Osteoporosis in the Nursing Home:
Screening and Interventions for Fracture Prevention

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To the faculty of Washington State University:

    The members of the committee appointed to examine the Intercollegiate College of Nursing research requirements and manuscript of Linda Ward find it satisfactory and recommend that it be accepted.

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Abstract

More than 80% of nursing home residents are believed to have osteoporosis, which leaves them susceptible to debilitating and life-threatening fractures. Vertebral fractures occur most commonly, causing pain, deformity and functional impairment. Fractures at other sites are associated with falls. Nursing home residents have a 60% risk to fall each year, with a hip fracture rate of 5-6%, nearly ten times that of community-dwelling persons the same age. Hip fracture in a nursing home resident is associated with a 41% mortality rate within four months, more than twice the rate for older persons who fracture a hip at home. Nursing home admission provides a critical opportunity to screen for osteoporosis and offer interventions to reduce the likelihood of fracture. A number of safe and effective therapies are available to improve bone health in nursing home residents, but no formal guidelines exist for preventing fractures in this most vulnerable population. A research-based analysis, that includes clinical, economic, and humanistic implications of available non-pharmacological and pharmacological interventions for osteoporosis, is presented. The analysis is synthesized as an algorithm for screening, preventing, and treating osteoporosis in nursing home residents.
Osteoporosis in the Nursing Home: Screening and Interventions for Fracture Prevention

Osteoporosis is a disease that primarily affects older persons. Similar to other chronic diseases, it progresses insidiously for years before becoming apparent in the form of a fracture. Ten million Americans already have osteoporosis, and 18 million have osteopenia, or low bone mass (National Institutes of Health [NIH], 2001). Half of all white women will experience an osteoporotic fracture in their lifetime (National Osteoporosis Foundation [NOF], 1999), along with 13% of white men (Messinger-Rapport & Thacker, 2002). In 1995, osteoporosis caused 1.5 million fractures in the United States at a cost of $14 billion. That cost may increase to as much as $240 billion over the next 50 years, as the population of Americans over age 85 increases (Osteoporosis Task Force, 2001).

Over 90% of osteoporotic fractures occur in persons aged 65 and older, and those at highest risk are the nearly two million residents of nursing homes. With a mean age of 84 years, nursing home residents have high rates of functional and cognitive impairment, chronic disease, and polypharmacy. It is no surprise, then, that falls are common in the nursing home; in fact, 60% of nursing home residents fall each year (Fuller, 2000). Most of these frail individuals also have osteoporosis. Studies of white female nursing home residents showed from 80% to 95% to be osteoporotic by World Health Organization (WHO) criteria (Chandler et al., 2000; Ekman, Michaelsson, Ljunghall, & Mallmin, 2001; Kanis, 1994; Wallace, 2000). The combination of high fall risk and weak bone results in a fracture rate among nursing home residents that is nearly ten times that of healthy community-dwelling elders (Chandler et al.).

Osteoporotic fractures occur most often at the spine, hip, and wrist. Vertebral fractures are most common and usually occur with normal activity. Many vertebral fractures go unnoticed,
about half are associated with back pain, 8% require hospitalization, and 2% result in long-term nursing care (Office of Disease Prevention, 2000). Hip and wrist fractures are usually associated with a fall. Hip fracture has such high morbidity and mortality that it is often a terminal event in older persons. Within a year of fracturing a hip, 20% of community-dwelling women and 40% of men die, about 60% never return to prefracture function, and 40% require long-term care (Field-Munves, 2001). The mortality rate following hip fracture in nursing home residents is twice as high; 41% of residents die within four months of fracture, and 46% die within one year (Baran et al., 1998).

Osteoporosis has been recently recognized as an important public health issue. Healthy People 2010 set goals to reduce the incidence of osteoporosis and hospitalizations for vertebral fractures by 20% and to reduce deaths and injuries from falls, including hip fracture, among elderly persons (Office of Disease Prevention, 2000). The purpose of this paper is to discuss current best practices in the management of osteoporosis in the nursing home population. The focus will be on clinical interventions, primarily screening, nutritional supplementation, and pharmacologic treatments, to prevent and treat osteoporosis.

Theoretical Framework

The Economic, Clinical, and Humanistic Outcomes (ECHO) model provides an integrated framework for evaluating osteoporosis treatment alternatives (Kozma, Reeder, & Schulz, 1993). The ECHO model differs from a traditional medical model by requiring systematic evaluation of economic and humanistic outcomes as well as traditional clinical outcomes in determining the best pharmaceutical treatment. Developed to guide pharmacoeconomic decision-making, the ECHO model is also useful in comparing non-
pharmaceutical treatments, and is particularly well suited to nursing home care, for reasons detailed below.

**Components of the ECHO Model**

The ECHO model (Figure 1) has three components. The first component, clinical variables, consists of clinical indicators and clinical outcomes. Clinical indicators are data gathered from resident assessment that indicate the degree of disease and guide the decision to treat. With osteoporosis, clinical indicators include risk factors for osteoporosis and radiographic measurements of bone health. Clinical outcomes are medical events that occur (or do not occur) as a result of the disease or treatment. Such outcomes include fracture, pain, and medication side effects.

The second component, economic outcomes, includes the total direct, indirect and intangible costs compared with the consequences of treatment alternatives. For example, the cost of hospitalizing a resident for a gastrointestinal bleed related to bisphosphonate treatment is included in determining the economic outcome of prescribing that medication. Likewise, dollars saved by preventing a hip fracture are also counted.

