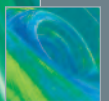


Chronic Disease and Medical Innovation in an Aging Nation

The Silver Book[®]: Osteoporosis



Preface

Americans are living longer than ever before. Unfortunately that longevity is not always experienced in good health. Ninety percent of Americans age 65 and older have at least one chronic condition. These conditions impose a huge burden on individuals, families, and the nation's economy. People with chronic ailments account for 85% of all health care spending, and with Baby Boomers beginning to qualify for Medicare in less than three years, health care policymakers are increasingly searching for ways to curb spending.

In order to promote national policies that look to investments in innovation rather than short-term cost-cutting and health care rationing, the not-for-profit Alliance for Aging Research publishes *The Silver Book®: Chronic Disease and Medical Innovation in an Aging Nation*. *The Silver Book* is a unique almanac of more than 1,000 compelling statistics and eye-opening facts that spotlight the mounting burden of chronic disease and the promise of innovation in mitigating that burden. While much of this information is usually buried in dense reports and diverse technical studies, *The Silver Book* extracts key findings from authoritative reports and brings the well-referenced information to the fingertips of those shaping policy.

The first volume of *The Silver Book* was launched in 2006 and has quickly become a trusted resource for health policy practitioners. *The Silver Book®: Osteoporosis* is the latest volume in this important collection. Each section in the volume includes charts, statistics, and key findings that together paint a comprehensive picture of the burden of osteoporosis and the tremendous potential of innovation. Much of the data focuses on the older population—those most at risk for osteoporosis-related fractures. **(Information pertaining specifically to the older population is noted in silver type).** All sources are cited so that users may easily integrate them into presentations and work, and return to the original sources for additional information.

In addition to data on cancer, cardiovascular disease, diabetes, neurological disease, and vision loss, the data from *The Silver Book®: Osteoporosis* can be found on-line at www.silverbook.org. The website is a dynamic resource that is updated on a regular basis, easily searchable, and enhanced by user-submitted data.



Daniel Perry
Executive Director
Alliance for Aging Research



Advancing Science. Enhancing Lives.

Introduction

Cost of Osteoporosis

Innovative Medical Research

Conclusion

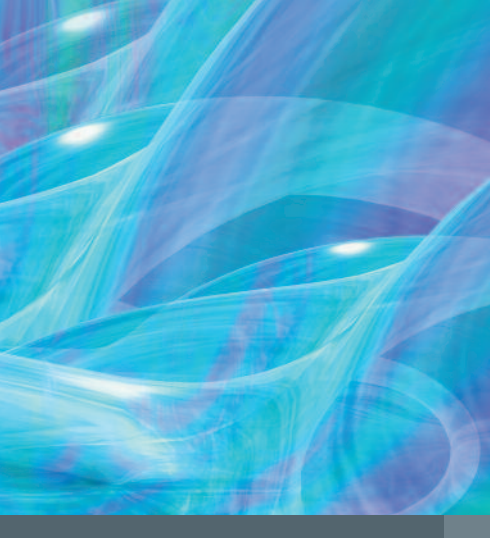
References



Chronic Disease and Medical Innovation in an Aging Nation

The Silver Book[®]: Osteoporosis

Preface	1
Introduction	3
Cost of Osteoporosis: The Human and Economic Burden	4
Prevalence and Incidence of Osteoporosis	5
Age—A Major Risk Factor	5
The Burden of Osteoporosis	6
The Human Burden	6
The Economic Burden	8
The Future Cost of Osteoporosis	9
The Future Human Cost	9
The Future Economic Cost	9
Innovative Medical Research: Investing in Science	10
The Human Value	11
The Economic Value	12
Conclusion	13
References	14



Introduction

The National Osteoporosis Foundation (NOF) is pleased to join the Alliance for Aging Research in presenting *The Silver Book®: Osteoporosis*. NOF is uniquely qualified to partner on this volume as the leading voluntary health organization solely dedicated to osteoporosis and bone health. While there have been many advances in recent years in prevention, diagnosis, and treatment, osteoporosis continues to be a major health threat for more than 44 million Americans. The biggest concern for individuals with the disease is fractures, and every year osteoporosis causes more than 2 million. Fractures can have a profound impact on quality of life—often leading to pain, disability, loss of independence, and even death.

-
-
-
-
-
-
-

Osteoporosis also takes a huge economic toll on both individuals and society. Fractures from osteoporosis cost the U.S. nearly \$19 billion each year and that number is only going to rise as our population ages. Osteoporosis disproportionately affects older Americans with around 70% of fractures occurring in the 65 and older population. Without a significant change of course in the bone health of Americans, NOF projects as many as 61 million Americans could be affected by the disease by 2020.

Fortunately, scientists are continuing to make exciting breakthroughs that are helping to keep bones healthy and prevent debilitating fractures. Research has led to a better understanding of the role of exercise and nutrition in bone health. Diagnostic tools are better assessing bone mass and bone quality, and new medicines are reducing the risk of fractures. At the time this volume of *The Silver Book* went to print, new study results were showing the link between osteoporosis and other chronic diseases, as well as the critical role of vitamin D on bone health and osteoporosis prevention.

The landscape of osteoporosis research is constantly changing and resulting in dramatic advances and benefits to patients. We encourage you to go to www.silverbook.org and check back regularly for the latest data resulting from these exciting new innovations.

Leo Schargorodski
Executive Director and CEO
National Osteoporosis Foundation





-
-
-
-
-

The Human and Economic Burden

Cost of Osteoporosis

■ After reaching peak bone mass at around age 30, our bones begin to lose mass little by little as we age. Osteoporosis is diagnosed when bone mass levels become critically low, putting individuals at risk for fracture. This is a reality for millions of Americans—1 in 2 women and up to 1 in 4 men over the age of 50 are at risk for an osteoporosis-related fracture during their lifetime.

■ Fractures can set off a downward spiral of events that affect overall health and well-being. In addition to pain and short-term disability, fractures can have a long-term impact on quality of life. Of those who are ambulatory before a fracture, 50% will never be able to walk again without assistance, and 1 in 5 will need long-term care. Fractures can also be expensive—hip fractures can cost an individual more than \$81,000 over their lifetime. Costs to the economy can add up to around \$19 billion each year.

