3. Provider inclusion criteria

The NH-PRIDE intervention will target the "usual" providers including nurses, CNAs, MDs, NPs and PAs routinely caring for NH patients. Nurses should be providing care at a NH facility for a minimum of 2 shifts most weeks. MDs, NPs, and PAs should spend, on average a minimum of four hours weekly in nursing home care. We estimate there will be 10 providers for the qualitative interviews on injurious falls prevention, 20 providers (4 from each facility) in the televideo sessions, and 60 providers (15 per facility) to participate in the post-intervention questionnaires.

Additional eligibility criteria for providers include:

1) Worked in the facility for ≥ 90 days
2) Can communicate in English (in order to participate in interviews and questionnaires),
3) Over 21 years of age.

5.1.4. Proxy/resident inclusion criteria

We will recruit 10 residents/proxies to participate in the qualitative interviews on falls prevention. Residents/family must meet the following criteria:

1) Affiliated resident has lived in the facility for ≥ 30 days
2) Can communicate in English
3) Over 21 years of age
4) Able to provide informed consent to participate in the interviews

5.2. Exclusion Criteria

5.2.1. Facility exclusion criteria

1) Population not primarily English speaking
2) Evidence of institutional instability at time of recruitment

5.2.2. Provider exclusion criteria

1) Does not provide routine care to NH residents (e.g. visiting hospice provider)
2) Does not speak English
3) Is less than 21 years old

5.2.3. Resident exclusion criteria

1. Life expectancy < 6 months, as indicated by MDS assessment
2. Living in nursing home for less than 30 days
3. Proxy has communicated wish to opt-out of study

Residents *will not* be excluded from the study based on any specific diagnosis (e.g., congestive heart failure or schizophrenia); however, the algorithm used to make recommendations for medication management will consider individual co-morbidities. (see **Table 3** for details)

5.2.4. Proxy/resident exclusion criteria

1) Affiliated resident has lived in the facility for < 30 days
2) Cannot communicate in English
3) Less than 21 years of age
4) Unable to provide informed consent to participate in the interviews

5.3. Study Enrollment Procedures

5.3.1. Facility Enrollment

A total of 2 Boston area and 2 NC NHs will be recruited. In preparation for this study, 5 facilities have already provided assent and a letter of support. The project director and/or PI will contact senior administrators of these facilities by email. The email will provide information on the intervention and implications of participation, including the need to share limited data from chart review and the Minimum Data Set with study investigators. Following the email, if the sites express interest, the project director and/or PI will contact the NHs' administrators by telephone to answer questions and seek their participation. Face to face meetings to further explain the study will be held with administrators upon request.

5.3.2. Provider Recruitment

We have requested an IRB waiver of written informed consent for provider recruitment. The research team works with the intervention NH leadership team and designated site champion to facilitate provider recruitment and orientation at the start of the intervention. A list of full-time charge nurses and nurse aides working with long-stay residents will be obtained from the facility Director of Nursing or designee. Study staff will contact them sequentially to recruit 10 for potential participation in the fall prevention ethnography. Study staff will verbally describe the procedure and provide a written brochure and informed consent document for review.

Staff will be provided written and verbal information on the Injury Liaison Service, including the available videoconferencing sessions. For staff participating in the Injury Liaison Service feedback interviews under a waiver of Informed Consent and HIPAA Authorization, study staff

will approach them for assent during previous agreed upon times to minimize interference with their work.

All aspects of provider participation are optional. Study staff will verbally describe the procedure and provide written material for staff to review. They can chose to participate in all, some or no aspects of the intervention, and can request exclusion at any time by contacting the research project manager, whose contact information is provided in all outreach materials. Providers who participate in the qualitative interviews on falls prevention will receive $50 as an incentive for their time.

5.3.3. Resident Enrollment

We are requesting an IRB waiver of individual authorization for disclosure of personal health information (PHI) to screen and identify eligible residents. One month before we plan to start the ILS Program in a NH facility, residents and/or proxies will be provided or mailed study information, including material on deprescribing, osteoporosis medications, and the project director's (PD's) contact information, if they wish to opt out. At the start of the study the IP nurse will identify eligible residents using the automated calculation of the FRAiL score, and with chart review. In addition, flyers will be posted in ALL participating facilities explaining that the study is being conducted and that it includes data collection from the charts of residents. The flyers will include contact information for the PD to ask further questions and an opportunity for proxies to "opt-out".

5.3.4. Proxy and Resident Enrollment

We have requested an IRB waiver of written informed consent for proxy recruitment for the 10 interviews related to falls prevention. A list of long-stay NH residents with a recent fall will be obtained from the local NH champion or Director of Nursing. Study staff will contact them sequentially to recruit 10 for potential participation in the fall prevention ethnography. Study staff will verbally describe the procedure (in person for residents, over the phone for LARs), and provide with written information about the study for review. The procedure for obtaining consent is described in detail in Section 12.2.

Proxies or residents who participate in the qualitative interviews on falls prevention will receive $50 for their time. If a patient has the ability to consent, the patient will be interviewed directly and receive $50. If the patient has moderate to advanced dementia and cannot participate, the proxy will be interviewed alone and receive $50. If the patient has mild/moderate dementia, and both the patient and proxy participate in the interview, they both will receive $50.

6. STUDY ACTIVITIES

The qualitative Aim 1 study will be conducted in the 2 facilities in North Carolina.

All four NH facilities (2 in Boston area, 2 in Durham, NC area) will receive the same ILS Quality Improvement Program. Each facility will participate for a total of 18 months, including a 6-month start-up/planning period, a 6 month implementation period, and a 6 month data collection period. Residents eligible for the ILS Program will be identified during the 6-month implementation period, and each

resident will be followed for up to 6 months.

The ILS Program is consistent with a quality improvement program because it is delivering guideline-recommended fall prevention and osteoporosis care. *Study interventions are therefore limited to the data collection procedures described previously to determine the feasibility and acceptability of the ILS program*. However, the components of the quality improvement program are summarized in **Table 2** and described in more details in the following sections.

Table 2. Intervention model components, who is responsible, timing and time involved.

Activity	Who, When, Time Required
High Risk Resident Identification	
FRAiL tool identifies high risk residents from MDS; facility champion may also suggest residents for participation	IP Nurse, monthly, 30 minutes
Resident Data Gathering	
EMR review and relevant data extraction into Redcap database	IP Nurse, 20 minutes/resident
Medication algorithm identifies those potentially eligible for deprescribing and osteoporosis treatment	Automated, database
Injury Prevention Plan Development and Documentation	
Documentation of IPP using standard template	IP Nurse with IDT review during weekly meeting, 5 min/resident
Telephone visit with resident/family for modification/acceptance	IP Nurse 10 min/patient
Telephone visit with Charge Nurse, scheduling of virtual cased based education session if staff has concerns about behaviors	IP Nurse 5 min/patient
Virtual case based education sessions for selected Residents with active behavioral issues	NH LPN, NA, RNs, ILS Nurse, IDT, Family; 15 min/resident; monthly
IPP Implementation and Follow-Up	
IPP placed in medical record for medical team cosignature	IP Nurse, 5 min/patient
Issues/problems discussed during next virtual case based education sessions session	MDS nurse, charge nurse, CNAs, Virtual case based education sessions IDT
1 and 4 EMR review and IPP update	IP Nurse with discussion by IDT as needed, 15 min/patient

6.1. Study Start-up Activities

The following activities will occur during the 6 month planning period within facilities:

1. Program the FRAiL model to predict residents at risk for injury.
2. Identify a NH-PRIDE site champion
3. Develop implementation plan with NH leadership through on-site planning meetings
4. Identify targeted providers
5. Provide orientation packages to targeted providers (*we will provide the IRB prior to implementation; packets will be developed in early 2020; estimate implementation*

summer 2020)

6. One month before the ILS Program is planned to start, notify long-stay residents/proxies about the program via letter with ability to opt out (HIPAA waiver of informed consent; *we will provide the IRB prior to implementation, estimate summer 2020*).

