HIPWATCH: OSTEOPOROSIS INVESTIGATION AND TREATMENT AFTER A HIP FRACTURE: A 6-MONTH RANDOMIZED CONTROLLED TRIAL

by

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ABSTRACT

Objective: To test a novel Patient Empowerment and Physician Alerting (PEPA) intervention that seeks to improve the proportion of older adults who are diagnosed and treated for osteoporosis after hip fracture.

Methods: Design: Six-month randomized controlled trial. Participants were randomized either to the PEPA group (intervention) or the ‘usual-care’ group (control).

Participants and Setting: Forty-eight women and men aged 60 years and older who were admitted to Vancouver General Hospital for a fall-related hip fracture.

Measurements: The Diagnosis and Management Questionnaire (DMQ) was administered to all participants to determine the initiation of investigation and treatment of osteoporosis. The responses were validated in part by physician report obtained for one fourth of the participants.

Statistical Analyses: I compared the difference between the two experimental groups in the number of individuals who received one or more osteoporosis specific ‘best practices’ within 6 months after their hip fracture using the chi-square test. The alpha level was set at p < 0.05.

Results: Of the 78 individuals who were eligible for this study, 48 agreed to participate. Among these participants, I found a significant difference between the intervention and the control group in the number of individuals who received one or more osteoporosis ‘best practices’ after their hip fracture (p < 0.01). In the PEPA group, 54% (p < 0.01) were prescribed bisphosphonate therapy, 29% (p < 0.01) were investigated by a bone mineral density test, 39% were initiated on Calcium and Vitamin D (p = 0.32) and 32% (p < 0.01) were recommended exercise within 6 months after experiencing a fragility hip fracture. In contrast, in the usual-care group 0% were prescribed bisphosphonate therapy, 0% were investigated by a bone mineral density test, 30% were initiated on Calcium and Vitamin D and 0% were recommended exercise within 6 months after experiencing a fragility hip fracture.

Summary and Conclusions: This cohort of individuals who fractured their hip did not receive guideline care unless recommended by the PEPA intervention letters sent to the participant and delivered to the primary care physician. Patients who sustain a low-trauma hip fracture have osteoporosis but did not routinely receive recommended osteoporosis ‘best practice’ care.
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### Glossary of Terms and Abbreviations

<table>
<thead>
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<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Diagnosis and Management Questionnaire (DMQ)</td>
<td>Used to assess the number and identity of osteoporosis specific ‘best practices’ offered to patients</td>
</tr>
<tr>
<td>Mini-Mental State Examination (MMSE)</td>
<td>Used to assess cognition. The MMSE is ranked on a scale of 0-30. Individuals with a MMSE score &gt; 24 were considered to be in an acceptable range for inclusion in this study.</td>
</tr>
<tr>
<td>Dual-energy X-ray Absorptiometry (DXA)</td>
<td>A two-dimensional representation of bone density (g/cm²)</td>
</tr>
<tr>
<td>Bone Mineral Density (BMD)</td>
<td>The amount of bone mineral contained within a specific area or volume (g/cm²)</td>
</tr>
<tr>
<td>Activities of Daily Living (ADL)</td>
<td>An individual's ability to perform regular daily activities and an assessment of their mobility.</td>
</tr>
<tr>
<td>Hormone Replacement Therapy (HRT)</td>
<td>An estrogen plus progestin supplement used to treat osteoporosis and menopause.</td>
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<tr>
<td>Geriatric Depression Scale (GDS)</td>
<td>Diagnostic screening tool for depression</td>
</tr>
<tr>
<td>Intention to Treat (ITT)</td>
<td>Principle that minimizes exclusion of patients randomized to either treatment groups in order to eliminate potential bias</td>
</tr>
<tr>
<td>Primary Care Physician (PCP)</td>
<td>Usually the family practitioner also known as the general practitioner- the first contact for healthcare</td>
</tr>
<tr>
<td>Fracture Liaison Nurse (FLN)</td>
<td>System whereby a nurse acts in a ‘triage’ function step in the identification of patients who have suffered a fracture. The FLN is responsible for determining their care pathway.</td>
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Preface: Publications and Abstracts Arising From This Thesis

REFEREED JOURNAL ARTICLES

1. JC Davis, MC Ashe, P Guy, KM Khan

2. MC Ashe, JC Davis.

3. JC Davis, MG Donaldson, MC Ashe, KM Khan
   The role of balance and agility training in fall reduction: A comprehensive review. Europa Medicophysica 2004 Sep;40(3):211-21

ABSTRACTS - INTERNATIONAL

1. JC Davis, MC Ashe, P Guy, KM Khan
   Under-servicing of Women and Men Following a Hip Fracture: A Retrospective Study of Osteoporosis Overlooked (Australian Falls Prevention Conference, Sydney, Australia, November 2004)

ABSTRACTS - NATIONAL

1. JC Davis, P Guy, MC Ashe, T Liu-Ambrose, KM Khan
   2006 COA Annual Meeting (June 2006) accepted
   HipWatch: Osteoporosis Treatment and Investigation after a Hip Fracture: A 6-Month Randomized Controlled Trial

2. JC Davis, P Guy, MC Ashe, T Liu-Ambrose, C Marra, KM Khan
   2006 BC Injuries and Prevention Conference
   HipWatch: Osteoporosis Treatment and Investigation after a Hip Fracture: A 6-Month Randomized Controlled Trial

3. JC Davis, P Guy, MC Ashe, T Liu-Ambrose, C Marra, KM Khan
   2006 Experimental Medicine Research Day November 2005
   HipWatch: Osteoporosis Treatment and Investigation after a Hip Fracture: A 6-Month Randomized Controlled Trial

4. JC Davis, MC Ashe, KM Khan, P Guy
   Experimental Medicine Research Day November 2004
   Inpatient Osteoporosis Investigation and Treatment in Women and Men Following a Hip Fracture

5. JC Davis, MC Ashe, KM Khan, P Guy
Breaking New Ground: MSFHR Themes 1&4 Symposium May 2004
Osteoporosis Investigation and Treatment in Women and Men Following a Hip Fracture
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1. **CHAPTER 1: INTRODUCTION, OBJECTIVES, OUTCOMES & HYPOTHESES**

1.1. **OSTEOPOROSIS AND HIP FRACTURES**

Osteoporosis is a condition of generalized skeletal fragility such that fractures occur with minimal trauma. These fractures are painful, disabling and can cause death (1). More Canadian women die annually following an osteoporotic fracture than from breast or ovarian cancer combined. Over 1.4 million Canadians have osteoporosis including 25% of women and 12% of men aged 50 years and older (1). In addition, Canadian health care costs for osteoporosis exceed $1.3 billion annually (2).

Hip fracture is a manifestation of osteoporosis in the elderly (3). There are over 24,000 hip fractures annually in Canada and the one-year direct and indirect costs are conservatively estimated to cost $30,000 (2). However, the real burden to the patient and the community far exceeds this amount. When a patient sustains her/his first hip fracture there is a 3-6 times greater chance that she/he will fracture the other hip (4). Hip fracture, therefore, provides an ideal opportunity to implement secondary prevention strategies. However, after a hip fracture, patients may not be routinely assessed and/or treated for osteoporosis. My own pilot data in 181 seventy-year old women who presented with a fall-related injury in the Emergency Department at Vancouver Hospital showed that fewer than 20% of these patients at high risk of hip fracture were investigated for osteoporosis (5). Fewer than 5% were provided with appropriate treatment. Similar gaps in care after a hip fracture have been reported internationally (6).

To my knowledge, there has been only one other prospective randomized controlled trial aimed at improving patient management after hip fracture through patient and physician education (7). In this study, which was published after my thesis began, the intervention was aimed at both 1) educating the patient while in hospital and 2) providing the patient with a list of questions for their primary care physician and this intervention improved the rate of osteoporosis treatment. My MSc thesis study, HipWatch, was a randomized controlled trial, that investigated a disease management intervention. This patient-empowering and physician-alerting intervention aimed to improve osteoporosis treatment and investigation of those individuals who had sustained a hip fracture. The goal was to compare the results of 'usual care' after a hip fracture with the Patient Empowerment and Physician Alerting (PEPA) intervention. The long-term aim of my research is to prevent fractures by ensuring better medical management following a fracture.
1.2. OBJECTIVES

My primary objective was to improve both the investigation and treatment of osteoporosis among older adults who have sustained a hip fracture and who were admitted to the Vancouver General Hospital. To do this, I intervened with a 2-pronged Patient Empowerment and Physician Alerting System (PEPA). My specific objectives were to:

a) record the number of participants who were offered one or more osteoporosis 'best practices'\(^1\) in the PEPA intervention group and the 'usual care' group as measured by elements of the self-reported Diagnosis and Management Questionnaire (DMQ) and;

b) use the patient self-reported Diagnosis and Management Questionnaire (DMQ) to record the number of participants prescribed: 1) bisphosphonate therapy; 2) a bone mineral density test; 3) calcium and vitamin D; and/or 4) exercise prescription in the PEPA intervention group and the 'usual care' group.

c) describe the participant population on a number of measures recorded at baseline including 1) demographic characteristics (age, gender, income, education level, co-morbidities, and number of medications) and 2) cognition as determined by the Mini Mental State Examination (MMSE).

My secondary objectives were to describe the change in participant population on two measures including: 1) prevalence of depression as determined by the Geriatric Depression Scale (GDS) and 2) functional status as determined by the Barthel Index.

\(^1\) As defined by the 2002 Canadian Medical Association Osteoporosis clinical practice guidelines (8)
1.3. OUTCOMES

1.3.1. Primary outcome

My primary outcome measure was the number of participants who were offered one or more osteoporosis 'best practices' as recommended by the 2002 Canadian Medical Association Osteoporosis Clinical Practice Guidelines (8) and as measured by elements of the self-reported Diagnosis and Management Questionnaire (DMQ) (9). A research assistant and I administered the DMQ via telephone. The DMQ determined which components of osteoporosis 'standard of care' were offered to participants during the six-month intervention. Patient responses were compared with the expert panel-defined 'standard of care'. Standard of care consists of: an awareness of the Primary Care Physician (PCP) and the participant that the participant has an osteoporosis diagnosis, participant counseling to optimize calcium and vitamin D intake, exercise and smoking cessation if appropriate and/or discussion of medication options. I graded clinical outcomes in the categories of (i) diagnosis [osteoporosis diagnosed, yes or no] (ii) bisphosphonate therapy offered [yes or no] and (iii) investigation [DXA scan offered yes or no].

1.3.2. Secondary variable of interest

I monitored changes over a 6-month period in: 1) incidence of depression; and 2) functional status.
1.4. HYPOTHESES

My hypotheses were as follows.

1.4.1. Primary Hypothesis

The PEPA intervention group will show a significantly higher rate of osteoporosis investigation as indicated by elements of the self-reported Diagnosis and Management Questionnaire (DMQ) compared with the usual care group. Specifically, in the PEPA intervention group there will be a:

a) significantly higher number of individuals offered one or more osteoporosis ‘best practices’ by their PCP;
b) significantly higher number of individuals prescribed/offered: i) bisphosphonate therapy; ii) a bone density test; iii) calcium and vitamin D; and iv) exercise and;
c) non-significant difference among the participant population at baseline compared with the ‘usual care’ group.

1.4.2. Secondary Hypotheses

Changes between baseline (recalled status immediately prior to the hip fracture) and the 6-month followup period in 1) incidence of depression; and 2) functional status will be significantly different in the ‘usual care’ control group compared with the PEPA intervention group.
2. CHAPTER 2: BACKGROUND AND SIGNIFICANCE

Hip fractures are a significant public health problem in our world today. The number of hip fractures is currently increasing exponentially. Although this exponential increase is expected to plateau, the consequences of hip fracture result in death, disability and pain. However, hip fractures are preventable both through falls prevention and though targeting individuals with low bone mineral density such as individuals who have sustained a low trauma hip fracture. Importantly, the PEPA intervention provides the patient and the PCP with the opportunity to engage in appropriate osteoporosis management subsequent to their hip fracture.

2.1. EPIDEMIOLOGY OF HIP FRACTURE

In this section I review the burden of hip fracture from the global scale, down to Canadian and BC data. Globally, hip fractures have been previously projected to increase exponentially. More recent evidence indicates that this exponential may plateau. Regardless, a substantial number of individuals will still sustain hip fracture even if the incidence may not increase from year to year.

2.1.1. Global data

Hip fractures are a major public health problem for societies with aging populations. Multiple factors affect the incidence of hip fracture including geography, age and climate. In 1990, the total estimated number of hip fractures worldwide was estimated at 1.7 million (10). The incidence of hip fracture among individuals aged 50 years and older increases dramatically with the most number of hip fractures occurring among individuals aged 80-89 years (11,12). The incidence of hip fracture among individuals aged 75 years and older increases exponentially (13). Estimates indicate that 93% of all hip fractures occur among Caucasians and 79% of all hip fractures occur among women (14). One out of every six Caucasian women will sustain a hip fracture in her lifetime (15). In the United States, it is estimated that a 50 year old white
woman has a 17% chance of a hip fracture in her lifetime and a 50 year old man has a 6% chance of a hip fracture in his lifetime (16). Among patients who suffer from osteoporotic hip fractures, approximately 50% of patients will have permanent function disability greater than before the fracture (17,18).

The frequency of hip fractures, which vary among countries, is globally predicted to increase due to the longer life expectancy of individuals aged 60 years and older (10,19-21). Gullberg and coworkers conservatively estimate a 100% increase in hip fracture numbers for women and a 135% increase in hip fracture numbers for men within the next 25 years (22). Global hip fracture occurrence is expected to rise to a number between 7.3-21.3 million by 2050 with a large proportion of the increase occurring in Asia; however, these findings remain somewhat controversial. For example, Herrera and coworkers reported that the annual incidence of hip fractures in Spain was between 0.42-3.33 cases per 1 000 depending on age (60-100 years) (23), and they suggest that their predictions of the annual increase in hip fracture incidence of 1-4% are consistent with other European countries (24) and the United States (25). Alternatively, others report that the incidence of osteoporotic hip fractures has reached a plateau (26). Specifically, Lofthus reports that by 2010, the number of hip fractures will decrease by 11% since 1996 (26). This decrease is expected to be greater in women (19%) than in men (7%) (26). The difference in predicted rates between Herrera and Loftus may be due to the differences in study design. Herrera and coworkers conducted both a retrospective and prospective study looking at hip fracture incidence. Given that Lofthus and coworkers relied on retrospectively retrieving data from the database, it is possible that patients may have not been coded correctly and the incidence of hip fracture could have been underestimated. Given that Herrera and coworkers included a prospective component, I feel this provided stronger evidence that the incidence of hip fracture is still increasing. The number of hip fractures is expected to quadruple in Australia over the next 56 years (27). An estimated 60 000 – 70 000 hip fractures occur every year in the UK (national service framework) and this number is expected to increase to 66 300 by 2015 (28,29). In African countries, the incidence of hip fracture remains controversial and in some it has not been found to increase with increasing age up to 74 years (personal communication with Dr. J Pankratz). This may be due to the observation that in some African countries, there are fewer older adults aged 60 years and older. However, other less developed African countries are experiencing an increase in the number of hip fractures possibly due to the increased life expectancy (22,30).
2.1.2. Canadian Data

Consistent with global data, Canadian data demonstrates that the annual incidence of hip fractures is increasing. Papadimitropoulos and coworkers demonstrated that there are a greater number of hip fractures with increasing age (31). This trend is less pronounced in British Columbia when compared with Alberta and Ontario (31). In 1993-1994, 29,293 individuals experienced a femoral fracture and 23,375 of these were proximal femoral fractures (17,823 in women and 5,552 in men) (31). Currently over 12% of Canada's population is aged 65 years and older (32). In 2041, 25% of Canada's population will be aged 65 years and older. The incidence of hip fracture in Canada is expected reach 88,124 (with a range between 78,649 and 103,954) by 2041 (31).

2.1.3. British Columbia Data

To date, BC data on individuals who suffer a hip fracture is sparse and therefore more information is necessary to determine: the burden of hip fractures in BC; the current management of hip fractures; and the current management of osteoporosis. British Columbia (33) contains the third largest population of elderly (aged 65 year and older) individuals in Canada (32). Given that fall prevention is a high priority in BC (33) and 95% of hip fractures are the result of a fall, hip fractures should also be considered an area of high priority.

