I. Objectives
To study the effect of a new clinical program for the care of patients who present with fragility fractures who require operative repair. We have initiated a streamlined admission process for patients with a fragility fractures and utilize standardize protocols to decrease variability/delays to surgery, with the goal of optimal fracture surgery within 24 hours of admission. Daily evaluations are performed to ensure earlier mobility and faster recovery and co-management with frequent communication to avoid errors and reduce adverse events is employed. Improved communication with patients, family and entire team as well as earlier initiation of rehabilitation and more effective use of discharge planning resources are program initiatives as well as complete screening for osteoporosis and plan management with the goal of future fracture prevention.

II. Background & Rationale
In 2004, the Surgeon General released a report on bone health, which he considered the next major health issue. As part of the worldwide Bone and Joint Decade initiative, U.S. patient and physician healthcare organizations, government agencies, and industry, came together to improve prevention of bone and joint disorders, and to improve the quality of life for those affected. Statics show that 1 in 2 women and 1 in 5 men over age 50 will suffer a fracture in their remaining life time\(^1\). At age 50, a woman’s lifetime risk of fracture exceeds combined risk of breast, ovarian & uterine cancer. At age 50, a man’s lifetime risk of fracture exceeds risk of prostate cancer.

Fragility fractures are fractures that results from minimal trauma (i.e. from a fall from a standing height) in an adult above the age of 50. Osteoporosis is a contributing factor in 1.5 million fractures treated each year. Breaking down the approximately 1.5 million fracture related to Osteoporosis approximately 300,000 hip fractures, 700,000 vertebral fractures, 250,000 wrist fractures and 300,000 fractures at other sites.

Looking at the consequences of fragility hip fractures alone statics show that within one year after a patient sustain the fracture 20% pass away, 30% are permanently disabled, 40% are unable to walk independently and 80% are unable to complete at least one activity of daily living on their own.

II. Procedures
A. Research Design
We propose a retrospective/prospective cohort study to collect and compare perioperative information from patients who have had a fragility fracture that required surgery. The data that is collected will be entered into a data repository. We want to assess changes in outcomes for older adults undergoing fracture surgery after implementation of improved processes and our multi-disciplinary approach with standardized protocols\(^2\). A secondary outcome is to impact future fracture prevention.

B. Patient Sample:
Patient recruitment
For this study, we will recruit individuals who have been identified as having a fragility fracture who
need surgical care. We will include all consenting patients aged 50 and older (no upper age limit). On average The Ohio State University sees 150. Of the 150 we can expect to enroll 120 into this study a year.

Eligibility

Eligibility will be determined by a patient’s status as having a fragility fracture. Subjects will be age 50 or older and must be able to speak and read English. Subjects must themselves be able to give consent or a person with power of attorney (POA) can sign the consent; will not enroll individuals who lack decision making capacity (who do not have a POA). We will not enroll prisoners or any other patients who, in the opinion of the investigator, are unlikely to return for follow-ups.

C. Measurement/Instrumentation

Outcome Variables (Dependent Variables):
- Surgical outcomes
- Standardized protocol
- Future fracture prevention

Explanatory Variables (Independent Variables):
- Disability status
- History of present condition
- Cognitive status
- Chronic diseases (listed independently – i.e., diabetes, hypertension, elevated cholesterol,....)

Potential Confounders:
- Age
- Gender
- Race
- Insurance status

D. Detailed study procedures

Timeline and duration of subject participation

Subject enrollment will commence upon receipt of IRB approval and continue on an ongoing basis. Each participant’s involvement is completely voluntary and all subjects are advised to contact the principal investigator at any time if they wish to discontinue participation or revoke consent. Patients will be followed in the study for 1 year.

<table>
<thead>
<tr>
<th>Time point</th>
<th>Data to be collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative visit (done when admitted for fracture)</td>
<td>Name</td>
</tr>
<tr>
<td></td>
<td>DOB</td>
</tr>
<tr>
<td></td>
<td>Medical record number</td>
</tr>
<tr>
<td></td>
<td>Address and telephone number</td>
</tr>
<tr>
<td></td>
<td>Gender</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Disability status</td>
</tr>
<tr>
<td>----------</td>
<td>------------------</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>History of present condition (location of pain/duration of symptoms)</td>
</tr>
<tr>
<td>Physical exam</td>
<td>Radiographic data</td>
</tr>
<tr>
<td>Charlson Index</td>
<td>SF12</td>
</tr>
<tr>
<td>Parker Mobility Score</td>
<td>ADL Katz Score</td>
</tr>
<tr>
<td>Pain (Rate on scale 1 to 10)</td>
<td></td>
</tr>
</tbody>
</table>