Osteoporosis tends to strike later in life with around 55% of the 50 and older population affected by osteoporosis or low bone mass. As Baby Boomers age, incidence is only going to increase and send both human and economic costs skyrocketing. The annual number of hip fractures could double or even triple by 2040, causing costs to rise to as much as \$25 billion by 2025. This disease will no doubt place an enormous strain on the nation's resources and productivity and we simply cannot afford to allow it to continue unabated.



Prevalence and Incidence of Osteoporosis

- Osteoporosis affects an estimated 44 million Americans over the age of 50—10 million have been diagnosed with the disease and 34 million more are estimated to have low bone mass, putting them at increased risk.

National Osteoporosis Foundation 2002, *America's Bone Health*

- 4 out of 5 people with osteoporosis are women.

National Osteoporosis Foundation 2002, *America's Bone Health*

- Of the 10 million Americans with osteoporosis, close to 8 million (80%) are women and over 2 million (20%) are men.

National Osteoporosis Foundation 2002, *America's Bone Health*

- Of the 34 million Americans with low bone mass, around 22 million (65%) are women and 12 million (35%) are men.

National Osteoporosis Foundation 2002, *America's Bone Health*

- A woman's lifetime risk of hip fracture equals her combined risk of breast, uterine, and ovarian cancer.

Riggs and Melton 1995, *Osteoporosis, Etiology, Diagnosis and Treatment*

Age—A Major Risk Factor

- 55% of the 50 and older population has osteoporosis or low bone mass.

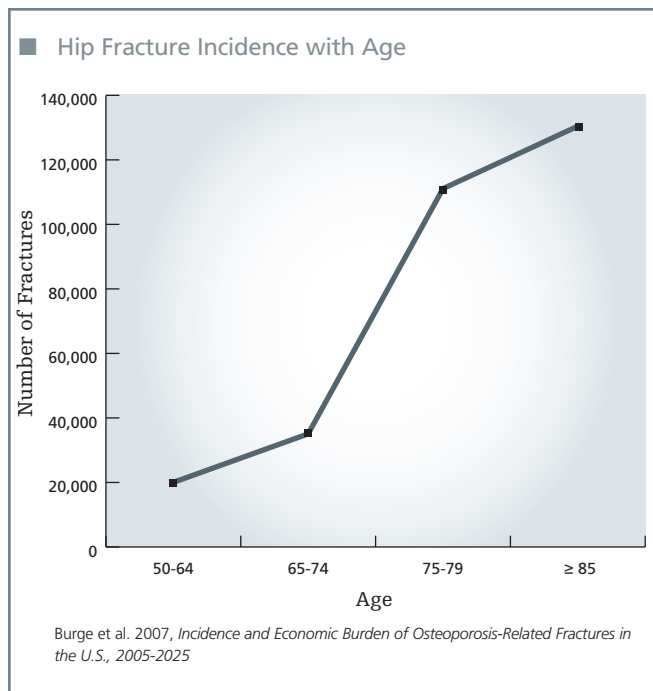
National Osteoporosis Foundation 2002, *America's Bone Health*

- An estimated 30% of postmenopausal white women have osteoporosis and 54% have osteopenia. By the age of 80, that number increases to an estimated 70% of white women with osteoporosis and 27% with osteopenia.

Melton 1995, *How Many Women Have Osteoporosis Now?*

- Around 70% of all osteoporosis-related fractures occur in patients age 65 and older.

Burge et al. 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the U.S., 2005-2025*



- Women age 85 years and older are close to 8 times more likely to be hospitalized because of a hip fracture than women ages 65-74.

Stevens et al. 1999, *Surveillance for Injuries and Violence Among Older Adults*

The Burden of Osteoporosis

The Human Burden

- “This 73-year-old wife and grandmother suffered her first fracture 18 years ago and has had eight additional fractures since that time. Each caused tremendous pain and required long hospital stays and extended periods on medication...As bad as the actual fractures have been, it is the fear of additional fractures that may well have the largest impact on her life. As a result of this fear, she limits the time she spends with her grandchildren, as well as the types of activities she enjoys with them (three of her fractures occurred while she was playing with her grandchildren). She finds it impossible to lie down on her back or right side and difficult to get in and out of bed or a chair. She has had to give up dancing, one of her favorite activities, and she feels she has become a ‘drag’ on family members who must slow down to accommodate her limitations.”

U.S. Dept. of Health and Human Services 2004, *Bone Health and Osteoporosis*

- In 2005, osteoporosis was responsible for more than 2 million fractures in men and women over the age of 50, including approximately:
 - 297,000 hip fractures
 - 547,000 vertebral fractures
 - 380,000 wrist fractures
 - 810,000 fractures at other sites

Burge et al. 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the U.S., 2005-2025*

- 1 in 2 women, and up to 1 in 4 men, over the age of 50 will have an osteoporosis-related fracture during their lifetime.

NIAMS 2007, *Handout on Health: Osteoporosis*

- At the age of 50, a white woman has a:
 - 17.5% chance of experiencing a hip fracture
 - 15.6% chance of experiencing a vertebral fracture
 - 16% chance of experiencing a forearm fracture

Melton 2000, *Who Has Osteoporosis?*

- At the age of 50, a white man has a:
 - 6% chance of experiencing a hip fracture
 - 5% chance of experiencing a vertebral fracture
 - 2.5% chance of experiencing a forearm fracture

Melton 2000, *Who Has Osteoporosis?*

- Each year, osteoporotic fractures in the U.S. lead to:
 - >432,000 hospital admissions
 - ~2.5 million medical office visits
 - ~180,000 nursing home admissions

National Osteoporosis Foundation 2008, *Clinician's Guide to Prevention and Treatment of Osteoporosis*

- Physician visits for osteoporosis increased 4-fold (from 1.3 million to 6.3 million) from 1994 to 2003.

Stafford et al. 2004, *National Trends in Osteoporosis Visits and Osteoporosis Treatment*

- About 315,000 Americans age 45 and older were admitted to hospitals with hip fractures in 2001—a majority with osteoporosis as the underlying cause.

Kozak et al. 2004, *National Hospital Discharge Survey*

- More than ¼ of individuals who suffer a hip fracture become disabled within a year.

Magaziner et al. 2003, *Changes in Functional Status Attributable to Hip Fracture*

- Six months after a hip fracture, only 15% of patients can walk across a room without assistance.

Marottoli et al. 1992, *Decline in Physical Function Following Hip Fracture*

- Half of people who fracture a hip will never be able to walk again without assistance.

