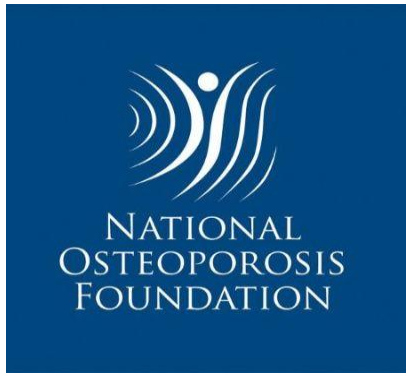
Secondary Fracture Prevention: Consensus Recommendations



Disclosures

- AOA – Own the Bone Steering Committee
- AAOS - EBQV Committee
- Osteogenesis Imperfecta Foundation – BOD
- USBJI – BOD
- American Bone Health – Medical Advisory
- Ultragenyx – research support

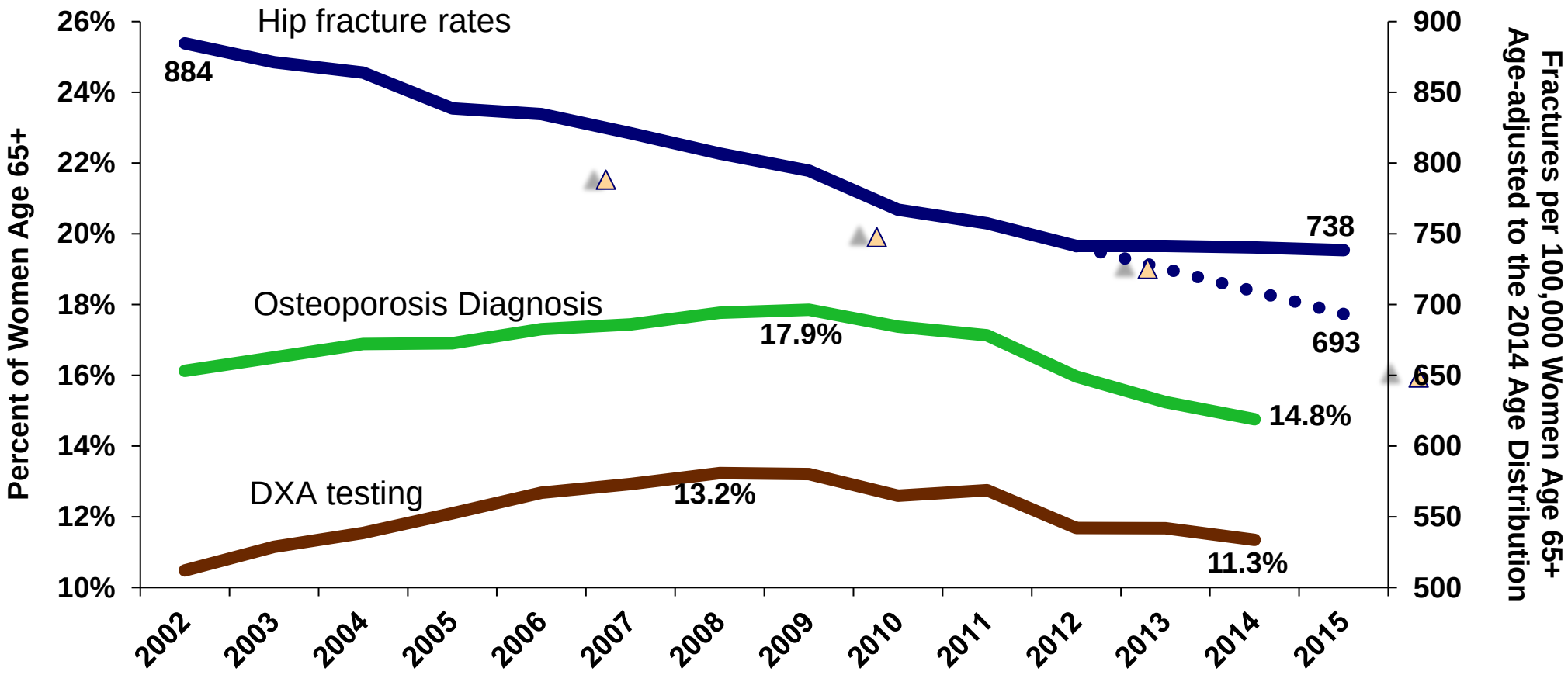
Objectives

- Appreciate the scope of the problem of untreated osteoporosis in hip and vertebral fracture patients over 65 years of age

