Bone Densitometry as a Screening Tool for Osteoporosis in Postmenopausal Women

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By OBGYN.net Staff [1]

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Introduction

Osteoporosis is a degenerative bone disease that affects approximately 24 million Americans. Of these, 33 percent are postmenopausal who have decreased bone density due to lowered estrogen levels. Over half of postmenopausal women will experience a bone fracture as the result of osteoporosis. The estimated costs of osteoporosis-related fractures in the United States is between $8-10 billion each year.

Given the impact of osteoporosis on individuals, families, and society, there is great interest in diagnosis, prevention and treatment of this disease. Specifically of interest are answers to such questions as: Are there ways to predict an osteoporosis-related fracture? How can osteoporosis be prevented or treated? Are there risks or side effects associated with treatment? Interest in answers to these questions have increased for three reasons. First, bone densitometry equipment used to screen for, diagnose, and manage the treatment of osteoporosis is moving from the traditional setting of doctors' offices and hospitals to mobile units and non-medical locations. Second, a number of drugs have been developed that either slow the bone loss experienced in osteoporosis or replace bone already lost. Finally, the increased availability of both screening and treatment for osteoporosis may increase costs but have uncertain benefits.

Background

Definition of Osteoporosis

Osteoporosis is defined as deterioration of the strength and fracture resistance of bone caused by a decrease in bone mineral content. The standard used to determine whether a women is osteoporotic was developed by the World Health Organization (WHO), which defines osteoporosis in terms of bone density. According to the WHO, a woman has osteoporosis when her bone density level falls more than 2.5 standard deviations below the mean for a young, normal woman, aged 30. A woman is osteopenic when her bone density falls between 1 to 2.5 standard deviations below this norm.

Osteoporosis occurs when the body's ability to repair and maintain bone tissue is out of balance. Normally, bones are constantly being rebuilt and remodeled. Old or damaged bone is dissolved through a process called resorption, while new bone is laid down in its place. For women, peak bone mass is usually reached by about age thirty, and declines thereafter. Bone mass of the hip, however, usually peaks around age 20.

There are a number of genetic, biological, and behavioral factors which increase a woman's risk of osteoporosis. These include: Caucasian or Asian race; small frame, short stature and light weight; lower than normal levels of estrogen (hypoestrogenia); early onset of menopause and fewer reproductive years; inadequate calcium or vitamin D intake; use of caffeine, alcohol, or tobacco; steroid use and insufficient physical exercise.

Hip Fractures Due to Osteoporosis are a Serious Health Problem

Because osteoporosis weakens bone, the risk of fracture is higher in those who have the . Of all osteoporosis related fractures, hip fractures pose the most serious public health problem. The incidence of hip fractures in the U.S. appears to be increasing with 250,000 to 300,000 occurring...
Fractures of the hip also have the greatest effect on disability and death—approximately 5-20 percent of people suffering from a hip fracture die within one year. For people living at home at the time of a hip fracture, about half experience decreased social functioning within 2 1/2 years. The U.S. Congress' Office of Technology Assessment estimated the costs of osteoporosis-related hip fractures for women 50 years and older as $5.4 billion in 1990. The average per patient cost of in-hospital services was $9,483 with an additional $9,852 per patient spent for post-hospital, outpatient services including nursing home and home health care.

Osteoporosis in Minnesota

Based on an Olmsted County, Minnesota study, it is estimated that 199,000, or 32 percent, of white women over age 50 in Minnesota have osteoporosis. The number with osteoporosis of the hip is approximately 148,400 (24 percent). Each year, approximately 3,700 white, Minnesota women suffer an osteoporosis-related hip fracture.

Bone Densitometry

Bone densitometry is used by health care providers as a screening, diagnostic, and management tool. A screening test is often applied broadly to classes of individuals, even though they do not display symptoms of illness, and regardless of whether they are at high- or low-risk for a disease or condition. In contrast, a diagnostic test is used when an individual presents with specific symptoms in order to “rule in” or “rule out” a diagnosis. Once diagnosed, additional tests may be used to help in the management of the disease or condition.