Programming the FRAiL model: During the 6 month start-up period, our IT personnel will work with the IT Departments at each of the 4 NH facilities in order to assist in the programming of the FRAiL model from the EMR/MDS repository. At the beginning of the implementation period, the IP nurse will be provided with a report of the FRAiL score for all long-stay residents. Residents with an estimated FRAiL score ≥5% will be reviewed for additional eligibility/exclusion criteria via chart review (see **Section 5**).

Identification of site champion: During the start-up period each NH will designate at least one champion. In order to prevent champion loss due to turn-over, we will appoint a secondary champion, whenever possible. The champions needs to be persons interested in falls prevention who understands the special concerns of managing medications in NH residents. The site champion may be the DON or a nurse directing direct patient care. The secondary champion may be a unit nursing director or other unit nurse. The site champions will work with the research team throughout the planning and implementation period to facilitate successful program implementation. He or she serves as a primary contact for both providers within the NH and for the research team. Site champions are provided with references and support tools at the start of the program and they will be encouraged to contact the project director with questions or concerns. During the implementation phase, the champions will be invited to participate in the monthly videoconferences with other site champions, in order to discuss the program and provide suggestions/support to one another. The champion is an on-site leader and resource, working with both facility and research team to increase likelihood of program success. Site champions should, 1) Help tailor the ILS Program to their facility, 2) Identify and motivate providers, 3) Review prescribing feedback reports, 4) Encourage adherence with IP nurse recommendations, and 5) Integrate program into quality improvement activities

Development of implementation plan with NH leadership

Successful program planning and implementation depends on teamwork between members of the facility team and the research team. This starts with the 6 month planning period wherein the research team and NH team meet at least monthly to review and optimize plan for program roll-out. Throughout the program, the research team will work with members of the facility team to optimize the program within the facility and to support program activities within the facility.

See details about enrolling providers and residents in **Section 5.3** on enrollment.

6.2. Implementation Phase Activities:

The following activities will occur during the 6 month implementation period within facilities:

1. The IP nurse will identify eligible residents for the program.
2. The IP nurse will provide recommendations to manage medications.
3. The IP nurse will offer feedback on prescribing practices.
4. Staff will be invited to participate in regularly scheduled virtual case based education sessions in order to education staff on falls, deprescribing, osteoporosis, and non-pharmacological management of dementia. Videoconference scheduling and content will be

individualized to participating facilities.

The IP nurse will identify eligible residents for the program. During the startup phase, our study team will assist the local IT Departments in creating a report to calculate the FRAiL score for all long stay residents. These reports will additionally indicate resident age < 60 years and whether a resident has less than a 6 month life expectancy. The IP nurse will use these reports to identify eligible residents and ensure no exclusion criteria. Any resident or proxy who notifies the study team and opts out of study participation, will not be included. The facility champion may also suggest other residents for participation.

The IP nurse will provide recommendations to manage medications. During the qualitative portion of the study, an algorithm will be created that includes evidence based decision making in deprescribing psychotropic and cardiometabolic drugs, as well as patient/proxy preference. We will work with our pharmacist investigator, consultants, and patients/proxies in order to identify the classes of medications we will target for deprescribing. Examples include medications associated with falls (e.g., benzodiazepines, beta-blockers) and medications associated with bone mineral density loss (e.g., proton pump inhibitors). We will use combinations of existing evidence-based tools to develop the deprescribing recommendations including Deprescribing.org (https://deprescribing.org/resources/deprescribing-guidelines-algorithms/) and the EMPOWER tool (https://deprescribing.org/news/empower -trial-empowering-older-adults-to-reduce-benzodiazepine-use/). Appendix 1 shows a medication algorithm:

For all eligible patients, The IP nurse will utilize the Medication Algorithm and will review the EMR and additionally available medical records in order to make informed recommendations regarding medication changes. The IP nurse will be supported by an interdisciplinary team (IDT) including geriatricians, bone health experts, dementia behavior management experts, nursing, and pharmacist. The IP nurse will discuss any recommendations with direct care staff as well as residents or proxies. The Injury Prevention Nurse will provide the resident and/or proxy with evidenced based literature, existing decision aid tools, and/or short videos so as to facilitate shared decision making. Using input from the IDT, direct care staff, residents and proxies, the IP nurse will then use the Injury Prevention Plan template to document recommended medication changes including deprescribing medications association with falls and a prescription for osteoporosis medications. Recommendations will be left for the primary providers to review, modify if desired, and co-sign. The IP Nurse will complete an Injury Prevention Service Consultation note summarizing communication with resident, family, NH PRIDE team, facility staff, and prescribers about recommendations for medication changes.

The IP nurse will offer feedback on prescribing practices. We will create monthly feedback forms for each provider to illustrate adherence with medication recommendations. The IP nurse will review these reports with the site champion. We will work with the site champion to employ other methods to maintain engagement specific to each site, such as publically displayed “thermometers” to document aggregate adherence. The IP nurse will also work with the site champion to ensure that staff are communicating any potential adverse events from deprescribing or osteoporosis medications as a result of the study recommendations.

Videoconferencing sessions to educate staff. We will hold regularly scheduled (up to monthly) telehealth videoconferences with our interdisciplinary team and staff (nurses, CNAs, and providers) from the 4 NH facilities. During the conferences we may review some of the residents from each facility who meet eligibility criteria and whom the staff feel are at high risk for injurious falls. In addition to the case-based discussions, these sessions may include educational material on non-pharmacologic strategies to manage dementia with behaviors, falls prevention, deprescribing, and osteoporosis management. These conferences will emphasize non-pharmacologic and behavioral interventions as alternatives to psychotropic drugs in the nursing

home. In addition they will review potentially adverse drug effects of deprescribing or the prescription of osteoporosis medications that concern the staff.

6.3. Data Collection Phase Activities:

The following activities will occur during the Data Collection Phase within facilities:

1. IP nurse will review the EMR at 1 and 4 months of patients with a finalized medication recommendation.
2. IP nurse will administer short survey to staff on feasibility and acceptability
3. Facilities will provide limited MDS data and a falls log in the 6 months following implementation.
4. Validate MDS injurious falls data with chart review and falls log
5. Select staff and proxies will be invited to participate in a follow-up semi-structured interview to understand any implementation barriers.

Planned data collection activities are described in **Section 7.**

7. DATA COLLECTION ELEMENTS AND PROTOCOL

7.1 Qualitative interviews. Participants (approximately 10 staff and 10 proxies) will be asked to tell the story of a recent fall and subsequent attempts to prevent additional falls; a semi-structured interview guide (See separate Interview Guide) is used to prompt for feelings, experiences, and "touch points" where care should be delivered differently. Staff members will be interviewed alone or in small groups. Interviews are audio recorded and transcribed. These interviews will be used to identify touchpoints that the broader research team and consultants can use when refining the intervention. Select staff and proxies will be approached for willingness to participate in a follow-up semi-structured interview (Guide to be submitted in Spring 2020) in order to better understand implementation barriers.

7.2 Facility Data

Nursing home data are collected prior to the start of the study for descriptive purposes and to inform the development of a list of eligible nursing homes for recruitment (see Section 5 for specific facility Eligibility criteria). Prior to recruitment efforts, NH characteristics that may be relevant to injurious falls, were abstracted from the Medicare Nursing Home Compare, including: the number of beds, hospital-based, special care dementia unit, nursing and nursing assistant hours/resident/day, and number of deficiencies on state inspections. Long-term Care: Facts on Care in the US (http://www.ltcfocus.org/) is also used to gather information including number of beds, number of residents with advanced cognitive impairment, and number of Black residents. Administrators of participating facilities are also asked whether NPs/PAs are on staff and whether there is an open or closed medical staff.