**During Hospitalization**

<p>| Mini-cog Test. Additional testing or referral, if warranted, to evaluate for dementia |
| Delirium screen (CAM) prn and by nursing staff; MMT informed of abnormal results |
| Medication review. Pharmacy for evaluation of medication contributing to falls |
| Social support system and Desire to Return to Pre-Injury Residence Questionnaire |
| Labs: pre-albumin levels, 25-hydroxy Vitamin D, PTH, and kidney function serum calcium, TSH, alkaline phosphatase, magnesium, phosphorus, ALT, AST, vitamin B12, serum glucose and if elevated HA1c |
| Pre-operative American Society of Anesthesia (ASA) physical rating score |
| Consider if referral needed per protocol to Endocrine evaluation of secondary cause for osteoporosis or to primary care for diabetes diagnosis |
| Dietician consult for pre-albumin &lt; 18 |
| Discuss results of assessments |
| Add referral to Geriatrician when warranted |
| Discuss osteoporosis as it relates to the patient; DEXA scan (to be scheduled) |
| Calcium and vitamin D intake, food sources and supplements. Dietician consult when needed. |
| Fall precautions; home safety checklist |</p>
<table>
<thead>
<tr>
<th><strong>2 weeks post-op (+/- 7 days)</strong></th>
<th>Discuss home fall risk assessment (to be scheduled) and balance testing (3 month visit)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PA to conduct appt</strong></td>
<td>Physical exam</td>
</tr>
<tr>
<td></td>
<td>Incision evaluated. Removal of stitches or staples.</td>
</tr>
<tr>
<td></td>
<td>Schedule DEXA</td>
</tr>
<tr>
<td></td>
<td>Schedule any labs not previously ordered: 25-hydroxyVit D, PTH intact, TSH, pre-albumin, Chem 12, Mag, Phos</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>6 weeks post-op (+/- 14 days)</strong></th>
<th>Review test results with patients:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgeon, NP and PT to conduct appt</strong></td>
<td>Physical exam</td>
</tr>
<tr>
<td></td>
<td>Evaluate healing and placement of fracture</td>
</tr>
<tr>
<td></td>
<td>Order X-Rays</td>
</tr>
<tr>
<td></td>
<td>Fall precautions and exercise recommendations and handouts</td>
</tr>
<tr>
<td></td>
<td>* Repeat Mini-cog Test if abnormal in hospital. Refer to PCP or Geriatrician if warranted</td>
</tr>
<tr>
<td></td>
<td>SF12 only if not done in hospital</td>
</tr>
<tr>
<td></td>
<td>ADL Katz</td>
</tr>
<tr>
<td></td>
<td>Pain Score---current (Rate on scale 1 to 10)</td>
</tr>
<tr>
<td></td>
<td>Fall Risk Assessment</td>
</tr>
<tr>
<td></td>
<td>• Fear of Falling Questionnaire</td>
</tr>
<tr>
<td></td>
<td>• CV—Heart RR, carotids</td>
</tr>
<tr>
<td></td>
<td>• Orthostatic BPs sitting and standing (immediate and 3-5 minutes) if able</td>
</tr>
<tr>
<td></td>
<td>• Hearing</td>
</tr>
<tr>
<td></td>
<td>• Vision: depth perception, contrast,</td>
</tr>
<tr>
<td></td>
<td>• Touch sensation feet---filaments</td>
</tr>
<tr>
<td></td>
<td>• Proprioception great toes</td>
</tr>
<tr>
<td></td>
<td>• Reflexes LEs if able</td>
</tr>
</tbody>
</table>
**Shoes**

**PT: Fall Prevention**

Evaluate and recommend
- Need for assistive devices
- Need for additional fall prevention strategies
- Recommendations for additional PT services
- Recommend exercise program if PT not needed

Tests:
Lower Extremity Fracture: Balance, gait and strength assessment
- Gait Speed Test by PT or NP
- Tinetti Assessment, if able
- Berg Balance Scale, if able
- Postural stability, Functional Movement Assessment using Simulation System, if able (e.g. Kinetic, Wii, or TrazerHRA assessment systems)