The final component of the model, humanistic outcomes, includes the consequences of both the disease and the treatment on the resident’s functional status and quality of life. Physical and social functioning, general health and well-being, and satisfaction with treatment are systematically assessed. For example, residents may object to having to swallow three large calcium tablets, or to being awakened early for their alendronate (Fosamax®) dose. Application of the ECHO model requires consideration of these patient responses to treatment.
Osteoporosis in the Nursing Home

Application of the ECHO model

The ECHO model is philosophically congruent with the way in which nursing home care is provided. In addition to traditional medical treatment (clinical variables), quality of life issues (humanistic outcomes) have long been emphasized in the nursing home. In fact, nursing homes are required to implement individualized care plans and to involve residents and families in the plan of care. Facilities also strive to achieve a home-like atmosphere with diligent attention to resident rights and autonomy. Implementation of a prospective payment system in 1998 provided an increased incentive to provide cost-effective care (economic outcomes). All three components of the ECHO model are thus integral to making treatment decisions in the nursing home.

Review of the Literature

Osteoporosis

Osteoporosis is defined by WHO in terms of bone mineral density (BMD). There is currently no accurate measurement of overall bone strength, but BMD accounts for approximately 70% of bone strength (NIH, 2001). Diagnostic criteria for osteoporosis are expressed in terms of T-score, or the number of standard deviations by which an individual BMD differs from the mean value for a young adult of the same sex. Osteopenia (low bone mass) is defined as having a T-score between -1 and -2.5, while osteoporosis is diagnosed when the T-score is less than -2.5 (Kanis, 1994). The baseline BMD of an individual correlates fairly well with fracture risk, in that a T-score of -1 at the lumbar spine predicts a two-fold increase in risk of vertebral fracture (Sharpe, Noble, & Spencer, 2001).

Determination of hip BMD is preferred for diagnosis of osteoporosis because of the severe consequences of hip fracture and the close correlation between low hip BMD and hip fracture. Spine BMD is often used for monitoring treatment, because vertebral response to
antiresorptive agents occurs relatively quickly. Peripheral measurements of BMD are easier to obtain, but do not reliably predict fracture risk (Broe et al., 2000).

**Osteoporosis Prevention and Treatment**

Many studies have been conducted in recent years regarding osteoporosis prevention and treatment, however they have important limitations. Most interventional studies measured change in BMD as an endpoint. While low BMD certainly contributes to fracture risk, a more useful endpoint is actual fracture. However, in order for fracture studies to have sufficient power, they must include large numbers of subjects and/or proceed for a lengthy time. A limited number of studies used fracture as an endpoint, and these provide the strongest evidence for intervention efficacy or lack thereof.

Evidence-based guidelines for nursing home residents are limited because most findings are based on studies of healthy, community-dwelling postmenopausal women. Very few trials have focused on nursing home residents. Consequently, the published clinical guidelines for osteoporosis treatment, most notably by the National Osteoporosis Foundation (NOF) and the American Association of Clinical Endocrinologists (AACE), are directed at the management of healthy postmenopausal women. Furthermore, the risk factors that form the basis of these treatment guidelines have not been demonstrated to independently predict fracture in nursing home residents (Chandler et al., 2000). It may be that risk factors for community-dwelling, “younger” elders are so common in the nursing home that they do not distinguish fracture risk.

Finally, the pathophysiology of bone formation and resorption in older persons is not clearly delineated. While osteoporosis is a chronic disease which typically progresses 20 to 30 years before fracture occurs, most clinical trials have lasted only three or four years (Lindsay & Meunier, 1998). Researchers commonly believed that bone loss occurred at a high rate beginning
with menopause, remained elevated for a few years, then slowed or ceased in older women. However, recent studies indicate that bone turnover remains elevated into old age and may accelerate rather than slow after age 65 (Villareal et al., 2001).

There is no question that bone health must be addressed in the nursing home, but the lack of research and treatment guidelines specific to this population makes treatment decisions difficult. Despite the challenges identified above, there are a number of cost-effective interventions that can reduce fractures among nursing home residents.

Assessment and Intervention: Application of the ECHO Model

Screening

Osteoporosis is both underdiagnosed and undertreated. Less than one-third of American women with osteoporosis have been diagnosed, and only one-seventh of those diagnosed receive treatment (Osteoporosis Task Force, 2001). A study of 934 women aged 60 and older who had chest x-rays during hospitalization showed 14% had significant vertebral fractures, however, only 1.8% had a discharge diagnosis of vertebral fracture. Of those, only 18% were prescribed medication or dietary supplements to increase or maintain bone density (Gehlbach et al., 2000). A study of 170 patients hospitalized with a new hip fracture revealed only 5% were discharged on a new medication to prevent subsequent fracture (Kamel, Hussain, Tariq, Perry, & Morley, 2000). Patients who have sustained one osteoporotic fracture are at high risk to refracture and clearly should be offered treatment to improve or maintain bone strength.

Nursing home admission provides a critical opportunity to screen for osteoporosis, especially since recent fracture often precipitates nursing home admission. Every new resident should be screened for bone health, despite their age or anticipated length of stay. Routine measurement of BMD, which is recommended for healthy older persons, is controversial in the
nursing home. Application of the ECHO model to risk factor assessment and BMD measurement is illustrative.