7.3 Resident assessments

Resident data will be collected by the IP nurse. Charts are abstracted at baseline and again at 1 and 4 months after the study recommendations are finalized, to determine in medication recommendations were followed, and if there was any evidence of adverse events. The IP nurse will hold weekly brief telephonic huddles (~10-15 minutes) with direct care staff to determine staff perceptions of the program and to collect critical information on data missing from chart, such as behaviors.

Demographic: (baseline; chart and MDS) age, gender, race, ethnicity, length of NH stay and proxy contact information (for mailing study information and ability to opt out) and relationship to resident.

Medical co-morbidity: (baseline; chart review) All active medical diagnoses.

Medications: (baseline, 1 and 4 months; chart review) All prescribed medications and doses.

Functional status: (baseline, 1-6 months follow-up via MDS) We will categorize functional status using the Katz ADLs at baseline and during followup

Falls, fractures, injurious falls: (baseline, 1 and 4 months: also via MDS and falls log) We will ascertain falls and falls with injury from the 2 MDS assessments during followup, the facility falls log, and also from chart review.

Adverse events – other major acute illnesses: (baseline, 1 and 4 months; MDS and chart review): We will consider the following adverse events due to medication changes: 1) escalating behaviors, worsening depression, or functional decline following psychoactive deprescribing; 2) unplanned medical visits for hypertension, tachycardia, or hyperglycemia for cardiometabolic deprescribing; 3) new gastroesophageal reflux disease or esophagitis following bisphosphonate

prescription. Each facility will provide limited MDS data at baseline and during follow-up in order to characterize the occurrence of these adverse events. Change in depression, behaviors, and functional status will be measured using the MDS assessment closest to and preceding the program implementation and the subsequent MDS assessment.

Lastly The IPN will enter all targeted adverse events into the RedCap database. At the next study team meeting, or within 14 days, the IPN will review the event with the team for a determination of an adverse event using the Drug Withdrawal Probability Scale to determine if there is a probably, possible, or doubtful relationship between the medication change and the adverse event. Discordance will be adjudicated by a third investigator.

Health services: (1 and 4 months; chart review) hospitalizations, emergency room visits.

Death or transfer: (1 and 4 months; chart review) date will be obtained from the chart.

7.4 Staff assessments

Staff satisfaction and estimated time spent on the ILS Program implementation will be collected by a 5 minute survey during followup. Questions include overall satisfaction with the NH PRIDE study, estimates of total amount of time staff spent on study, satisfaction with key components of the study, reasons for not accepting pharmacologic and nonpharmacologic recommendations, and likelihood that staff would recommend the study to a colleague. The survey will be made available to staff electronically using the Qualtrics Survey Platform and will be administered at the beginning of a regularly scheduled Zoom meeting. After staff have completed the survey, the research team will ask three open ended questions on what worked well and what could have been improved during the study. The meeting will be recorded on the Zoom platform and will be transcribed by study staff. Staff will be informed at the beginning of the meeting that it is being recorded and can choose not to participate.

Surveys related to deprescribing, osteoporosis treatment, and medical provider workflow will be administered to nurse practitioners and physicians via zoom meeting or via the Qualtrix Survey Platform. Zoom meetings will be recorded and transcribed by study staff. Staff will be informed at the beginning of the meeting that it is being recorded and can choose not to participate. Participants will receive a 50.00 gift card.

8. HUMAN SUBJECTS PROTECTION

Because the ILS is providing guideline recommended clinical care to residents, and all resident-level data collection is via the EMR (i.e., no direct resident contact) we request waiver of informed consent and HIPAA authorization for resident data collection.

Because staff are voluntarily participating in the interviews on injury prevention and the videoconferencing component of the program, we request waiver of documentation of informed consent to record their interview and obtain feedback about the ILS.

Because proxies/residents who participate in the interviews are voluntarily participating in the low-risk activity, we request a waiver of documentation of informed consent. Study staff will verbally describe the procedure (in person for residents, over the phone for LARs), and provide written material for review before participating in the interview.

8.1. Sources of Data

Qualitative interviews. Approximately 15 staff and 15 residents/proxies will participate in an audiorecorded interview on falls prevention prior to study implementation. Interviews will be transcribed and we will use qualitative software (NVivo) to analyze themes. Approximately 5 staff and 5 proxies will participate in a follow-up audiorecorded interview to understand implementation barriers.

Resident NH records: We will obtain information on medical diagnoses, medications, behaviors and adverse events from the EMR (see description of data to be obtained in **Section 7**).

MDS records: We will request limited information from the MDS for all participants at baseline and quarterly. This includes functional status, depression, pain, falls and injurious falls, behaviors, or unstable or new medical conditions.

Staff surveys. Approximately 60 staff from the 4 facilities will provide data on acceptability and feasibility through a brief survey during follow-up.

8.2. Protection against Risk

The NH-PRIDE study poses minimal risks; however, below we list possible risks and our proposed strategies to minimize them:

- Loss of privacy and confidentiality of research data. Only PHI necessary to complete study aims will be collected. All data will remain behind either the Duke, NH or the Hebrew Senior Life data firewall, all of which meet HIPAA standards for clinical and research data. Data will be transferred between the NH and HSL database via secure data-sharing software (Accelion). No research data containing PHI will be stored on portable devices. PHI/data for eligible residents will be stored on secure Duke servers accessible only to study staff, and communicated to providers by secure email behind the Duke firewall.
- Loss of confidentiality through videoconferencing sessions. Videoconferencing will include discussions of Protected Health Information in an effort to manage medications and behaviors in nursing home residents at the greatest risk for injurious falls. These

conferences will use secure platforms (e.g., Zoom) and we will only discuss information necessary to make informed medical recommendations.

- Loss of confidentiality with audiorecording patient, proxy and provider interviews: After audiorecording the interviews, investigators will use NVivo software to extract themes and touch points described by participants in an open coding process. Short audio clips illustrating each touch point may be re-organized into an ethnography of the fall prevention experience, with audioclips preserving the family and staff voices, while removing most identifiable information.
- Interference of study procedures with Nursing Home staff duties. We recognize that NH staff have competing clinical demands and study procedures may impact resident care. Using successful procedures from prior studies, we will establish preferred communication times and venues with each facility's staff. We will train study staff to avoid interrupting shift change or medication passes.
- Adverse events due to deprescribing medications increasing fall risk. Although guidelines recommend minimizing the dose or discontinuing medications associated with falls in high-risk patients, they may experience adverse drug withdrawal events related to dose changes. These are class specific and include escalating behaviors, worsening depression or functional decline following psychoactive deprescribing; hypertension or tachycardia, or hyperglycemia for cardiometabolic deprescribing. To minimize this risk, we will: 1) ensure that the medical provider has reviewed and concurs with each change by providing a consult note and having them sign all medication change orders; 2) use slow tapers and geriatric dosing ranges under the guidance of the study geriatricians and geriatric pharmacist; 3) develop rapid communication channels between NH staff and the ILS nurse/study team so that any symptoms can be reported early. These include weekly huddles with nursing staff, a study contact phone number, and regular virtual case based education sessions
- Adverse events related to prescribing osteoporosis medication. Adverse drug reactions related to osteoporosis medications include gastrointestinal distress, esophagitis, injection site reactions (for subcutaneous medications), hypocalcemia/hypercalcemia. Rare events such as osteonecrosis of the jaw or atypical subtrochanteric fractures occur in 1/50,000-100,000 patient years of exposure and are not expected in this small, short term study. To minimize risks we will: 1) instruct NH staff on proper bisphosphonate administration procedures (fasting, sitting upright at least 30 minutes, >8 oz water); 2) ensure study protocols do not recommend oral bisphosphonates to residents with dysphagia or known esophageal stricture; 3) ensure vitamin D sufficiency or adequate loading dose prior to beginning oral bisphosphonates; 4) ensure anabolic agents are not given to patients at risk for hyperparathyroidism or with prior hypercalcemia; 4) discontinue antiresorptive agents after 5 years of treatment.