NIAMS 2007, *Handout on Health: Osteoporosis*

- Four months after a hip fracture, less than 20% of patients recovered their prefracture competence in activities.

Van Balen et al. 2003, *Quality of Life After Hip Fracture*

- Six months after a hip fracture, many patients are unable to return to their activities of daily living at their pre-fracture status:

- 49% could dress themselves—compared to 86% before the fracture
- 32% could move from chair to standing—compared to 90% before
- 15% could walk independently across the room—compared to 75% before
- 8% could climb a flight of stairs—compared to 63% before

Marottoli et al. 1992, *Decline in Physical Function Following Hip Fracture*



■ **Postfracture Dependency* at 12 and 24 Months Among Patients Who Were Independent Prior to Hip Fracture**

	12 months %	24 months %
Lower extremity physical activity of daily living		
Climbing 5 stairs	90	91
Getting in/out of bath/shower	83	83
Walking 1 block	55	53
Getting into a car	45	50
Rising from an armless chair	50	54
Walking 10 feet	40	37
Taking a shower/bath/ sponge bath	38	44
Getting on/off the toilet	66	63
Putting socks and shoes on	33	33
Getting in/out of bath	31	33
Putting on pants	20	20
Instrumental activities of daily living		
Housecleaning	62	43
Getting places out of walking distance	53	53
Shopping	42	41
Cooking	24	23
Handling money	31	31
Taking medications	28	29
Using the telephone	22	23

*Dependency is defined as the need for either human or equipment assistance or the inability to perform the activity due to health reasons.

Magaziner et al. 2000, *Recovery From Hip Fracture in Eight Areas of Function*

- Of those who were ambulatory before their hip fracture, 1 in 5 end up needing long-term care afterwards—a situation that participants in this study said was less desirable than death.

Salkeld et al. 2000, *Quality of Life Related to Fear of Falling and Hip Fracture in Older Women*

- Osteoporosis accounts for close to 14% of all nursing home stays.

Hoerger et al. 1999, *Healthcare Use Among U.S. Women Aged 45 and Older*

- One study found that women age 65 and older, who suffered a vertebral fracture, were more than twice as likely to suffer back pain than women who hadn't.

Nevitt et al. 1998, *The Association of Radiographically Detected Vertebral Fractures with Back Pain and Function*

- A prior vertebral fracture increases risk of another vertebral fracture by 5-fold for the year following.

Lindsay et al. 2001, *Risk of New Vertebral Fracture in the Year Following a Fracture*

- Two or more vertebral fractures increase risk of a subsequent vertebral fracture by 12-fold.

Ross et al. 1991, *Pre-Existing Fractures and Bone Mass Predict Vertebral Fracture Incidence in Women*

- In a National Osteoporosis Foundation survey of women who had already had an osteoporotic fracture:

- 89% feared breaking another bone
- 80% were afraid they would be less able to perform daily activities
- 80% feared losing their independence
- 73% were concerned they would have to reduce activities with family and friends
- 68% worried that another fracture would result in them needing a nursing home

U.S. Dept. of Health and Human Services 2004, *Bone Health and Osteoporosis*

- A study that measured QALY (Quality Adjusted Life Year) reductions in people suffering from osteoporotic fractures found reductions ranging from 0.05 to 0.55 on a scale of 0 (represents death) to 1 (represents perfect health).

U.S. Dept. of Health and Human Services 2004, *Bone Health and Osteoporosis*

- Relatively healthy hip fracture patients report a 52% reduction in QALY (Quality Adjusted Life Year) in the first 12 months, and a 21% reduction in the first 2 years.

Tosteson et al. 2001, *Impact of Hip and Vertebral Fractures on Quality-Adjusted Life Years*

- Vertebral fractures are associated with a 20% reduction in QALY (Quality Adjusted Life Year) in the first 12 months, and a 15% reduction in the first 2 years.

Tosteson et al. 2001, *Impact of Hip and Vertebral Fractures on Quality-Adjusted Life Years*

- Women who experience a vertebral fracture are 2 to 3 times more likely to die of pulmonary causes than women without a fracture.

Kado et al. 1999, *Vertebral Fractures and Mortality in Older Women*

- The risk of death in the first few weeks after a hip fracture is 10-times more than the expected death rate.

U.S. Dept. of Health and Human Services 2004, *Bone Health and Osteoporosis*

- Hip fracture raises the risk of mortality by 2.8 to 4-times during the first 3 months after the fracture.

U.S. Dept. of Health and Human Services 2004, *Bone Health and Osteoporosis*

- Around 1 in 5 people who experience a hip fracture die within a year.

Leibson et al. 2002, *Mortality, Disability, and Nursing Home Use for Persons with and without Hip Fracture*

- The 1-year mortality after a hip fracture increases from 20% in individuals younger than 70 years, to close to 40% in those between 80 and 89.9 years old.

Miller et al. 1999, *Management of Osteoporosis*

- Even though women are more likely to sustain a hip fracture, men who suffer a hip fracture are twice as likely as women to die within 1-2 years of that fracture.

Wehren et al. 2003, *Gender Difference in Mortality After Hip Fracture*

The Economic Burden

- In 2005, osteoporosis-related fractures cost nearly \$17 billion—\$19 billion if costs of prevalent fractures are included.

Burge 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025*

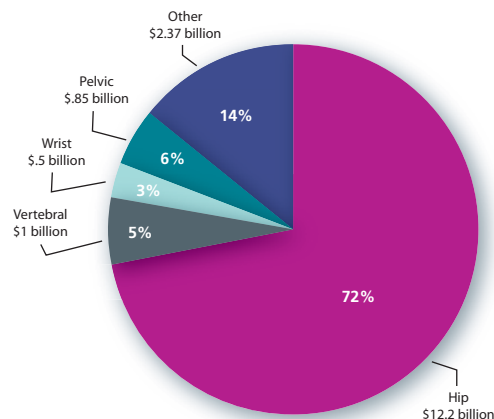
- Hip fractures account for 72% of total costs related to osteoporosis fractures.

Burge 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025*

- During the first year after a hip fracture, the average cost in the U.S. ranges from \$36,000 to over \$47,000 per patient.