<table>
<thead>
<tr>
<th>3 month post op  (+/- 28 days)</th>
<th>Surgeon, NP and PT to conduct appt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical exam</td>
<td>Physical exam</td>
</tr>
<tr>
<td>Evaluate healing and placement of fracture</td>
<td>Evaluate healing and placement of fracture</td>
</tr>
<tr>
<td>Review X Rays</td>
<td>Review X Rays</td>
</tr>
<tr>
<td>Order new set of X rays</td>
<td>Order new set of X rays</td>
</tr>
<tr>
<td>Evaluate Activity</td>
<td>Evaluate Activity</td>
</tr>
<tr>
<td>- New falls</td>
<td>- New falls</td>
</tr>
<tr>
<td>- Compliance with home safety recommendations</td>
<td>- Compliance with home safety recommendations</td>
</tr>
<tr>
<td>- Compliance with activity and exercise recommendations</td>
<td>- Compliance with activity and exercise recommendations</td>
</tr>
</tbody>
</table>

Medications
- Evaluate compliance with Calcium and Vitamin D supplements
- Review medications to treat osteoporosis. Adjust as needed.

SF12

ADL Katz

Pain Score---current (Rate on scale 1 to 10 )

Continue Fall Risk Assessment
- Fear of Falling Questionnaire
- CV—Heart RR, carotids
- Orthostatic BPs sitting and standing (immediate and 3-5 minutes) if able and not previously done
- Shoes
- Check use of assistive devices
- Evaluate compliance with recommendations from previous fall assessment

**PT: Fall prevention**

Evaluate and recommend
- Need for assistive devices
- Need for additional fall prevention strategies
- Recommendations for additional PT services
- Recommend exercise program if PT not needed

Tests:
Lower Extremity Fracture: Balance, gait and strength assessment
- Gait Speed Test by PT or NP, include stride length
- Tinetti Assessment, if able
- Berg Balance Scale, if able
- Postural stability, Functional Movement Assessment using Simulation System, if able (e.g. Kinetic, Wii, or TrazerHRA assessment systems)

### 6 month post op**
**(+/- 28 days)**

**Surgeon, NP and PT to conduct appt**

<table>
<thead>
<tr>
<th>Physical exam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluate healing and placement of fracture</td>
</tr>
</tbody>
</table>

Review X Rays

Order new set of X rays

Evaluate Activity
- New falls
- Compliance with home safety recommendations
- Compliance with activity and exercise recommendations

Medications
- Evaluate compliance with Calcium and Vitamin D supplements
- Review medications to treat osteoporosis. Adjust as needed.

SF12

ADL Katz

Pain Score---current (Rate on scale 1 to 10 )

Continue Fall Risk Assessment
- Fear of falling questionnaire
- CV—Heart RR, carotids
- Orthostatic BPs sitting and standing (immediate and 3-5 minutes) if able
- Shoes
- Check use of assistive devices
- Evaluate compliance with recommendations from previous fall assessment

**PT: Fall prevention**

Evaluate and recommend
- Need for assistive devices
- Need for additional fall prevention strategies
- Recommendations for additional PT services
- Recommend exercise program if PT not needed

**Tests:**
Lower Extremity Fracture: Balance, gait and strength assessment
- Gait Speed Test by PT or NP
- Tinetti Assessment, if able
- Berg Balance Scale, if able
- Postural stability, Functional Movement Assessment using Simulation System, if able (e.g. Kinetic, Wii, or TrazerHRA assessment systems)

<table>
<thead>
<tr>
<th>1 year post-op and every year after^^</th>
<th>Physical exam</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Evaluate healing and placement of fracture</td>
</tr>
<tr>
<td></td>
<td>Review X Rays</td>
</tr>
<tr>
<td></td>
<td><strong>Labs:</strong> 25(OH)D, calcium and pre-albumin; others as indicated</td>
</tr>
<tr>
<td></td>
<td><strong>DEXA</strong> if indicated</td>
</tr>
</tbody>
</table>

**Evaluate Activity**
- New falls
- Compliance with home safety recommendations
- Compliance with activity and exercise recommendations

Review test results with patients, if ordered:
- **DEXA** scan
- **Lab** tests

**Medications:**
- Evaluate compliance for sufficient calcium and Vitamin D.
- Provide handouts as needed
- Prescribe or review current medications taken to treat osteoporosis.
Review Home Safety Assessment for fall risk and home modifications

- Fall precautions and exercise recommendations and handouts
- Patient to continue to use assistive device

Mini-cog Test. Refer to PCP or Geriatrician if warranted

SF12

ADL independence

Pain Score---current (Rate on scale 1 to 10 )