8.3. Potential Benefits of the Proposed Research to Human Subjects and Others

- Benefits to providers. The ILS service will reduce the workload of the clinical staff by centrally coordinating programs and communicating with patients and families. NH staff may additionally benefit from educational activities offered during virtual case based education

- Benefits to NH Residents and Families. If the program is effective, patients and families will benefit from improved fall prevention services, with fewer expected to suffer painful and debilitating low-trauma fractures and other fall-related injuries.

8.4. Study Discontinuation

Individual NHs may withdraw from study participation at any time at the discretion of their senior management or corporate supervisors. Providers can opt out of any part of ILS Program participation at any time, and while not being asked to provide informed consent for this research, resident proxies can opt out of reading the fliers at the facility or mailed letter and contacting the research team at any time to request exclusion of their resident from ongoing data collection efforts. Participants may choose to terminate data collection via interviews at any time. If a participant withdraws consent, no additional data will be used, although data previously collected and de-identified may remain in the analyses. There are no anticipated circumstances under which subjects will be withdrawn without their consent.

9. SAFETY MONITORING

The study meets criteria for minimal risk. The ILS Program represents best practices in care coordination and medication review for NH residents. All the resident data will be obtained from their medical record, MDS, and staff interviews, and coded at the time of data entry to protect their confidentiality. Given that the program is based on consensus, peer reviewed guidelines, the risk from the ILS with regards to medication management is minimal.

Overall framework for safety monitoring: The study will employ strategies specific to the 4 types of risk expected; 1) loss of privacy and confidentiality of research data; 2) interference of study procedures with Nursing Home staff duties; 3) Adverse drug withdrawal events due to deprescribing medications increasing fall risk; and 4) Adverse drug reaction related to prescribing osteoporosis medication. In addition, we will monitor for suspected abuse and neglect by NH staff.

All safety events will be reported to the PIs immediately upon recognition by study or NH staff, with additional actions as outlined below. An **independent safety monitoring board** (will be alerted to all Serious Adverse Events (SAEs) potentially related to the study within 24 hours of PI notification. The monitoring board will review all other events during bi-annual safety meetings with the PIs.

The safety monitoring board will be appointed by the NIA and comprised of three individuals not otherwise involved in the study. All of the individuals should have expertise in NH care and at least one individual should be a physician.

Information to be monitored:

- Loss of privacy and confidentiality of research data: The PIs will ask study staff to report any potential breaches of data security procedures, such as inadvertent recording or transfer of PHI outside of the firewall, during monthly study meetings. Staff will be reminded to report such breaches immediately. Any identified will be reported to the IRBs, site data privacy officer, and awarding IC within 24 hours of discovery. Staff will be retrained on data security procedures at least annually.
- Interference of study procedures with Nursing Home staff duties: Study staff will enquire about such interference during the structured staff interviews during the implementation, feasibility, and acceptability testing. All reported instances will be reviewed during regular study team meetings, and remediation plans discussed with the Data Safety Monitoring Board as appropriate.
- Withdrawing medications can lead to worsening symptoms. These can include worsening anxiety, depression, or behavior, insomnia, elevated blood pressure, or gastrointestinal upset, or exacerbation of underlying disease. NH staff will be provided with written and telephonic means of communicating with MD/NP if these symptoms occur. If one of these symptoms is significant enough to warrant an unplanned visit from the MD/NP, it will be considered a study-related Adverse Event. Potentially study-related Adverse Events will be recorded in the study database, reviewed with the study PIs to assess relationship to medication changes, and reviewed with the Safety Board during bi-annual safety meetings.
- Serious Adverse Events include death, hospitalization, life threatening events, and unanticipated problems that pose a risk to subjects or others. All such events that are considered study-related as defined above will be reported to the Safety Board, IRBs, and awarding IC within 24 hours.

- Adverse events related to prescribing osteoporosis medication will be monitored in the same fashion as above. The following will be considered potentially study-related: gastrointestinal distress, esophagitis, injection site reactions (for subcutaneous medications), hypocalcemia/hypercalcemia significant enough to warrant an unplanned visit from the MD/NP.
- Resident reports of or suspected abuse and neglect by NH staff witnessed by study staff: Study staff will be trained to report such events to the PIs immediately. We will follow the process described in Human Subjects to report these to the NH leadership and/or the State Ombudsman. Study staff will follow-up within 1 week and then as needed for resolution of the issue. All such events and their resolution will be reported in writing by the co-PIs and within 24 hours to the Safety Board and the IRBs.
- Non-study related Serious Adverse Events (SAEs) including deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs) will be identified via MDS review quarterly, and additional information (clinical notes, hospital discharge summaries) will be reviewed in the EMR by study staff. These non-study related SAEs will be reviewed by the Safety Board during bi-annual meetings.

The frequency of monitoring varies with the type of event and is described above. Safety Monitoring Board meetings will be scheduled bi-annually. Given the short duration and small sample size of this pilot study, there are no plans for interim analysis or stopping rules.

If a resident discloses acute symptoms, or reports/displays signs of abuse or neglect to study staff during any of the planned interviews, we will employ a process that has worked successfully in other NH studies. We will work with nursing leadership at each facility at the onset of the interviews to establish a plan that will include completion of a standardized report form to be given to the NH Director of Nursing and Administrator within 24 hours

Individual(s) responsible for trial monitoring and advising the appointing entity include the PIs and Independent Safety Board as described above.

10. STATISTICAL CONSIDERATION

This is a pilot study to test design and test implementation of the ILS Program in four nursing home facilities. We will largely use descriptive statistics to present our results, and to inform the sample size calculation for a future pragmatic RCT. The following statistical considerations will be considered:

- Qualitative Study (Aim 1) - Using NVivo software, investigators will identify themes and touch points described by participants in an open coding process. Short audio clips may be created to illustrate each theme and re-organized into *ethnography of the fall prevention experience,* with audio clips preserving the family and staff voices.[42] A similar process will occur to analyze the post-implementation interviews from staff and proxies, in order to identify themes surrounding implementation barriers.

  In addition, the team will use process *flow mapping* techniques to describe each step, however minor, necessary to 1) program the automatic calculation of injury risk using the FRAiL model, 2) deprescribe psychoactive and cardiometabolic medications associated with falls and injury, 3) prescribe osteoporosis treatment to reduce injury risk in the setting of a fall, and 4) introduce other best practices to prevent injurious falls in the NH.

- ILS Implementation (Aim 2) - Quantitative measures of acceptability, demand, fidelity, and practicality as defined in **Table 1** will be described using descriptive statistics. As is standard in pilot studies, our sample size target is based on the expected proportion of high-risk residents in the 4 pilot facilities and no statistical testing is planned, thus, formal power calculation was not conducted. However, our goal is to achieve 50% adherence with suggested medication changes, and our sample of 80 residents is sufficient to demonstrate this with a 95% Confidence Interval of +/- 5% [95% CI assuming SD 10% is 47.8-52.2%; assuming SD 20% is 45.6-54.5%]. We will refine the ILS Program until >50% acceptance of ILS recommendations is achieved, using the targets set in Table 1.