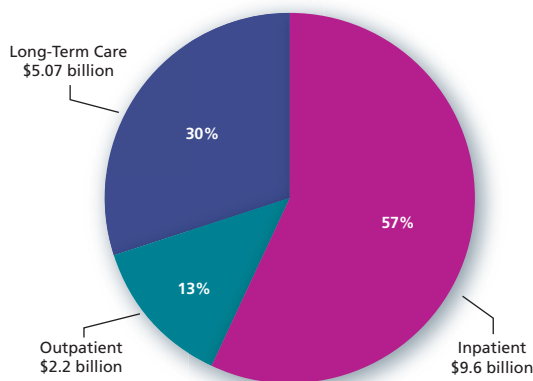
Burge et al. 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025*

Distribution of Fracture Costs by Site of Fracture



Burge 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025*

Distribution of Fracture Costs by Site of Care



Burge 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025*

- The cost of a hip fracture for one individual over their lifetime can be more than \$81,000—nearly half can be attributed to nursing facility costs.

Braithwaite et al. 2003, *Estimating Hip Fracture Morbidity, Mortality, and Costs*

- From 2001 to 2003, about 2.39 million fractures occurred among women aged 65 and older with osteoporosis—this cost Medicare \$12.96 billion.

King et al. 2005, *Fracture Reduction Affects Medicare Economics*



The Future Cost of Osteoporosis

The Future Human Cost

- By 2010, an estimated 52 million Americans over the age of 50 will be affected by osteoporosis—12 million will be diagnosed with the disease and 40 million more will have low bone mass, putting them at increased risk for the disease.

National Osteoporosis Foundation 2002, *America's Bone Health*

- By 2020, an estimated 61 million Americans over the age of 50 will be affected by osteoporosis—14 million will be diagnosed with the disease and 47 million more will have low bone mass, putting them at increased risk for the disease.

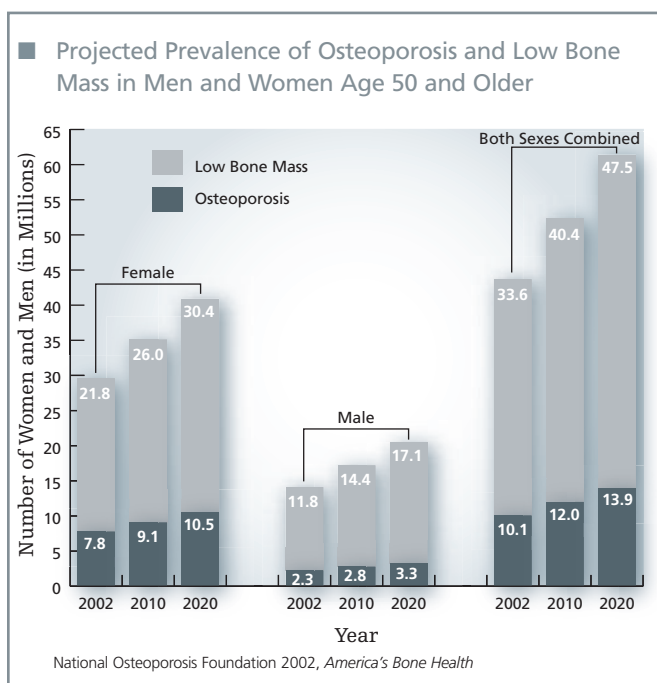
National Osteoporosis Foundation 2002, *America's Bone Health*

- The number of women over the age of 50 and diagnosed with osteoporosis or at risk for the disease, will increase from close to 30 million in 2002 to more than 35 million in 2010, and around 41 million in 2020.

National Osteoporosis Foundation 2002, *America's Bone Health*

- The number of men over the age of 50 and diagnosed with osteoporosis or at risk for the disease, will increase from 14 million in 2002 to over 17 million in 2010, and to well over 20 million in 2020.

National Osteoporosis Foundation 2002, *America's Bone Health*



- By 2020, more than 50% of Americans over the age of 50 will be diagnosed with or at risk of developing osteoporosis.

U.S. Dept. of Health and Human Services 2004, *Bone Health and Osteoporosis*

- The annual number of osteoporosis-related fractures is expected to rise by almost 50% to more than 3 million by 2025.

Burge et al. 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025*

- Over the next 20 years, the non-White population will comprise a growing proportion of the number of fractures, increasing from 282,000 fractures (13% of total fractures) in 2005, to over 637,000 fractures by 2025.

Burge et al. 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025*

The Future Economic Cost

- By 2025, annual direct costs from osteoporosis are estimated to rise to around \$25.3 billion.

Burge et al. 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025*

- During the 10-year period of 2006 to 2015, annual costs of osteoporosis will increase by more than 20%.

Burge et al. 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025*

- The cumulative cost of incident fractures is predicted to rise from \$209 billion during the 10-year period of 2006 to 2015, to \$228 for the 10-year period of 2016 to 2025.

Burge et al. 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025*

- Over the next 20 years, the non-White population will comprise a growing proportion of the costs of osteoporosis-related fractures, increasing from \$1.9 billion (12% of total costs) in 2005, to over \$4.7 billion (19% of total) by 2025.

Burge et al. 2007, *Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025*



-
-
-
-
-

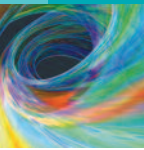
Investing in Science

Innovative Medical Research

■ While the burden of osteoporosis will increase as our population ages, advances in medical research can transform the future of osteoporosis in this country. Researchers are currently exploring new ways to prevent and reverse bone loss so that future generations won't have to worry about the devastating consequences of fractures. Advances in treatment have already changed the way people view an osteoporosis diagnosis. Further research could make osteoporosis-related fractures a thing of the past.

■ Studies on nutritional interventions have proven that fractures do not have to be an accepted part of aging. Vitamin D has been found to play a crucial role in calcium absorption, and when taken together, the two can reduce hip fractures by 43%. Imaging technologies and the discovery of new classes of pharmacologic treatment are allowing physicians to closely monitor bone mineral density (BMD) and promptly treat individuals with low BMD scores—stopping bone loss before it leads to fracture. Recent research on ultrasound technology could lead to a low-cost option for diagnosing bone mass.

Improvements in osteoporosis prevention and treatment often produce health gains that far outweigh the initial financial investments in research. As the conversation on health care reform heats up we must be sure to consider both the financial and human impact that medical innovation can have on osteoporosis. Short-sighted efforts to reduce spending too often target the initial expenses of investing in medical innovation, while ignoring remarkable returns on investment.