Techniques to measure bone mineral density (BMD) include: radiographic methods; ultrasonography, and biochemical markers. The chart in Appendix I summarizes the advantages and disadvantages of these techniques. Costs of equipment and average charges are summarized in Appendix II. The two methods being used in Minnesota, and which are diffusing most rapidly, are dual x-ray absorptiometry (DXA) and quantitative computed tomography (QCT). Of the two, DXA is the most common. It uses x-rays of two energy levels to distinguish between bone and the surrounding soft tissue. As a result, a two-dimensional image is generated and a measure of BMD can be calculated. Unlike dual-energy radiographic methods, QCT is a three-dimensional imaging technique which measures bone density volume (g/cm$^3$) rather than mineral content per unit area (g/cm$^2$). QCT is primarily a diagnostic tool rather than a screening device. Although more expensive to use and less common than DXA, there is potential for rapid diffusion of this bone densitometry method as well. Currently there are about 10,000 advanced CT scanners in the United States. A software package may be purchased which allows use of an existing CT scanner as a QCT scanning device. Recently there has been renewed interest in Minnesota in radiographic absorptiometry (RA), or conventional radiography. Use of this technology to measure BMD is currently prohibited under Minnesota Rules 4730.1210 for ionizing radiation and is beyond the scope of this report.

Treatments for Osteoporosis

It is important to note that if an individual's bone mass or density has deteriorated to the point where fractures may occur, treatment options are limited. Preventive measures, such as adequate calcium and vitamin D intake, smoking cessation, and weight-bearing exercise should be undertaken early in life by all women to decrease their risk of osteoporosis. Once diagnosed as osteoporotic, treatment options include: replacement therapy (HRT), which uses the hormones estrogen, progesterone, or both; calcitonin; and, calcium and vitamin D supplements. These treatments can maintain existing bone, thereby decreasing the risk of fracture, but can not significantly increase bone mass. By contrast, alendronate (brand name Fosamax®) appears to both slow the bone resorption process and increase bone mass. HRT is the most widely used treatment for osteoporosis. The benefits of HRT appear greatest when treatment is begun close to menopause, before rapid bone loss occurs, and is continued for 5 or more years. There is also evidence that the incidence of all osteoporotic fractures is substantially reduced (by 30-50 percent) with an exposure to HRT of 3-10 years. However, some women refuse HRT because of its reported association with an increased risk of breast or endometrial cancer. In 1995, the FDA approved a second generation bisphosphonate, alendronate for the treatment of osteoporosis. Unlike other treatments for bone loss, alendronate prevents the resorption of bone and has been shown to increase bone mass and decrease fracture risk. A recent three year, multicenter,
randomized clinical trial demonstrated that post-menopausal women taking alendronate experienced a 51 percent reduction in hip fracture risk, a 47 percent reduction in spinal fracture risk, and a 48 percent reduction in forearm fracture risk. As a result of this and other studies, the FDA has approved alendronate for use both as a treatment and a preventive for osteoporosis and osteoporosis-related fractures. This makes alendronate the first alternative to HRT judged effective by the FDA for the prevention of osteoporosis. A summary of the advantages and disadvantages associated with the available treatments for osteoporosis appear in Appendix III.

Use of Bone Densitometry-Guidelines from Other Sources

The available guidelines agree that the use of bone densitometry should be dependent on whether a woman will (or will not) accept treatment for osteoporosis. However, the World Health Organization (WHO) recommends screening women who are within 5 years of menopause to stratify risk and offer intervention. By contrast, the U.S. Preventive Services Task Force (USPSTF) recommends selective bone mineral density testing of high-risk women only. Finally, the National Osteoporosis Foundation (NOF) and the American Association of Clinical Endocrinologists (AACE) agree that women receiving long term glucocorticoid therapy and who have asymptomatic primary hyperparathyroidism should be tested for low bone mass. A summary of the guidelines is contained in Appendix IV. Findings

0. Although the FDA has determined that bone densitometry devices are safe, it has not approved the use of bone densitometry to predict osteoporosis-related fracture risk. However, a number of prospective studies, which examined the relationship between bone density and the risk of osteoporotic fracture, have shown that bone density measurements can predict future fracture risk. One study found that each standard deviation decrease in bone mineral density of the proximal femur of the hip increased hip fracture risk 2.5 to 2.8 times. Another study concluded that bone mineral density measurements at various common fracture sites (forearm, spine and hip) can be used to group patients based on their relative risk of an osteoporosis-related fracture, enabling prediction of moderate trauma fractures for up to 8 to 10 years.