Risk Factor Assessment: Clinical, Economic and Humanistic Impact

Risk factor assessment is designed to determine which residents are likely to have osteoporosis and benefit from therapy. The clinical utility of assessing risk factors depends on counting those factors that actually predict fracture risk. While the risk factors listed in Table 1 were developed specifically to assess fracture risk in nursing home residents, there are no specific studies to document their predictive value. In order to maximize the accuracy of osteoporosis screening, more information about fracture risk in nursing home residents must be collected. Fracture risk assessment has minimal economic impact, requiring only time on the part of the admitting nurse to complete the assessment. From a humanistic standpoint, assessment of risk factors offers potential benefit without harm to the resident.

Guidelines for osteoporosis screening are well established for healthy older persons, and both the NOF and the AACE have published specific risk factors for fracture in that population. While no formal guidelines exist for screening nursing home residents, Baran et al. (1998) utilized an expert panel and available research to develop a step-wise approach for evaluating fracture risk in nursing home residents. The authors developed an algorithm intended for use by primary care providers. However, with minimal adaptations to the algorithm, the admitting nurse at the nursing home can complete a similar evaluation (Figure 2). Steps include determining intention to treat, carefully reviewing the resident’s medical history for evidence of osteoporosis, and assessing clinical risk factors for fracture (Table 1). The nurse should then present the findings to the primary care provider for consideration of specific therapies to promote bone health and prevent fracture.
**Bone Mineral Density: Clinical, Economic and Humanistic Impact**

Osteoporosis is defined in terms of bone mineral density, and BMD is the single best predictor of fracture risk. Both the NOF and AACE recommend BMD testing for all women over age 65 and specifically warn that treatment decisions should not be based on risk factors alone. However, these guidelines were written for community-dwelling older persons. Bone density screening is probably not indicated for most nursing home residents, as application of ECHO criteria demonstrates.

In terms of clinical indicators, there is no doubt that determination of hip BMD provides useful information. In addition to confirming a diagnosis of osteoporosis and measuring baseline bone density, BMD measurement is useful in determining the cost effectiveness of expensive treatments. Nomograms developed by the NOF help providers make rational and cost-effective prescribing decisions for various antiresorptive agents by plotting a resident’s age, number of risk factors, and hip BMD (Lindsay & Meunier, 1998). However, the clinical utility of a “screening” test for bone density is limited in the nursing home population, where at least 80% of individuals are expected to have positive tests.

The economic impact of BMD measurement is substantial in the nursing home. The measurement that provides the best correlation with fracture risk is hip BMD determined by dual-energy x-ray absorptiometry (DEXA) of the hip. This scan requires the use of stationary equipment and costs approximately $250. Under the current payment system, the nursing home is usually required to pay for both the scan and the cost of transporting the patient to the testing site. Portable systems are available to determine peripheral BMD at less cost, but those measurements do not reliably predict fracture risk (Broe et al., 2000).
The humanistic impact of hip BMD testing on nursing home residents is substantial, requiring that residents be transported from the nursing home to the testing site, be positioned correctly for the scan and lie still for as long as ten minutes. Many residents cannot tolerate scanning, due to impaired mobility or cognition. Even peripheral measurements of BMD utilizing portable equipment are not easy to obtain in this population. In a large Maryland study, 34% of nursing home residents were unable to complete a portable BMD test of the distal forearm, due to cognitive or physical impairment (Zimmerman et al., 1999).

In light of clinical, economic and humanistic factors, routine BMD screening of nursing home residents is not indicated. Given the high incidence of osteoporosis in this population, BMD screening loses much of its clinical utility, and the economic and humanistic factors provide compelling reasons not to routinely measure bone density. Careful evaluation of each resident’s history and risk factors associated with osteoporosis provides a more rational approach to identifying those likely to benefit from further evaluation and treatment.

Treatment of Osteoporosis: Application of the ECHO Model

The primary goal of osteoporosis treatment is fracture prevention through reducing bone loss, increasing bone mass, and preventing falls. A multidisciplinary approach including dietary interventions, pharmaceuticals, physical conditioning, and fall prevention provides the best opportunity to improve bone health and reduce fractures in nursing home residents. Dietary supplements and pharmaceuticals that have been shown to improve bone density and/or reduce fracture risk include calcium and vitamin D, bisphosphonates, estrogens, selective estrogen receptor modulators and calcitonin. In addition, hip protectors have demonstrated efficacy in reducing hip fractures in nursing home residents. These interventions will be examined within the framework of the ECHO model.
Calcium

The role of calcium in bone health is well established. The skeleton stores 99% of the body’s calcium, and when insufficient calcium is present in the diet, bone is demineralized to maintain serum levels. The average American diet provides less than 600 mg/d of elemental calcium, about half the recommended daily allowance (NOF, 1999), and only about 50% to 60% of older adults are believed to consume adequate calcium to maintain bone health (NIH, 2001). Calcium supplementation is widely recommended for older persons. While the NOF recommends at least 1200 mg/d dietary calcium for all patients with risk factors for osteoporosis, the NIH specifies an optimal calcium intake for women over age 65 to be 1500 mg/d.

The clinical benefits of adequate calcium for nursing home residents are well demonstrated. Lindsay and Meunier (1998) summarized randomized trials of calcium supplementation in about 1800 postmenopausal women, demonstrating a lower rate of bone loss in women receiving supplemental calcium. Bone density was 1%-3% higher in the treatment groups, with a greater effect noted in women who were more than five years postmenopausal.