Fall Risk Assessment

- CV—Fear of falling questionnaire
- CV—Heart RR, carotids
- Orthostatic BPs sitting and standing (immediate and 3-5 minutes) if able
- Hearing
- Vision: depth perception, contrast, near vision
- Touch sensation feet—filaments
- Proprioception great toes
- Reflexes LEs if able
- Shoes

Schedule Annual Fall Risk Assessment

**PT: Fall Prevention**

Evaluate and recommend

- Need for assistive devices
- Need for additional fall prevention strategies
- Recommendations for additional PT services
- Recommend exercise program if PT not needed

Tests:
Balance, gait and strength assessment
Lower Extremity Fracture: Balance, gait and strength assessment

- Gait Speed Test by PT or NP, include stride length
- Tinetti Assessment, if able
- Berg Balance Scale, if able
- Postural stability, Functional Movement Assessment using Simulation System, if able (e.g. Kinetic, Wii, or TrazerHRA assessment systems)

**Screen by phone, patients not seen for 6 month or 12 month**

Evaluate Activity

- New falls
- Compliance with home safety recommendations
appointments.
(+/- 28 days)

• Compliance with activity and exercise recommendations
• Evaluate return to pre-injury residence

Medications

• Evaluate compliance with Calcium and Vitamin D supplements
• Review medications to treat osteoporosis. Adjust as needed.

Tests:

• SF12
• ADL independence
• Pain Score---current (Rate on scale 1 to 10 )

***6 and ^^^12 month appointment for patients at high risk for falling again. Patients that are not high risk will have their appointment conducted via phone.

Risks and benefits

This is a minimal risk study. Participants are not expected to experience harms or discomforts greater than those ordinarily encountered during daily life or during the performance of routine physical or psychological examination. However, since PHI will be recorded as part of the study data, there is an inherent risk of loss of confidentiality. This risk is identified for patients in the informed consent.

There are direct patient benefits to study participants. Patients are expected to have a shorter wait for surgery, quickly recovery, earlier initiation of rehabilitation, screening and treatment (if needed) for Osteoporosis.

Safeguarding of subject confidentiality

PHI will be recorded as part of the study data and the data will be fully identifiable.

The research database will be encrypted and password-protected, accessible only by those listed on the study as investigators and key personnel. All paper forms containing patient information will be stored in a locked file in a secure area. Only authorized research staff will have access to this file.

Potential impact

• Standardized protocols/improved communication/Decreased time to surgery =>
  – Decreased patient morbidity\(^1,2\)
  – Decreased patient mortality\(^1,2\)
  – Shorter length of stay\(^1,2\)
  – Increased likelihood to return to pre-injury status
  – Treatment of previously undiagnosed osteoporosis
  – Prevent repeat fragility fractures
• Cost savings
  – Estimate savings of $3879 /case
  – Assuming 350,000 hip fxs per year in the US => 1.36 billion dollars cost savings per year

E. Internal Validity
Measures that have been taken to avoid study bias include the following:
- All patients in the study will receive the same education regarding fragility fractures from gerontologist study personnel, PCRN.
- Study personnel will all receive the same training regarding the study and research visits so that all studies will be conducted in the same manner and that all data will be collected appropriately.

F. Data Analysis
The data analysis is largely descriptive. Bivariate analyses will be used to show the relationship between two variables, such as surgical outcome and age, or surgical outcome and insurance status. Multivariate analyses will be conducted to adjust for confounders. Multivariate logistic regression models will be used to answer most of the research questions. There are two main uses of logistic regression: to predict group membership and to provide knowledge of the relationships and strengths among the variables (Hair et al., 1998). For this study project, it is the latter reason that logistic regression models will be used. Odds ratios will be calculated to compare the probability that a certain event is the same for two groups (Hair et al., 1998). The odds ratio gives the amount of change expected when there is a one unit change in the predictor variable and all of the other variables in the model are held constant. Profile likelihood confidence intervals of 95% will be used. Significant effects are suggested when confidence intervals do not contain the value 1.0. (Hair et al., 1998). Patient-centered and complex systems analytical techniques will be used to evaluate for potential complex variable interrelationships that may be relevant to the population. (Quatman et al., 2009)

III. References:

Fisher AA J Orthop Trauma 2006


National Osteoporosis Foundation, 2000

Johnell et al. Osteoporos Int. 2005; 16: S3-7

U.S. Surgeon General 2004