2.2. HIP FRACTURE

In this section I will review the clinical definition of hip fractures including the three types of hip fractures: femoral neck, intertrochanteric and subtrochanteric. I will also discuss clinical risk factors for hip fracture (including BMD, prior fragility fracture, age, family history and female gender). I will conclude this section with a discussion of the consequences of hip fracture include: economic burden on the healthcare system, government, community and patient; the increased morbidity and loss of function as reflected by ability to perform regular daily activities and; the greater mortality rate subsequent to sustaining a hip fracture.
2.2.1. Defining type of hip fractures clinically

The most common type of hip fracture is a fracture of the proximal femur (34-38) and these are sub classified into three categories depending on the anatomic location of the injury: femoral neck, intertrochanteric, and subtrochanteric regions (Figure 1). Femoral neck fractures occur distal to the femoral head and proximal to the greater and lesser trochanter. These type of fractures can be associated with a high incidence of healing problems resulting from disruption in blood supply (34,39). Femoral neck fractures are the most common type of fracture because the superior aspect of the femoral neck experiences preferential bone loss (40). During walking this region of the femoral neck is under minimal stress. However, experiencing a fall on the hip leads to high compressive stresses at the superior region of the femoral neck increasing the likelihood of fracture in this region (41). In the elderly, bone loss at the femoral neck is often stressed by a fall because sustaining a hip fracture in this region is a probable result of a fall (41). Intertrochanteric fractures occur in between the greater and lesser trochanters and are not associated with the healing problems of femoral neck fractures (42-44). However, individuals with this type of fracture may experience a malunion and shortening as a result of compromised bone quality. Subtrochanteric fractures occur below the lesser trochanter and are the least common type of hip fracture accounting for only 5-10% of hip fractures.

Figure 1: Proximal femur classification by region. Reproduced from Zuckerman, 1996 (34)
Chapter 2: Background and Significance

A hip fracture occurs if the biomechanical load exceeds the bone's biomechanical competence (45). A physical examination for a patient who has sustained a hip fracture will often reveal a discrepancy in leg length and an externally rotated limb. Symptoms will vary between patients and will depend on cognition. A patient with a hip fracture will usually be unable to walk and complain of severe hip pain accompanied by localized tenderness over the hip and a limited range of motion of the affected limb during rotation and flexion (35).

2.2.2. Causes of hip fracture

Most low trauma hip fractures are the result of a fall. Hip fractures resulting from overwhelming trauma (motor vehicle accident) or specific pathological conditions (cancer) account for only 11% of hip fractures and are relatively uncommon (46). In addition, an increased incidence of falling also increases the risk of a second hip fracture (47). At the site of a hip fracture, bone mineral density (BMD) may continue to decrease by 4-5% during the first year (48,49). For the purpose of this study, only individuals suffering from a fragility hip fracture were included. In Canada, 95% of hip fractures results from falls (Canadian Centre for Activity and Aging-CCAA) (50).

2.2.3. Clinical risk factors for hip fracture?

Given the increasing incidence of hip fracture, identification of key risk factors associated with hip fracture is essential. The five key risk factors for fracture are low areal bone mineral density (aBMD), prior fragility fracture, age, gender and family history of osteoporosis (8). The categorization of risk factors varies, but the key risk factors can be categorized into the following groups: factors affecting i) bone strength, ii) falling, and iii) related to other clinical characteristics (such as cognition, functional status, fear of falling and prevalence of depression).
2.2.3.1. Bone Mineral Density

Areal BMD is considered the most quantifiable predictor of fracture risk among those individuals who have not yet suffered a fragility fracture (51). For each standard deviation below the mean bone density of a 30 year old healthy individual, the risk of fracture approximately doubles. Specifically, aBMD measurements at the hip have shown to be most predictive of hip fracture risk with each standard deviation below baseline increasing hip fracture risk 2.9 fold (16,52). Bone strength is determined by bone mineral density (BMD), bone architecture and geometry, bone turnover, microdamage accumulation in bone and the degree of mineralization of bone (53). By 2020, it is estimated that approximately 61.4 million Americans will have low bone mass or osteoporosis (51).

Hip fractures are associated with low BMD (54-56). For example, women with hip BMD in the lowest quartile aged 65 years and older have an 8.5 fold greater risk of hip fracture when compared with those in the highest quartile. In addition, low hip BMD is the strongest predictor of hip fracture than BMD at alternate sites (57). In considering prevention of a second hip fracture, it is important to recognize that low hip BMD in patients with a hip fracture increases the risk of a second hip fracture (4).

2.2.3.2. Prior fragility fractures predictive of future fracture

Prior fragility fractures including the wrist, spine and hip increase the risk of subsequent fracture. This risk varies from 1.5-9.5 fold depending on the site and number of prior fragility fractures (58-66). Specifically, prior hip fracture (47,67-69) is a risk factor for a subsequent hip fracture. Prevention of second hip fractures is extremely important as the annual incidence of second hip fracture (3.6 per 1000) is much higher than the annual incidence of first hip fracture (1.6 per 1000) (70). Men who have suffered a previous fragility hip fracture have approximately a 3-fold increase in risk of a second hip fracture in comparison to men without a prior fragility fracture; more than half of all subsequent fractures occur within the first year post initial fracture (68,71).
2.2.3.3. Age as a determinant of fracture risk

Age is an important contributor to fracture risk. Between the ages of 45 and 85, the probability of experiencing a fragility fracture increases 8-fold in women while the probability of experiencing a fragility fracture increases 5-fold in men (8). Kanis and coworkers noted that among a population of Swedish women, the impact of age was 11-fold greater than the impact of BMD on risk of hip fracture (72).

2.2.3.4. Family history and fracture risk

Family history is another important risk factor (8,73). More specifically, maternal history (mother or grandmother) of osteoporosis has been identified as a risk factor for fracture (59). A portion of hip fracture risk is due to genetic influence. To date, researchers have identified associations between specific genes (vitamin D receptor gene, estrogen receptor gene, transforming growth factor gene, tumor necrosis factor gene and sclerostin gene) that are associated with osteoporosis (74).

2.2.3.5. Gender as a determinant of fracture risk

Gender is another variable that differs among hip fracture patients. Hip fractures have been found to increase exponentially with age (50-89 years of age) in both sexes (75). Despite the reality that hip fractures are a burden for both men and women, a large proportion of previous studies of hip fracture outcome have focused only on women disregarding the known risk factors associated with hip fracture in men (76-84). Jaglal and coworkers found the hip fracture rate to be higher in women than in men (i.e., 4.6 per 1000 women and 1.7 per 1000 men) (75). Although women suffer a higher incidence of hip fracture, evidence demonstrates that men suffer a higher mortality from a hip fracture (85). Jaglal and coworkers found that for men, the in-hospital mortality rate was 10.3% compared with 5.8% for women (75). Statistically significant differences between men and women also existed by age group; however, the mean age of hip fracture among men and women appears to be similar.
2.2.3.6. Risk factors for second hip fracture

Prior hip fracture (47,67-69) is a risk factor for a subsequent hip fracture. Prevention of second hip fractures is extremely important as the annual incidence of a second hip fracture is much higher than the annual incidence of a first hip fracture (3.6 per 1000 compared to 1.6 per 1000) (70).

Aside from prior fracture, other risk factors for a second hip fracture are not well defined. The following risk factors have been identified for subsequent hip fracture (86): poor perceived health status, dizziness, decreased bone mineral density, low body weight, occurrence of a new fall and decreased mobility scores. In addition, walking speed, postural sway and muscle strength, all of which are affected after a hip fracture, may also lead to recurrent hip fractures (4,87-89).

2.2.3.7. Summary of risk factors for hip fracture

In summary, additional risk factors that are associated with increased risk of hip fracture are: low aBMD at the femur, previous hip fracture (90), previous vertebral fracture, advanced age, gender and maternal history (59). A strength of my present study is that it provides osteoporosis management data for both men and women. Additional risk factors may include: lower extremity weakness, Caucasian (91,92), high transfer independence, multiple medications, fall history, distal forearm fracture, cognitive impairment (dementia) (93), neuromuscular impairment, and visual impairment (59). The following evidence-based risk factors remain uncertain and include: health status, weight change or low body weight (94), hip axis length, psychotropic medications (95-99), Parkinson’s disease, coffee consumption (100), smoking and alcohol, and calcium intake (101).

2.2.4. Economic consequences of hip fracture

Hip fractures have a large direct medical cost in comparison with other osteoporotic fractures. (102). In the UK, it is estimated that the acute inpatient cost of osteoporotic hip fractures were estimated at £4 808 per person and the social care costs and long stay hospital costs were estimated at £7 152 per person (28). Johansen and Stone (103) report that Dolan and Torgerson’s fracture costs are an underestimate of total
costs in the UK since they extrapolated data from a study done 20 years ago to estimate their costs. Their incidence of hip fracture 20 years ago were lower than they are now. Converting these cost to Canadian dollars, it is estimated that the one year hip fractures direct and indirect costs amount too $24 000-$34 000/hip fracture (Canadian dollars) worldwide without referring to the lifetime costs of hip fractures (28,29,31) and these costs are less for community dwelling residents ($21 385 in Canada) than long-term care residents ($33 729 in Canada). Indirect costs are defined as a patient's out of pocket expenses including the time of patients and families consumed or freed up by the hip fracture. Direct costs refer to resources used within the healthcare sector. These costs arise because hip fracture patients require inpatient and operating room resources. Melton and coworkers demonstrated that the incremental cost for all osteoporotic fractures combined was 46% greater than that for hip fractures alone in women and 47% greater in men. Incremental costs are defined as the difference in cost or effect between two comparators. In this case the comparators are osteoporotic fractures, hip fractures and gender. With regards to healthcare costs, in 1995, hip fractures consumed 8.8 billion dollars of the healthcare budget in the United States and 942 million pounds in the United Kingdom (28,104). The lifetime attributable cost (defined as the sum of all direct and indirect costs that occur subsequent to the hip fracture in an individual's lifetime) of hip fracture was estimated at $81 300 (105). These costs include initial hospitalization, subsequent hospitalizations, rehabilitation facilities, cost of nursing facilities, cost of home care, and indirect costs accounting for help received from family and friends.

Hip fractures result in substantial burden to the patient, the health care system and the community. Hip fractures are the leading cause of hospitalization for older adults (mean age 78.4 ± 8.8 years) (82,106). In Canada, the one-year direct and indirect costs were conservatively estimated for each hip fracture as approximately $30 000 (2). With an approximate 5% increase per year in medical costs, the resultant cost of hip fractures each year is expected to dramatically rise (107). Delaying hip fracture surgery for medical reasons or because of insufficient resources (staff, operating rooms) adds to inpatient costs. Between 1981 and 1995 the number of hip fractures in Canada increased from 17 823 to 27 375 and is expected to increase to 88 124 by 2041 (1,31). Despite the already large numbers and substantial costs of hip fracture to the health care system, the real burden to the patient and the community far exceeds this amount.
2.2.5. Clinical consequences of hip fracture

Although few studies in Canada have attempted to measure the influence of a fragility fracture on health-related quality of life among community dwelling and nursing home residents, it has been demonstrated that hip fractures have an adverse effect on health related quality of life (108). Following a hip fracture, nearly 33% of patients become dependent on others for aid in activities of daily living (109) on a long-term basis (110). When a patient sustains the first hip fracture, there is a 3-6 times greater chance that she will fracture the other hip (4,111). Eighty percent of women report that they would rather be dead than experience loss of independence, dignity and possessions that often accompany a transfer to a nursing home (112). The following is a quote from an 82 year old female who sustained a hip fracture. “The minute I hit that floor my life changed. To lose your independence is horrible. That’s the worst thing is to lose your independence. To just be able to go by yourself and do what you want. Before the hip fracture, I had done a lot. It has been downhill ever since” (113). This quote provides us with a personal perspective of the substantial change a hip fracture can have on an individual’s perceived quality of life.

Hip fractures are associated with a greater morbidity compared with other fragility fractures. Reports of associated permanent disability among those suffering from a hip fracture vary widely from 32%-80% (114-120). In addition, the proportion of individuals requiring nursing care ranges from 6%-60% (2,105,115,119,121-131). In particular, hip fracture patients are at risk for experiencing a number of post-operative medical complications such as urinary retention, cardiac ischemia, thromboembolism, infection and delirium. All of these conditions can benefit from either medical consultation or pharmacological interventions (132,133). Upon discharge, hip fracture patients also remain at risk of developing further medical complications that may lead to readmission into the hospital. According to Boockvar and coworkers, approximately one third of hip fracture patients require readmission in the first 6-months and 34% of all readmissions occur in the first month (134). After discharge, these patients remain at high risk for subsequent fractures (71,90,135). Hospital readmission is associated with added disability (134).
2.2.6. Functional disability after a hip fracture

Quality adjusted life years (QALY) are an important outcome for hip fracture patients (136). Hip fractures result in substantial burden to the patient, the health care system and the community. Hip fractures are the leading cause of hospitalization for older adults (mean age 78.4 ± 8.8 years) (82,106). Women who have had a hip fracture report the lowest quality of life compared with individuals who sustained a vertebral fracture and individuals who did not sustain a fracture (136). The disability following hip fracture may have significant consequences with regard to ambulatory status and activities of daily living (137). The number of individuals returning to their pre-fracture ambulatory status can vary from 30% to 80% depending on the study and length of followup (138-141). Overall, results across studies show a trend in a long-term residual disability in ambulatory status (137). Forty percent of individuals suffering from a hip fracture are unable to walk independently and 60% are limited in at least one activity of daily living (ADL) (i.e., dressing, toileting, feeding) one year post fracture (105). Hip fracture patients are also at risk of falls and future fractures (142). In addition, deficits of 36% were found in new permanent ADL impairments following a hip fracture. Cobey and coworkers found that after 6 months post hip fracture, only 23.5% of patients achieved a full recovery in their ADL (143). Overall, hip fractures have a negative impact on an individual's quality of life; a recent US survey stated that 80% of women aged 75 years and older stated they would rather be dead than suffer a hip fracture leading to their institutionalization (112).

2.2.7. Mortality after a hip fracture

Hip fractures are also associated with a high mortality. Internationally, the last four decades show an improvement in mortality rates possibly reflecting improved medical management among hip fracture patients (144-146). Braithwaite and coworkers found that hip fracture results in a 25% decrease in life expectancy and that 17% of their remaining life would be spent in a nursing care facility (105). In addition, 6 months following a hip fracture, mortality was greater than 11%. Among an average 80 year old population, the patient life expectancy decreased by 1.8 years accounting for a 25% reduction in life expectancy. Additionally, 56% of this decrease was due to the one year mortality rate. The remaining 44% was due to a higher six month mortality rate associated with new deficits in Activity of Daily Living and factors associated with institutionalization (105). When considering a one year mortality rate, it is important to note that
approximately 24% of the mortality is directly attributed to the hip fracture while 32% is unrelated to the hip fracture (147). The remaining 43% of the mortality rate is possibly due to the hip fracture (147).

Previous studies indicate that mortality rate after a hip fracture is actually higher in men than in women (148). More specifically, Forsen and coworkers reported a 1-year post hip fracture mortality probability of 17% for women and 31% for men (149). Among 15/70 hip fracture deaths in the acute care setting, 999 hip fracture deaths were among women and 571 hip fracture deaths were men (31). By 2041, the number of hip fracture deaths is expected to increase to 7000 (4404 in women and 2596 in men) (31). Kiebzak's retrospective chart review further supported the higher mortality rate in men than in women after a hip fracture (148). Meyers and coworkers have reported that the higher death rate in men may be a result of illness prior to falling, less social support, delirium at time of fall, more severe falls or poorer pre-fracture functional status (146).

Numerous studies have shown that a hip fracture is associated with a significantly increased risk of mortality 6-12 months after a hip fracture (150,151). Mortality after a hip fracture is estimated from 6-44%, equal to that of breast cancer and the mortality after a hip fracture is twice as high in men (152). In summary, an increased risk of mortality after a hip fracture is associated with male sex (83), advanced age (83), psychiatric illness, institutionalization, reduced mental status (82) postoperative complications and operative managements and subsequent hospital readmission (134). Thus, there is a large and growing body of evidence that there is an increase in the prevalence of hip fractures and osteoporosis and that there is substantial morbidity and mortality associated with these events.

### 2.3. BEST PRACTICE GUIDELINES FOR HIP FRACTURES

The following section will summarize the 'best practice' guidelines for osteoporosis investigation and treatment following a hip fracture. Currently, best practice guidelines for the management of osteoporosis following a hip fracture have been published (8) but are not followed uniformly throughout Canada (5,152,153). It is recommended that patients presenting to an orthopaedic department with a fracture or fractures known to be associated with osteoporosis should be investigated, or at least alerted that their
fracture may be osteoporosis-related. If alerted, the patient should be directed towards their primary care physician for the correct management of osteoporosis and possibly the prevention of falls (154, 155).

I recently conducted a retrospective chart review at a Vancouver teaching hospital that highlighted the gap in care regarding osteoporosis investigation and treatment after a fragility hip fracture (156). I reviewed the charts of all eligible patients (N=181, mean age = 83 years; range 65-97) admitted to Vancouver Hospital and Health Science Centre for a low-trauma hip fracture between June 1, 2001 and May 30, 2003. During patients’ inpatient stays, one patient had bone mineral density measured by DXA. Fewer than 18% of patients were offered complete Guideline Care for osteoporosis management.

Despite the wealth of evidence-based guidelines for management of osteoporotic fractures, this study highlighted that hip fracture patients were not investigated nor treated for osteoporosis by the hospital team as recently as 2001-2003. The argument that, after discharge, these patients would have their osteoporosis managed by the primary care physician is not supported by evidence. In a randomized trial among patients who suffered a hip fracture, only 19% of comparable patients had a family physician address their osteoporosis (7). That I did not follow participants beyond their inpatient stay is a limitation of this study. Nevertheless, there remains a major gap between guideline recommendation and patient management. Given that patients with a prior hip fracture are more susceptible to future fragility fractures, it is crucial that these high risk patients be treated and identified (157). Morrison and coworkers have defined the numerous roles that need to be addressed by the medical physicians involved in care for hip fracture patients (133).