Fewer studies have evaluated the effect of calcium on fracture. Four randomized, controlled trials in community-dwelling postmenopausal women demonstrated modest but clinically significant reductions in fractures, primarily vertebral fractures, with calcium supplementation (Chevalley et al., 1994; Orimo et al., 1994; Recker et al., 1996; Reid et al., 1995). In a classic study, Chapuy, Arlot, Delmas and Meunier (1994) demonstrated a 43% reduction in overall fractures among nursing home residents with calcium and vitamin D supplementation over three years. Hip fractures were reduced by 29%. It is unknown whether the protective effect was from calcium or vitamin D, or was a result of both in combination.
The economic impact of providing supplementary calcium is minimal. The NOF, while admitting that the precise effect of calcium on fracture risk is unknown, estimates it is “highly probable” that calcium supplementation reduces fracture rates by 10%. At that level of effectiveness, calcium is cost-effective if purchased inexpensively (at a cost of about $50/year), even for women who have high BMDs (Lindsay & Meunier, 1998).

There are some humanistic considerations in providing routine calcium supplements. Calcium supplementation at the recommended level is safe, with few side effects if the doses are provided with meals (Lindsay & Meunier, 1998). However, residents sometimes complain about the size and/or number of calcium tablets, because two or three large tablets are required for a 1200-1500 mg dose. Dividing doses enhances absorption, but requires residents to take calcium tablets two or three times a day. Residents sometimes have difficulty swallowing the pills. However, chewable antacids that contain calcium are an economical alternative and may be better tolerated. Chewable antacids are also easily crushed and can be added to applesauce or pudding.

Applying the ECHO model to calcium supplementation reveals little reason to deviate from the recommended level of supplementation. Nursing home residents should consume 1200 to 1500 mg of elemental calcium per day unless there is a specific contraindication. Calcium supplements should be used to augment dietary calcium to the target level.

_Vitamin D_

Like calcium, vitamin D is essential for bone health. Vitamin D is not a true vitamin because it can be synthesized in the skin with adequate ultraviolet exposure. Vitamin D is required for absorption of dietary calcium and for bone mineralization. Insufficiency leads to hyperparathyroidism, which in turn causes high bone turnover, bone loss, and increased fracture
risk (Fairfield & Fletcher, 2002). Vitamin D insufficiency is widespread, especially among older persons who are institutionalized or homebound. There is general agreement that sunlight-deprived people, particularly those in nursing homes, commonly have vitamin D deficiency. LeBoff et al. (1999) found 50% of postmenopausal women with hip fractures to be vitamin D deficient. The NOF recommends 400 to 800 IU daily of vitamin D for nursing home residents, while the AACE guidelines call for 800 IU per day.

Clinical outcomes show clear benefit with vitamin D supplementation. The largest trials among elderly persons revealed increased hip BMD and fewer upper-extremity fractures, but no reduction in hip fractures with vitamin D supplementation (Heikinheimo et al, 1992; Lips, Graafmans, Ooms, Bezemer, & Bouter, 1996). Pfeifer and Minne (1999) demonstrated improved neuromuscular coordination and body sway with vitamin D supplementation, proposing that vitamin D can reduce fall risk. Most studies of vitamin D and fracture risk included supplemental calcium as well, and the efficacy of vitamin D alone in preventing fracture has not been clearly demonstrated. Supplements in the recommended amount (up to 800 IU per day) are safe (Fairfield & Fletcher, 2002).

Vitamin D supplementation incurs little economic impact. Milk and cereals that are fortified with vitamin D can provide a large part of the daily requirement. Most multivitamins contain vitamin D, as do many calcium supplements. Vitamin D supplements are also available. These are all inexpensive interventions. Vitamin D in the amounts recommended is well tolerated, and there are no compelling humanistic reasons to deviate from these recommendations. All nursing home residents without specific contraindications to vitamin D should receive 400 to 800 IU per day.
Bisphosphonates

The bisphosphonates are a group of medications that bind to bone and inhibit osteoclast-mediated bone resorption. In 1995, alendronate (Fosamax®) was the first bisphosphonate to be labeled by the FDA for the prevention and treatment of osteoporosis. Risedronate (Actonel®), a second-generation bisphosphonate, was approved in 2000. Application of the ECHO model to these powerful antiresorptive agents is revealing.

Clinical outcomes associated with bisphosphonate therapy are positive in terms of fracture prevention. Bisphophonates increase BMD irrespective of degree of underlying osteoporosis and reduce fractures in patients with documented osteoporosis (Hodsman, Hanley, & Josse, 2002). In randomized trials among community-dwelling elderly females, both alendronate and risedronate were found to significantly increase BMD at the lumbar spine and hip (Black et al., 2000; Hodsman et al.; McClung et al., 2001; Sharpe et al., 2001). More importantly, alendronate use over three years in the Fracture Intervention Trial (FIT) decreased the incidence of new vertebral, hip, and wrist fractures by 50% (Black et al.). Trials with risedronate showed 30% to 50% reductions in fractures at all sites over three years compared to placebo (Harris et al., 1999; McClung et al.). With both bisphosphonates, fracture reduction occurred only among women with BMD-documented osteoporosis; those with osteopenia fractured at the same rate as the placebo groups (Black et al.; Harris et al.).