The Human Value

Note that pharmacologic therapies should not be compared using the below data since study conditions vary widely. Also note that while BMD data is a good indicator of bone health, improvements in bone density and reductions in fracture risk do not necessarily directly correlate.

- Clinical studies in nutrition and physical activity interventions have proven that fractures can be prevented, even in older individuals, and that they do not need to be a natural consequence of aging.

National Institutes of Health, *NIH Fact Sheet: Osteoporosis*

- The Study of Osteoporotic Fractures, which began over 20 years ago, found that bone mineral density (BMD) of the hip is one of the best predictors of fracture for women, and that weight loss in the elderly and family history of hip fractures are two of the most important risk factors for this condition. Similar studies have now begun to learn about osteoporosis risk factors in men.

National Institutes of Health, *NIH Fact Sheet: Osteoporosis*

- An increase in bone mineral density (BMD) testing and osteoporosis treatment was associated with a decrease in hip fracture incidence.

Jaglal et al. 2005, *Population Trends in BMD Testing, Treatment, and Hip and Wrist Fracture Rates*

- Reducing risk of first fracture from 8% to 2% reduces the 5-year fracture incidence from approximately 34% to 10%.

Lindsay et al. 2005, *Longitudinal Progression of Fracture Prevalence through a Population of Postmenopausal Women with Osteoporosis*

- A meta-analysis of clinical trials found that calcium supplements reduced the risk of vertebral fractures by around 23%.

Shea et al. 2002, *Meta-Analysis of Calcium Supplementation for the Prevention of Postmenopausal Osteoporosis*¹

- A meta-analysis of clinical trials found that Vitamin D supplements reduced the risk of vertebral fractures by around 37%.

Papadimitropoulos et al. 2002, *Meta-Analysis of the Efficacy of Vitamin D Treatment in Preventing Osteoporosis in Postmenopausal Women*

- A study that looked at a combination of calcium and Vitamin D found that hip fractures were reduced by around 43%.

Chapuy et al. 1992, *Vitamin D3 and Calcium to Prevent Hip Fractures in the Elderly Women*

- Randomized controlled trials give evidence that pharmacologic therapy can reduce risk of fractures by 40 to 50%.

Papaioannou et al. 2002, *Diagnosis and Management of Vertebral Fractures in Elderly Adults*

- A systematic review of osteoporosis therapies found good evidence that many are effective in preventing fractures, but concluded that the data are insufficient to determine if any one therapy is better than the others.

MacLean et al. 2008, *Systemic Review: Comparative Effectiveness of Treatments to Prevent Fractures in Men and Women with Low Bone Density or Osteoporosis*

- Alendronate, a bisphosphonate, has been shown to increase vertebral bone mineral density (BMD) by as much as 8% over 3-years in postmenopausal women with osteoporosis.

Liberman et al. 1995, *Effect of Oral Alendronate on Bone Mineral Density and the Incidence of Fractures in Postmenopausal Osteoporosis*

- Alendronate, a bisphosphonate, has been shown to reduce risk of hip fracture by around 53%, clinical vertebral fracture by 45%, and wrist fracture by 30%.

Black et al. 2000, *Fracture Risk Reduction with Alendronate in Women with Osteoporosis*

- Risedronate, a bisphosphonate, has been shown to increase vertebral bone mineral density (BMD) by around 5% and hip BMD by 2% to 3% in postmenopausal women with osteoporosis.

Harris et al. 1999, *Effects of Risedronate Treatment on Vertebral and Nonvertebral Fractures in Women with Postmenopausal Osteoporosis*

- Risedronate, a bisphosphonate, has been shown to reduce vertebral fractures by around 41%, hip fractures by 30%, and non-vertebral fractures by 39%.

Harris et al. 1999, *Effects of Risedronate Treatment on Vertebral and Nonvertebral Fractures in Women with Postmenopausal Osteoporosis*

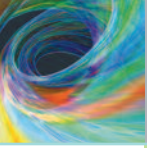
- Ibandronate, a bisphosphonate, taken daily has been shown to reduce the risk of new vertebral fractures by around 62%.

Chestnut et al. 2004, *Effects of Oral Ibandronate Administered Daily or Intermittently on Fracture Risk in Postmenopausal Osteoporosis*

- Treatment with zoledronic acid over a 3-year period reduced risk of vertebral fracture by around 70% and risk of hip fracture by 41%, and increased bone mineral density (BMD) by 5% to 6%.

Black et al. 2007, *Once-Yearly Zoledronic Acid for Treatment of Postmenopausal Osteoporosis*





- Teriparatide, or human recombinant PTH, has been shown to increase vertebral bone mineral density (BMD) by 9% to 13%.

Neer et al. 2001, *Effect of Parathyroid Hormone (1-34) on Fractures and Bone Mineral Density in Postmenopausal Women with Osteoporosis*

- Teriparatide, or human recombinant PTH, has been shown to decrease vertebral fractures by 65% to 69%, and non-vertebral fragility fractures by around 53%.

Neer et al. 2001, *Effect of Parathyroid Hormone (1-34) on Fractures and Bone Mineral Density in Postmenopausal Women with Osteoporosis*

- Raloxifene, a selective estrogen receptor modulator (SERM), has been shown to decrease vertebral fractures by up to 50% after 3 years.

Ettinger et al. 1999, *Reduction of Vertebral Fracture Risk in Postmenopausal Women with Osteoporosis Treated with Raloxifene*

- Raloxifene, a selective estrogen receptor modulator (SERM), has been shown to increase vertebral bone mineral density (BMD) by 2% to 3% after 3 years.

Ettinger et al. 1999, *Reduction of Vertebral Fracture Risk in Postmenopausal Women with Osteoporosis Treated with Raloxifene*

- Patients with vertebral fractures who underwent kyphoplasty, a procedure that stabilizes fractures of the spine, were found in one study to have reduced pain, fewer new fractures, and less healthcare utilization for at least 12 months.

Grafe et al. 2005, *Reduction of Pain and Fracture Incidence After Kyphoplasty*

- Genetics can account for up to 75% of bone mineral density (BMD). Researchers have identified a gene that strongly influences peak bone mass in mice. The gene was not previously known to be involved in bone biology, and can help researchers develop drugs that could prevent or reverse the bone loss that leads to osteoporosis.