In general, it is understood that patients who suffer from a fragility hip fracture should be given advice on lifestyle measures that will act to minimize bone loss (158). Advice to promote bone health may include: eating a balanced diet rich in calcium; exercising regularly; being exposed to adequate sunlight; and limiting smoking or drinking alcohol (158). Yet this type of care does not fall under the current ‘usual care’ practices (5, 152).

It has been suggested that the pharmaco or rehabilitation therapy should be based on what broad category (i.e., osteoporosis, frequent faller) that each hip fracture patient falls under (i.e., does the patient have low aBMD and/or is the patient a frequent faller). Individuals who are classified as frail elderly individuals who have a limited life expectancy and are relatively inactive should receive calcium and vitamin D
supplementation in addition to hip protectors where appropriate. Upon a second hip fracture, bisphosphonate therapy should be initiated. Among this group, patients obtain the greatest gains through calcium and vitamin D supplementation rather than alternative therapies (159). Recently, Finkelstein published an editorial highlighting the role of calcium plus vitamin D supplementation in postmenopausal women (101). The evidence remains controversial and suggests at the most, that the benefit of calcium and vitamin D in combination on BMD and risk of fracture is minimal (159-163). Based on a major trial conducted by Jackson and coworkers (164), Finkelstein recommends that women consume the recommended daily levels of calcium plus vitamin D but he also emphasizes that calcium with vitamin D supplementation is not sufficient alone to ensure optimal bone health.

Individuals who were independent and mobile prior to the fracture should be treated with calcium and vitamin D without investigation if aged 75 years and older (158). However, individuals aged 75 years and younger would benefit from a more rigorous investigation and intervention as both their quality of life and life expectancy can be improved by preventing future fractures.

Results from an anti-fracture efficacy study indicate that treatment with alendronate, calcium plus vitamin D, hip protectors and risedronate all receive a Grade A recommendation (158). Nasal calcitonin received a Grade B recommendation and is considered a "second-line treatment" for postmenopausal women with osteoporosis (8). Calcium alone or vitamin D alone, cyclical etidronate, hormone replacement therapy, physical exercise all received a Grade B recommendation. In general, for secondary prevention of hip fractures, treatment with bisphosphonates and Calcium and Vitamin D together is recommended for patients under the age of 75 only if they have low bone mass (158). Lastly, individuals should have a hip BMD assessment every 2-3 years.

The following figure (Figure 2) represents recommendations of the Canadian Task Force on Preventative Health Care for the prevention of osteoporotic fractures in postmenopausal women (165). This same type of pathway is corroborated by Chevalley and coworkers clinical pathway for low-trauma fracture management (166).

The Canadian Task Force on Preventative Health Care guidelines for the prevention of osteoporosis and osteoporotic fractures (165) are the most recent suggested guidelines published since the 2002 Canadian
Guidelines for Osteoporosis (8). Cheung and coworkers suggest that only individuals aged 65 years and older be screened for osteoporosis provided they have at least one risk factor including: age ≥ 65 yr or, previous fragility fracture or, weight ≤ 60 kg or, SCORE questionnaire ≥ 6 or, ORAI score ≥ 9 (165). Consistently, Brown and coworkers also suggest that individuals aged 65 years and older with one or two minor risk factors be given a BMD assessment (8). In addition, Brown and coworkers also suggest that individuals under age 65 with one or more minor clinical risk factors be given a BMD assessment. More specifically, individuals who have received long-term moderate to high dose glucocorticoid therapy or individuals who have a history of a low trauma fracture are also recommended to receive a BMD assessment. Based upon all BMD results, individuals may or may not be evaluated for treatment with an antiresorptive medication (i.e., bisphosphonate therapy). Regardless of age, I believe that individuals who sustain a low trauma fragility fracture should be investigated for osteoporosis- this is consistent with the 2002 Canadian Guidelines for Osteoporosis.
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Figure 2: Best Practice Care for Osteoporotic Fractures in Canada

2 Summary of 2002 Canadian Guidelines for Osteoporosis (8) and the Canadian Task Force on Preventative Health Care (165)
2.4. CURRENT MANAGEMENT OF HIP FRACTURES

The following section will review the current short-term and long-term clinical management of hip fractures. Individuals who suffer a hip fracture usually require surgical treatment. Surgical treatment generally consists of inserting a pin or nail through the fracture site, to compress the fracture fragments, or to replace the head of the femur (hemiarthroplasty to eliminate possible nonunion at the femoral neck) (34). Guideline care of hip fracture patients includes the pre-operative management of fracture and co-morbidities (167) and followup care includes early mobilization, antibiotic prescription, pain control and rehabilitation. Hip fracture management requires a number of health care professionals to cooperate to address the medical and psychosocial problems that may be present. The in-hospital clinical pathway for the management of osteoporosis following a hip fracture should include: calcium/vitamin D, bisphosphonates, nutrition, and exercise (168). Specific osteoporosis treatment recommendations should be individualized according to four risk factors: advancing age, low bone mineral density, previous fracture risk and family history (169).

Published literature suggests that medical management focuses on treatment of the hip fracture rather than prevention of future fractures (5,8,70,152,170). There have been few studies of tertiary treatment of hip fracture in elderly individuals presenting with a hip fracture (158). Tertiary treatment of osteoporosis due to a hip fracture occurs after the fragility fracture is sustained and should include the initiation of antiresorptive therapy or other forms of therapy specific to osteoporosis and future fracture prevention. Although hip fractures are a common problem among the elderly, orthopedic surgeons are divided on whether their role should include treatment of osteoporosis and prevention of future fractures (171). Alwyn Abraham responded to Kiebzak and coworkers research that previously demonstrated the undertreatment of osteoporosis in men (172). Abraham emphasized his view that orthopedic surgeons should be responsible to osteoporosis investigation and treatment. However, Kiebzak and colleagues argued that orthopedists, PCPs and patients should all share the responsibility (173). He defended the orthopedists because 12-months after their fracture, only 18% of patients had returned to the orthopedist; whereas, 83% of patients had returned to the PCP (174).
2.5. HIP FRACTURE PREVENTION - GENERAL OVERVIEW

Hip fractures are associated with an underlying risk of osteoporosis (175). Kanis and coworkers estimated the prevalence of osteoporosis to be 21.2% among Swedish women aged 50-84 (72). The relative risk of hip fracture among men and women with osteoporosis was 7.4 compared with the risk of hip fracture among men and women without osteoporosis (RR=6.1) (72). Yet, the observation that older adults are at risk of hip fracture regardless of whether or not they have osteoporosis does not dispute the evidence that an osteoporosis-related fracture increases the risk of a subsequent fracture. In addition, the disability caused by osteoporotic fractures is 4.5 times greater than that caused only by hip fracture (176).

In this section I discuss the pharmacotherapeutic management of osteoporosis. Vitamin D and calcium supplements, bisphosphonates and hormone replacement therapy all reduce the rate of bone loss and reduce the risk of fractures (159,177-180).

2.5.1. Bisphosphonate therapy

A systematic review of the effectiveness of etidronate (first bisphosphonate approved in North America) revealed no significant difference between intervention and control groups for combined non-vertebral fractures (including hip and extremity fractures) over two years. Two systematic reviews of six randomized controlled trials of a 'second generation' bisphosphonate – alendronate (10mg daily) found that the drug significantly reduced combined nonvertebral fractures (i.e., hip and extremity fractures). Although fewer people assigned to the intervention had hip fractures over a 1-4 year period; these differences were not statistically significant. Risedronate (2.5-5mg), like alendronate, was found to significantly reduce combined non vertebral fractures. Given that hip fractures accounted for a substantial proportion of the non vertebral fractures, there is reason to believe that risedronate plays a substantial role in hip fracture reduction. The side effects of both risedronate and alendronate appear to be similar. They include upper gastrointestinal discomfort particularly esophagitis. Recent advancement in the delivery of medications allows patients to take only one pill once a week. The minimal burden of this dosing regimen may support long-term compliance, but this theory has not yet been tested.
2.5.2. Calcitriol and Calcitonin

Calcitriol and calcitonin have not been shown to reduce hip fractures (181).

2.5.3. Environmental Manipulation

One randomized controlled trial (RCT) compared participants receiving a visit from a home-care nurse (intervention) aimed at assessing the following: smoking and alcohol intake; muscle tone and fitness; nutritional deficiencies; current medical conditions; medications and home environment with participants not receiving a visit from a home-care nurse (control) (182). The nurses aimed to assess the appropriateness of all medications the patients were receiving, correct any environmental hazards (i.e., loose carpets, trailing wires) and improve general muscle tone and fitness. There was no significant difference in fracture control between participants who had a health care visitor and those who did not (182). In general, patients with a higher level of disability had more falls regardless of environment.

2.5.4. Exercise

To date, three RCTs (183-186) comparing the effects of a brisk walking intervention to usual care, found no significant difference in the number of falls leading to fracture from an 8-month to one year period of exercise. To my knowledge, there is no evidence to show that exercise interventions reduce hip fractures. Previous research has shown that exercise (including strength and balance training) can reduce the number of falls, reduce fall risk, but not hip fractures. I recognize that these studies were possibly not sufficiently powered to show a reduction in hip fractures. To undertake such a study would be very expensive and extremely difficult to implement among an older frail population of individuals who have sustained a hip fracture.

2.5.5. Hip protectors
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Hip protectors have been found to reduce the risk of hip fracture by approximately 50%; by damping and absorbing the energy upon impact from a fall on the proximal femur (187). However, the compliance of elderly in wearing hip protectors is known to be low. Hip protectors have not been widely marketed because of their unknown acceptability. The evidence for hip protectors is still among debate depending on the type of analysis used. In RCTs that used cluster analysis, hip protectors reduced fractures at 11-19 months (187-191). Singh and coworkers investigated the cost-effectiveness of hip protectors in the prevention of osteoporosis related hip fractures among older nursing home residents (192). After conducting an incremental cost-effectiveness analysis comparing nursing home residents who used hip protectors with “no treatment” and “calcium plus vitamin D,” they concluded that use of hip protectors was a dominant strategy implying a lower cost and a higher effect.

2.5.6. Calcium alone

One systematic review summarizing the results of 15 randomized controlled trials found no significant difference between calcium alone (600-2000mg) compared with placebo at reducing non vertebral fractures (183,193).

2.5.7. Vitamin D alone

Three randomized controlled trials of vitamin D alone compared with placebo aimed at reducing hip fracture rates have taken place in different settings and populations; none of them found a beneficial effect of vitamin D alone (194-196). There was no significant difference between vitamin D alone compared with placebo treatment among; (i) independently dwelling women and men aged 65 years and older (196,197) or among (ii) nursing home residents with a mean age of 85 years (195) and older.

2.5.8. Calcium and Vitamin D together

In contrast, a now-classic RCT, calcium and vitamin D together reduced hip fractures over a period of 18 months to 3 years among women aged 69-106 who resided in nursing homes (198). Additional studies of
varying sample sizes have found that this combination reduces non vertebral fractures within a three year followup period (197,198).

2.5.9. Hormone Replacement Therapy (HRT)

Considerable harms (i.e., greater baseline risk of developing breast cancer) have resulted from hormone replacement therapy and this 'risk' currently outweighs the potential benefits for a large number of patients considering HRT as a treatment for osteoporosis (199). However, HRT has shown benefits in several chronic diseases including osteoporosis, colorectal cancer, depression, and cognitive decline. Specifically, in the Women's Health Initiative Study, after an average 5.2 year followup, HRT significantly reduced hip fractures compared with placebo (200).

2.6. PREVENTION OF FIRST HIP FRACTURE

The following section will discuss prevention of the first hip fracture through both fall prevention and environment manipulation. Preventing falls through minimizing risk factors for falling is an important part of preventing hip fractures because 95% of hip fractures result from a fall (201). Prevention of first hip fracture requires reducing the occurrence of falls. Previous research has established that falls are most effectively prevented through a multifaceted approach including: community intervention, physical activity, environmental modifications, health education, and fall risk factor reduction (202-204). Successful multifactorial interventions (205-208) have been conducted, one of which was by Tinetti and coworkers and the intervention group had 30% fewer falls than the control group. However, the effectiveness of this intervention for hip fracture prevention has still been limited by inadequate sample sized in studies (204).

Specifically, physical activity is also an important component of fall prevention because it can target activities to improve coordination, strength and balance and thus reduce the risk of fall and related injuries in frail and healthy elderly individuals (209-211). Given that 50-60% of all falls occur at home, environmental modifications that assess home hazards may (212) or may not (182) assist in preventing falls. Although Vetter and coworkers (182) report that their multifactorial intervention aimed at reducing
environmental hazards has no significant effect on fall and fracture rate, Connell’s review paper (212) still promotes the idea that environmental change can offer an approach to falls prevention. The appropriate environmental changed necessary to induce a reduction in falls has still not been proven (212). In addition, it is thought that health education in combination with other interventions may help to change behavior. Prevention strategies for hip fracture can work towards reducing the external load by preventing traumas or by increasing the bone’s biomechanical competence (45). Lastly, prevention strategies specifically targeting fall risk factors will also help reduce falls and fall related injuries (213).

2.7. PREVENTION OF SECOND HIP FRACTURE

Upon discharge, hip fracture patients remain at high risk for falls and subsequent fractures (114,123,124). The annual incidence of second hip fracture is 20 per 1000 among women and 15 per 1000 among comparably-aged men (70). This is substantially higher than the annual incidence of first hip fracture (3.6 per 1000 for women and 1.6 per 1000 for men). Dr. Dorothy Baker (CCAA-2nd Hip Fracture Symposium) (50) supports the strategy of fracture prevention through fall prevention. As falls are the result of multiple risk factors acting together, a multifactorial approach is needed to prevent falls and reduce fractures.

To date, prevention of a second hip fracture is not managed consistently because there have not been any clinical trials in patients who have just had their first hip fracture. To significantly reduce secondary hip fractures, the role of bisphosphonate therapy still needs to be more clearly defined. Currently, the evidence is that bisphosphonate therapy is most effective when started after the age of 65 and prior to the age for 80. The question of whether or not bisphosphonate therapy can still prove effective in preventing the second hip fracture after being initiated upon a first hip fracture is yet to be proven (CCAA-2nd Hip Fracture Symposium) (50).

In identifying individuals who are at high risk of hip fracture, there exists the potential possibility of reducing the fracture rate by up to 50% through the implementation of a community based fall prevention strategy as demonstrated by Close and coworkers (214). Although Close and coworkers did not power their study to look at fracture rate, they demonstrated the importance of the role of the PCP in identification and modification of various fall related risk factors. In addition, there is evidence that multifactorial interventions
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(204), residential setting interventions (203) and exercise interventions (213) can reduce falls and fall related risk factors in the older individuals. The reduction of falls is particularly relevant to the reduction of hip fractures because 95% of low trauma hip fractures are the result of a fall. McClung and coworkers have demonstrated that risedronate alone compared with placebo significantly reduces the risk of hip fracture among elderly women with confirmed osteoporosis but not among elderly women with other risk factors aside from osteoporosis (215). McClung's intervention proved effective for women with osteoporosis; however, it is clear that providing multidisciplinary care is an important part in the prevention and management of hip fractures (216,217). The hope is that multidisciplinary care will help ensure that patients will receive the most appropriate treatment as and this may or may not be risedronate.

2.8. SUMMARY AND HIPWATCH RATIONALE

In summary, hip fractures result in a significant burden on our society including the government, the healthcare system, the community and the patient. Given that hip fractures are painful, disabling, and can result in death, it is important to aim future efforts at prevention of hip fractures. The initiation of preventative therapy can be influenced by simple interventions. More specifically, the PEPA intervention provides the patient and the PCP with the opportunity to engage in appropriate osteoporosis management subsequent to their hip fracture. The present HipWatch study was based on a recent four part intervention conducted by Ashe and coworkers (9,218) aimed at improving osteoporosis investigation following a low-trauma wrist fracture through education of both the patient and the physician. Ashe and coworkers demonstrated the success of a patient education and physician alerting system in improving the rate of investigation and treatment of osteoporosis among individuals who sustained a low-trauma wrist fracture (9). The current HipWatch study refined the four-part intervention to a three-part intervention aimed at improving the rate of osteoporosis investigation and treatment following a hip fracture. The focus of HipWatch is to initially educate the patient and subsequently educate the physician.
3. **CHAPTER 3: METHODS**

3.1. **STUDY DESIGN**

My study, HipWatch, was a prospective randomized controlled trial that evaluated the effectiveness of a 2-pronged intervention designed to increase osteoporosis 'best practice' investigation treatment in accordance with the recommendation by the Canadian Consensus on Osteoporosis guidelines (8).

3.1.1. **Participants and Setting**

I identified men and women over 60 years of age, who were admitted to the orthopedic trauma ward at Vancouver General Hospital (VGH) after sustaining a minimal trauma (defined as falling from a standing height or less) hip fracture. Upon obtaining participants informed consent, participants were randomized to either receive 'usual care' (control group) or 'best practice care' (PEPA intervention group).