While clinical trials have firmly established the efficacy of bisphosphonates in treating community-dwelling osteoporotic women, only a single, much smaller trial (N=327) with nursing home residents has been published. Greenspan et al. (2002) found significantly increased BMD at the spine and hip after 2 years of alendronate treatment among ambulatory female nursing home residents. The treatment group had a lower fracture rate, but this was not
statistically significant. However, the small size of this study severely limited its ability to demonstrate fracture reduction.

While the clinical efficacy of bisphosphonates in reducing fractures among nursing home residents has not been clearly demonstrated, there is strong evidence to support their use. Alendronate produced a pronounced reduction in fracture in women with very low BMD (Black et al., 2000). Nursing home residents as a group have significantly lower BMD than participants in the FIT trial, and may have greater treatment benefit than community-dwelling elderly persons.

Bisphosphonates are expensive, costing approximately $600 per year (Vestergaard, Rejnmark, & Mosekilde, 2001), and specific dosing requirements increase the cost of administration. Bisphosphonates must be administered apart from other medications, with a full glass of water, at least 30 minutes before the first food or drink of the day. Taking the drug with liquid other than water, with other medications, or with food reduces the bioavailability (which is <1% at best) by 40%-90% (Sharpe et al., 2001). After taking the drug, residents must remain upright for 30 minutes to prevent esophageal irritation. The need to separate bisphosphonates from the regular medication pass and to monitor that residents remain upright after the dose is labor intensive, but failure to comply destroys the bioavailability of the drug, risks serious gastrointestinal side effects, or both (Sharpe et al.). The FDA recently approved weekly dosing of bisphosphonates, which greatly reduces cost of administration.

The cost effectiveness of bisphosphonate therapy is dependent upon careful selection of residents likely to benefit from treatment and by vigilant attention to administration instructions. Bisphosphonates have been demonstrated to reduce fractures only in individuals with documented osteoporosis, and limited knowledge of hip BMD makes it difficult to know which
residents are actually osteoporotic. The NOF nomograms, which are useful in determining the
cost-effectiveness of treatment in individual patients, rely heavily on hip BMD measurements.
However, because the increase in BMD with bisphosphonates is greater in older than in younger
postmenopausal women (Greenspan et al., 2000), and because nursing home residents in general
have been demonstrated to have a very high incidence of osteoporosis, bisphosphonates may be
more cost effective in the nursing home than in the community. Still, because these drugs have
not yet been demonstrated to reduce fractures in randomized nursing home trials, their efficacy
and cost effectiveness truly remain unknown.

Humanistic factors associated with bisphosphonate use include administration
requirements and safety. These dosing requirements are not always appreciated by residents.
Most residents must be awakened early in the morning to take their bisphosphonate. They must
then remain upright for half an hour before their morning coffee, juice, or breakfast. The advent
of weekly dosing was a blessing to nursing staff and residents alike, greatly reducing the burden
related to dosing regimen.

Esophageal safety with bisphosphonates has economic, clinical and humanistic
implications. Gastrointestinal side effects with alendronate, including occasional serious
esophageal injury, have been more commonly reported in practice than in clinical trials (Sharpe
et al., 2001). However, a high proportion of those reports are associated with failure to follow
dosing recommendations (Watts, Freedholm, & Daifotis, 1999). Endoscopic studies have not
shown gastrointestinal erosions or ulcers related to weekly alendronate (Lanza et al., 2002).
Fewer problems have been reported with risedronate (Greenspan et al., 2000). Bisphosphonates,
which quickly bind to bone and thus have little systemic effect, are otherwise well tolerated.
Bisphosphonate therapy should be considered for all nursing home residents who are at high risk for fracture. Because of the high cost, both bone health and fall risk should be carefully considered when deciding if bisphosphonate therapy is indicated. Residents who can participate in treatment decisions should have a voice regarding this therapy, because of the stringent dosing requirements. Nursing staff must scrupulously follow the recommended dosing protocol. The clinical efficacy, cost, and dosing implications for alendronate and risedronate are similar, and there is little to recommend one over the other.

Estrogen

Estrogen has been widely believed to prevent osteoporotic fractures and is approved by the FDA for prevention of osteoporosis in postmenopausal women. Historically, estrogen was approved for osteoporosis treatment as well, however the FDA removed that indication because estrogen was never demonstrated to reduce fracture risk. Controversy about estrogen's role in osteoporosis management has been ongoing.

There is little dissent regarding estrogen's efficacy in preventing the rapid loss of bone density that normally occurs in the immediate postmenopausal period. The Study of Osteoporotic Fractures was a large (N=9704) observational study that linked estrogen use to reduced fracture risk in women over age 65 (Cauley et al., 1995). The protective effect of estrogen appeared to cease if therapy was stopped. The Postmenopausal Estrogen/Progestin Intervention (PEPI) trial demonstrated that estrogen actually increases bone density, not merely slows bone loss or maintains BMD. The authors noted that older women and those with lower initial BMD gained significantly more bone than women who were younger and/or had higher BMD (PEPI Writing Group, 1996).
While few studies focused on older women, a small (N=67) randomized trial involving women over age 75 showed an increase in hip and spine BMD after only nine months of estrogen therapy compared to the control group. The magnitude of the increase in both lumbar spine and total hip BMD was equal to or greater than that found in studies of younger women (Villareal et al., 2001).

