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# A cross sectional study comparing osteoporosis screening rates among AIM clinic patients grouped according to their resident's knowledge of current guidelines

## A. Study Purpose and Rationale

An estimated 10 million Americans over the age of fifty have osteoporosis and each year approximately 1.5 million Americans have osteoporosis-related fractures.(1) Osteoporosis is defined as a loss of bone mass and microarchitectural deterioration of bone tissue, leading to an increased risk of fracture.(4) In 1999, the World Health Organization further defined osteoporosis based on bone density obtained via dual x-ray absorptiometry (DEXA) scan. Diagnosis of osteoporosis requires a bone density of more than 2.5 standard deviations below the mean for young white adult women.(6) The number of people affected by osteoporosis is expected to grow even further over the next few decades as the United States population undergoes a change in demographics, resulting in an increase in the proportion of elderly Americans. It is estimated that by 2020, if there is no change in current practice, one in two Americans over the age of 50 will have, or be at high risk of developing, osteoporosis.(1)

Osteoporosis has a significant impact on both individual and public health. For example, about 300,000 hip fractures occur each year in the United States. (4) These fractures often precipitate a significant decline in physical health: 20% of elderly who suffer a hip fracture die within 1 year. (1) In addition, hip fractures are associated with a high incidence of deep vein thrombosis and pulmonary embolism (approximately 20 to 50%) and nearly one third of hip fracture patients end up discharged to nursing homes within the year following a fracture. (4, 6) This also translates to a significant financial burden for our health care system, with direct care expenditures for osteoporotic fractures alone ranging from \$12.2-17.9 billion each year.(1)

Given the impact on individual and public health, there has been an increased focus on raising awareness of osteoporosis. The United States Preventive Services Task Force (USPSTF), National Osteoporosis Foundation (NOF), and American Association of Clinical Endocrinologists (AACE) recommend all women have a bone density measurement at age 65.(2) This guideline is considered a grade B recommendation, meaning that the USPSTF recommends clinicians routinely provide screening to eligible patients and that at least fair evidence was found that indicates screening improves health outcomes and the benefits outweigh harms.(3) The USPSTF also recommends women age 60 to 65 with multiple risk factors. Most sources agree important risk factors for post-menopausal women include low body weight and no current use of estrogen therapy, which are both incorporated in the Osteoporosis Risk Assessment Instrument. (2) However, the most important risk factor, independent of low bone density, is a history of a fragility fracture, which is defined as fracture occurring after trauma no greater than a fall from standing height.(2) Risk factors useful for younger women have less supportive

evidence but include smoking, family history, alcohol or caffeine use, and low calcium and vitamin D intake.(1) In addition to a lack of consensus on consideration of risk factors, the recommended screening interval is also unclear. It is felt that screening more often than every 2 years is not helpful in light of precision limitations of the test and that an interval of five years for women with normal bone mineral density is likely adequate.(2)

Studies have suggested that despite the impact of osteoporosis and availability of DEXA scans for screening, routine screening for osteoporosis remains underutilized. (3). One study found the general screening rate in primary care clinics was only 10.8%. (5) This lack of appropriate screening is highlighted by the fact that even among patients who have had fragility fractures, and are thus at high risk, fewer than one third are appropriately evaluated and treated for osteoporosis. (3) Similarly, studies have shown that screening modalities for other diseases, like breast cancer, are also not used enough. Screening rates for breast cancer using mammography for females over age 40 ranged from only 20 to 48% in primary care clinics. (7, 9) However, studies have shown that educating physicians can improve screening rates. For example, in the Improving Osteoporosis Screening study, rates of screening went from 10.8% to 28.9% when patients were reminded to come to clinic for their DEXA scan and physicians received medical record prompts.(5) Similarly, a study done through the Mailman School of Public Health showed that educating physicians on breast cancer and the American Cancer Society guidelines for screening improved screening rates.(8) This suggests that lack of knowledge regarding screening guidelines could explain the underutilization of screening tests.

This study is a cross sectional study to assess rates of osteoporosis screening among patients grouped according to their resident physician's knowledge of the guidelines. If knowledge of screening guidelines does increase utilization of DEXA scans, interventions could target educating residents, and potentially lead to increased osteoporosis detection.

## **B. Study Design and Statistical Analysis**

This study is a cross sectional study using patient data collected retrospectively from the Associates in Internal Medicine (AIM) Clinic at Columbia Presbyterian Medical Center. The primary outcome variable will be the rate of ordering DEXA scans for female patients age 65 to 70 at AIM clinic. All second and third year residents will be eligible to participate. Residents will be categorized according to their knowledge of osteoporosis screening guidelines as assessed by a written questionnaire. The question will be nested among other questions regarding screening guidelines for breast and colon cancer. Residents will be grouped into two categories based on their answers- either informed or uninformed regarding osteoporosis screening guidelines.