Vancouver, Canada has a population of 1.97 million people (32) and Vancouver Acute health is comprised of the Vancouver General Hospital (VGH) and the University of British Columbia (UBC) hospital that both serve a large proportion of the lower mainland. Due to the large numbers of patients presenting to VGH with a hip fracture, VGH was the sole site of recruitment.

The baseline interview of this study was conducted in the Jim Pattison Pavilion North at VGH, floors 7 and 10. In addition the 3-month and 6-month telephone followup interviews were done via telephone.

3.1.2. **Timeline**

Recruitment and followup interviews took place from December 2003 until February 2006. This was intended to allow participants in the intervention group time to visit the PCPs with the osteoporosis information package that I mailed to them.
3.2. STUDY SAMPLE

3.2.1. Sample Size

The sample size for this study was based on comparing proportions from two independent samples. Assuming that the proportion of participants in the 'usual care' group and the PEPA intervention group who were correctly diagnosed and managed over the 6 month period was 0.30 and 0.75 respectively, and establishing α and β a priori at 0.05 and 0.2 (80% power) respectively, means I would need to measure 38 people (19 per group) for this study. Ashe and coworkers found in a younger population of patients who sustained fragility wrist fractures that the proportion of participants in the usual care group and intervention group who were correctly diagnosed and managed for osteoporosis over the 6 month period was 0.30 and 0.75 respectively. From Ashe and coworkers, I assumed that the proportion of participants receiving osteoporosis investigation and treatment would be similar. I made the assumption that this investigation and treatment rate would be similar for older patients with hip fractures. Allowing a 15% margin for dropouts and deaths, I aimed to recruit 44 men and women (22 per group). Although this was a very conservative estimate of the number of subjects needed, I believe that a reasonable number of patients added to the credibility of the study. If the minimum number of patients are used from a more pragmatic power calculation, the target population of physicians may feel that the data represents a small, unrepresentative sample of patients.

3.2.2. Randomization

All participants were randomized to receive either the PEPA intervention or usual care. The randomization sequence was generated before the start of the study and it used a random numbers table (generated from a computerized random-number generator) generated independently of the principle investigator. An odd number of one indicated the participant would be allocated to the intervention group and an even number of zero indicated the participant would be allocated to the control group. Randomization occurred when I made initial contact with the participant upon obtaining informed consent.
3.2.3. Blinding

All participants were blinded to group allocation. I was not blinded to group allocation. Thus, HipWatch was a single-blind study. Although the control group received 'usual care,' they were also given the PEPA intervention upon completion of their six-month followup.

3.2.4. Inclusion Criteria

All community dwelling and nursing home residents both men and women aged 60 years and older who resided in the Vancouver area or the Lower Mainland and who were admitted to VGH with a fragility hip fracture were invited to participate in this study.

3.2.5. Exclusion Criteria

Potential participants were excluded if she/he: i) was already being treated for osteoporosis prior to having her/his fragility hip fracture; ii) suffered from dementia and/or cognitive impairment (219) iii) was unable to communicate in English and iv) had a severe medical pathology (i.e., cancer, chronic renal failure etc). Patients with specific pathologies such as cancer were excluded because it is difficult to determine whether their fracture occurred with minimal trauma or whether it was the result of low bone mass due to their treatment.

3.2.6. Exposure

A fragility hip fracture was defined as a fracture resulting from a low-trauma fall—i.e. a fall from standing height or less (214). The charts of each patient were reviewed to determine each hip fracture sustained was the result of a low-trauma fall. The details of the accident were confirmed with enrolled participants upon obtaining informed consent.
3.2.7. Recruitment

The orthopedic trauma wards on floors 7A and 10D in the Jim Pattison Pavilion North (VGH) served as the site for recruitment with direct patient contact. I reviewed the records for all patients suffering from a hip fracture to determine eligibility. All men and women aged 60 years and older and who fitted the inclusion criteria were invited to participate by Jennifer Davis or Margie Bell or Dr. Guy or Dr. Khan.

3.2.8. Consent

I obtained written consent for the baseline, 3-month and 6-month interviews from the participant during the initial contact made while the participant was admitted to VGH (Appendix A).

3.2.9. Experimental Protocol

Participants were enrolled at the orthopaedic trauma ward at Vancouver General Hospital from December 5, 2003-July 15, 2005. Six-month followup interviews of participants occurred from June 2004-February 2006. I enrolled participants following their surgical treatment while in hospital. Using a computer generated random numbers table, participants were allocated to receive 'usual care' (the control group) or a Patient Education Physician Alert (PEPA) system (the intervention group). All participants were followed for a period of 6-months. I outline the recruitment and the interview flow for this study in Figure 3. I outline the flow of participants through this investigation in Figure 4.
Figure 3: Participant recruitment and followup pathway

1. Presentation for a hip fracture
   \rightarrow
   \text{Determination of eligibility}
   \rightarrow
   \text{Eligible patients invited to participate while in hospital}
   \rightarrow
   \text{Informed consent obtained}
   \rightarrow
   \text{Initial baseline interview completed at VGH-Jim Pattison Pavilion North}
   \rightarrow
   \text{Participant's 3-month telephone followup}
   \rightarrow
   \text{Participant's 6-month telephone followup}
Chapter 3: Methods

272 hip fracture presentations seen
Dec 5, 2003 – July 15, 2005

78 Eligible Presentations

30 unable to participate
- Refused (9)
- Unable to make initial contact (21)

48 Enrolled
34 women, 14 men

194 Ineligible (71.1%)
- Cognitive impairment (77)
- Language barrier (41)
- Currently receiving osteoporosis treatment (46)
- Medically unfit (19)
- Too young (8)
- Deceased (1)
- Out of province (1)
- Deaf (1)

Received ‘usual care’
(Control group)
n=20

Received PEPA intervention
(Intervention group)
n=28

Completed Study (using Intention to Treat Analysis)
34 women, 14 men

Developed hip fracture related complications
- 4 deaths

Did not complete study
- 3 Lost to followup

Figure 4: Study Profile
3.2.9.1. Intervention

The 3-part PEPA intervention consisted of:
(i) usual care for the fracture including surgical treatment for the fracture by the hospital staff with a possible physiotherapy referral upon transfer to UBC hospital for recovery in addition to any other followup plans.
(ii) an information brochure about osteoporosis and an information sheet given to the participants explaining she/he has suffered a minimal trauma fracture which may be diagnostic of osteoporosis. This letter encouraged the patient to return to the PCP for further investigation;
(iii) a request for participants to take a letter from the orthopaedic surgeon (who was managing the hip fracture) to the PCP alerting the PCP to the recent minimal trauma fracture and encouraging osteoporosis investigation; and
(iv) a followup telephone call at 3 months to remind the participant to visit her/his PCP and assess osteoporosis status.

3.2.9.2. Control

The control group participants received 'usual care' - surgical treatment for the fracture by the hospital staff with a possible physiotherapy referral upon transfer to UBC hospital for recovery in addition to any other followup plans. The control group was told that the study was investigating outcomes for 6-months following a hip fracture. Table 1 illustrates the comparison between the intervention and control group protocols.

3.2.9.3. Six-month followup

Both control and intervention groups were telephoned at 6-months post-fracture by a researcher not blinded to treatment allocation. I administered the Diagnosis Management Questionnaire (DMQ) (Table 2). This questionnaire was developed to specifically ascertain the osteoporosis investigation rate and osteoporosis 'best practices' offered as recommended by the 2002 Osteoporosis Consensus guidelines (8).
Chapter 3: Methods

Following the administration of the DMQ at 6-months, the Control group was given the PEPA intervention. I attempted to inform all control participants of the risks of osteoporosis and a recommendation was made to return to the PCP for management of osteoporosis.

Table 1: A description of fracture care for the Intervention and Control group

<table>
<thead>
<tr>
<th>PEPA Intervention</th>
<th>Usual care (Control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Usual care for fracture</td>
<td>1. Usual care for fracture</td>
</tr>
<tr>
<td>2. Followup phone call at 3-months and 6-months post hip fracture</td>
<td>2. General followup call at 3-months and 6-months post hip fracture</td>
</tr>
<tr>
<td>3. Letter from Orthopedic Surgeon for PCP alerting to risk of osteoporosis (for patient to take to PCP).</td>
<td></td>
</tr>
<tr>
<td>4. Information brochure and letter to patient indicating risk of osteoporosis</td>
<td></td>
</tr>
</tbody>
</table>
Table 2: Diagnosis and Management Questionnaire

<table>
<thead>
<tr>
<th>Diagnosis and Management Questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have you been to your family doctor since your hip fracture?</td>
</tr>
<tr>
<td>Yes  No</td>
</tr>
<tr>
<td>2. Has your doctor told you that you have osteoporosis?</td>
</tr>
<tr>
<td>Yes  No</td>
</tr>
<tr>
<td>3. What health services were you offered?</td>
</tr>
<tr>
<td>• DXA</td>
</tr>
<tr>
<td>• Medications (bisphosphonates, calcitonin, hormone therapies, selective estrogen receptor modulators)</td>
</tr>
<tr>
<td>• Exercise prescription</td>
</tr>
<tr>
<td>• Calcium/Vitamin D</td>
</tr>
<tr>
<td>• other</td>
</tr>
</tbody>
</table>

3.3. STUDY OUTCOMES

The following section will describe the outcome measures used to assess both the primary and secondary objectives of this study.

3.3.1. Interviews

Interviews were conducted at baseline, 3-months post hip fracture and 6-months post hip fracture. Information collected from baseline interviews included 1) demographic characteristics (age, gender, income source, education level, living arrangements); 2) cognition as determined by the Mini Mental State Examination (MMSE) (219); 3) circumstances surrounding the hip fracture; 4) prevalence of depression as determined by the Geriatric Depression Scale (220), physical health and medications prior to the hip fracture and; 5) a questionnaire regarding functional status prior to the hip fracture (Appendix B). The baseline measurements took approximately 45 minutes to complete.
The 3-month followup assessed the following measures: 1) number of participants offered one or more components of 'best practice' care as measured using elements of the Diagnoses and Management Questionnaire (DMQ); 2) functional status as measured using the Barthel Index and 3) prevalence of depression as measured using the Geriatric Depression Scale (GDS).

The 6-month follow up reassessed all baseline and 3-month follow up measurements. Both the 3-month and the 6-month follow up interviews took approximately 30 minutes to complete. In addition, all individuals in the control group were offered the intervention and referred to the UBC Falls Clinic upon completion of the study.

### 3.4. DATA COLLECTION

The following describes all the demographic information and followup information obtained during the 6-month post hip fracture period.

#### 3.4.1. General Information

I obtained demographic information including age, gender, income source, education level and living arrangements from baseline interviews and participants' medical records (Appendix 2). In addition, I noted the location of the fall that caused the hip fracture. Cognitive status was assessed once at baseline using the Folstein Mini Mental State Examination. In addition participants' general health, medications, vision, disability, emotional health and functional status were tracked throughout the 6-month period. Previous and subsequent falls were also recorded during the 6-month period. In addition, to confirm the validity of osteoporosis diagnosis, 20% of the PCPs were telephoned to seek corroboration of the patients' self-report of osteoporosis management. In 100% of these cases, the patients' self-report of osteoporosis management was consistent with the PCPs report of osteoporosis management. This was primarily done to ensure the validity of the DMQ.
3.4.2. Folstein Mini-Mental State Examination (MMSE)

This tool is extensively used to assess cognitive impairment (219). In addition to its wide use in numerous hip fracture studies, it has also been used with the Bone Health Research Group’s previous students (221-223). All individuals obtaining a score > 24 were considered eligible for inclusion in this study.

3.4.3. Geriatric Depression Scale (GDS)

The GDS is extensively used among those aged 60 years and older individuals as a diagnostic screening tool for depression (220). This scale is commonly used among hip fracture patients and fallers (214). This study investigated the prevalence of depression prior to the hip fracture and followed up with any changes in depression status subsequent to the hip fracture at the 3-month and the 6-month followups.

3.4.4. Barthel Index

The Barthel Index (224) is a 10-item questionnaire used to assess individual’s activities of daily living and mobility. It is measured on a 0-100 point scale and a higher score indicates a more independent individual. In this study, the Barthel Index was administered upon initial contact to determine a baseline level of functional status. The Barthel Index was then administered at 3-months and 6-months to track any changes in activities of daily living. The baseline measures were also checked with participants’ charts to ensure validity of participant responses. This questionnaire has also been previously used in large trials of Emergency Department fallers (214).

3.4.5. Diagnosis and Management Questionnaire (DMQ)

This 3-item questionnaire was administered to both the control and intervention group at the 3-month and 6-month time points to determine whether participants had been investigated for osteoporosis and if so, what best practices they were offered. Best practices included in the questionnaire were: Bone mineral density as determined using DXA, medications (eg. bisphosphonate therapy), exercise prescription,
calcium and vitamin D together or any other treatments prescribed (i.e., falls prevention program). This questionnaire has been previously used by Dr. Maureen Ashe (9).

3.4.6. Clinical Guideline care defined

Guideline care was assessed as defined by the 2002 Canadian Medical Association Osteoporosis clinical practice guidelines (8).

3.5. DATA

3.5.1. Entry

All participant information was reviewed and entered promptly after each interview was conducted to identify and minimize missing data. Demographic information was confirmed using medical records and the Emergency Department (ED) database.

3.5.2. Confidentiality

The confidentiality of all participants was maintained by using a number code to identify all participants and all files of participants were kept in a locked drawer in the Vancouver General Hospital Research Pavilion.

3.5.3. Ethics

This study was approved by Vancouver Coastal Health Research Initiative and the Clinical Research Ethics Board of the University of British Columbia (Appendix E).
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3.6. STATISTICAL ANALYSIS

The data was analyzed on an intention to treat (ITT) basis, using SPSS Windows Version 13.0. In cases where there were missing data, I used the most conservative estimate for each outcome measure. Data were examined for outliers, defined as those 3 standard deviations (SDs) above and below the mean. Data were also assessed for normality, skewness, and kurtosis. I used the Kolmogorov-Smirnov Test to assess normality. The data were checked for normality by calculating skewness and kurtosis. If the ratio of each statistic to its standard error is less than 2 or greater than -2, this indicates a normal population distribution. Descriptive data were reported for all variable of interest (mean (SD) or number (% of total) where appropriate). Chi-square analyses were used to determine any differences between the control and intervention group at baseline for differences in proportions in demographic characteristics. The alpha level was set at p < 0.05.

3.6.1. Primary Analyses

I compared the difference between the two experimental groups in the proportion of individuals who received one or more elements of osteoporosis specific 'best practice' care within 6 months after their hip fracture using the chi-square test. The alpha level was set at p < 0.05. No adjustments were made to the p-value to account for multiple testing.

3.6.2. Secondary Analyses

As both the Barthel Index and the GDS data were not normally distributed and were skewed, I used the non-parametric Mann-Whitney Test to determine between-group differences. The alpha level was set at p < 0.05. No adjustments were made to the p-value to account for multiple testing.
3.6.3. Exploratory Analysis

I compared the difference between the two experimental groups in the proportion of men and women who received one or more elements of 'best practice' care within 6 months after their hip fracture using the chi-square test. The alpha level was set at $p < 0.05$. No adjustments were made to the p-value to account for multiple testing.
4. **CHAPTER 4: RESULTS**

There were 270 patients who sustained a hip fracture seen during the followup period between December 5, 2003 and January 30, 2006. A total of 192 of these 270 hip fractures were ineligible for my study due to cognitive impairment, language barrier, current treatment for osteoporosis, chronically ill health, deafness, or death prior to establishing contact for study participation. Of the 78 eligible patients, 48 (62%) agreed to participate in the study. During the 6-month followup period of this study, 3 participants were lost to follow up and 4 participants died. Of the 4 participants who died, their medical records were reviewed to obtain followup information.

4.1. **PARTICIPANT CHARACTERISTICS AT BASELINE**

Baseline characteristics of the 48 participants are presented in Table 3. No outliers were found, and thus, no exclusions were made. The mean time between the participant hip fracture admission and the baseline interview was 7 (±5) days. All patients were interviewed post-operatively during their initial hospital stay at a time when it was felt that the patient would be medically “well enough” to participate in an interview. The mean age of all the participants was 81.3 (±8.2) years. A total of 20 (41.7%) participants had experienced at least one prior fracture and 9 (18.8%) had experienced two or more prior fractures.

Review of participants’ medical records and self-reports indicated a wide range of different medical conditions among this cohort of individuals. For example, the mean number of chronic conditions in the control and intervention group were 3.9 (±2.3) and 3.9 (±2.9), respectively. These conditions included the following: hearing impairment, Parkinson’s disease, peripheral vascular disease, diabetes, stroke, transient ischemic attack, heart disease, hypertension, urinary incontinence, arthritis, vertigo, lightheaded feeling and painful feet. It is also important to note that the average number of medications taken by participants was 6.2 (±3.8) and some of these medications have been implicated in increasing the risk of falling and subsequent hip fracture. Osteoporosis was not diagnosed among any of the participants at baseline as an established osteoporosis diagnosis was an exclusion criterion for participation in this study.
There were no significant differences among demographics, prevalence of depression, activities of daily living, number of medications, MMSE score, number of co-morbidities or number of fractures at baseline between the PEPA intervention group and the usual care group.