  Following current recommendations, we will not power the future pragmatic trial on the results of this small implementation study with unstable efficacy estimates, but rather we will use our clinical knowledge and results of previously published trials of deprescribing in order to inform the sample size calculation.[43]

- Validate Injurious Falls (Aim2c) - We will compare the occurrence of falls with injuries using MDS data with the occurrence according to chart review. The MDS defines major injury as any fall resulting in a fracture, joint dislocation or intracranial hemorrhage, whereas a minor injury includes falls resulting in abrasions, lacerations requiring sutures, hematoma, or pain. Participating facilities (Croasdaile Village and Hebrew Rehabilitation Center) will be asked to provide limited MDS data for all residents in the facility. A research assistant will conduct a chart review (all provider and nursing notes from EMR) of a random sample of approximately 300 patients to determine whether any injurious falls were documented. Agreement between the MDS and chart review will be compared using Cohen's Kappa test. We will also calculate the sensitivity, specificity, and positive and negative predictive value of the MDS to identify injurious falls, as compared with the gold standard of chart review.

11. DATA SECURITIES

11.1. Data Transfer Agreement

We will request a Memorandum of Understanding between Hebrew SeniorLife and each of the four facilities allowing for the facilities to share limited MDS information and falls log for all long stay residents during the study. Other data collected will not require a data agreement: for example the facility level data comes from public data sources and resident data will be obtained from residents' medical charts, and a brief nurse interview.

11.2. Safety Measures

Data recorded on paper by NH staff for the support of the program management or data collection (e.g., lists of eligible staff/residents, fall logs) as well as audiorecorded interviews, will be maintained in the study staff in a locked case at all times when in the facility, and transported back to Hebrew SeniorLife and/or Duke University School of Medicine to be stored in a locked cabinet. PHI/data for eligible residents will be stored on secure Duke servers accessible only to study staff, and communicated to providers by secure email behind the Duke firewall.

All other data (e.g., EMR reports, chart abstraction) will be entered directly into a research database (REDCap) stored behind the Hebrew SeniorLife firewall. Only IRB-approved study staff will have access to these data. The co-PIs and informatics personnel bear primary responsibility for overseeing privacy and security of research data. Risk mitigation strategies include: 1) developing a limited dataset with direct identifiers maintained separately in a cross-walk file as soon as data collection is completed; 2) restricting access to folders containing research data to approved personnel only; 3) individual research data will be used only for analyses to complete study aims; 4) not transmitting individual data outside the HSL firewall; 5) never storing research data on a computer hard drive.

Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported according to HSL policy. All incidents regarding information security/privacy incidents will be reported to the HSL IRB and NIH within 24 hours of acknowledgement of issue. Reporting of results, such as in scientific papers and presentations, will never identify individual subjects. Data will be presented in aggregate and individual-level data will not be published.

11.3. Data Management

Data management and analysis for the study will take place at HSL under the direction of the informatics and biostatistics cores at the Marcus Institute for Aging Research (IFAR). Audio recorded interviews will be transcribed at Duke University with identifiers removed, whenever possible, and stored on Duke University's secure IT network. GMR Transcription Services, Inc. will be provided with the audio files, which are considered protected health information. Duke will establish a services contract with GMR Transcription Services for this project. All access to data is restricted to those on the research team who have been authorized by the PI to use this information. The HSL information technology (IT) department adheres to all the policies and practices under HIPAA regulations and is responsible for securing IFAR's IT infrastructure including physical servers and application software. IFAR has

established additional sensitive data policies and procedures in concert with the IRB to ensure safe data handling by faculty and staff.

12. PARTICIPANT RIGHTS AND CONFIDENTIALITY

12.1. Institutional Review Board (IRB) Review

This protocol and the HIPAA waiver applications will be reviewed and approved by Hebrew Senior Life's IRB. Duke University School of Medicine and Brown University will cede IRB review to Hebrew SeniorLife. Continuation of study is contingent on annual review and approval by the IRB. Any changes to study protocol or materials will be submitted to the IRB for review and approval prior to implementation.

12.2. Informed Consent

Because the ILS program poses minimal risk to subjects and represents best practices for medication optimization, we will request a waiver of individual authorization for disclosure of personal health information necessary to screen and follow residents. All long-term stay residents/families in the facilities will be mailed a letter describing the study with the option to opt out, as described above. Staff will provide verbal assent to provide feedback on study feasibility and acceptability, but no PHI will be recorded and a waiver of informed consent will also be requested for this minimal risk activity.

We are audiorecording and transcribing stories from a subset of residents, proxies, and staff about their fall prevention experiences. While transcripts will remove all names, the stories themselves may remain identifiable. Therefore, we will approach potential subjects for informed consent (non-written).

For the patient/proxy interviews, residents may lack capacity to consent for research due to cognitive impairment. Those with severe dementia indicated in their medical record will be unlikely to participate in the interview, and their proxy will be contacted as below. Those with moderate dementia indicated on their medical record will be approached in their room for assent to contact their proxy and participate in an interview together with their proxy; those who agree will have their proxy contacted as below. Those with no or mild dementia indicated on their medical record will be approached in their room and the study procedures described. We will then administer the Evaluation to Sign Consent (ESC) measure, which is an assessment of understanding that has been validated in NH residents (see attached ESC). Those who are able to describe a risk of participation and summarize study activities will be asked to proceed with the interviews (verbal informed consent). They will have as much time as they choose to consider and read the informed consent document. Phone numbers of study staff will be provided to answer additional questions. Those who do not pass the ESC will be asked for assent, and if provided their proxy contacted as below. Proxies will be contact in-person if encountered in the NH, or by phone if not. Study procedures will be described and written informed consent obtained as above. Proxies are assumed to have capacity to provide informed consent for research for this low risk study by virtue of their designated role as proxy for a vulnerable older adult. Phone numbers of study staff will be provided to answer additional questions.

12.3 Participant Confidentiality

This trial will be granted a HIPAA Waiver of Requirement for Authorization for Release of Protected Health Information for Research Purposes from the Hebrew Senior Life IRB. In order to preserve confidentiality, subjects will be assigned a study number for tracking and reporting purposes. All physical documentation and IT assets are stored in a locked areas within the participating NHs and within HSL, monitored 24-hours a day by security personnel, and

accessible only by authorized employees. Access to the HSL cooperate computer network is strictly prohibited and all electronic research data will be stored on dedicated IFAR systems located on our private network. Access to these data will be limited to study personnel on a “need to know” basis. If a NH resident is deemed ineligible for the study, all personal health information obtained for screening purposes will be destroyed as soon as possible.

13. PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this trial will be governed by the co-PIs.

14. REFERENCES:

1. Rubenstein LZ, Josephson KR, Robbins AS. Falls in the nursing home. *Ann Intern Med.* 1994;121(6):442-451.
2. Burke RE, Rooks SP, Levy C, Schwartz R, Ginde AA. Identifying Potentially Preventable Emergency Department Visits by Nursing Home Residents in the United States. *J Am Med Dir Assoc.* 2015;16(5):395-399.
3. Thapa PB, Brockman KG, Gideon P, Fought RL, Ray WA. Injurious falls in nonambulatory nursing home residents: a comparative study of circumstances, incidence, and risk factors. *J Am Geriatr Soc.* 1996;44(3):273-278.
4. Berry SD, Lee Y, Zullo AR, Kiel DP, Dosa D, Mor V. Incidence of Hip Fracture in U.S. Nursing Homes. *J Gerontol A Biol Sci Med Sci.* 2016;71(9):1230-1234.
5. Sorensen SV, de Lissovoy G, Kunaprayoon D, Resnick B, Rupnow MF, Studenski S. A taxonomy and economic consequences of nursing home falls. *Drugs Aging.* 2006;23(3):251-262.
6. Orive M, Anton-Ladislao A, Garcia-Gutierrez S, et al. Prospective study of predictive factors of changes in pain and hip function after hip fracture among the elderly. *Osteoporos Int.* 2016;27(2):527-536.
7. Dharmarajan TS, Tankala H, Patel B, Sipalay M, Norkus EP. Outcome in ambulatory status immediately following hip fracture surgery in the acute setting: a comparison of nursing home residents and community older adults. *J Am Med Dir Assoc.* 2001;2(3):115-119.
8. Beaupre LA, Jones CA, Johnston DW, Wilson DM, Majumdar SR. Recovery of function following a hip fracture in geriatric ambulatory persons living in nursing homes: prospective cohort study. *J Am Geriatr Soc.* 2012;60(7):1268-1273.
9. (CMS) CfMMS. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes.html.
10. Berry SD, Zullo AR, Lee Y, et al. Fracture Risk Assessment in Long-term Care (FRAiL): Development and Validation of a Prediction Model. *J Gerontol A Biol Sci Med Sci.* 2017.
11. Gambassi G, Landi F, Peng L, et al. Validity of diagnostic and drug data in standardized nursing home resident assessments: potential for geriatric pharmacoepidemiology. SAGE Study Group. Systematic Assessment of Geriatric drug use via Epidemiology. *Med Care.* 1998;36(2):167-179.
12. Mor V, Angelelli J, Jones R, Roy J, Moore T, Morris J. Inter-rater reliability of nursing home quality indicators in the U.S. *BMC Health Serv Res.* 2003;3(1):20.
13. Del Rio RA, Goldman M, Kapella BK, Sulit L, Murray PK. The accuracy of Minimum Data Set diagnoses in describing recent hospitalization at acute care facilities. *Journal of the American Medical Directors Association.* 2006;7(4):212-218.
14. Lawton MP, Casten R, Parmelee PA, Van Haitsma K, Corn J, Kleban MH. Psychometric characteristics of the minimum data set II: validity. *Journal of the American Geriatrics Society.* 1998;46(6):736-744.
15. Mor V. A comprehensive clinical assessment tool to inform policy and practice: applications of the minimum data set. *Medical care.* 2004;42(4 Suppl):III50-59.
16. Snowden M, McCormick W, Russo J, et al. Validity and responsiveness of the Minimum Data Set. *Journal of the American Geriatrics Society.* 1999;47(8):1000-1004.
17. Campbell AJ, Robertson MC, Gardner MM, Norton RN, Buchner DM. Psychotropic medication withdrawal and a home-based exercise program to prevent falls: a randomized, controlled trial. *J Am Geriatr Soc.* 1999;47(7):850-853.
18. Ray WA, Taylor JA, Meador KG, et al. A randomized trial of a consultation service to reduce falls in nursing homes. *Jama.* 1997;278(7):557-562.

19. Benetos A, Labat C, Rossignol P, et al. Treatment With Multiple Blood Pressure Medications, Achieved Blood Pressure, and Mortality in Older Nursing Home Residents: The PARTAGE Study. *JAMA Intern Med.* 2015;175(6):989-995.
20. Tinetti ME, Han L, Lee DS, et al. Antihypertensive Medications and Serious Fall Injuries in a Nationally Representative Sample of Older Adults. *JAMA Intern Med.* 2014.
21. Pit SW, Byles JE, Henry DA, Holt L, Hansen V, Bowman DA. A Quality Use of Medicines program for general practitioners and older people: a cluster randomised controlled trial. *Med J Aust.* 2007;187(1):23-30.
22. Darowski A, Whiting R. Cardiovascular medication and falls. *Rev. Clin. Gerontol.* 2011;21(2):170-179.
23. Zarowitz BJ, Cheng LI, Allen C, O'Shea T, Stolshek B. Osteoporosis prevalence and characteristics of treated and untreated nursing home residents with osteoporosis. *J Am Med Dir Assoc.* 2015;16(4):341-348.
24. Pham AN, Datta SK, Weber TJ, Walter LC, Colón-Emeric CS. Cost-Effectiveness of Oral Bisphosphonates for Osteoporosis at Different Ages and Levels of Life Expectancy. *Journal of the American Geriatrics Society.* 2011;59(9):1642-1649.
25. Greenspan SL, Schneider DL, McClung MR, et al. Alendronate improves bone mineral density in elderly women with osteoporosis residing in long-term care facilities. A randomized, double-blind, placebo-controlled trial. *Ann Intern Med.* 2002;136(10):742-746.
26. Greenspan SL, Perera S, Ferchak MA, Nace DA, Resnick NM. Efficacy and safety of single-dose zoledronic acid for osteoporosis in frail elderly women: a randomized clinical trial. *JAMA Intern Med.* 2015;175(6):913-921.
27. Broe KE, Chen TC, Weinberg J, Bischoff-Ferrari HA, Holick MF, Kiel DP. A higher dose of vitamin d reduces the risk of falls in nursing home residents: a randomized, multiple-dose study. *J Am Geriatr Soc.* 2007;55(2):234-239.
28. Colon-Emeric CS, Lekan D, Utley-Smith Q, et al. Barriers to and facilitators of clinical practice guideline use in nursing homes. *J Am Geriatr Soc.* 2007;55(9):1404-1409.
29. Catic AG, Mattison ML, Bakaev I, Morgan M, Monti SM, Lipsitz L. ECHO-AGE: an innovative model of geriatric care for long-term care residents with dementia and behavioral issues. *J Am Med Dir Assoc.* 2014;15(12):938-942.
30. Gordon SE, Dufour AB, Monti SM, et al. Impact of a Videoconference Educational Intervention on Physical Restraint and Antipsychotic Use in Nursing Homes: Results From the ECHO-AGE Pilot Study. *J Am Med Dir Assoc.* 2016;17(6):553-556.
31. Low LF, Fletcher J, Goodenough B, et al. A Systematic Review of Interventions to Change Staff Care Practices in Order to Improve Resident Outcomes in Nursing Homes. *PLoS One.* 2015;10(11):e0140711.
32. Colon-Emeric CS, Lyles KW, House P, et al. Randomized trial to improve fracture prevention in nursing home residents. *Am J Med.* 2007;120(10):886-892.
33. Colon-Emeric CS, Corazzini K, McConnell ES, et al. Effect of Promoting High-Quality Staff Interactions on Fall Prevention in Nursing Homes: A Cluster-Randomized Trial. *JAMA Intern Med.* 2017;177(11):1634-1641.
34. Colon-Emeric CS, McConnell E, Pinheiro SO, et al. CONNECT for better fall prevention in nursing homes: results from a pilot intervention study. *J Am Geriatr Soc.* 2013;61(12):2150-2159.
35. Saliba D, DiFilippo S, Edelen MO, Kroenke K, Buchanan J, Streim J. Testing the PHQ-9 interview and observational versions (PHQ-9 OV) for MDS 3.0. *J Am Med Dir Assoc.* 2012;13(7):618-625.
36. Perlman CM, Hirdes JP. The aggressive behavior scale: a new scale to measure aggression based on the minimum data set. *J Am Geriatr Soc.* 2008;56(12):2298-2303.

37. Lowe B, Kroenke K, Herzog W, Grafe K. Measuring depression outcome with a brief self-report instrument: sensitivity to change of the Patient Health Questionnaire (PHQ-9). *J Affect Disord.* 2004;81(1):61-66.
38. Morris JN, Fries BE, Morris SA. Scaling ADLs within the MDS. *J Gerontol A Biol Sci Med Sci.* 1999;54(11):M546-553.
39. Carpenter GI, Hastie CL, Morris JN, Fries BE, Ankri J. Measuring change in activities of daily living in nursing home residents with moderate to severe cognitive impairment. *BMC Geriatr.* 2006;6:7.
40. Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. *Clin Pharmacol Ther.* 1981;30(2):239-245.
41. Graves T, Hanlon JT, Schmader KE, et al. Adverse events after discontinuing medications in elderly outpatients. *Arch Intern Med.* 1997;157(19):2205-2210.
42. Crichton S, Childs E. Clipping and Coding Audio Files: A Research Method to Enable Participant Voice. *International Journal of Qualitative Methods.* 2005;4(3):40-49.
43. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA. Caution regarding the use of pilot studies to guide power calculations for study proposals. *Arch Gen Psychiatry.* 2006;63(5):484-489.