- Understand that osteoporosis treatment reduces the risk of future fractures in these high risk patients

- Describe how patients should optimally be managed in the context of a multi-disciplinary clinical system that includes case management, such as a fracture liaison service, to assure that they are appropriately evaluated and treated for osteoporosis

Changing Hip Fracture Rates

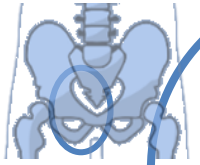


Lewiecki EM, Wright NC, Curtis JR et al. "Hip fracture trends in the United States, 2002 to 2015." Osteoporos Int 2018; 29 717-722.

Near-Term Risk is Substantial in the Year Following a Hip Fracture

Risk of subsequent fracture after recent hip fracture is similar to risk of subsequent acute myocardial infarction (AMI) after initial AMI

Recent hip fracture[1,2]

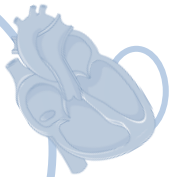


8.3%

95% CI: 8.1%–8.5%

Risk of subsequent clinical fracture within 1 year

Initial acute myocardial infarction[3]



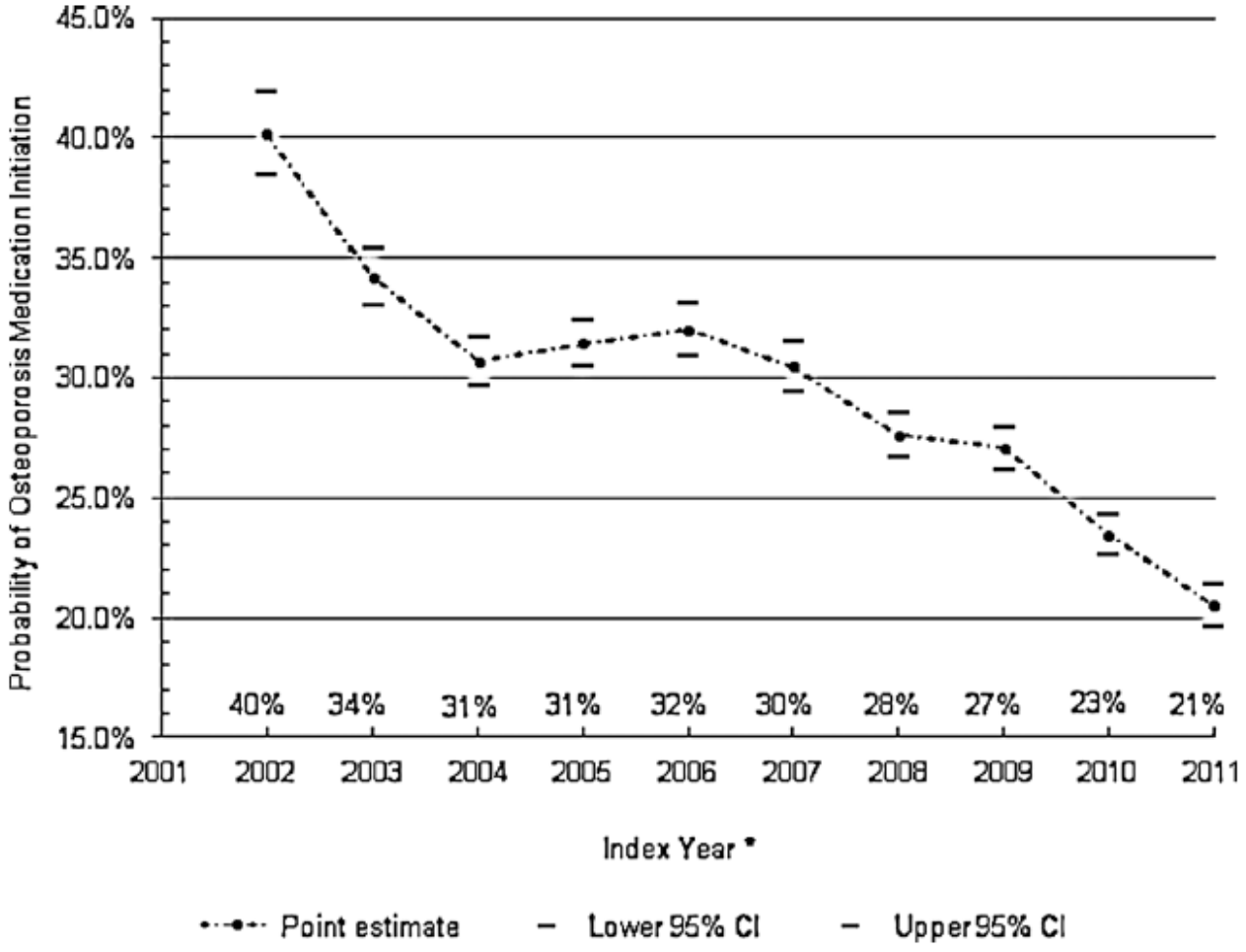
9.2%

95% CI: 9.0%–9.5%

Risk of subsequent AMI hospitalization within 1 year

1. Balasubramanian A, et al. Presented at: ASBMR annual meeting; October 16-18, 2016; Atlanta, GA. Abstract FR0233.
2. Data on file, Amgen.
3. Chaudhry SI, et al. " National trends in recurrent AMI hospitalizations 1 year after acute myocardial infarction in Medicare beneficiaries: 1999-2010." J Am Heart Assoc 2014; 3 e001197.

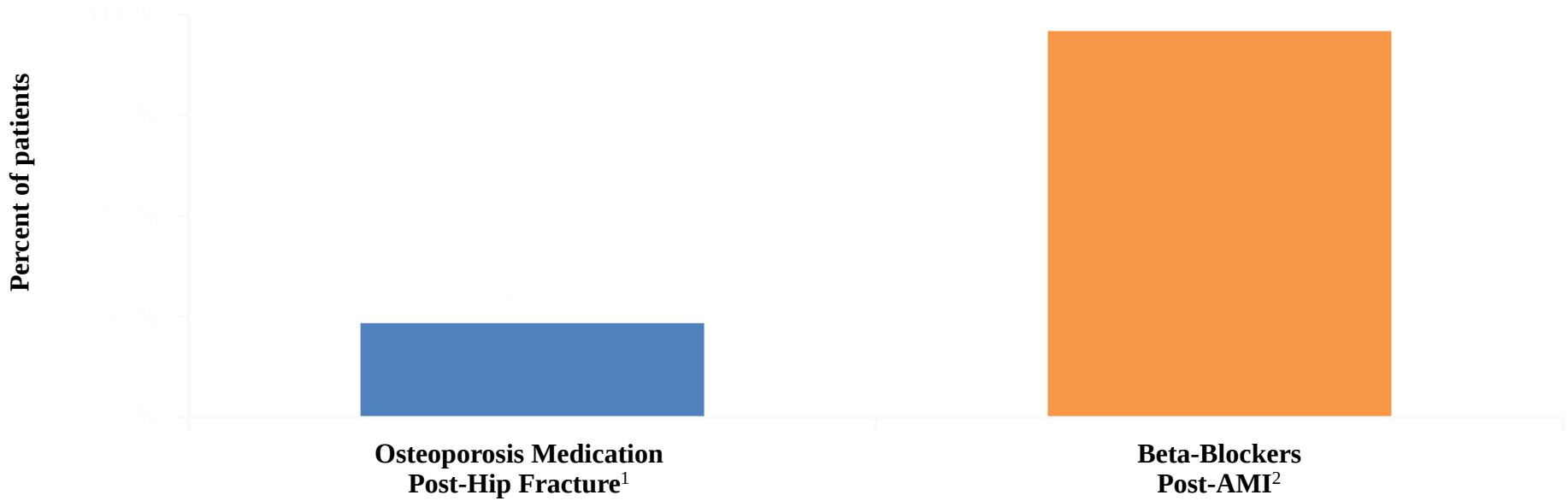
Probability of Osteoporosis Medication Use Following Hip Fracture within 12 Months of Discharge