Table 3: Participant Demographics – Usual Care Group (n = 20) and PEPA Intervention Group (n = 28)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Usual Care (Control)</th>
<th>PEPA Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of Yes Cases (%) or Mean (225)</td>
<td>Number of Yes Cases (%) or Mean (225)</td>
</tr>
<tr>
<td><strong>Demography</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>82.6 (9.9)</td>
<td>80.4 (6.8)</td>
</tr>
<tr>
<td>Female</td>
<td>13 (65%)</td>
<td>21 (75%)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>165.5 (9.7)</td>
<td>165.5 (9.8)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>66.8 (12.2)</td>
<td>65.0 (12.0)</td>
</tr>
<tr>
<td>Education (years)</td>
<td>13.3 (2.9)</td>
<td>13.0 (4.0)</td>
</tr>
<tr>
<td>Race (Caucasian)</td>
<td>18 (90%)</td>
<td>26 (93%)</td>
</tr>
<tr>
<td>MMSE Score (Max 30 points)</td>
<td>27.5 (2.6)</td>
<td>28.1 (1.9)</td>
</tr>
<tr>
<td><strong>Medical History</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Medical conditions</td>
<td>3.9 (2.3)</td>
<td>3.9 (2.4)</td>
</tr>
<tr>
<td>Hearing Impairment</td>
<td>10 (50%)</td>
<td>9 (32%)</td>
</tr>
<tr>
<td>Parkinson’s Disease</td>
<td>2 (10%)</td>
<td>2 (7%)</td>
</tr>
<tr>
<td>PVD / Leg Ulcers</td>
<td>1 (5%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>3 (15%)</td>
<td>4 (14%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>2 (10%)</td>
<td>4 (14%)</td>
</tr>
<tr>
<td>Transient Ischemic Attack</td>
<td>2 (10%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>6 (30%)</td>
<td>8 (29%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>12 (60%)</td>
<td>14 (50%)</td>
</tr>
<tr>
<td>Urinary Incontinence</td>
<td>4 (20%)</td>
<td>5 (18%)</td>
</tr>
<tr>
<td>Arthritis-Back</td>
<td>5 (25%)</td>
<td>6 (21%)</td>
</tr>
<tr>
<td>Arthritis-Hip</td>
<td>4 (20%)</td>
<td>3 (11%)</td>
</tr>
<tr>
<td>Arthritis-Knee</td>
<td>7 (35%)</td>
<td>10 (36%)</td>
</tr>
<tr>
<td>Arthritis-Hands</td>
<td>7 (35%)</td>
<td>12 (43%)</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Usual Care (Control)</td>
<td>PEPA Intervention</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td></td>
<td>Number of Yes Cases (%) or Mean (225)</td>
<td>Number of Yes Cases (%) or Mean (225)</td>
</tr>
<tr>
<td>Vertigo</td>
<td>5 (25%)</td>
<td>10 (36%)</td>
</tr>
<tr>
<td>Lightheaded</td>
<td>5 (25%)</td>
<td>13 (46%)</td>
</tr>
<tr>
<td>Painful feet</td>
<td>3 (15 %)</td>
<td>6 (21 %)</td>
</tr>
<tr>
<td>Previous Fracture (B)</td>
<td>10 (50%)</td>
<td>10 (36%)</td>
</tr>
<tr>
<td>Total number of fractures (C)</td>
<td>17</td>
<td>21</td>
</tr>
<tr>
<td>Number of Prescribed Medications (D)</td>
<td>6.6 (4.2)</td>
<td>6.0 (3.6)</td>
</tr>
</tbody>
</table>

**Hip Fracture Classification**

<table>
<thead>
<tr>
<th></th>
<th>Usual Care (Control)</th>
<th>PEPA Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral Neck</td>
<td>8 (40%)</td>
<td>13 (46%)</td>
</tr>
<tr>
<td>Intertrochanteric</td>
<td>7 (35%)</td>
<td>8 (29%)</td>
</tr>
<tr>
<td>Subtrochanteric</td>
<td>1 (5%)</td>
<td>3 (11%)</td>
</tr>
<tr>
<td>Right Side</td>
<td>12 (60%)</td>
<td>12 (43%)</td>
</tr>
</tbody>
</table>

\(A\) PVD = peripheral vascular disease

\(B\) Number of participants in ‘usual care’ group who have had a previous fracture

\(C\) Total number of fractures among participants in ‘usual care’ group

\(D\) Mean number of prescription medications and doctor recommended supplements taken by participants at the time of their hip fracture

### 4.2. LIVING ARRANGEMENTS

Participants consisted of both community dwelling \((n = 42, 87.5\%)\) participants and nursing home \((n = 6, 12.5\%)\) residents at the time of baseline interviews. Overall, 29 (60\%) participants lived alone and 17 (40\%) live with family or friends. Twenty-six (54.2\%) participants lived in a house, 16 (33.3\%) participants lived in an apartment, 1 (2.1\%) participant lived in an independent living facility and 5 (5\%) participants lived in a nursing home. In addition, 29 (60.4\%) participants lived alone, 10 (20.8\%) participants lived with a spouse, 4 (8.3\%) participants lived with a spouse and children, 4 (8.3\%) participants lived with a relative and/or friends, 1 (2.1\%) participant lived with other arrangements with friends. Please refer to Table 4 for specific details for both the PEPA intervention group and the ‘usual care’ group regarding living arrangements and living accommodations.
Table 4: Living arrangements and living accommodations at baseline (N = 48)

<table>
<thead>
<tr>
<th>Living Arrangements</th>
<th>Baseline</th>
<th>Usual Care</th>
<th>PEPA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)^A</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Alone</td>
<td>29 (60.4%)</td>
<td>10 (50%)</td>
<td>19 (68%)</td>
</tr>
<tr>
<td>Spouse</td>
<td>10 (20.8%)</td>
<td>3 (15%)</td>
<td>7 (25%)</td>
</tr>
<tr>
<td>Spouse and children</td>
<td>4 (8.3%)</td>
<td>2 (10%)</td>
<td>2 (7%)</td>
</tr>
<tr>
<td>Relatives/Friends</td>
<td>4 (8.3%)</td>
<td>4 (20%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Other (religious group home)</td>
<td>1 (2.1%)</td>
<td>1 (5%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Accommodation</th>
<th>Baseline</th>
<th>Usual Care</th>
<th>PEPA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>House</td>
<td>26 (54.2%)</td>
<td>7 (35%)</td>
<td>19 (68%)</td>
</tr>
<tr>
<td>Apartment</td>
<td>16 (33.3%)</td>
<td>10 (50%)</td>
<td>6 (21%)</td>
</tr>
<tr>
<td>Basement Suite</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Independent Living Unit</td>
<td>1 (2.1%)</td>
<td>0 (0%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Nursing Home</td>
<td>5 (5%)</td>
<td>3 (15%)</td>
<td>2 (7%)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

^A n = number of “Yes” cases within each group; % = percent of “Yes” cases within each group

4.3. MECHANISMS OF HIP FRACTURE AND IMMEDIATE INITIAL CARE

All participants enrolled in this study experienced a low-trauma hip fracture as an entry criterion. Of the falls, 32 (66.7%) participants experienced a fall inside the home while 16 (33.3%) participants experienced a fall outdoors. The hip fracture classification for the ‘usual care’ group was: 8 (40%) femoral neck; 7 (35%) intertrochanteric and; 1 (5%) subtrochanteric. The hip fracture classification was as follows for the PEPA intervention group: 13 (46%) femoral neck; 8 (29%) intertrochanteric and; 3 (11%) subtrochanteric. Among these fractures, 23 (48%) participants experienced a right hip fracture while 25 (52%) participants experienced a left hip fracture.

For all participants, the mean wait time to see an Emergency Physician (EP) was 29 minutes after triage. Their total time in the Emergency Department area until seeing an EP was 96 minutes and their total time spent in emergency prior to their admission was 679 minutes. Of the 679 minutes, an average of 393
minutes were spent in the transitory area while awaiting a bed on Floors 7 or 10. On average, all participants were treated in a reasonable time frame and I did not anticipate that patient wait times would have an affect on their long term outcomes.

4.4. GUIDELINE CARE

In total, 17 participants in the PEPA intervention group (n = 28) and 6 participants in the ‘usual care’ group (n = 20) received one or more components of osteoporosis specific ‘best practice’ care (p < 0.02). Among the ‘usual care’ group participants, 13 did not receive any ‘best practice’ care and 6 received only one element of ‘best practice’ care. Among the PEPA intervention group, 7 participants did not receive any ‘best practice’ care, 5 participants received one element, 6 participants received 2 elements, 4 participants received 3 elements, and 4 participants received all 4 elements of ‘best practice’ treatment.

Table 5 details the number of participants who were offered each component of ‘best practice’ care. Table 5 reports the results obtained from the DMQ for all participants because I used an intention to treat (ITT) analysis. To demonstrate the potential effectiveness of HipWatch, I included all 48 participants in the analysis including those who died (n = 4) and those who did not complete a 3-month and a 6-month DMQ (n = 3).

The purpose of the PEPA intervention was to assess the effectiveness of the intervention compared with ‘usual care’ provided by the healthcare professionals (i.e., nurses, general practitioners, orthopaedic surgeons). Among the control group, guideline care was not commonly provided (35%). However, among the intervention group, partial or complete guideline care was provided for 68% of the participants.
Table 5: Best Practices offered to Usual Care and PEPA intervention participants at 6-month followup (N = 48)-Intention to Treat Analysis

<table>
<thead>
<tr>
<th></th>
<th>Usual Care</th>
<th>PEPA Intervention</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(n = 20)</td>
<td>(n = 28)</td>
<td></td>
</tr>
<tr>
<td>Osteoporosis Diagnosis B</td>
<td>4 (20%)</td>
<td>11 (39%)</td>
<td>0.22</td>
</tr>
<tr>
<td>Participants offered ‘Best Practice’ care C</td>
<td>7 (35%)</td>
<td>19 (68%)</td>
<td>&lt;0.02*</td>
</tr>
<tr>
<td>Bisphosphonate Therapy D</td>
<td>0 (0%)</td>
<td>15 (54%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Dual-Energy X-Ray Absorptiometry E</td>
<td>0 (0%)</td>
<td>8 (29%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Calcium/Vitamin D F</td>
<td>6 (30%)</td>
<td>11 (39%)</td>
<td>0.32</td>
</tr>
<tr>
<td>Exercise prescription G</td>
<td>0 (0%)</td>
<td>9 (32%)</td>
<td>&lt;0.01*</td>
</tr>
<tr>
<td>Other H</td>
<td>0 (0%)</td>
<td>1 (4%)</td>
<td>0.58</td>
</tr>
</tbody>
</table>

* p < 0.05

A n = number of “Yes” cases within each group; % = percent of “Yes” cases within each group
B Number of participants who reported having an osteoporosis diagnosis by their doctor
C Number of participants offered one or more components of ‘Best Practice’ care for osteoporosis
D Number of participants who were receiving bisphosphonate therapy at the time of their followup phone call
E Number of participants who received a bone density assessment within 6-months of their hip fracture
F Number of participants who were taking Calcium/Vitamin D at the time of their followup phone call
G Number of participants who were recommended some type of exercise program
H Number of participants who were offered some other type of treatment or intervention related to their hip fracture (i.e., a referral for a falls prevention program)

4.5. EXPLORATORY ANALYSIS

The present study was not powered to observe a difference between men and women being offered one or more elements of the DMQ. However, I note that a significantly greater number of women in the intervention group were offered, ‘best practice’ care than in the ‘usual care’ group for the treatments -- bisphosphonate therapy, DXA and exercise.
### Table 6: Best Practices offered to Usual Care and PEPA intervention participants at 6-month followup (N = 48) - Intention to Treat Analysis

<table>
<thead>
<tr>
<th></th>
<th>Usual Care</th>
<th>Usual Care</th>
<th>PEPA Intervention</th>
<th>PEPA Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td></td>
<td>(n = 7)</td>
<td>(n = 13)</td>
<td>(n = 7)</td>
<td>(n = 21)</td>
</tr>
<tr>
<td>Osteoporosis Diagnosis</td>
<td>0 (0%)</td>
<td>4 (31%)</td>
<td>2 (29%)</td>
<td>9 (43%)</td>
</tr>
<tr>
<td>Any ‘Best Practice’ care</td>
<td>2 (29%)</td>
<td>5 (38%) *</td>
<td>3 (43%)</td>
<td>16 (76%)</td>
</tr>
<tr>
<td>Bisphosphonate Therapy</td>
<td>0 (0%)</td>
<td>0 (0%) *</td>
<td>2 (29%)</td>
<td>13 (62%)</td>
</tr>
<tr>
<td>DXA</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (8%)</td>
<td>8 (38%)</td>
</tr>
<tr>
<td>Calcium/Vitamin D</td>
<td>2 (29%)</td>
<td>4 (31%)</td>
<td>2 (29%)</td>
<td>9 (43%)</td>
</tr>
<tr>
<td>Exercise prescription</td>
<td>0 (0%)</td>
<td>0 (0%) *</td>
<td>2 (29%)</td>
<td>7 (33%)</td>
</tr>
<tr>
<td>Other</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (5%)</td>
</tr>
</tbody>
</table>

* p < 0.05

A Number of participants who reported having an osteoporosis diagnosis by their doctor  
B Number of participants offered one or more components of ‘Best Practice’ care for osteoporosis  
C Number of participants who were receiving bisphosphonate therapy at the time of their followup phone call  
D Number of participants who received a bone density assessment within 6-months of their hip fracture  
E Number of participants who were taking Calcium/Vitamin D at the time of their followup phone call  
F Number of participants who were recommended some type of exercise program  
G Number of participants who were offered some other type of treatment or intervention related to their hip fracture (i.e., a referral for a falls prevention program)

#### 4.6. ADVERSE EVENTS

No adverse events related to treatment group allocation were reported by participants in either the PEPA intervention group or the ‘usual care’ control group.

#### 4.7. WHO DROPPED OUT?

In total, 7 participants (n = 7, four male, three female) were lost to followup. More specifically, four participants (n = 4, two female, two male) died before the 6-month follow-up period. Of these participants, two were in the control group and two were in the intervention group and these deaths were a result of
complications post hip fracture. Three \( n = 3 \), two male, one female) participants were lost to follow-up. It is possible that these participants were deceased, transferred to a nursing home or moved out of the lower mainland. In addition, regarding the 3-month and 6-month followup interviews, six participants \( n = 6 \), four female, two male) completed the baseline interview and the 6-month followup DMQ but not the 3-month followup interview. One participant \( n = 1 \), female) completed the baseline and 3-month followup questionnaire only. Two participants \( n = 2 \), one female, one male) completed the baseline interview, the 3-month follow up and the 6-month follow up DMQ only.

4.8. CHANGES IN SECONDARY OUTCOMES

4.8.1. Barthel Index

I found a statistically significant difference between the 'usual care' group and the PEPA group at the 3-month time point (Table 7).

<table>
<thead>
<tr>
<th>Table 7: Descriptive statistics for Barthel Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usual Care Control Group</td>
</tr>
<tr>
<td>--------------------------</td>
</tr>
<tr>
<td>Barthel Index - Median (IQR)</td>
</tr>
<tr>
<td>PEPA Intervention Group</td>
</tr>
<tr>
<td>Barthel Index - Median (IQR)</td>
</tr>
</tbody>
</table>

* Significantly different from the PEPA Intervention Group at \( P = 0.02 \).

4.8.2. Geriatric Depression Scale

I did not find a statistically significant difference between the 'usual care' group and PEPA group at the baseline, the 3-month and the 6-month followups (Table 8).
### Table 8: Descriptive statistics for Geriatric Depression Scale

<table>
<thead>
<tr>
<th></th>
<th>Usual Care (Control)</th>
<th>Baseline (n = 20)</th>
<th>3-month (n = 10)</th>
<th>6-month (n = 9)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GDS - Median (IQR)</strong></td>
<td>0 (1)</td>
<td>1 (2)</td>
<td>1.5 (2)</td>
<td></td>
</tr>
<tr>
<td><strong>PEPA (Intervention Group)</strong></td>
<td>Baseline (n = 28)</td>
<td>3-month (n = 19)</td>
<td>6-month (n = 21)</td>
<td></td>
</tr>
<tr>
<td><strong>GDS - Median (IQR)</strong></td>
<td>0 (2)</td>
<td>0 (2)</td>
<td>0 (1)</td>
<td></td>
</tr>
</tbody>
</table>
5. CHAPTER 5: DISCUSSION

Although evidence-based guidelines exist for osteoporosis investigation and treatment, there remains a gap in care among individuals who sustain a fragility hip fracture (9,70,85,152,218). However, to my knowledge, there has only been one other study among elderly hip fracture patients examining the efficacy of a multifactorial intervention. Thus, I evaluated the delivery of osteoporosis ‘best practices’ as defined by the Canadian Medical Association clinical practice guidelines (8) in participants aged 60 years and older after admission to a hospital for a low-trauma hip fracture at VGH. I found that 68% (19 out of 28) participants in the PEPA intervention group compared with 35% (7 out of 20) participants in the ‘usual care’ group were offered one or more components of osteoporosis specific ‘best practice’ care. This difference was statistically significant (Table 5).