Using participating residents' patient lists, all females age 65 to 70 years of age with at least 2 visits with the resident, will have their charts reviewed. The following information will be collected from charts:

- 1. Whether or not the resident ordered a DEXA scan. Reading progress notes or finding the results of a scan with the physician's name as ordering MD will determine this.
- 2. Information regarding the patient's medical problems (to calculate a Charlson Comorbidity Index). (10)
- 3. Information regarding the patient's first language and whether or not their physician utilized a translator.
- 4. Whether or not a mammogram was ordered in the past 1-2 years.

Patients will be excluded from analysis if they had a DEXA scan ordered in the past prior to coming under the resident's care.

Results will be analyzed using a Chi-square test to compare proportions between the two groups of patients. The primary outcome variable will be the rate of ordering DEXA scans among the 2 groups of patients, classified according to whether or not their resident was informed of the guidelines. Patient data will be pooled together in each category. A patient population of 114 in each group allows for 80% power to detect a statistically significant (p<0.05) difference in screening rates between the groups. This calculation is based on the range of screening rates found in the literature review, using a rate of 10% for residents unaware of guidelines and 25% for those knowledgeable of guidelines. This difference is clinically significant given the prevalence of osteoporosis in this population of 65-70 year old women ranges from 12-20%. (11) Increasing screening rates by 15% would result in diagnosing 3 more women with osteoporosis for every 100 female patients in this age range seen in AIM clinic. In addition, even more osteopenic patients would be identified. In a recent longitudinal observational study of over 200,000 postmenopausal females, the prevalence of osteopenia was estimated at 39.6%, and was associated with 1.7 -fold higher rate of fracture. (3, 11) Increasing screening 15% would also translate to identifying 6 more osteopenic patients for every 100 females patients age 65-70 seen in AIM clinic.

There are approximately 80 second and third year internal medicine residents at CPMC. Assuming each resident has approximately 5 patients that fit these criteria, 46 residents will need to complete the questionnaire to obtain approximately 230 patients. Assuming a 90% survey completion rate, 52 residents will need to be asked to participate.

A multiple logistic regression will be also performed using the following covariates: Charlson Comorbidity index, use of translator to communicate with patient, year of residency training of primary physician, whether or not patient had an up to date mammogram, and number of office visits with physician.

# **C. Study Procedure**

The study will last approximately one year. This allows for 4 months to collect completed questionnaires and approximately 8 months for chart review. Resident participation will last approximately 10 minutes, the time needed to complete the questionnaire. After the 4-month time frame for questionnaire completion, all

participating residents will receive a handout listing current USPSTF screening guidelines.

## **D. Study Drugs**

Not applicable.

## **E. Medical Device**

Not applicable.

# F. Study Questionnaires

What year of residency training are you in?

Are there recommended guidelines from the United States Preventive Services Task Force (USPSTF) regarding screening of healthy women for breast cancer?

## Yes – No – I Don't Know

If you answered yes to the above question: Which of the following statements is most accurate regarding breast cancer screening guidelines:

1. All women over age 40 should have screening mammograms every 1-2 years.

2. All women over age 50 should have screening mammograms every 1-2 years.

3. All women over age 50 should have screening mammograms every 10 years.

4. All women over age 40 should have screening mammograms every 10 years.

Are there recommended guidelines from the USPSTF regarding screening of healthy women for osteoporosis?

## Yes – No – I Don't Know

If you answered yes to the above question: Which of the following statements is most accurate regarding osteoporosis screening guidelines:

1. All women over age 65 should have a screening DEXA scan, the interval regarding repeat depends on the results and individual patient.

2. All women over age 70 should have a screening DEXA scan, the interval regarding repeat depends on the results and individual patient.

3. All women over age 75 should have a screening DEXA scan, the interval regarding repeat depends on the results and individual patient.

4. All women over age 80 should have a screening DEXA, the interval regarding repeat depends on the results and individual patient.

Are there recommended guidelines from the USPSTF regarding screening of healthy patients for colon cancer?

Yes – No – I Don't Know

If you answered yes to the above question: Which of the following statements is most accurate regarding colon cancer screening guidelines:

1. All men and women over age 40 should be screened for colon cancer.

2. All men and women over age 50 should be screened for colon cancer.

3. All men and women over age 60 should be screened for colon cancer.

4. All men and women over age 65 should be screened for colon cancer.

## **G. Study Subjects**

All second and third year internal medicine residents at the Columbia Presbyterian Medical Center AIM Clinic will be asked to participate.