Solomon et al. "Osteoporosis medication use after hip fracture in U.S. patients between 2002 and 2011." JBMR 2014; 29 1929-37.

Only 23% of Patients Receive Osteoporosis Medication After a Hip Fracture

A fracture is to osteoporosis what an acute myocardial infarction is to cardiovascular disease



1. Yusuf A, et al. Presented at: ASBMR annual meeting. October 9-12, 2015; Seattle, WA. Abstract MO0350.
2. Faridi KF, et al. "Timing of First Postdischarge Follow-up and Medication Adherence After Acute Myocardial Infarction." JAMA Cardiol 2016;1 147-155.

ASBMR Call to Action, Strategic Roadmap, and Action Plan

Catalyst: New York Times Article (2016)

- *Fearing Drugs' Rare Side Effects, Millions Take Their Chances with Osteoporosis* by Gina Kolata


The New York Times

NEW RULES AIM TO CURB SPIRAL OF PAYDAY LOANS

Osteoporosis Drugs Shunned For Fear of Rare Side Effects

Awaiting Trial, Willing to Pay for a Gilded Cage

Wealthy Defendants Offer Alternatives to Avoid Jail

Clinton to Paint A Mugabe Ally,

ASBMR Call to Action (2016)

- 39 US and global organizations signed on
- Pledged to intensify efforts to increase screening, screening, diagnosis and treatment of high risk individuals to prevent fractures

Strategic Roadmap and Action Plan to Prevent Secondary Fractures (2017-2019)

- Neutral platform for multi-stakeholder dialog and action, 39 organizational members in Coalition
- Problem is global, and elements of plan apply globally, but action steps largely focused on U.S. context

Target Population for Action Plan

- **Men and women age ≥ 65 years who have suffered a hip or vertebral fracture**
  - This subpopulation is at high-risk for a second fracture
  - Evidence supporting treatment for this population is robust
- Not intended to imply that other populations should **not** be treated (focus of other initiatives)
- Represents a well-defined at-risk subpopulation for which consensus on a public health initiative is achievable

Consensus Clinical Recommendations

Overarching principle:

- Women and men, age 65 years or older, with a hip or vertebral fracture, optimally should be managed in the context of a **multi-disciplinary clinical system that includes case management (one example is a fracture liaison service)** to assure that they are appropriately evaluated and treated for osteoporosis and risk of future fractures.

Bottom line:

- Patients 65 years of age or older who experience a hip or vertebral fracture should be treated for osteoporosis!

United States FLS Outcomes

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1. Kaiser Permanente

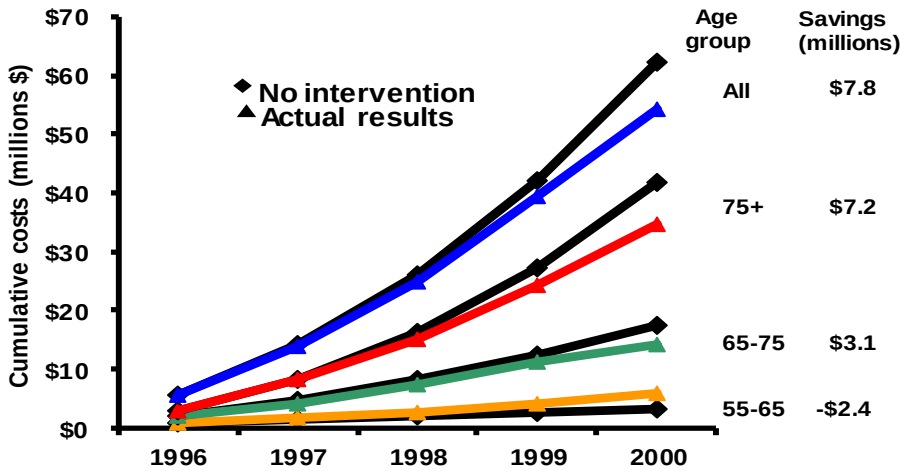
- **Reduced the hip fracture rate expected by over 40%** (since 1998)
- If implemented nationally, Kaiser estimates a similar effort could **reduce the number of hip fractures by over 100,000 (and save over $5 billion/year)**