0. There is evidence that bone density alone does not adequately explain the increased incidence of hip fracture that occurs with increased age. Other factors, such as bone elasticity and structure, may need to be considered in combination with bone density to identify women at high-risk of fracture.

0. Bone densitometry measurements for prediction of fractures is not without controversy. Although the short term effectiveness of bone densitometry in predicting fracture risk has been demonstrated, no studies have determined how well the bone density of women approaching menopause predicts their long-term risk of fracture. This is due to the fact that the rate of postmenopausal bone loss varies among women. As a result, a woman's bone mass at menopause may not accurately predict her bone mass 10-30 years later, when most fractures occur.

0. FDA approval of alendronate (Fosamax®) for the treatment of osteoporosis has in part fueled the increased interest in BMD screening and measurement.

0. There is evidence that women who are informed that they have low bone density consciously alter their behavior. In one study, 38 percent of women who learned they had lower than normal BMD reported they began hormone replacement therapy compared to 10 percent of women with normal BMD results. The study also found that 38 percent of women with low BMD reported they became more fearful of falling and 24 percent limited their activities to avoid falling. By avoiding exercise or limiting their daily activities, researchers note these women may actually increase their risk of fractures. The authors of the study conclude, “The potential adverse psychological effects of abnormal [BMD] results need to be considered before densitometry is widely used for unselective screening.”

0. The Minnesota Department of Health has raised concerns regarding proliferation and use of bone densitometry equipment. Although a single scan exposes an individual to less radiation than a chest x-ray, the effects of repeated exposure to this and other forms of ionizing radiation should be considered. Adequate protections and oversight by MDH need to be available to ensure that the equipment is safe for the operators and for the persons being
Cost-Analyses of Bone Densitometry as a Screening Tool for Osteoporosis

**Cost-effectiveness Analysis**

Only one cost-effectiveness study was found in the literature which addresses screening and treatment for osteoporosis. This study was undertaken by the Office of Technology Assessment (OTA) and examined the costs and effectiveness of two scenarios:

0. Screening women for bone density once, at the time of menopause (age 50), and placing those with low bone mineral density on long-term hormone replacement therapy (HRT); or
0. Screening women once at age 65, and placing those with low bone mineral density on long-term hormone replacement therapy (HRT).

Effectiveness was measured in terms of years of life saved and were not adjusted for the quality of those years. Measures of cost from the payer's perspective included hospital care, nursing home care and other long-term care due to disease-related disabilities, as well as the costs of screening and HRT. Societal costs - i.e., unpaid care provided by family and , work lost, and the patient's time costs - were not included. OTA's analysis was based on the following assumptions about HRT, separating the effects of estrogen replacement therapy (ERT) and progestin/estrogen replacement therapy (PERT):

0. ERT decreases a woman's risk for heart disease (0.5 fold), increases her risk of breast cancer (1.35 fold), increases her risk of endometrial cancer (7.0 fold), and increases her risk of gallbladder disease (2.5 fold).
0. PERT decreases a woman's risk for heart disease (0.8 fold), increases her risk of breast cancer (1.35 fold), has no increased risk of endometrial cancer, and increases her risk of gallbladder disease (2.5 fold).

Using these assumptions, cost effectiveness ratios were calculated. OTA found that screening at the time of menopause and placing those with low bone density on long-term ERT would deliver an additional year of life for about $27,000. Placing all women on long-term ERT at menopause, without screening for bone density would deliver an additional year of life for about $23,000. The latter approach is much more expensive because all women are treated. However, more lives are saved so the cost per life year saved is less. OTA also found that the cost per added year of life declined dramatically with longer use of ERT, whereas treatment for 10 - 20 years was much less cost-effective.