National Institutes of Health, *NIH Fact Sheet: Osteoporosis*

- Researchers are looking at the use of micro-computed tomography and magnetic resonance imaging to better understand the relationship between bone structure and fracture risk. Other tools are also being evaluated for clinical use including ultrasound and dental x-rays—both would be less expensive options for patients.

National Institutes of Health, *NIH Fact Sheet: Osteoporosis*

The Economic Value

- Hip fracture prevention in at-risk, postmenopausal women saves \$333 million annually.

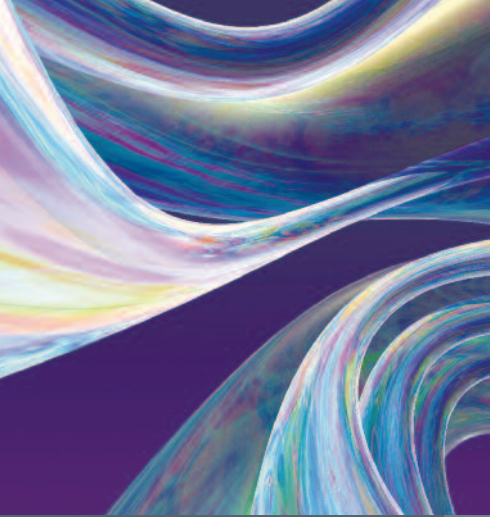
The Lasker Foundation 2000, *Exceptional Returns*

- Treatment with bisphosphonates are highly cost-effective in women over the age of 70 with osteoporosis and a previous fracture.

Fleurence et al. 2007, *The Cost Effectiveness of Bisphosphonates for the Prevention and Treatment of Osteoporosis*

- A study of a number of osteoporosis treatments found cost-effectiveness ratios as low as \$55,000 per Quality-adjusted Life-year (QALY).

Mobley et al. 2006, *Cost-Effectiveness of Osteoporosis Screening and Treatment with Hormone Replacement Therapy, Raloxifene, or Alendronate*



-
-
-
-
-

Conclusion

■ **T**he *Silver Book®: Osteoporosis* volume projects a growing burden of osteoporosis in America and makes a strong case for the value of innovation in reducing that burden. We fully expect this volume to join *The Silver Book* collection as an important tool for encouraging policy decisions that invest in medical research and innovation. The U.S. and our ever-increasing numbers of older Americans face unprecedented challenges including osteoporosis that could affect 61 million Americans in as little as 12 years.

■ Sound public policy should strive for cost containment strategies that provide for high quality health care that is patient-centered, values-driven, knowledge-intensive, innovation-rich, and prevention-oriented. We must consider how our long-range plans for research aim for ultimate reduction of both the economic and human burdens imposed by osteoporosis. Historically, investments that produce new medical innovations have paid for themselves many times over through decreased medical expenses and increased human productivity. Medical innovation will be essential to containing the costs of health care as the Baby Boom generation ages. Research and discovery, properly applied to health care and prevention, will be essential to avoid an unacceptably high toll of osteoporosis.

References

- Black, Dennis M., Pierre D. Delmas, Richard Eastell, Ian R. Reid, Steven Boonen, Jane A. Cauley, Felicia Cosman, Péter Lakatos, Ping Chung Leung, Zulema Man, Carlos Mautalen, Peter Mesenbrink, Huilin Hu, John Caminis, Karen Tong, Theresa Rosario-Jansen, Joel Krasnow, Trisha F. Hue, Deborah Sellmeyer, Erik F. Eriksen, and Steven R. Cummings; for the HORIZON Pivotal Fracture Trial. 2007. Once-Yearly Zoledronic Acid for Treatment of Postmenopausal Osteoporosis. *NEJM* 356(18):1809-22.
- Black, Dennis M., Desmond E. Thompson, Douglas C. Bauer, Kris Ensrud, Thomas Musliner, Marc C. Hochberg, Michael C. Nevitt, Shailaja Suryawanshi, and Steven R. Cummings; for the FIT Research Group. 2000. Fracture Risk Reduction with Alendronate in Women with Osteoporosis: The fracture intervention trial. *J Clin Endocrinol Metab* 85(11):4118-24.
- Braithwaite, R. Scott, Nananda F. Col, and John B. Wong. 2003. Estimating Hip Fracture Morbidity, Mortality, and Costs. *J Am Geriatr Soc* 51(3):364-70.
- Burge, Russel T., Bess Dawson-Hughes, Alison B. King, Daniel H. Solomon, Anna Tosteson, and John B. Wong. 2007. Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005-2025. *J Bone Miner Res* 22(3):465-75.
- Chapuy, Marie C., Monique Arlot, Francoisi Duboeuf, Jacqueline Brun, Brigitte Crouzet, Simone Arnaud, Pierre D. Delmas, and Pierre Meunier. 1992. Vitamin D3 and Calcium to Prevent Hip Fractures in the Elderly Women. *NEJM* 327(23):1637-42.
- Chestnut, Charles H., Arne Skag, Claus Christiansen, Robert Recker, Jacob A. Stakkestad, Arne Hoiseth, Dieter Felsenberg, Hermann Huss, Jennifer Gilbride, Ralph C. Schimmer, and Pierre D. Delmas; for the Oral Ibandronate Osteoporosis Vertebral Fracture Trial in North America and Europe (BONE). 2004. Effects of Oral Ibandronate Administered Daily or Intermittently on Fracture Risk in Postmenopausal Osteoporosis. *J Bone Miner Res* 19(8):1241-9.
- Ettinger, Bruce, Dennis M. Black, Bruce H. Mitlak, Ronald K. Knickerbocker, Thomas Nickelsen, Harry K. Genant, Claus Christiansen, Pierre D. Delmas, Jose R. Zanchetta, Jacob Stakkestad, Claus C. Gluer, Kathryn Krueger, Fredric J. Cohen, Stephen Eckert, Kristine E. Ensrud, Louis V. Avioli, Paul Lips, and Steven R. Cummings; for the Multiple Outcomes of Raloxifene Evaluation Investigators. 1999. Reduction of Vertebral Fracture Risk in Postmenopausal Women with Osteoporosis Treated with Raloxifene: Results from a 3-year randomized clinical trial. *JAMA* 282(7):637-45.
- Fleurence, Rachael L., Cynthia P. Iglesias, and Jeanene M. Johnson. 2007. The Cost Effectiveness of Bisphosphonates for the Prevention and Treatment of Osteoporosis: A structured review of the literature. *PharmacoEcon* 25(11):913-33.
- Gabriel, Sherine, Anna Tosteson, Cynthia Leibson, Cynthia Crowson, Gregory Pond, Cristina Hammond, L. Joseph Melton. 2002. Direct Medical Costs Attributable to Osteoporotic Fractures. *Osteoporos Int* 13(4):323-30.
- Grafe, Ingo A., Katharina Da Fronseca, Jochen Hillmeier, Peter-Jürgen Meeder, Martin Libicher, Gerd Nöldge, Hubert Bardenheuer, Walter Pyerin, Linus Basler, Christel Weiss, Rod S. Taylor, Peter Nawroth, and Christian Kasperk. 2005. Reduction of Pain and Fracture Incidence After Kyphoplasty: 1-year outcomes of a prospective controlled trial of patients with primary osteoporosis. *Osteoporos Int* 16(12):2005-12.
- Harris, Steven T., Nelson Watts, Harry Genant, Clark McKeever, Thomas Hangartner, Michael Keller, Charles Chesnut III, Jacques Brown, Erik F. Eriksen, Mohammad Hoseyni, Douglas Axelrod, and Paul Miller; for the Vertebral Efficacy with Risedronate Therapy (VERT) Study Group. 1999. Effects of Risedronate Treatment on Vertebral and Nonvertebral Fractures in Women with Postmenopausal Osteoporosis: a randomized controlled trial. *JAMA* 282(14):1344-52.
- Hoerger, Thomas J., Kristen Downs, Mark Lakshmanan, Richard Lindrooth, Leo Plouffe, Brett Wendling, Suzanne West, and Robert Oshfeldt. 1999. Healthcare Use Among U.S. Women Aged 45 and Older: Total costs and costs selected postmenopausal health risks. *J Womens Health Gen Based Med* 8(8):1077-89.
- Jaglal, Susan B., Ian Weller, Muhammad Mamdani, Gillian Hawker, Hans Kreder, Liisa Jaakkimainen, and Jonathan Adachi. 2005. Population Trends in BMD Testing, Treatment, and Hip and Wrist Fracture Rates: Are the hip fracture projections wrong? *J Bone Miner Res* 20(6):898-905.
- Kado, Deborah H., Warren S. Browner, Lisa Palermo, Michael C. Nevitt, Harry K. Genant, and Steven R. Cummings; for the Study of Osteoporotic Fractures Research Group. 1999. Vertebral Fractures and Mortality in Older Women: A prospective study. *Arch Intern Med* 159(11):1215-20.
- King, Alison, Kenneth Saag, Russel T. Burge, Maria Pisu, and Niti Goel. 2005. Fracture Reduction Affects Medicare Economics (FRAME): Impact of increased osteoporosis diagnosis and treatment. *Osteoporos Int* 16(12):1545-57.
- Kozak, Lola Jean, Maria Owings, and Margaret Hall. 2004. National Hospital Discharge Survey: 2001 annual summary with detailed diagnosis and procedure data. *Vital Health Stat* 13(156):1-198.
- The Lasker Foundation. Exceptional Returns: *The economic value of America's investment in medical research*. New York, NY: Funding First.
- Leibson, Cynthia, Anna Tosteson, Sherine Gabriel, Jeanine Ransom, and L. Joseph Melton. 2002. Mortality, Disability, and Nursing Home Use for Persons with and without Hip Fracture: A population-based study. *J Am Geriatr Soc* 50(10):1644-50.