2. Geisinger Health System

- Achieved **$7.8 million in cost savings from 1996-2000**

3. American Orthopaedic Association *Own the Bone®* Program

- Achieved statistically significant changes in professional behavior/referral (calcium and vitamin D, exercise, fall prevention, etc.)
- Over **272 sites and 64,000+ patients** involved from 50 states and the District of Columbia (since mid-2009)



4. CECity-Premier/NBHA/NOF/Johns Hopkins Armstrong Institute Demonstration Project

- Accessible suite of FLS registry, quality improvement and care coordination tools
- Delivered through a secure HIPAA-compliant cloud-based platform

Figure: Newman ED, et al. "Osteoporosis disease management in a rural health care population: hip fracture reduction and reduced costs in postmenopausal women after 5 years." Osteoporos Int 2003; 14 146-51.

Fundamental Recommendations

1. Communicate three simple messages to people age 65 years or older with a hip or vertebral fracture (as well as to their family/caregivers) consistently throughout the fracture care and healing process:

- A broken bone likely means they have osteoporosis - high risk for breaking more bones, especially over the next 1 to 2 years;
- Breaking bones means they may suffer declines in mobility or independence;
- There are actions they can take to reduce their risk

2. **Ensure that the usual healthcare provider for a person age 65 years or older with a hip or vertebral fracture is made aware of the occurrence of the fracture.** If unable to determine whether the patient's usual healthcare provider has been notified, take action to be sure the communication is made.

3. Regularly assess the risk of falling of people age 65 years or older with a hip or vertebral fracture.

- At a minimum, take a history of their falls within the last year.
- Minimize use of medications associated with increased fall risk.
- Evaluate patients for conditions associated with an increased fall risk.
- Strongly consider referring patients to physical and/or occupational therapists or a physiatrist for evaluation and interventions to improve impairments in mobility, gait, and balance, and to reduce fall risk.

4. Offer pharmacologic therapy for osteoporosis to people age 65 years or older with a hip or vertebral fracture to reduce their risk of additional fractures.

- Do *not* delay initiation of therapy for bone mineral density "("BMD") testing. Although BMD testing may be performed to monitor responses to treatment, therapy should be offered regardless of BMD levels.
- Consider patients' oral health before starting therapy with bisphosphonates or denosumab.

Critical Issue for Orthopaedic Surgeons:

- For patients who have had repair of a hip fracture or are hospitalized for a vertebral fracture:
  - –Oral pharmacologic therapy can begin in the hospital
  - –IV and SQ pharmacologic agents may be therapeutic options **outside the first two weeks** of the postoperative period.
  - –Concerns during this early recovery period include:
    - Hypocalcemia because of factors including vitamin D deficiency or perioperative overhydration.
    - Acute phase reaction of flu-like symptoms following zoledronic acid infusion, particularly in patients who have not previously taken zoledronic acid or other bisphosphonates.
  - – If pharmacologic therapy is not provided during hospitalization, then mechanisms should be in place to ensure timely follow-up.

5. **Initiate a daily supplement of at least 800 IU vitamin D per day** for people age 65 years or older with a hip or vertebral fracture.
6. **Initiate a daily calcium supplement** for people age 65 years or older with a hip or vertebral fracture **who are unable to achieve an intake of 1200 mg/day of calcium from food sources.**

7. **Because osteoporosis is a life-long chronic condition, routinely follow and re-evaluate**

   Purposes include:

- Reinforce key messages
- Identify any barriers to treatment plan adherence
- Assess fall risk;
- Monitor for adverse treatment effects;
- Evaluate the effectiveness of the treatment plan;
- Determine whether any changes in treatment should be made,

Additional Recommendations

8. Consider referring people age 65 years or older with a hip or vertebral fracture who have possible or presumed secondary causes of osteoporosis to the appropriate subspecialist for further evaluation and management.