Data for all 65 to 70 year old female patients of participating residents will be included. Patients must have had at least 2 visits with the resident to be considered under the resident's care. Exclusion criteria include patients who received DEXA scans prior to coming under the care of the current resident.

## H. Recruitment of Subjects

Internal medicine residents will be notified of the study via email. Questionnaires will be distributed at noon conference, two times per month over a four-month span, in an attempt to increase the return rate. Residents will only complete the survey once. Potential patients will be identified via Webcis by accessing each participating resident's outpatient panel.

# I. Confidentiality of Study Data

All study data will be coded with each resident receiving a unique code. The investigator chart reviewing will be unaware of residents' answers to the questionnaire. All patient data will be stripped of identifying information aside from information being collected. Data will be stored in a secure location, accessible only to investigators.

## J. Potential Conflict Of Interest

No potential conflicts of interested are identified.

# K. Location of Study

Columbia Presbyterian Medical Center and AIM Clinic.

## L. Potential Risks

No risks to patients are identified, as information will be de-identified. Residents face the risk of having other residents observe their answers to the questionnaire. An effort will be made to provide privacy to residents completing the survey. However once questionnaires are completed, residents will only be identified with a unique code, in an attempt to minimize the risk of information becoming available to others.

## **M.** Potential Benefits

Residents will have the opportunity to learn screening guidelines by receiving a handout with appropriate screening guidelines after the 4-month time frame for questionnaire completion. No potential benefits are identified for patients.

## **N. Alternative Therapies**

Not applicable

## **O.** Compensation to Subjects

No compensation to residents will be provided for participation.

Score for Each Condition	Condition
1	Myocardial Infarct
1	Congestive Heart failure
1	Peripheral vascular disease
1	Cerebrovascular disease
1	Dementia
1	Chronic pulmonary disease
1	Connective Tissue disease
1	Ulcer disease
1	Mild liver disease
2	Diabetes
2	Hemiplegia
2	Moderate or severe renal disease
2	Diabetes with end organ damage
2	Any tumor
2	Leukemia
3	Lymphoma
3	Moderate or severe liver disease
6	Metastatic solid tumor
6	AIDS

Calculation of the Charlson Comorbidity Index (10)

## References

1.Bone Health and Osteoporosis: A Report of the Surgeon General. Washington, DC: U.S. Department of Health and Human Services; 14 October 2004. Accessed on June 11, 2007.

2. Cunningham G. F., Raisz L. G. Screening for Osteoporosis. NEJM 2005; 353: 164-171.

3. Nelson, Mark, et al. Screening for Osteoporosis in Postmenopausal Women: Recommendations and Rationale. U.S. Preventive Services Task Force. Annals of Internal Medicine 2003, 137: 526-528.

4. Lindsay, R and Cosman, F. Harrison's Principles of Internal Medicine Online. Chapter 333: Osteoporosis. 16<sup>th</sup> Edition. 2005. Accessed on June 11, 2007.

5. Lafata, Kolk, et al. Improving Osteoporosis Screening: Results from a Randomized Cluster Trial. J Gen Internal Medicine. 2007 Mar, 22 (3): 346-351.

6. NIH Consensus Development Panel on Osteoporosis Prevention, Diagnosis, and Therapy. Osteoporosis Prevention, Diagnosis, and Therapy. JAMA 2001;285:785-795.

7. Wallace, MacKenzie, Weeks. Women's primary care providers and breast cancer screening: who's following the guidelines? Am J Obstet Gynecol. 2006 Mar; 194 (3): 744-8.

8. Sherri Sheinfeld Gorin, Alfred R. Ashford, Rafael Lantigua, Ashfaque Hossain, Manisha Desai, Andrea Troxel, and Donald Gemson. Effectiveness of Academic Detailing on Breast Cancer Screening among Primary Care Physicians in an Underserved Community. J Am Board Fam Med, March-April 2006; 19: 110 - 121.

9. Ruffin, Gorenflo, and Woodman. Predictors of screening for breast, cervical, colorectal, and prostate cancer among community-based primary care practices. J Am Board Fam Pract. 2000 Jan-Feb; 13 (1): 1-10.

10. DeGroot V, Beckerman H, Lankhorst G, and Bouter L. How to measure comorbidity: a critical review of available methods. J Clin Epidmiol. 2003;56:221–229.

11. Siris et al. Identification and Fracture Outcome of Undiagnosed Low Bone Mineral Density in Postmenopausal women. JAMA 2001; 286:2815-2822.