Appendix 1

NH PRIDE Study Medication Algorithms

Table 1. Algorithm for Deprescribing Medications Associated with Falls and Injury in NH-PRIDE Study

Drug Class	Criteria	Deprescribing Schedule	Study Team will Monitor	Nursing will notify MD/NP for new symptoms	Alternative Therapies and Approaches
Benzodiazepines	• Used for insomnia, OR • Used for other sleep disorder and alternative therapies not tried, OR • Well-controlled mental health condition AND no acute anxiety for 1 year, OR • Restless Legs Syndrome (RLS)/ Periodic Limb Movement Disorder (PLMD)	• 25% dose reduction from starting dose every 2 weeks, 12.5% last 2 weeks (over a total of 8 weeks) • If withdrawal symptoms appear (see "Monitoring "), maintain the current dose for one to two additional weeks and then resume the taper	• 2 MDS assessments post intervention: MDS items pertaining to mood, behaviors and function (ADLs) • Chart review at 1 and 4 months post intervention: behaviors, worsening psychiatric symptoms, insomnia, functional decline hospitalizations, ED visits	• Nursing to notify MD/NP for withdrawal symptoms during medication reduction period including insomnia, anxiety, irritability, and gastrointestinal symptoms (End date for this order is the same end date of the taper)	• For insomnia, employ non-pharmacologic strategies described below if insomnia reoccurs or persists during tapering • If used for RLS/PLMS, may try dopamine agonist • If anxiety recurs and drug therapy is required, consider a selective serotonin reuptake inhibitor (SSRI) antidepressant, particularly citalopram or sertraline
Antipsychotics	• Used for behavior problems in or symptoms of dementia (e.g., psychosis, agitation, aggression) OR • Well-controlled mental health condition AND no psychosis	• Dementia with behaviors: 25% dose reduction every 2 weeks with goal of discontinuing or lowest dose possible to control symptoms (over a total of 8 weeks) • Other	• 2 MDS assessments post intervention: MDS items pertaining to mood, behaviors and function (ADLs) • Chart review at 1 and 4 months post intervention: behaviors, worsening psychiatric	• Nursing to notify MD/NP for dyskinesias, insomnia, nausea, worsening psychosis, aggression, or hallucinations during medication reduction period (End date for this order is the same end date of the taper)	• For insomnia, behavioral strategies, specifically consistent wake-sleep times, opening curtains during the day to maximize bright light exposure, increasing daytime activity, decreasing napping, and

	past year AND dose higher than minimal effective dose, OR • Used for insomnia	mental health condition: 25% dose reduction every 2 weeks with goal of minimal effective dose or lowest dose to control symptoms. • Insomnia: 25% dose reduction every 2 weeks with goal of discontinuation	symptoms, insomnia, functional decline hospitalizations, ED visits		toileting before bed
Antidepressants	• Well-controlled symptoms on stable dose >1 year • 1st episode of depression OR dose > minimal effective dose • No history of symptom relapse on discontinuation in the prior 2 years	• Recurrent: 50% dose reduction every 2 weeks to minimal effective dose or lowest dose to control symptoms (over a total of 8 weeks) • 1st episode: 50% dose reduction every 2 weeks to d/c or lowest dose to control symptoms	• 2 MDS assessments post intervention: MDS items pertaining to mood, behaviors and function (ADLs) • Chart review at 1 and 4 months post intervention: behaviors, worsening psychiatric symptoms insomnia, functional decline hospitalizations, ED visits	• Nursing to notify MD/MP for withdrawal symptoms, including akathisia, anxiety, chills, gastrointestinal distress, headache, insomnia, irritability, malaise, myalgia, during medication reduction period (End date for this order is the same end date of the taper)	• If drug therapy is necessary, consider an SSRI, particularly citalopram or sertraline
Hypnotics	• Periodic insomnia not impacting quality of life	• 50% dose reduction every 2 weeks to d/c • If withdrawal symptoms appear (see "Monitoring	• 2 MDS assessments post intervention: MDS items pertaining to mood, behaviors and function	• Nursing to notify MD/NP for withdrawal symptoms, including insomnia, anxiety, irritability, and gastrointestinal	• Melatonin • Behavioral strategies, specifically consistent wake-sleep times, opening curtains during the day to

		"), maintain the current dose for one to two additional weeks and then resume the taper	(ADLs) • Chart review at 1 and 4 months post intervention: behaviors, worsening psychiatric symptoms, insomnia, functional decline hospitalizations, ED visits	symptoms, during medication reduction period. (End date for this order is the same end date of the taper)	maximize bright light exposure, increasing daytime activity, decreasing napping, and toileting before bed
Anticholinergics	• Used for insomnia, OR • Used for muscle relaxant, OR • Short acting agent used for urinary urgency, OR • Itching	• No taper needed	• 2 MDS assessments post intervention: MDS items pertaining to pain and urinary incontinence • Chart review at 1 and 4 months post intervention: pain, new urinary incontinence, itching, insomnia, functional decline, hospitalizations, ED visits	• Nursing to notify MD/NP for withdrawal symptoms specific to the agent being deprescribed during medication reduction period. (End date for this order is the same end date of the taper)	• Alternatives depend on indication (e.g., melatonin for insomnia, topicals for itching) •
Antiepileptics	• Taper only attempted if used for behavioral symptoms of dementia	• Variable based on agent	• 2 MDS assessments post intervention: MDS items pertaining to mood, behaviors and function (ADLs) • Chart review at 1 and 4 months post intervention: behaviors, worsening psychiatric symptoms,	• Nursing to monitor for increased confusion, irritability, tachycardia, and diaphoresis; if noted, perform dose increases no more frequently than every 14 days • Some individuals may experience insomnia, so prioritize deprescribing of doses earlier in	• Consider non-pharmacologic therapies and approaches like implementation of activities, music therapy, sensory interventions (e.g., massage), structured routines, and light therapy

			insomnia, functional decline hospitalizations, ED visits	the day first (End date for this order is the same end date of the taper)	
Alpha Blockers	• Used for BPH, OR • Used for hypertension with majority of SBP < 140 mmHg OR other antihypertensives have not been tried	• No taper needed	• 2 MDS assessments post intervention: MDS items pertaining to function (ADLs) • Chart review at 1 and 4 months post intervention: elevated blood pressure, tachycardia, functional decline hospitalizations, ED visits	• Nursing will check blood pressure twice weekly during medication reduction period; report 2 or more readings of SBP > 160 mmHg to clinician. (End date for this order is the same end date of the taper)	• If drug therapy is ultimately necessary, try other antihypertensive (e.g., amlodipine) • Alternative treatments for hypertension are unlikely to be necessary
Beta Blockers	• Used for hypertension OR another indication aside from rate control	• 50% dose reduction every 2 weeks to discontinuation (over a total of 8 weeks)	• 2 MDS assessments post intervention: MDS items pertaining to behaviors, mood, function (ADLs) • Chart review at 1 and 4 months post intervention: elevated blood pressure, tachycardia, behaviors, anxiety, functional decline hospitalizations, ED visits	• Nursing will check blood pressure twice weekly during medication reduction period; report 2 or more readings of SBP > 160 mmHg to clinician (End date for this order is the same end date of the taper)	• Alternative treatments are unlikely to be necessary
Other Antihypertensive Drugs (calcium channel blocker, angiotensin	• SBP <140mmHg	• 50% dose reduction every 2 weeks to d/c or SBP 141-	• 2 MDS assessments post intervention: MDS items	• Nursing will check blood pressure twice weekly during medication	• Alternative treatments are unlikely to be necessary, but behavioral