The issue of fracture reduction with estrogen was not demonstrated in randomized trials until preliminary results from the Women's Health Initiative (WHI) were released in 2002. This large trial of 16,608 healthy women aged 50-79 years showed a 33% reduction in the rate of hip fracture with hormone replacement therapy (HRT) versus placebo. However, the study was terminated early (after 5.2 years) by the National Institutes of Health, when the breast cancer risk in the treatment group reached a prespecified upper boundary. The authors concluded that HRT caused net harm when used for 5.2 years, with reductions in fracture risk and colorectal cancer outweighed by increased risk of cardiovascular disease and breast cancer (Writing Group for the WHI, 2002). While the protective effect of estrogen on bone was clearly demonstrated by the WHI, the use of HRT for extended periods of time for the primary prevention of chronic disease was determined not to be justified.

The clinical impact of HRT on the bone of nursing home residents is unknown. While significant fracture reduction was achieved in the WHI, that population was younger and healthier than the nursing home population. The small Villareal study demonstrated a favorable effect of estrogen on bone, but no study has demonstrated estrogen to reduce fractures in the nursing home. Because of estrogen's widespread systemic effects and potential adverse clinical outcomes related to cardiovascular and breast disease, it has an overall negative clinical profile for osteoporosis prevention.
Estrogen has a relatively low direct cost. Hormone replacement therapy costs approximately $300 per year, about half the cost of bisphosphonates. While Vestergaard et al. (2001) claim HRT to be cost effective in terms of fracture prevention in women over the age of 70, application of the ECHO model requires that indirect costs also be considered, including those costs related to potential adverse effects. Overall, HRT is not a cost-effective therapy for fracture reduction in most nursing home residents.

Humanistic impact of HRT on nursing home residents is primarily related to potential medication side effects and satisfaction with treatment. The single daily dose has no special administration requirements. Some older females are quite convinced that estrogen confers a number of benefits and are not interested in stopping therapy. Application of the ECHO model requires providers to consider such patient preferences in making clinical decisions.

While estrogen has a significant protective effect on bone in younger women, it has never been demonstrated to increase bone density or prevent fractures in women long past menopause (Baran et al., 1998). Therefore, and because a wide range of adverse effects are associated with prolonged therapy, estrogen should not be used for osteoporosis prevention.

**Selective Estrogen Receptor Modulators**

Raloxifene (Evista®) is one of a new class of drugs, selective estrogen receptor modulators (SERMs), which bind to estrogen receptors but exhibit tissue-specific effects that are distinct from estradiol. For example, raloxifene acts as an estrogen agonist on bone and on lipid metabolism, but as an antagonist on breast and uterine receptors (Khovidhunkit & Shoback, 1999). The FDA approved raloxifene for the prevention of osteoporosis in postmenopausal women in 1997. The health risks demonstrated with estrogen in the WHI fueled increased
interest in SERMs. The hope is that the tissue specificity of SERMs can produce benefits associated with HRT without some of the risks.

The clinical efficacy of raloxifene been explored in a number of large randomized trials. Trials involving 1800 healthy postmenopausal women demonstrated raloxifene’s positive effect on bone and were cited in the FDA approval. Fracture was not an endpoint in these studies, however significant increases in BMD at all sites were demonstrated in the treatment versus placebo groups (Delmas et al., 1997; Johnston et al., 2000).

The largest American raloxifene study, the Multiple Outcomes of Raloxifene Evaluation (MORE), demonstrated significant risk reduction for vertebral fracture with raloxifene (RR 0.5 to 0.7) compared to placebo in healthy postmenopausal women. There was no risk reduction for nonvertebral fractures, although BMD at the hip increased by 2.1% with raloxifene. Thus, raloxifene is less effective than both HRT and bisphosphonates in preventing fracture (Scott, DaCamara, & Early, 1999). The mean age of participants in the MORE trial was 54 years, and no raloxifene studies have focused on nursing home residents. The MORE trial demonstrated a significantly lower incidence of breast cancer (RR 0.3 compared to placebo) and a 12% reduction in serum LDL in the treatment group (Ettinger et al., 1999). Raloxifene increased the risk of venous clots, with a risk similar to estrogen.

Raloxifene is expensive, with a cost equivalent to the bisphosphonates. In light of its lower clinical efficacy, it is significantly less cost-effective than other agents. Raloxifene has a favorable humanistic profile. Dosing involves taking a single pill daily, without regard to food. Raloxifene was generally well tolerated in studies, in fact pooled data from several studies showed that raloxifene was discontinued less often than placebo (Scott et al., 1999).
Applying the ECHO model to raloxifene illustrates a favorable humanistic profile, but poorer clinical outcomes and cost effectiveness as compared to bisphosphonates. Raloxifene is an appropriate second-line drug for residents who are unable to tolerate bisphosphonates.

**Calcitonin**

Calcitonin is a hormone produced by the parafollicular cells of the thyroid gland. Calcitonin is normally secreted in response to elevated serum calcium, whereupon it inhibits the activity of osteoclasts, the cells responsible for resorbing bone. The resulting slowing of bone resorption is thought to preserve, or even increase, bone density. While endogenous calcitonin levels have little influence on bone mass, randomized trials in postmenopausal women showed an increase in bone density with the use of subcutaneous or intranasal calcitonin. Salmon calcitonin (Miacalcin®) was approved by the FDA in 1984 in its injectable form, and in 1995 as a nasal spray.