5.1. WHY DOES A PEPA INTERVENTION WORK?

Compared with the control group, approximately twice as many participants (p=0.008) in the intervention group were offered one or more elements of ‘best practice’ care for osteoporosis after experiencing a fragility hip fracture. None of the ‘usual care’ (control) group participants reported being prescribed and taking bisphosphonate therapy whereas 60% (p<0.001) of the best practice (intervention) group reported being prescribed and taking bisphosphonate therapy. These results highlight the potential effectiveness of a multi-component intervention that empowered both the patient and reminded the PCP of the problem of osteoporosis treatment and investigation following a hip fracture.

Given that the PEPA was a two-pronged patient dependent intervention, it is not possible to determine whether a single component, or which single component, of the intervention had the most significant effect. However, I would postulate that each component influenced the outcome. I mailed all participants in the intervention group a letter explaining to the patient that she/he are at risk for osteoporosis and should visit a PCP for follow up. Participants were also mailed a letter from the treating orthopedic surgeon to give to the PCP indicating the risk for osteoporosis the need for investigation. I believe this two-pronged patient dependent intervention likely initiated the patient to become more pro-active in seeking treatment.
Although this intervention involved multiple components, it refined previous work of Ashe and coworkers (9). Ashe and coworkers implemented a multifactorial intervention that included a fax sent directly to the PCP indicating that a participant should be investigated for osteoporosis after a fragility wrist fracture. That the HipWatch intervention did not include a PCP fax referral suggests that this component of the multifactorial intervention may not add substantially to improving patient management. However, conclusions must be limited as the populations studies in HipWatch and Ashe's WristWatch differ substantially in age and health status.

Not only does the HipWatch intervention engage the patient, it also engages the PCP. The average age of individuals in the control and intervention groups was 83 and 80 years, respectively. These individuals are typically accustomed to a traditional doctor-patient relationship where the patient is usually passive. Over time, the doctor-patient relationships have changed and currently patients' are encouraged to play a more active role with regard to their healthcare (152,170). My intervention may have bridged this gap by educating the patient and encouraging the patient to see her/his PCP to engage in a discussion of osteoporosis investigation and subsequent treatment.

5.2. WHY DOES 'USUAL CARE' NOT INCLUDE CONSISTENT OSTEOPOROSIS MANAGEMENT?

Among participants receiving usual care for the 6-month followup period, only 30% reported being recommended calcium and vitamin D and none (0%) were prescribed bisphosphonate therapy. There are several potential reasons for the lack of osteoporosis management in this 'at risk' population of elderly individuals. First, the patient may be unaware that she/he is at risk for osteoporosis. Chevalley and coworkers report that 73% of participants in their study who had sustained a low trauma fracture believed their fracture was not related to osteoporosis or bone fragility prior to their enrollment in the osteoporosis clinical pathway program (166). Consequently, these patients believed that they had no reason to visit a PCP or to seek investigation or treatment after to their hip fracture.

In addition, the awareness of osteoporosis also differs among men and women. Kiebzak and coworkers highlighted that fewer men are investigated (11% given a bone mineral density measurement compared
Chapter 5: Discussion

with 27% of women) and treated for osteoporosis than women after a hip fracture (85). Kiebzak suggested this may be due to a lack of osteoporosis knowledge among men compared with women. He also suggests that physicians may have this same gap in knowledge. Since the existence of a knowledge gap remains to be proven, the PEPA intervention empowered participants and alerted the physicians and resulted in approximately 60% of the participants receiving bisphosphonate therapy after a 6-month followup period.

When seeing a patient for followup after a hip fracture, the PCP must commonly address numerous medical problems. Thus a second reason for lack of osteoporosis management following a hip fracture is that other conditions may take precedence over osteoporosis management. The PEPA intervention may have stimulated the PCPs to bring osteoporosis higher up on their list of priorities. The multifactorial PEPA intervention that targeted behavior change of the participant and the PCP yielded a larger change than just targeting physician behavior alone (153). This is based on the “readiness for change” transtheoretical model which suggests that behavioral changes evolve in the following stages: precontemplation, contemplation, preparation, initiation and maintenance of change (153,226). Given the multiple components necessary to implement change, strategies that involve physicians, staff and patients have proven successful.

Third, previous research has shown that practice change is also affected by peer influence and practice feedback reports (153,227,228). Consequently, it is possible that participants in the PEPA intervention were more likely to experience the positive effects of behavior change because they were educated about their risk of having underlying osteoporosis and prompted to consider changing their behavior. PCPs were also prompted to change their clinical practice behavior by the patient and the letter from the orthopaedic surgeon. Since participants who received ‘usual care’ and their respective PCPs were not exposed to any strategy of behavioral change, I would expect them to be less likely to experience the positive effects of behavior change. This is further demonstrated by the significant difference between the number of participants offered some element of best practice care in the control (35%) compared with intervention group (68%, p=0.008). These results demonstrate that in the PEPA intervention group, more participants sought osteoporosis investigation and treatment following their hip fracture compared with the usual care control group. In addition, more PCPs investigated and treated their patients in the PEPA intervention group compared with the control group.
5.3. WHY EMPOWER A FRAIL POPULATION OF OLDER ADULTS?

Participants in both the ‘usual care’ group and the intervention group of this study had approximately four medical co-morbidities. Some may argue that the PEPA intervention is not practical among this elderly population because of the number of other medical conditions they often have. However, hip fractures are associated with both a high rate of morbidity and mortality (229). Up to 50% of individuals who suffer a hip fracture will have some type of permanent functional disability resulting from their hip fracture (17,18).

The PEPA intervention is also important because the number of hip fractures is increasing (22) due to increasing life expectancy (230). Given the aging population, a greater number of individuals will be elderly and at risk for fracture. From 1990, a four-fold increase in hip fractures by 2050 is projected (10). Given the estimated increasing burden of hip fractures in men and women (22) this problem should not be trivialized. The PEPA intervention has led to significant improvements in osteoporosis investigation and treatment.

5.4. BRIDGING THE GAP: WHO IS RESPONSIBLE FOR OSTEOPOROSIS MANAGEMENT?

Papers reporting a gap in medical care are not novel. In a highly-cited paper, Hajcsar and coworkers reported a 32% treatment rate after one year following a fragility fracture by the PCPs (231). Also, Al-Allaf and coworkers evaluated rehabilitation referrals post-fracture and found that osteoporosis diagnosis and treatment was not initiated during rehabilitation (232). These data were supported by Juby and coworkers who highlighted the need for osteoporosis to be addressed by PCPs, orthopaedic surgeons, and geriatric consultants (152). Morrison and coworkers had earlier argued for the role of the medical specialist as part of the hip fracture management team (133). Nevertheless, the question remains: is a team approach optimal and if so, what are the respective duties of the team members?

A model of care that empowers the patient to follow-up with his/her PCP and brings osteoporosis to light was successful in improving treatment rates for upper limb fractures. Majumdar and coworkers conducted an intervention educating both the physician and the patient (233). The letter given to both the physician and the patient included the following three points: 1) the patient should be offered a DXA as they are at high risk for osteoporosis, 2) the patient is at increased risk of future fracture and 3) bisphosphonate
therapy will reduce risk for fracture by approximately 50%. These University of Alberta researchers found that the rates of testing and treatment for osteoporosis more than tripled in patients who suffered a fragility wrist fracture (233). Ashe and colleagues' WristWatch study, designed to educate the patient and the PCP, significantly improved osteoporosis investigation and management; this indicated that specific interventions can improve osteoporosis investigation and management (9). Whether systems that are proven effective in the upper limb alone can also be effective in the older, frailler hip fracture population remains to be proven.

5.5. ALTERNATIVE MODELS OF GUIDELINE CARE DELIVERY

Despite these publications, however, it is apparent that the traditional model of care delivery is not fail-safe. Patients in the present study did not benefit from a ‘team approach’ in the way that Morrison and colleagues had suggested (133). Might hip fracture patients benefit from some contemporary models of care delivery? The ‘fracture liaison service’ (FLS) is gaining support in various centres. In an ecological study (two centres, not randomized), Murray and colleagues reported an 85% treatment rate of hip fractures with bisphosphonate therapy in the centre where there was a fracture liaison service (217). The other centre had treatment rates of 27% which are comparable to the finding of 19% in the present study. McLellan and coworkers also conducted a multi-centre trial utilizing the FLS (216). An osteoporosis specialist nurse directed patients to appropriate osteoporosis investigation (i.e., DXA), treatment (i.e., bisphosphonate therapy, calcium/vitamin D) and management (i.e., treatment adherence review). Results indicated the FLS helped identify and evaluate over 4 600 patients which was estimated to represent most fractures occurring in the area surrounding the three hospitals involved. This was an improvement compared with only 10% of the population receiving investigation prior to the FLS (216).

5.6. BISPHOSPHONATE THERAPY-ISSUES TO CONSIDER

Bisphosphonates are proven to reduce hip fractures. McClung and coworkers evaluated the impact of the bisphosphonate, risedronate, on older women at high risk of fracture with and without osteoporosis (234). Primary hip fractures were prevented in 28% of women with osteoporosis (235). In addition, another bisphosphonate trial with alendronate revealed a 51% reduction in future hip fractures (57).
Chapter 5: Discussion

Currently, bisphosphonate therapy is the treatment of choice and is given a pre- eminent position among other therapeutic options for individuals who have sustained a fracture and have been diagnosed with osteoporosis (235). Bisphosphonate therapy is used in both the treatment and the prevention of various forms of osteoporosis through its potent inhibition of bone resorption (235). All participants in HipWatch suffered a fragility hip fracture.

McClung recommends that bisphosphonate therapy be focused only on those individuals who are at high fracture risk (235). Some of the most important markers for risk for future fracture include fracture since the age of 50, family history of fractures and body size. Given that all HipWatch participants were aged 60 years and older when they suffered their fragility hip fracture, they should potentially be considered ideal candidates for osteoporosis investigation and bisphosphonate therapy.

Generally, bisphosphonate therapy is well tolerated provided its dosage and administration are correct (236). Despite the promising future of bisphosphonates, they do have some skeletal, gastrointestinal, ocular and metabolic side effects. For example, continuous administration of high doses of etidronate or long term use of etidronate may impair bone mineralization consequently leading to bone pain, fractures and osteoid accumulation. However, intermittent low dose etidronate therapy has not been associated with impairment of bone formation or skeletal mineralization. Large clinical trials of alendronate therapy have demonstrated that 20-40% of older women in both the placebo group and the control group experienced upper GI side effects (237,238). Through clinical experience and level IV evidence, McClung estimated that the true incidence of upper GI side effects is closer to 10% (235). The other 10-30% could be side effects caused from concomitant medications such as calcium supplements and NSAIDs. Clinical trials of risedronate therapy have not demonstrated an increase in upper GI side effects. Given that upper GI side effects are minimized if dosing and administration are followed correctly, bisphosphonate therapy is generally well tolerated by patients who comply with this regimen. Bisphosphonate therapy can also be rarely associated with some ocular effects such as conjunctivitis, iritis and uveitis. Usually ocular effects only include in patients receiving pamidronate therapy and the symptoms are reversible when therapy is discontinued (239). Only isolated cases of ocular side effects have been reported for other forms of bisphosphonate therapy. In this study, only one patient receiving bisphosphonate therapy reported experiencing upper GI side effects. At the 6-month followup her symptoms were not severe enough to
discontinue bisphosphonate therapy. None of the participants in HipWatch reported any skeletal or ocular side effects.

One issue of concern with regard to bisphosphonate therapy is short-term and long-term compliance. The participants in HipWatch were prescribed oral bisphosphonate therapy. Compliance with any type of oral therapy is affected by a number of factors such as age, disease type and duration, treatment regimen, tolerability, and lifestyle (240). Importantly, compliance measured in clinical trials may differ from 'real world' compliance. Generally, medications that cause GI side effects that affect quality of life are more likely to be associated with noncompliance than those therapies without major side effects. For example, daily oral bisphosphonate therapy has been associated with a somewhat high rate of noncompliance due to the high rate of GI side effects and due to the complex dosage and administration regimen (241-244). However, it is important to note that the above trials all consisted of participants with bone metastases. Given that these participants were receiving other therapies, it is not possible to determine which of their treatments, or if a combination of their treatments were responsible for the adverse side effects. Regarding long-term oral bisphosphonate therapy for the treatment of osteoporosis, the global rate of non-compliance is reported as >50%. Noncompliance can have a substantial impact on clinical outcomes as demonstrated by the Eastell and coworkers in their IMPACT study (245). These authors measured levels of C-telopeptide (a bone turnover maker) and found that 60% of the compliant patients had a >50% reduction in C-telopeptide and 20% of the noncompliant patients had a >50% reduction in C-telopeptide. Thus, compliance can be, at times, associated with clinical outcomes. Despite this knowledge, oral bisphosphonate therapy is still proven effective regardless of issues of compliance and is considered one of the top treatments of choice to osteoporosis treatment and prevention in individuals who are at high risk of future fracture.

5.7. SETTING: NURSING HOME OR COMMUNITY DWELLING PARTICIPANTS

HipWatch participants consisted of both community dwelling and nursing home residents both of whom met all the inclusion criteria including a MMSE score >24. Nursing home residents often present unique challenges regarding osteoporosis management. For example individuals who reside in a nursing home often have serum Vitamin D levels that fall below those normally recommended. These patients may need
diet modifications and supplements (246). In addition, while they are without supervision, they may often be unable to remain out of bed, ambulatory or upright. Community dwelling residents will often have a family member or home help which may lead to more one on one care.

5.8. PREVALENCE OF DEPRESSION AND FUNCTIONAL STATUS

Given that the followup rate for both the Barthel Index and the Geriatric Depression Scale were fewer, I do not intend to draw conclusions from the results. My secondary exploratory analyses indicated that there were no significant differences between the groups at baseline, 3-months and 6-months in depression status (as measured by the GDS). However, for the Barthel Index, a difference was noted between the 'usual care' control group and the PEPA intervention group at the 3-month time point. Overall, the general trend was that functional status (as measured by the Barthel Index) remained the same in the PEPA group, whereas functional status appeared to decrease in the 'usual care' group. The sample size in the PEPA group was approximately twice as large as the sample size in the 'usual care' group. Because the sample sizes were smaller for these secondary outcome measures, I would anticipate that is likely that participants who did not complete these followup questions were the ones who experienced either a greater loss of function or a change in their depression status.

5.9. STRENGTHS AND INNOVATIONS OF THE STUDY

The PEPA intervention contains the following innovations. Firstly, it demonstrated that an interactive intervention empowering the patient and alerting the physician can affect clinical practice among a frail, elderly population of individuals who have suffered a hip fracture. One previous multifactorial intervention also aimed to improve osteoporosis investigation and treatment (7). Gardner and coworkers focused their efforts on educating participants in the hospital in addition to giving participants information on osteoporosis and information for the participants to give their family doctor. Forty-two percent of participants in the study group compared with 19% of participants in the control group had their osteoporosis addressed by their PCP (p=0.036) (7). The PEPA intervention focused on education of the participants once they were released from the hospital. This approach allowed the participants some extra time to recover.
is a strength of my study because often individuals who suffer a hip fracture may experience delirium for 2-3 days post surgery. In addition, hip fracture patients are often overwhelmed with multiple visits by healthcare professionals (e.g. orthopedic surgeons, nurses, physiotherapists, social workers and occupational therapists), thus distracting their attention from potential osteoporosis management.

Secondly, the PEPA intervention extended previous work that empowered the patient to prioritize osteoporosis for follow-up with the PCP; this was successful in improving treatment rates for upper limb fractures (233). Rates of testing and treatment for osteoporosis more than tripled in patients who suffered a fragility wrist fracture (233). The PEPA intervention fills in the gap as to whether an innovative intervention, effective in the population that suffers upper limb fracture, will also prove effective in the older, frailer hip fracture population.

5.10. LIMITATIONS

Limitations of this study include:

1) Patient self report: All the outcomes of this study are obtained via patient self report and this is subject to bias and might overestimate, or more likely underestimate osteoporosis investigation and treatment. It is conceivable that patients could temporarily forget they received their osteoporosis management-related information due to the traumatic experience of a hip fracture. However, all medications, especially osteoporosis medications were carefully recorded and patients were able to get their medications from their cupboard if they could not remember drug names. Thus, I attempted to obtain the most accurate information possible. For example, if a participant was unsure about their medications, I would ask them to look at their prescription bottle and read it to me. In addition, questionnaires such as the GDS and the Barthel Index have previously been validated (247).

2) Investigator not blinded to treatment allocation: As the Primary Investigator of this study, I was not blinded to treatment allocation; consequently, there is potential for bias. I expect this to be unlikely because it would be extremely difficult to bias answers to the following question: "Are you taking any new medications? Yes or no?"
3) **DMQ phrased differently in control group and in intervention group** - I blinded all participants to their treatment allocation. To blind participants, the DMQ for the 'usual care' group was phrased slightly differently than the DMQ for the PEPA intervention group. For example, the DMQ for the 'usual care' group did not directly ask participants if they received any of the following best practices: Bone Density Scan or exercise prescription. The 'usual care' group DMQ did ask all participants if they were aware of having osteoporosis and if they were on any new medications. All control participants were phoned upon completion of the study to confirm they had not received an osteoporosis diagnosis or investigation.