Liberman, Uri A., Stuart R. Weiss, Johann Bröll, Helmut W. Minne, Hui Quan, Norman H. Bell, Jose Rodriguez-Portales, Robert W. Downs, Jan Dequeker, Murray Favus, Ego Seeman, Robert R. Recker, Thomas Capizzi, Arthur C. Santora, Antonio Lombardi, Raksha V. Shah, Laurence J. Hirsch, and David B. Karpf; for the Alendronate Phase III Osteoporosis Treatment Study Group. 1995. Effect of Oral Alendronate on Bone Mineral Density and the Incidence of Fractures in Postmenopausal Osteoporosis. *NEJM* 333(22):1437-43.

Lindsay, Robert, Simon Pack, and Li Zhengqing. 2005. Longitudinal Progression of Fracture Prevalence through a Population of Postmenopausal Women with Osteoporosis. *Osteoporos Int* 16(3):306-12.

Lindsay, Robert, Stuart L. Silverman, Cyrus Cooper, David A. Hanley, Ian Barton, Susan B. Broy, Angelo Licata, Laurent Benhamou, Piet Geusens, Kirsten Flowers, Hilmar Stracke, and Ego Seeman. 2001. Risk of New Vertebral Fracture in the Year Following a Fracture. *JAMA* 285(3):320-3.

MacLean, Catherine, Sydne Newberry, Margaret Maglione, Maureen McMahon, Veena Ranganath, Marika Suttrop, Walter Mojica, Martha Timmer, Alicia Alexander, Melissa McNamara, Sheetal Desai, Annie Zhou, Susan Chen, Jason Carter, Carlo Tringale, Di Valentine, Breanne Johnsen, and Jennifer Grossman. 2008. Systematic Review: Comparative Effectiveness of Treatments to Prevent Fractures in Men and Women with Low Bone Density or Osteoporosis. *Ann Intern Med* 148(3):186-96.

Magaziner, Jay, L. Fredman, William Hawkes, J. Richard Hebel, Sheryl Zimmerman, Denise Orwig, and Lois Wehren. 2003. Changes in Functional Status Attributable to Hip Fracture: A comparison of hip fracture patients to community-dwelling aged. *Am J Epidemiol* 157(11):1023-31.

Marottoli, Richard A., Lisa Berkman, and Leo Cooney. 1992. Decline in Physical Function Following Hip Fracture. *J Am Geriatr Soc* 40(9):861-6.

Melton, Joseph L. 2000. Who Has Osteoporosis? A conflict between clinical and public health perspectives. *JBMR* 15:2309-14.

Melton, Joseph L. 1995. How Many Women Have Osteoporosis Now? *J Bone Miner Res* 10(2):175-7.

Miller, Paul D. 1999. Management of Osteoporosis. *Adv Intern Med* 44:175-207.