The clinical efficacy of calcitonin was best demonstrated in the Prevent Recurrence of Osteoporotic Fractures Study (PROOF), a large, five-year, randomized trial of calcitonin nasal spray among women with osteoporosis. PROOF demonstrated a modest increase in lumbar spine BMD and a 36% reduction in vertebral fractures with calcitonin compared to placebo (Chestnut et al., 2000). While the results are encouraging for patients at risk for vertebral fracture, no protective effect against hip fracture was demonstrated. A major flaw in the study was that 59% of the original participants dropped out before the study was completed and were “lost” to follow-up. Critics of the PROOF trial claim the study leaves uncertainty about the value of nasal calcitonin and suggest calcitonin should be reserved for patients who are unable to take agents with demonstrated efficacy (Cummings & Chapurlat, 2000).
The cost of calcitonin is approximately the same as the bisphosphonates or raloxifene, while its protective effect on bone is considerably less. Calcitonin is not associated with significant indirect costs, having few side effects and being administered as a once-daily nasal spray without regard food or other medications. Its cost effectiveness is limited by its marginal effect on bone.

Calcitonin has a positive humanistic profile. The single daily administration of the nasal spray is well tolerated. Occasional reports of nasal irritation are avoided by alternating nostrils, and residents rarely complain about calcitonin. Another benefit of calcitonin is its demonstrated analgesic effect in some patients with vertebral fractures. In the form of suppository, a particularly dramatic analgesic effect was achieved in patients with acutely painful vertebral fractures (Lyritis et al., 1999).

Calcitonin has limited usefulness in the nursing home. It may be helpful in residents with vertebral fractures, especially if back pain is present. But the bisphosphonates and raloxifene, with their demonstrated greater beneficial effect on both bone density and fracture risk, have greater efficacy.

**Hip Protectors**

A great deal of effort in nursing home care is directed toward fall protection. Overall, nursing home residents have a hip fracture rate of about 5-6% per year, and 90% of these fractures are associated with falls. The most dangerous are falls to the side, with direct trauma to the hip. About 24% of those falls result in hip fracture (Lauritzen, 1997). Biomechanical studies reveal that a fall from standing height causes impact with a force that exceeds the proximal femur strength in half of elderly men and women (Greenspan et al., 1998). While dietary
supplements and antiresorptive agents improve bone strength, interventions to prevent falls and/or reduce injury associated with falls are necessary to reduce hip fractures.

Hip protectors are shallow, shell-shaped devices that cover the greater trochanter and are designed to shunt impact energy away from the bone to surrounding soft tissues. The protectors fit into pockets sewn onto a stretchy undergarment. Hip protectors have been used in both community-dwelling elders and nursing home residents to reduce the incidence of hip fracture with some success.

The clinical efficacy of hip protectors has been demonstrated in a number of controlled trials, in which the protectors reduced hip fractures in elderly persons from 50% to 80%. A finding common to these studies was that most fractures that did occur happened when the protectors were not being worn (Harada et al., 2001; Kannus et al., 2000; Lauritzen, Petersen, & Lund, 1993; Parker, Gillespie, & Gillespie, 2001).

The cost of a hip protector is between $100 and $200, and with some care in handling the overall cost is relatively low. Vestergaard et al. (2001) estimate the cost-effectiveness of hip protectors to exceed that of calcium and vitamin D. Indirect costs include monitoring that the resident wears the protector, and assisting with donning the garment, if needed.

The humanistic aspect of hip protector use appears to be the most significant, because compliance with the protectors has been an ongoing problem. Cameron et al. (2001) achieved only 57% compliance with hip protector use in an Australian study, and all fractures in their study occurred when protectors were not in place. In a Swiss study of 548 nursing home residents, only one third of residents were still wearing the protectors after 10 months (Hubacher & Wettstein, 2001). However, in a Finnish nursing home, hip protectors were introduced with a short training sessions for caregivers. The caregivers then helped select residents at high risk for
Osteoporosis in the Nursing Home

fracture, and protectors were offered to those residents. Use of the protectors was carefully monitored over six months. With this program, residents wore the protectors for more than 90% of their active hours. At the end of the study, most of the comments made by staff and residents regarding the hip protectors were positive (Parkkari, Heikkila, & Kannus, 1998). Education and motivation of nursing home staff may have been the crucial difference in achieving this excellent level of compliance.

Hip protectors can be a useful and cost-effective adjunct to fracture prevention in the nursing home. Selected residents, particularly those who are either ambulatory or at high risk to fall, should be offered hip protectors and encouraged to use them regularly. Efforts to enlist staff support in the use of these devices may be critical to success.

Best Practice Recommendations

Research demonstrates that a number of effective therapies are available to decrease osteoporotic fracture risk. These interventions have been discussed in terms of the ECHO model, which served as a framework for evaluating the clinical, economic and humanistic impact of the various treatments on nursing home residents. Based on that analysis, the following guidelines are advocated to promote bone health and prevent fractures in the nursing home:

1. Nursing home residents should be screened for osteoporosis on admission and on a regular basis thereafter.
2. Nursing home residents should be offered calcium and vitamin D supplementation to bring total calcium intake to 1200 to 1500 mg/day of elemental calcium, and total vitamin D intake to 400 to 800 IU/day.
3. Residents should be screened for fall risk on admission and on a regular basis thereafter. Those found to be at high risk for fracture should be considered for antiresorptive therapy with a bisphosphonate.
4. Residents who have contraindications to bisphosphonates, or who are unable to tolerate them, should be offered a second-line treatment in the form of raloxifene or calcitonin.
5. Ambulatory patients at risk to fracture, as well as nonambulatory residents who are at risk to fail through self transferring, should be encouraged to use hip protectors.
6. Nursing home staff should receive training in the proper administration of bisphosphonates and in the use of hip protectors to maximize the efficacy of these therapies.