9. Counsel people age 65 years or older with a hip or vertebral fracture:

- Not to smoke or use tobacco;
- To limit any alcohol intake to a maximum of 2 drinks a day for men and 1 drink a day for women; and
- To exercise regularly (at least 3 times a week),
  - including weight-bearing, muscle strengthening, and balance and postural exercises,

10. When offering pharmacologic therapy for osteoporosis to people age 65 years or older with a hip or vertebral fracture, discuss the benefits and risks of therapy, including, among other things:

- The risk of osteoporosis-related fractures without pharmacologic therapy; and
- For bisphosphonates and denosumab, the risk of atypical femoral fractures and osteonecrosis of the jaw and how to recognize potential warning signs.

11. First line pharmacologic therapy options for people age 65 years or older with a hip or vertebral fracture include:

- The oral bisphosphonates alendronate and risedronate, which are generally well tolerated, familiar to health care professionals, and available at low cost; and
- Intravenous zoledronic acid and subcutaneous denosumab, if oral bisphosphonates pose difficulties.

For patients at high risk of fracture, particularly those with vertebral fractures, anabolic agents may be useful

12. The optimal duration of pharmacologic therapy for people age 65 years or older with a hip or vertebral fracture is not known.

- Most published guidelines recommend that the need for therapy with bisphosphonates be reassessed after 3-5 years.
- Stopping denosumab without starting another antiresorptive drug should be avoided because of the possibility of rapid bone loss and increased fracture risk. Similarly, patients stopping anabolic agents also should be placed on an antiresorptive therapy.

13. **Primary care providers who are treating people age 65 years or older with a hip or vertebral fracture may want to consider referral to an endocrinologist or osteoporosis specialist for those patients who, while on pharmacotherapy, continue to experience fractures or bone loss**

- Please refer back to Dr Lewiecki's discussion of when it's not osteoporosis e.g., hyperparathyroidism, chronic kidney disease).

Coalition Member Organizations

ASBMR Secondary Fracture Prevention Initiative

- American College of Physicians
- American Geriatrics Society
- American Academy of Physician Assistants
- American Association of Nurse Practitioners
- American Physical Therapy Association
- American Academy of Orthopaedic Surgeons
- International Osteoporosis Foundation
- Fragility Fracture Network
- National Council on Aging
- National Osteoporosis Foundation
- National Bone Health Alliance
- American Association of Clinical Endocrinologists / American College of Endocrinology
- American Orthopaedic Association
- Orthopaedic Trauma Association
- International Society for Clinical Densitometry
- Osteoporosis Canada
- AHRQ
- US Bone and Joint Initiative
- Endocrine Society
- Geisinger Health System
- American Pharmacists Association
- American Society of Health-System Pharmacists
- Academy of Nutrition and Dietetics
- National Quality Forum
- American Medical Society for Sports Medicine
- Dutch Society of Calcium and Bone Metabolism
- American College of Rheumatology
- National Institute of Arthritis and Musculoskeletal and Skin Diseases* (liaison)
- National Institute on Aging
- American Bone Health
- Hellenic Osteoporosis Foundation
- National Osteoporosis Society (UK)
- Osteoporosis Australia
- Slovak Society for Osteoporosis and Metabolic Bone Diseases
- Syrian National Osteoporosis Society
- University of Rochester Department of Orthopaedics and Rehabilitation
- American Academy of Physical Medicine and Rehabilitation

References

1. Conley R et al. Secondary Fracture Prevention: Consensus Recommendations from a Multistakeholder Coalition. J Bone Miner Res. 2020;35(1):36-52.

2. ASBMR Secondary Fracture Prevention Initiative website: www.secondaryfractures.org

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Thank You