4) **Exclusion of Non-English Speaking Patients**: The population of Vancouver constitutes the highest proportion of Asian people in Canada (32). Participants who could not speak English were excluded due to the limited budget for this study which prohibited having an 'on-call' translator available for both recruitment on a daily basis and for participant followup. Future studies may want to access the Non-English speaking Asian population through volunteers to assist with translation for recruitment and participant followup.

5) **Not powered for hip fractures**: The primary outcome of this study was to determine the rate of investigation and treatment of osteoporosis in the PEPA intervention group as compared with the 'usual care' group. This study was not powered to see a reduction in second hip fractures and thus, the study does not shed light on the effectiveness of the PEPA intervention in reducing the incidence of second hip fracture.

6) **6-month followup period**: Some individuals may believe that a 6-month followup period is too short and that subsequent osteoporosis management will occur up to 12-months after a hip fracture. Although this is a possibility, I would consider this unlikely since all but two participants were home by the 3-month mark after their hip fracture. In addition, after an individual has had her/his first hip fracture, risk of second fracture increases 4-fold. Thus, osteoporosis management should occur shortly after a hip fracture to prevent future fractures.

7) **Osteoporosis definition**: The DMQ asked all participants whether or not they were diagnosed with osteoporosis (yes/no). It is possible that participants may have confused osteoporosis with osteopenia or even osteoarthritis. Consequently, I reported the 'best practices' offered to participants rather than relying on their definition of osteoporosis.
6. CHAPTER 6: CONCLUSIONS, RECOMMENDATIONS AND FUTURE RESEARCH DIRECTIONS

6.1. PRIMARY OBJECTIVES

6.1.1. Conclusions

1) Despite the efforts expended to educate physicians that minimal-trauma fractures are associated with osteoporosis, and are an indication for investigation and/or therapy, there remains a substantial care gap in osteoporosis management for patients receiving 'usual care'.

2) The Patient Empowerment and Physician Alert system significantly improved osteoporosis investigation and treatment as demonstrated by the significant difference in the number of participants who received one or more elements of 'best practice' care in the PEPA intervention group as compared with the control group (*p<0.02). Furthermore, 0% of 'usual care' group participants were offered bisphosphonate therapy compared with 68% of individuals offered bisphosphonate therapy in the PEPA intervention group (*p<0.001).

6.1.2. Recommendations

1) Although there have been a number of surveys sent out to PCPs and orthopedic surgeons that have allowed health care professionals to gain insight into the barriers that limit 'best practice' care delivery, the research has not resulted in a solution that can be implemented into our healthcare system. Further investigation is needed to determine the root of the problem and plausible cost-effective solutions.

2) The different methods existing of educating both the patient and the physician need to be evaluated to determine which of these interventions proves to be most effective in terms of both costs and consequences.

3) After the evaluation of all existing intervention programs, further investigation is needed to determine the steps involved in implementing a low-cost intervention such as the PEPA intervention.
6.2. SECONDARY VARIABLES

6.2.1. Conclusions

1) There was no group or time interaction in functional status and prevalence of depression over the 6-month followup period as measured by the Barthel Index and the Geriatric Depression Scale.

6.2.2. Recommendations

1) Measures such as functional status, prevalence of depression and quality of life measures (e.g. EQ-5D, SF-6D) should be further investigated over a longer time period to determine the potential impact the PEPA intervention may or may not have on these outcome measures.

6.3. FUTURE RESEARCH DIRECTIONS

Conducting this randomized controlled trial and writing this thesis raised the following ideas and issues for future research.

1) Is the PEPA intervention a superior intervention for improving osteoporosis management compared with other multifactorial interventions (7)?

2) Is the PEPA intervention also cost-effective?

3) What is the best method of alerting both PCPs and orthopedic surgeons of the existing care gap and the existing evidence to encourage the practice of evidence based medicine?

4) This study excluded individuals with specific pathologies, cognitive impairment and inability to speak English. As a consequence, further investigation is needed to determine the steps necessary to include these individuals so that the results may be further generalizable to the Vancouver population as a whole.
5) Further investigation into whether the PEPA intervention helped reduce the incidence of second hip fractures would also be useful. This would require a subsequent randomized controlled trial powered for hip fractures; consequently, a large sample size would be required.

6) Given that the PEPA intervention significantly improved osteoporosis management as indicated by the delivery of ‘best practice’ care, further analysis into whether this outcome also had a positive impact on health related quality of life might be warranted.
7. CHAPTER 7: REFERENCES

33. Officer B 2004 (Ministry of Health Planning). Prevention of Falls and Injuries Among the Elderly: A Special Report From the Office of the Provincial Health Officer.
Chapter 7: References


Chapter 7: References


Chapter 7: References


Chapter 7: References


8. APPENDICES

APPENDIX A: Letter of Consent & Letter of Invitation
HIPWATCH

K. Khan (Principal Investigator) - Department of Family Practice, UBC
M. Ashe- Department of Family Practice, UBC
K. Kruse - BC Women’s and Children’s Hospital
P. Guy – Vancouver Hospital and Health Sciences Centre

RESEARCH PROJECT CONSENT FORM

This study is looking at hip fractures and falls. The results of our study will assist us in designing healthcare and hopefully the prevention of future fractures. You have been invited to participate in this study because you are over 60 years of age and you have broken your hip. This study is being sponsored by Aventis Pharmaceuticals Inc.

Procedures: When you are in hospital a trained researcher will invite you to participate in this study. You may feel free to participate in this study or withdraw at any time. This will not affect your treatment.

The researcher will ask you to consent to participating in the study and ask you questions about how you broke your hip and your general health. In approximately 3 months, and again at 6 months following your fracture, a researcher with the study will telephone you and ask you questions about your hip and general health. The interview should last approximately 30 minutes. You may choose not to answer any question for any reason. Simply say that you would like to pass.

Exclusions:
It is necessary to exclude those individuals who are younger than 60 years.

Rights and Welfare of the Individual:

It is understood that you are free to withdraw from any or all parts of the study at any time without penalty. Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of Health Canada and the UBC Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigators’ offices.
Please be assured that you may ask questions at any time. We will be glad to discuss your results with you when they have become available and we welcome your comments and suggestions. Should you have any concerns about this study or wish further information please contact Dr. Karim Khan (__________) at the University of British Columbia. The UBC phone number for research subjects to call should they have any concerns about their rights or experience as research subjects is ______ and is called the 'Research Subject Information Line in the UBC Office of Research Services'. This information line is not intended to provide urgent service to subject with immediate needs for medical care for research-related injury.

**Participant Consent:**

I, ______________________________________

(please print your name)

understand the purpose and procedures of this study as described and I voluntarily agree to participate. I understand that at any time during the study I will be free to withdraw without jeopardizing any medical management, employment or educational opportunities. I have received two pages of the consent form and understand the contents of these pages, the proposed procedures and possible risks. I understand that I am not waiving any legal rights. I have had the opportunity to ask questions and have received satisfactory answers to all inquiries regarding this study.

<table>
<thead>
<tr>
<th>Signature of Participant</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>________________________</td>
<td>______</td>
</tr>
</tbody>
</table>

Name of Witness (Please Print) | Signature of Witness | Date

| ________________________ | ________________________ | ______|

Name of Investigator (Please Print) | Signature of Investigator | Date

| ________________________ | ________________________ | ______|
RESEARCH PROJECT CONSENT FORM

The purpose of this research is to look at ways to improve care of people who have suffered a hip fracture. These injuries are common and the results of our study will help us determine ways of managing fractures better and preventing them in future. You have been invited to participate in this study because you are over 60 years of age and you have broken your hip. This study is being sponsored by Aventis Pharmaceuticals Inc.

Procedures: When you are in hospital you will be invited to participate in this study. You may feel free to participate in this study or withdraw at any time. This will not affect your treatment. If you agree to participate in the study, a trained researcher will ask you to fill out a consent form and will ask some questions about your fracture and general health. You will be given a sealed envelope to open later. The envelope will contain 3 items:

- information that you might be at an increased risk of osteoporosis and that you should visit your family doctor to determine this. This letter has been written by a number of Osteoporosis Experts in our medical community.
- a letter for you to give to your doctor about Osteoporosis. We ask that you visit your family doctor to give her/him this letter. This letter is similar to the letter you have been given and has been written by the panel of experts.
- a pamphlet on osteoporosis.

In approximately 3 months, and again at 6 months following your fracture, a researcher with the study will telephone you and ask you questions about your hip and general health. The interview should last approximately 30 minutes. You may choose not to answer any question for any reason. Simply say that you would like to pass.

Exclusions:
It is necessary to exclude those individuals who are younger than 60 years and are already being treated for osteoporosis.

Rights and Welfare of the Individual:

It is understood that you are free to withdraw from any or all parts of the study at any time without penalty. Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the
presence of the Investigator or his or her designate by representatives of Health Canada and the UBC Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices.

Please be assured that you may ask questions at any time. We will be glad to discuss your results with you when they have become available and we welcome your comments and suggestions. Should you have any concerns about this study or wish further information please contact Dr. Karim Khan ( ) at the University of British Columbia. The UBC phone number for research subjects to call should they have any concerns about their rights or experience as research subjects is , and is called the 'Research Subject Information Line in the UBC Office of Research Services'. This information line is not intended to provide urgent service to subject with immediate needs for medical care for research-related injury.

**Participant Consent:**

I, ________________________________
(please print your name)
understand the purpose and procedures of this study as described and I voluntarily agree to participate. I understand that at any time during the study I will be free to withdraw without jeopardizing any medical management, employment or educational opportunities. I have received two pages of the consent form and understand the contents of these pages, the proposed procedures and possible risks. I understand that I am not waiving any legal rights. I have had the opportunity to ask questions and have received satisfactory answers to all inquiries regarding this study.

<table>
<thead>
<tr>
<th>Signature of Participant</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>_________________________</td>
<td></td>
</tr>
</tbody>
</table>

Name of Witness (Please Print)  Signature of Witness  Date

Name of Investigator (Please Print)  Signature of Investigator  Date
APPENDIX B: Baseline Data Collection Forms

Baseline Interview
Mini-Mental State Examination
Barthel Index (BI)
Geriatric Depression Scale (GDS)
Name: ______________________________________________________
Phone: ______________________________________________________
Address: _____________________________________________________
Next of Kin: __________________________________________________
GP: __________________________________________________________
Height: _______  Weight: _________  Race: _________________________
Type of Fracture: ______________________________________________
Type of Surgery: ____________________________  Date: _____________
Details of accident: ____________________________________________
________________________________________________________________
________________________________________________________________
History of fractures:
________________________________________________________________
________________________________________________________________
________________________________________________________________
Chapter 8: Appendices

ID NUMBER ___________ INITIALS ___________

PREDICTORS OF INJURY IN OLDER PEOPLE- QUESTIONNAIRE

[THE PRINCE OF WALES MEDICAL RESEARCH INSTITUTE and
THE UNIVERSITY OF NEW SOUTH WALES]

1. What is your age? _______________

2. What is your date of birth? _______________

3. What is your gender? Male / Female

4. What is your major income source?
   Unable to determine [ ]
   Disability pension [ ]
   Canadian Pension Plan [ ]
   Veteran’s Affairs [ ]
   Superannuation [ ]
   Other (please state) [ ]

5. How many years of education have you had? (Please circle the number at each level)
   Primary school 0 1 2 3 4 5 6 7 8
   Secondary school 0 1 2 3 4 5 6 7 8
   Technical college 0 1 2 3 4 5 6 7 8
   University 0 1 2 3 4 5 6 7 8
   Other 0 1 2 3 4 5 6 7 8

6. What type of accommodation do you live in?
   House [ ]
   Apartment [ ]
   Basement Suite [ ]
   Independent living unit [ ]
   Nursing Home [ ]
   Other (please state) [ ]

7. Who else lives in the home with you?
   I live alone [ ]
   I live with my spouse only [ ]
   I live with my spouse and children [ ]
   I live with a child/children [ ]

85
Mental State - MMSE

(Add points for each correct response)

<table>
<thead>
<tr>
<th>Orientation</th>
<th>Score</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is the Year?</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Season?</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Date?</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Day?</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Month?</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>2. Where are we?</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Province?</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Region?</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>City?</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Village/ Building?</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Unit/Room/ Floor?</td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

Registration

3. "I'm going to say three objects APPLE CHAIR PEN. Can you repeat them?" Give one point for each correct answer. ___ 3

Attention

4. Serial sevens. "I'd now like you to count backwards from 100 by 7s." Give one point for each correct answer. Stop after five answers. 93 86 79 72 65 ___ 5

Recall

5. Ask for the names of the three objects learned in Q.3. Give one point for each correct answer. ___ 3

Language

6. Point to a pen and a watch. Have the subject name them as you point. ___ 2

7. Have the subject repeat "No ifs and/or buts". ___ 1

8. Have the subject follow a three-stage command: "Take this paper in your left hand. Fold the paper in half. Put the paper on the floor." ___ 3

9. Have the subject read and obey the following: 'CLOSE YOUR EYES'. (on back of sheet) ___ 1

10. Have the subject write a sentence of his or her choice in the space on the back of the sheet.
11. The sentence can be about anything they like and as long or short as they like.
   (The sentence should contain a subject and an object and should make sense).

   ___ 1

12. Have the subject copy the design on the back of the sheet next to the design.
   Give one point if all sides and angles are preserved and if the intersecting sides
   form a quadrangle.

   ___ 1

   ___ = Total 30

* if the subject is unable to complete any section due to impaired vision, divide the score by the number
of points able to be attempted and multiply by 30.
CLOSE YOUR EYES
### HEALTH – Disease

Do you have/have you ever had any of the following diseases?

<table>
<thead>
<tr>
<th>Disease</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hearing Impairment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parkinson’s Disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral Vascular Disease/Leg Ulcers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TIAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart Disease/ Heart Attack</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incontinence – Urinary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthritis – Back/ Neck</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthritis – Hip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthritis – Knee</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthritis – Hands</td>
<td></td>
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</tr>
</tbody>
</table>

Do you have/have you ever had any of the following symptoms?

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertigo/ Dizziness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Light Headedness when standing up from seat/ bed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Painful Feet</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### MEDICATIONS

What medications are you currently taking? Include medications bought directly from the chemist or shop without prescription. (Tablets, capsules, mixtures, powders, injections, eye drops sprays etc. Please also indicate the frequency of taking the medication by circling 1 = daily, 2 = weekly or 3 = less than once a week).

None [ ]

<table>
<thead>
<tr>
<th>Medication</th>
<th>Frequency</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1/2/3</td>
<td>1/2/3</td>
</tr>
<tr>
<td></td>
<td>1/2/3</td>
<td>1/2/3</td>
</tr>
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<td></td>
<td>1/2/3</td>
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<td>1/2/3</td>
</tr>
<tr>
<td></td>
<td>1/2/3</td>
<td>1/2/3</td>
</tr>
</tbody>
</table>

### VISION

---

89
1. How do you rate your distance vision without glasses?
   - Very poor
   - Poor
   - Fair
   - Good
   - Very good

2. Do you wear glasses?
   - Yes
   - No

Walking aids

1. What aids do you usually use to help you move about inside the house?
   - No aids used
   - Walking stick
   - Walking frame
   - Crutches
   - Wheel chair

2. What aids do you usually use to help you move about outside the house?
   - No aids used
   - Walking stick
   - Walking frame
   - Crutches
   - Wheel chair

Geriatric Depression Scale

   Depression scale
   (Score one point for each "Yes")

1. Have you had low energy? [ ]
2. Have you had loss of interests? [ ]
3. Have you lost confidence in yourself? [ ]
4. Have you felt hopeless? [ ]
THE BARTHEL INDEX

FEEDING
0 = unable
5 = needs help cutting, spreading butter, etc., or requires modified diet
10 = independent

BATHING
0 = dependent
5 = independent (or in shower)

GROOMING
0 = needs to help with personal care
5 = independent face/hair/teeth/shaving (implements provided)

DRESSING
0 = dependent
5 = needs help but can do about half unaided
10 = independent (including buttons, zips, laces, etc.)