Routine screening and therapeutic interventions to promote bone health are necessary to protect nursing home residents from painful and debilitating fractures. Nurses who care for this vulnerable population can make a real difference by implementing admission procedures that include osteoporosis screening and dietary supplementation of calcium and vitamin D for all residents, and by advocating for antiresorptive medications for at-risk residents. Nurses should maximize the efficacy of these measures by carefully following dosing recommendations and promoting the use of hip protectors. Finally, nurses should attend to new developments in the area of fracture prevention, including pharmaceuticals now being evaluated, such as bone-building medications and a bisphosphonate that is given with an annual injection. Using the ECHO model to ensure positive clinical, economic, and humanistic outcomes for nursing home residents maximizes systematic attention to these issues and provides early opportunities for prevention and intervention in the older population, the group most likely to suffer from osteoporosis.
References


*The Consultant Pharmacist, 16*(Suppl B); 6-14.


Villareal, D. T., Binder, E. F., Williams, D. B. Schechtman, K. B., Yarasheski, K. E., & Kohrt, W. M. (2001). Bone mineral density response to estrogen replacement in frail elderly...


Figure 1
Economic, Clinical and Humanistic Outcome (ECHO) Model
(adapted from Kozma, et al., 1993)

Osteoporosis

Clinical Indicators
- Intention to treat
- History of fracture
- Clinical risk factors
- Kyphosis/loss of height
- Bone mineral density

Clinical Outcomes
- Fracture
- Mobility
- Pain
- Skeletal changes
- Medication side effects

Costs
- Medications
- Medication administration
- Treatment of medication side effects
- Hip protectors
- Hip protector monitoring
- Fracture treatment

Humanistic Outcomes
- Dosing requirements
- Medication side effects
- Pain
- Mobility
- Satisfaction with treatment

Treatment Alternatives
- Prophylactic measures
  - Calcium
  - Vitamin D
- Bisphosphonate
- Raloxifene/calcitonin
- Hip protectors

Economic Outcomes
- Savings related to fracture prevention
- Cost per quality-adjusted life-year savings
Figure 2
Algorithm for Risk Factor Assessment for Osteoporosis Prevention and Treatment among Nursing Home Residents (Adapted from Baran, et al., 1998)

Nursing home admission

Issues exist that preclude intervention

Stop (exclude from diagnosis and treatment)

Identify appropriate candidates:
Consider:
- Life expectancy
- Terminal illness
- Resident preferences regarding treatment

No issues exist that preclude intervention

Negative history

Review of resident history
- Previous diagnosis of osteoporosis
- Antiresorptive therapies
- X-ray findings
- Information from hospital records

Positive history of osteoporosis diagnosis or fragility fracture

Complete risk factor assessment
- Review of history
- Resident interview
- Family interview

0 to 5 risk factors (see Table 1)

- Calcium and vitamin D supplementation
- Fall prevention
- Re-evaluate in 1 year

6 or more risk factors (see Table 1)

- Calcium/vitamin D supplementation
- Fall prevention
- Advocate for further interventions by primary care provider
  - evaluation for causative factors
  - pharmacological therapy
  - hip protectors
  - physical conditioning
Table 1
Risk Factors Associated with Fracture in Nursing Home Residents
(Adapted from Baran, et al., 1998)

<table>
<thead>
<tr>
<th>Risk Factor</th>
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<tbody>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Age 80 years or greater</td>
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<tr>
<td>Maternal history of hip fracture</td>
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<tr>
<td>Fracture after the age of 50</td>
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<tr>
<td>History of fragility fracture (i.e. fracture without significant trauma)</td>
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<tr>
<td>Poor general health</td>
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<tr>
<td>Previous hyperthyroidism</td>
</tr>
<tr>
<td>Severe cognitive impairment</td>
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<tr>
<td>Current weight in lowest 25% for age group (per nutritional assessment)</td>
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<tr>
<td>BMD with T score &lt;=-2.5</td>
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<tr>
<td>No walking exercise</td>
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<tr>
<td>Ambulatory status (either independently or with assistance)</td>
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<tr>
<td>Inability to rise from chair without using arms</td>
</tr>
<tr>
<td>Reported height loss &gt;4 cm (1½&quot;)</td>
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<tr>
<td>History of falls, or at high risk to fall using standardized fall risk assessment</td>
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<tr>
<td>Visual acuity worse than 20/30</td>
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<tr>
<td>Anticonvulsant use</td>
</tr>
<tr>
<td>Current therapy with long-acting benzodiazepine, tricyclic antidepressant, or antipsychotic medication</td>
</tr>
<tr>
<td>Caffeine intake &gt; equivalent of 2 cups coffee per day</td>
</tr>
</tbody>
</table>

Total number of risk factors: __________

To score fracture risk, count number of risk factors:
- Presence of 0-5 risk factors indicates low risk for fracture
- Presence of six or more risk factors indicates high risk for fracture