Mobley, Lee R., Thomas J. Hoerger, John S. Wittenborn, Deborah A. Galuska, and Jaya K. Rao. 2006. Cost-Effectiveness of Osteoporosis Screening and Treatment with Hormone Replacement Therapy, Raloxifene, or Alendronate. *Medical Decision Making* 26(2):194-206.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). 2007. *Handout on Health: Osteoporosis*. NIH Pub. No. 07-5158.

National Institutes of Health. *NIH Fact Sheet: Osteoporosis*. www.nih.gov/about/researchresultsforthepublic/Osteoporosis.pdf.

National Osteoporosis Foundation. 2008. *Clinician's Guide to Prevention and Treatment of Osteoporosis*. Washington, D.C.: National Osteoporosis Foundation.

National Osteoporosis Foundation. 2002. *America's Bone Health: The State of Osteoporosis and Low Bone Mass in Our Nation*. Washington, D.C.: National Osteoporosis Foundation.

Neer, Robert M., Claude D. Arnaud, Jose R. Zanchetta, Richard Prince, Gregory A. Gaich, Jean-Yves Reginster, Anthony B. Hodsman, Erik F. Eriksen, Sophia Ish-Shalom, Harry K. Genant, Ouhong Wang, Bruce H. Mitlak, Dan Mellstrom, Erik S. Oefjord, Ewa Marciniowska-Suchowierska, Jorma Salmi, Henk Mulder, Johan Halse, and Andrzej Z. Sawicki. 2001. Effect of Parathyroid Hormone (1-34) on Fractures and Bone Mineral Density in Postmenopausal Women with Osteoporosis. *NEJM* 344(19):1434-41.

Nevitt, Michael C., Bruce Ettinger, Dennis M. Black, Katie Stone, Sophie A. Jamal, Kristine Ensrud, Mark Segal, Harry K. Genant, and Steven R. Cummings. 1998. The Association of Radiographically Detected Vertebral Fractures with Back Pain and Function: A prospective study. *Ann Intern Med* 128(10):793-800.

Papadimitropoulos, Emmanuel, George Wells, Beverley Shea, William Gillespie, Bruce Weaver, Nicole Zytaruk, Ann Cranney, Jonathan D. Adachi, Peter Tugwell, Robert Josse, Carol Greenwood, and Gordon Guyatt. 2002. VIII: Meta-Analysis of the Efficacy of Vitamin D Treatment in Preventing Osteoporosis in Postmenopausal Women. *Endocr Rev* 23(4):560-9.

Papaioannaou, Alexandra, Nelson B. Watts, David L. Kendler, Chiu Kin Yuen, Jonathan D. Adachi, and Nicole Ferko. 2002. Diagnosis and Management of Vertebral Fractures in Elderly Adults. *Am J Med* 113(3):220-8.

Riggs, Lawrence B. and Joseph Melton. 1995. *Osteoporosis, Etiology, Diagnosis and Treatment, Second Edition*. Philadelphia: Lippincott-Raven.

Ross, Philip, James Davis, Robert Epstein, and Richard Wasnich. 1991. Pre-Existing Fractures and Bone Mass Predict Vertebral Fracture Incidence in Women. *Ann Intern Med* 114(11):919-23.

Salkeld, Glenn, Ian D. Cameron, Robert G. Cumming, S. Easter, Jamie Seymour, Susan E. Kurrle, and Susan Quine. 2000. Quality of Life Related to Fear of Falling and Hip Fracture in Older Women: A time trade off study. *BMJ* 320(7231):341-6.

Shea, Beverley, George Wells, Ann Cranney, Nicole Zytaruk, Vivian Robinson, Lauren Griffith, Zulma Ortiz, Joan Peterson, Jonathan Adachi, Peter Tugwell, and Gordon Guyatt. 2002. VII: Meta-Analysis of Calcium Supplementation for the Prevention of Postmenopausal Osteoporosis. *Endocr Rev* 23(4):552-9.

Stafford, Randall S., Rebecca Drieling, and Adam Hersh. 2004. National Trends in Osteoporosis Visits and Osteoporosis Treatment, 1988-2003. *Arch Intern Med* 164(14):1525-30.

Stevens, Judy A., La Mar Hasbrouck, Tonji Durant, Ann Dellinger, Prabhansu Batabyal, Alexander Crosby, Balarami Valluru, Marciejo Kresnow, and Janet Guerrero. 1999. Surveillance for Injuries and Violence Among Older Adults. *MMWR* 48(SS-8):27-50.





Tosteson, Anna N., Sherine Gabriel, Margaret Grove, Megan Moncur, Terry Kneeland, L. Joseph Melton. 2001. Impact of Hip and Vertebral Fractures on Quality-Adjusted Life Years. *Osteoporos Int* 12(12):1042-9.

United States Department of Health and Human Services. 2004. *Bone Health and Osteoporosis: A report of the surgeon general*. Rockville, MD: U.S. Department of Health and Human Services, Office of the Surgeon General.

Van Balen, Romke, Marie Louise Essink-Bot, Ewout Steyerberg, Herman Cools, and Dik F. Habbema. 2003. Quality of Life After Hip Fracture: A comparison of four health status measures in 208 patients. *Disabil Rehabil* 25(10):508-19.

Wehren, Lois E., William G. Hawkes, Denise L. Orwig, Richard J. Hebel, Sheryl I. Zimmerman, and Jay Magaziner. 2003. Gender Differences in Mortality After Hip Fracture: The role of infection. *J Bone Miner Res* 18(12):2231-7.

■ Facts in silver type deal specifically with older Americans.



Advancing Science. Enhancing Lives.

2021 K Street , NW, Suite 305
Washington, DC 20006
T 202.293.2856
F 202.785.8574

www.agingresearch.org

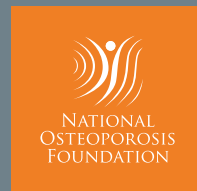


Acknowledgements:

The Alliance extends its thanks to the following experts for reviewing *The Silver Book®: Osteoporosis*:

- **Michele F. Bellantoni, MD**, Associate Professor of Medicine and Associate Director for Post-acute and Long-term Care, Division of Geriatric Medicine & Gerontology; Johns Hopkins University School of Medicine
- **Rachael Fleurence, MBA, PhD**, Research Scientist and Director of Health Economics, Center for Health Economics, Epidemiology, and Science Policy; United BioSource Corporation

This volume of *The Silver Book®* is brought to you in partnership with



This volume of *The Silver Book®* made possible by an unrestricted educational grant from