converting enzyme inhibitor, or angiotensin receptor blocker)		160mmHg	pertaining to function (ADLs) • Chart review at 1 and 4 months post intervention: elevated blood pressure, tachycardia, functional decline hospitalizations, ED visits	reduction period; report 2 or more readings of SBP > 160 mmHg to MD/NP (End date for this order is the same end date of the taper)	therapies like transcendental meditation or biofeedback techniques may have a role
Diuretics	• Used for venous stasis or lymphedema, OR • Used for hypertension with SBP < 140mmHg OR other classes not tried	• No taper needed	• 2 MDS assessments post intervention: MDS items pertaining to function (ADLs) • Chart review at 1 and 4 months post intervention: elevated blood pressure, CHF exacerbation, functional decline, hospitalizations, ED visits	• Nursing will check blood pressure twice weekly during medication reduction; report 2 or more readings of SBP > 160 mmHg to MD/NP. • Obtain weekly weights x 4 weeks; nursing to notify MD/NP of weight gain >=5 lbs (End date for this order is the same end date of the taper)	• Employ compression hose • May try other antihypertensive (e.g., lisinopril), especially if SBP increases to >180 mmHg or DBP increases to >100 mmHg
Proton Pump Inhibitors	• Continuous PPI use >8 weeks, AND • No long-term use of non-steroid anti-inflammatory drugs, history of bleeding stomach ulcer(s), severe inflammation of the esophagus, or Barrett's esophagus	• Reduce dose by half every 2 weeks (over a total of 4 weeks), OR • In the case of capsules that cannot be split or broken in half, take a dose every other day for 2 weeks and then take a dose every 3 days	• 2 MDS assessments post intervention: MDS items pertaining to behaviors, pain, function (ADLs) • Chart review at 1 and 4 months post intervention: gastroesophageal reflux, functional decline hospitalizatio	• Nursing to notify MD/NP for symptom recurrence, including heartburn, dyspepsia, regurgitation, or anorexia during medication reduction period. (End date for this order is the same end date of the taper)	• If heartburn, acid reflux, or rebound symptoms occur after discontinuation, elevate resident's head by using extra pillows

		for 2 weeks (over a total of 4 weeks)	ns, ED visits		
Hypoglycemics – Sulfonylureas, Meglitidines	• Most recent hemoglobin A1C <8.5, OR • Insulin dose is >40 units/day, OR • Patient refusing to eat or is eating irregularly	• No taper needed	• 2 MDS assessments post intervention: MDS items pertaining to function (ADLs) • Chart review at 1 and 4 months post intervention: severe hyperglycemia (>400), polydipsia, polyuria, functional decline hospitalizations, ED visits	• Nursing will measure fasting blood twice weekly for 2 weeks. Notify MD/NP for any BG >300 or >2 values over 200. (End date for this order is the same end date of the taper)	• Substitute dipeptidyl peptidase-4 inhibitor if A1C rises to >9 (Goal is to achieve hemoglobin A1C 8-9 AND no episodes of severe hypoglycemia or severe hyperglycemia)
Hypoglycemics – Sliding Scale Insulin (SSI)*	• Type II Diabetes, AND • SSI is the only insulin treatment, OR • SSI in addition to basal insulin, OR • SSI in addition to basal insulin and mealtime insulin	• No taper needed • If most recent hemoglobin A1C<=8.5, discontinue SSI without adding treatment	• 2 MDS assessments post intervention: MDS items pertaining to function (ADLs) • Chart review at 1 and 4 months post intervention: severe hyperglycemia (>400), polydipsia, polyuria, functional decline hospitalizations, ED visits	• Nursing will measure fasting blood sugar daily for 2 weeks. Notify MD/NP for any BG >300 or >2 values over 200 (End date for this order is the same end date of the taper)	• If most recent hemoglobin A1C>8.5, review average daily insulin requirement over prior 5–7 days, then initiate basal insulin at 50–75% of that average daily insulin requirement
	*Please see separate table for additional scenarios related to sliding scale insulin which deprescribing may be appropriate.				

Table 2. Algorithm for Prescribing Osteoporosis Treatment in NH-PRIDE study

Drug Class	Prescribing Criteria	Study Team will Monitor	Nursing will notify MD/NP for new symptoms	Treatment Options
Calcium and Vitamin D	• Life expectancy > 6 months based on MDS question J1400 or validated tool, and not enrolled in hospice, AND • No evidence of hypercalcemia (>10.5mg/dL) by chart review	• 2 MDS assessments post intervention: MDS items pertaining to function (ADLs) • Chart review at 1 and 4 months post intervention: elevated serum calcium (>10.5mg/dL), worsening constipation, functional decline hospitalizations, ED visits	• Nursing will notify MD/NP for worsening constipation	• Ensure 1200mg calcium through diet and supplements. • 1000-2000IU vitamin D daily
Antiresorptives	• Estimated FRAiL score≥ 10% OR Estimated FRAiL score ≥ 5% + history of fracture • Life expectancy >6 months based on MDS question J1400 or validated tool, and not enrolled in hospice • No contraindications (allergy, etc.)	• 2 MDS assessments post intervention: MDS items pertaining to function (ADLs) • Chart review at 1 and 4 months post intervention: gastroesophageal reflux, esophagitis, injection site reactions (for subcutaneous medications), hypocalcemia (<8.7mg/dL), functional decline, hospitalizations, ED visits	• Nursing will assure proper administration of oral bisphosphonates (taken on empty stomach, sit upright for at least 30 minutes afterwards). • Nursing will notify MD/NP for worsening indigestion, injection site reactions (for subcutaneous medications)	• Oral bisphosphonate • IV bisphosphonate • SQ denosumab

Table 3. Sliding Scale Insulin (adapt from Munshi et al. *Management of Diabetes in Long-term Care and Skilled Nursing Facilities: A Position Statement of the American Diabetes Association*. Diabetes Care. 2016)

Criteria	Schedule and Alternative Therapies
Scenarios in Which Deprescribing is a Focus	
• SSI is the only insulin treatment	• Discontinue (no taper necessary) • If most recent hemoglobin A1C<=8.5, discontinue SSI without adding treatment • If most recent hemoglobin A1C>8.5, review average daily insulin requirement over prior 5–7 days, then initiate basal insulin at 50–75% of that average daily insulin requirement
• SSI is used in addition to scheduled basal insulin	• Discontinue SSI AND • Add 50-75% of the average insulin requirement used as SSI to the current dose of basal insulin -- • If postprandial hyperglycemia persists, add either fixed-dose mealtime insulin OR a non-insulin agent (preferably a dipeptidyl peptidase-4 inhibitor or other agent with low hypoglycemia risk)
• SSI is used in addition to scheduled basal insulin AND scheduled meal time insulin (i.e., correction dose insulin)	• Discontinue correction doses AND • Add the average correction dose before a meal to the scheduled mealtime insulin dose at the **preceding** meal -- • See Munshi et al. *Diabetes Care* 2016 position statement for additional details and examples.
Other Scenarios in Which Immediate Deintensification May Be Appropriate	
• SSI is used in short term due to irregular dietary intake or due to acute illness	• Discontinue SSI and return to previous regimen once health and glucose levels stabilize • Monitor acute illness prior to discontinuation and promote regular dietary intake • Short-term use of SSI is appropriate during the episode of acute illness while dietary intake is irregular
• Wide fluctuations in glucose levels in patients with cognitive decline and/or irregular dietary intake on a chronic basis	• Order scheduled basal and mealtime insulin based on individual needs with the goal of avoiding hypoglycemia • Consider a simple scale such as "give 4 units of mealtime insulin if glucose >300 mg/dL" • Focus on keeping residents hydrated, especially when glucose levels are high (e.g., >300 mg/dL)