BOWELS
0 = incontinent (or needs to be given enemas)
5 = occasional accident
10 = continent

BLADDER
0 = incontinent, or catheterized and unable to manage alone
5 = occasional accident
10 = continent

TOILET USE
0 = dependent
5 = needs some help, but can do something alone
10 = independent (on and off, dressing, wiping)

TRANSFERS (BED TO CHAIR AND BACK)
0 = unable, no sitting balance
5 = major help (one or two people, physical), can sit
10 = minor help (verbal or physical)
15 = independent

MOBILITY (ON LEVEL SURFACES)
0 = immobile or < 50 yards
5 = wheelchair independent, including corners, > 50 yards
10 = walks with help of one person (verbal or physical) > 50 yards
15 = independent (but may use any aid; for example, stick) > 50 yards

STAIRS
0 = unable
5 = needs help (verbal, physical, carrying aid)
10 = independent

TOTAL __________________________
APPENDIX C:

PEPA INTERVETION LETTERS:
   1) LETTER TO PARTICIPANT
   2) LETTER TO PCP

CONTROL LETTER:
   1) LETTER TO PARTICIPANT
To the participant,

We are looking for participants who are 60 years of age and older and have broken a hip. The results of our study will provide important information regarding the outcomes after a hip fracture, improved health care, and hopefully the prevention of future fractures. This is a joint project involving three hospitals in the Lower Mainland: Richmond Hospital, Royal Columbian Hospital, and Vancouver Hospital and Health Science Centre, as well as Vernon Hospital and Abbotsford Hospital. The procedures are outlined in detail in the Consent Form which is attached.

Your total time commitment will be 2 hours spread over the 6 months of the study. An hour will be while you are still in the hospital; we will ask you questions about your hip and general health. The remaining time will be spent on parts of the study that do not involve you leaving your home. In approximately three months, and again at six months, you will receive a telephone call from one of the investigators and you will be asked questions about your hip fracture and your general health.

If, after reading the study description carefully, you would like to participate, please sign the consent form.

Should you have any questions about this study, please contact Dr. Karim Khan (email) or Margie Bell (email) in the HipWatch Study at the University of British Columbia. Thank you for your interest.

Sincerely,

Karim Khan, M.D., PhD.
Principal Investigator
You have been given this letter because you have had a hip fracture. Osteoporosis may be a factor in your fracture and you need to be assessed.

We would like you to return to your family doctor for review. Please take the referral letter that is contained in this package to your family doctor within the next two or three weeks to discuss osteoporosis assessment and management.

Your fracture will continue to be managed by your Orthopaedic Surgeon at Vancouver Hospital.

Sincerely,

Dr. Pierre Guy  MD, FRCSC
Consulting Orthopaedic Surgeon
Dear Doctor,

Your patient recently had a hip fracture and is involved in a study evaluating the medium term management of such fractures. A fracture as a result of a low trauma fall is considered a diagnostic criterion for osteoporosis. We are following these patients to see if they are in fact diagnosed with osteoporosis and how they are managed.

The purpose of this letter is to alert you to the possibility that your patient may have osteoporosis. The current guidelines from a panel of doctors at the Osteoporosis Program at BC Women's Hospital and Health Centre would suggest that patients might benefit from a DXA scan to assess BMD at the hip and lumbar spine.

We feel that osteoporosis is a condition that is well managed by family physicians. The orthopaedic surgeon involved in the care of your patient is collaborating in this study and has referred the patient back to you for osteoporosis assessment and management.

Sincerely,

Dr. Karim Khan
Osteoporosis Program
British Columbia Women's & Children's Hospital
APPENDIX C:

3-MONTH & 6-MONTH FOLLOWUP QUESTIONNAIRES FOR CONTROL GROUP
3-MONTH & 6-MONTH FOLLOWUP QUESTIONNAIRES FOR PEPA INTERVENTION GROUP
Telephone Script: 3 month post enrollment:

Hello. This is ________ speaking, I am the researcher involved in “HipWatch”, the study that you enrolled in at ________ VGH approximately 3 months ago. I need to ask you a few questions about your hip fracture. This will take about 30 minutes. Is this a good time for you to talk? Great.

1. Can I please check your information: name________________; age:___
   Date of Injury:_________________ GP:________________________

2. Have you had any falls since you returned home from the hospital?
   (If so, collect the dates and the details of each of the falls).

3. Have you been to your family doctor since you broke your hip?
   Yes ___ No ___

4. Has your doctor ever said that you have the following:
   diabetes, cancer, osteoporosis, high blood pressure, heart disease  (circle)

5. Are you taking any new medications or vitamins since your hip fracture?
   Yes ___ No ___

6. What aids do you usually use to help you move about inside the house?
   No aids used [ ]
   Walking stick [ ]
   Walking frame [ ]
   Crutches [ ]
   Wheel chair [ ]

7. What aids do you usually use to help you move about outside the house?
   No aids used [ ]
   Walking stick [ ]
   Walking frame [ ]
   Crutches [ ]
   Wheel chair [ ]

FEAR OF FALLING
1. Do you feel your balance is:
   Poor [ ]
   Fair [ ]
   Good [ ]
   Very good [ ]
   Excellent [ ]

2. How fearful/ nervous of falling are you?
Chapter 8: Appendices

Not at all [ ]
A little bit [ ]
Moderately [ ]
Quite a lot [ ]
Extremely [ ]

FALLS
1. How many falls did you have in the past year? ______ falls
2. As a result of these falls, did you suffer any injuries that affect your mobility now?
   YES [ ] NO [ ]

Depression scale
(Score one point for each “Yes”)
1. Have you had low energy? Yes [ ] No [ ]
2. Have you had loss of interests? Yes [ ] No [ ]
3. Have you lost confidence in yourself? Yes [ ] No [ ]
4. Have you felt hopeless? Yes [ ] No [ ]

THE BARTHEL INDEX

FEEDING
0 = unable
5 = needs help cutting, spreading butter, etc., or requires modified diet
10 = independent

BATHING
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10 = walks with help of one person (verbal or physical) > 50 yards
15 = independent (but may use any aid; for example, stick) > 50 yards

STAIRS
0 = unable
5 = needs help (verbal, physical, carrying aid)
10 = independent

TOTAL

Thank you very much for your time. I will be contacting you again in approximately 6 months from your fracture date to follow-up on your function. Thank you for your time I look forward to speaking to you soon.
Telephone Script: 6 month post enrollment:

Hello. This is speaking, I am the researcher involved in “HipWatch”, the study that you enrolled in at VGH approximately 6 months ago. I need to ask you a few questions about your hip fracture. This will take about 30 minutes. Is this a good time for you to talk? Great.

6. Can I please check your information: name: __________ age: __________
   Date of Injury: __________ GP: __________

7. Have you had any falls since you returned home from the hospital?
   (If so, collect the dates and the details of each of the falls).

8. Have you been to your family doctor since you broke your hip?
   Yes No

9. Has your doctor ever said that you have the following:
   diabetes, cancer, osteoporosis, high blood pressure, heart disease  (circle)

10. Are you taking any new medications or vitamins since your hip fracture?
    Yes No

6. What aids do you usually use to help you move about inside the house?
   No aids used [ ]
   Walking stick [ ]
   Walking frame [ ]
   Crutches [ ]
   Wheel chair [ ]

7. What aids do you usually use to help you move about outside the house?
   No aids used [ ]
   Walking stick [ ]
   Walking frame [ ]
   Crutches [ ]
   Wheel chair [ ]

FEAR OF FALLING
1. Do you feel your balance is:
   Poor [ ]
   Fair [ ]
   Good [ ]
   Very good [ ]
   Excellent [ ]

2. How fearful/nervous of falling are you?
Chapter 8: Appendices

FALLS

1. How many falls did you have in the past year? _____ falls

2. As a result of these falls, did you suffer any injuries that affect your mobility now?
   YES [ ] NO [ ]

Depression scale
(Score one point for each "Yes")

1. Have you had low energy? Yes [ ] No [ ]
2. Have you had loss of interests? Yes [ ] No [ ]
3. Have you lost confidence in yourself? Yes [ ] No [ ]
4. Have you felt hopeless? Yes [ ] No [ ]

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15 = independent (but may use any aid; for example, stick) > 50 yards

STAIRS
0 = unable
5 = needs help (verbal, physical, carrying aid)
10 = independent

TOTAL

Thank you very much for your time. That concludes the participation in the research project. Good Bye.
Telephone Script: 3 months enrollment:

Hello. This is __________ speaking. I am the researcher involved in “HipWatch”, the study that you enrolled in at VGH approximately 3 months ago. I need to ask you a few questions about your hip fracture. This will take about 30 minutes. Is this a good time for you to talk? Great.

1. Can I please check your information? Name________________ age:_______
   Date of Injury:____________________ GP:____________________

2. Did you read the information given to you in the package about osteoporosis? It is important that you read it.

3. Have you had any falls?

5. Have you been to your family doctor since you broke your hip? Yes No
   5a. If no, why not? ____________________________________________
      It is important that you visit your doctor and deliver the letter.

5b. If yes, did you give your doctor the letter from your specialist?
   Yes No

5c. Did the doctor say you had or were at risk for OP: Yes No

5d. Best Practices Offered: DXA Bone Density medications________________
      exercise calcium & vitamin D other ________________

6. Are you taking any new medications or vitamins since your hip fracture? Yes No

7. What aids do you usually use to help you move about inside the house?
   No aids used [ ]
   Walking stick [ ]
   Walking frame [ ]
   Crutches [ ]
   Wheel chair [ ]

8. What aids do you usually use to help you move about outside the house?
   No aids used [ ]
   Walking stick [ ]
   Walking frame [ ]
   Crutches [ ]
   Wheel chair [ ]
**Depression scale**
(Score one point for each "Yes")

1. Have you had low energy?  
   Yes [ ]  No [ ]

2. Have you had loss of interests?  
   Yes [ ]  No [ ]

3. Have you lost confidence in yourself?  
   Yes [ ]  No [ ]

4. Have you felt hopeless?  
   Yes [ ]  No [ ]

**FEAR OF FALLING**

1. Do you feel your balance is:
   - Poor [ ]
   - Fair [ ]
   - Good [ ]
   - Very good [ ]
   - Excellent [ ]

2. How fearful/ nervous of falling are you?
   - Not at all [ ]
   - A little bit [ ]
   - Moderately [ ]
   - Quite a lot [ ]
   - Extremely [ ]

**FALLS**

1. How many falls did you have in the past year? ______ falls

2. As a result of these falls, did you suffer any injuries that affect your mobility now?  
   YES [ ]  NO [ ]
THE BARTHEL INDEX

FEEDING
0 = unable
5 = needs help cutting, spreading butter, etc., or requires modified diet
10 = independent

BATHING
0 = dependent
5 = independent (or in shower)

GROOMING
0 = needs help with personal care
5 = independent face/hair/teeth/shaving (implements provided)

DRESSING
0 = dependent
5 = needs help but can do about half unaided
10 = independent (including buttons, zips, laces, etc.)

BOWELS
0 = incontinent (or needs to be given enemas)
5 = occasional accident
10 = continent

BLADDER
0 = incontinent, or catheterized and unable to manage alone
5 = occasional accident
10 = continent

TOILET USE
0 = dependent
5 = needs some help, but can do something alone
10 = independent (on and off, dressing, wiping)

TRANSFERS (BED TO CHAIR AND BACK)
0 = unable, no sitting balance
5 = major help (one or two people, physical), can sit
10 = minor help (verbal or physical)
15 = independent

MOBILITY (ON LEVEL SURFACES)
0 = immobile or < 50 yards
5 = wheelchair independent, including corners, > 50 yards
10 = walks with help of one person (verbal or physical) > 50 yards
15 = independent (but may use any aid; for example, stick) > 50 yards

STAIRS
0 = unable
5 = needs help (verbal, physical, carrying aid)
10 = independent
Thank you very much for your time. I will be contacting you again in approximately 6 months from your injury to follow-up on your arm function. Thank you for your time I look forward to speaking to you soon. Good-bye.
Telephone Script: 6 months enrollment:

Hello. This is _______ speaking, I am the researcher involved in “HipWatch”, the study that you enrolled in at VGH approximately 6 months ago. I need to ask you a few questions about your hip fracture. This will take about 30 minutes. Is this a good time for you to talk? Great.

1. Can I please check your information? Name________________ age:______
Date of Injury:_________________________ GP:________________________

2. Did you read the information given to you in the package about osteoporosis? It is important that you read it.

3. Have you had any falls?

5. Have you been to your family doctor since you broke your hip? Yes No

5a. If no, why not? ____________________________________________________________

It is important that you visit your doctor and deliver the letter.

5b. If yes, did you give your doctor the letter from your specialist?
Yes No

5c. Did the doctor say you had or were at risk for OP: Yes No

5d. Best Practices Offered: DXA Bone Density medications________
exercise calcium & vitamin D other _____________

6. Are you taking any new medications or vitamins since your hip fracture?
Yes No

7. What aids do you usually use to help you move about inside the house?
No aids used [ ]
Walking stick [ ]
Walking frame [ ]
Crutches [ ]
Wheel chair [ ]

8. What aids do you usually use to help you move about outside the house?
No aids used [ ]
Walking stick [ ]
Walking frame [ ]
Crutches [ ]
Wheel chair [ ]
Depression scale
(Score one point for each "Yes")

1. Have you had low energy? Yes [ ] No [ ]
2. Have you had loss of interests? Yes [ ] No [ ]
3. Have you lost confidence in yourself? Yes [ ] No [ ]
4. Have you felt hopeless? Yes [ ] No [ ]

FEAR OF FALLING

1. Do you feel your balance is:
   Poor [ ]
   Fair [ ]
   Good [ ]
   Very good [ ]
   Excellent [ ]

2. How fearful/nervous of falling are you?
   Not at all [ ]
   A little bit [ ]
   Moderately [ ]
   Quite a lot [ ]
   Extremely [ ]

FALLS

1. How many falls did you have in the past year? ________ falls

2. As a result of these falls, did you suffer any injuries that affect your mobility now? YES [ ] NO [ ]
THE BARTHEL INDEX

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15 = independent (but may use any aid; for example, stick) > 50 yards

STAIRS
0 = unable
5 = needs help (verbal, physical, carrying aid)
10 = independent
Thank you very much for your time. We appreciate your participation in the research project. Good-bye.
APPENDIX D: 6-MONTH CROSS-OVER LETTER

LETTER TO CONTROL GROUP PARTICIPANTS SENT AFTER 6-MONTHS
You have been given this letter because you have had a hip fracture. Osteoporosis may be a factor in your fracture and you need to be assessed.

We would like you to return to your family doctor for review. Please take the referral letter that is contained in this package to your family doctor within the next two or three weeks to discuss osteoporosis assessment and management.

Your fracture will continue to be managed by your Orthopaedic Surgeon at Vancouver Hospital.

Sincerely,

Dr. Pierre Guy MD, FRCSC
Consulting Orthopaedic Surgeon
APPENDIX E: ETHICS
Certificate of Expedited Approval: Amendment

Clinical Research Ethics Board Official Notification

<table>
<thead>
<tr>
<th>PRINCIPAL INVESTIGATOR</th>
<th>DEPARTMENT</th>
<th>NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Khan, K.</td>
<td>Family Practice</td>
<td>C02-0341</td>
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INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT
Richmond Hospital, UBC Campus, Vancouver Coastal Health Authority

CO-INVESTIGATORS:
Ashe, Maureen, Family Practice; Guy, Pierre, Orthopaedics

SPONSORING AGENCIES
Aventis Pharmaceuticals Inc.

TITLE:
Hip Watch: Changing Management Patterns in Patients at Risk of Hip Fracture

APPROVAL DATE (yy/mm/dd) | TERM (YEARS) | AMENDMENT: |
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<td>Contact consent, intervention consent, control consent forms dated 21 January 2004</td>
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AMENDMENT APPROVED: Feb 19 2004

CERTIFICATION:
In respect of clinical trials:
1. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations.
2. The Research Ethics Board carries out its functions in a manner consistent with Good Clinical Practices.
3. This Research Ethics Board has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of this Research Ethics Board have been documented in writing.

The amendment(s) for the above-named project has been reviewed by the Chair of the University of British Columbia Clinical Research Ethics Board and the accompanying documentation was found to be acceptable on ethical grounds for research involving human subjects.

The CREB approval period for this amendment expires on the one year anniversary date of the CREB approval for the entire study.

Approval of the Clinical Research Ethics Board by one of:
Dr. P. Loewen, Chair
Dr. A. Gagnon, Associate Chair
Dr. J. McCormack, Associate Chair
Certificate of Expedited Approval: Amendment

Clinical Research Ethics Board Official Notification

PRINCIPAL INVESTIGATOR
Miran-Khan, K.

DEPARTMENT
Family Practice

NUMBER
C02-0341

INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT
Richmond Hospital, UBC Campus, Vancouver Coastal Health Authority

CO-INVESTIGATORS:
Ashe, Maureen, Family Practice; Guy, Pierre, Orthopaedics

SPONSORING AGENCIES
Aventis Pharmaceuticals Inc.

TITLE:
Hip Watch: Changing Management Patterns in Patients at Risk of Hip Fracture

APPROVAL DATE (yy/mm/dd)
04-07-30

TERM (YEARS)
1

AMENDMENT:
Intervention consent form dated August 2004; Control consent form dated August 2004

AMENDMENT APPROVED:
20 August 2004

CERTIFICATION:
In respect of clinical trials:

1. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations.

2. The Research Ethics Board carries out its functions in a manner consistent with Good Clinical Practices.

3. This Research Ethics Board has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of the this Research Ethics Board have been documented in writing. The amendment(s) for the above-named project has been reviewed by the Chair of the University of British Columbia Clinical Research Ethics Board and the accompanying documentation was found to be acceptable on ethical grounds for research involving human subjects.

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Dr. A. Gagnon, Associate Chair
Dr. J. McCormack, Associate Chair