Estimates of cost per additional life year were much higher for PERT primarily due to this regimen's decreased effect on lowering heart disease, even though there is less endometrial cancer associated with PERT than ERT. Cost per added life year of placing all women on PERT was about $71,000. Placing only those with low bone density on long-term PERT would cost about the same. OTA's estimates of cost effectiveness assume complete compliance with HRT. However, studies have shown a long-term compliance rate of below 20 percent. OTA estimated that if 50 percent of women terminated HRT after 10 years, cost per added life year would be $73,000. OTA speculated that bone density screening may increase the compliance rate and this should be evaluated against other methods for improving compliance.

OTA also conducted an analysis of a hypothetical drug to maintain bone density without any of the side effects or benefits associated with HRT. Assuming the drug would cost $250 per year, the same annual cost of PERT today, the cost per additional life year saved would be approximately $155,000. Adjustments for quality of life based on a decrease in hip fractures would most likely decrease this amount.

**Cost-benefit Analysis**

In contrast to OTA, a cost-benefit study was done by ECRI, a nonprofit health technology evaluation firm, to determine whether BMD screening should be done at all and under what circumstances. ECRI found that a one-time BMD measurement by DXA of the hip, taken at the time of menopause,
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Published on Diagnostic Imaging (http://www.diagnosticimaging.com)

has benefits that exceed the costs, assuming 100 percent compliance with HRT. However, they state that if the monetary value of future costs and benefits are discounted, then costs exceed benefits. This is due to the fact that the benefits of HRT in preventing hip fractures accrue 20 years in the future when most hip fractures occur. ECRI concluded that the benefits of BMD screening and HRT depend on hip fracture costs. If the payer's perspective is used and only hospital costs are considered, then screening has more costs than benefits. However, if a societal perspective is taken and the costs of lost productivity and the cost of long-term care for women who lose the ability to live independently after a hip fracture are considered, screening has a positive net benefit. Bone Densitometry in Minnesota

As of April 1997, 28 sites in Minnesota provide bone densitometry services. Concentrated in urban centers, such as Minneapolis, St. Paul, and Rochester, bone densitometry is available on a more limited basis in Greater Minnesota. The diffusion of this technology however, appears to be occurring at a rapid rate. According to the Minnesota Department of Health, the number of DXA and QCT scanners which measure bone density has increased in the last year and a half from 1 to 28. Of these, 1 is a mobile peripheral DXA unit and 4 are fixed QCT scanners. Recently, a mobile bone densitometry unit visited 4 Minnesota pharmacies, spending 6 weeks at each site. A woman could be screened if she had a doctor's referral. This has raised concerns about the quality of care received in these non-traditional screening settings, and the ability of regulators to insure that safety standards are adhered to by screening personnel. Conclusions

The rapid proliferation of bone densitometry equipment in the State of Minnesota has caused concern among health care policy makers, payers and providers. Rapid diffusion of technologies may result in inappropriate use and higher costs to delivering health care services. The increased use of bone densitometry in Minnesota appears to coincide with the development of new treatments, such as alendronate, for osteopenic women, and evidence that bone densitometry measurements can be used to predict future fracture risk.

Based on the available evidence, the HTAC concludes that state of the art bone densitometry is safe and indicated as a diagnostic and treatment aid for postmenopausal women at risk for osteoporosis. Bone densitometry provides beneficial information to women about their relative risk of having an osteoporosis-related fracture and may be used by them and their providers to decide whether treatment should be initiated. However, bone densitometry is not indicated as a broad screening tool for all postmenopausal women regardless of whether they are at risk for the disease. Further, there would be no additional value to screening women currently on HRT since they are already being treated for osteoporosis. Those women who are opposed to using HRT, but would consent to treatment if found to be at risk for osteoporosis as indicated by low BMD, would benefit from the test. However, those postmenopausal women refusing treatment and not amenable to treatment under any circumstances would not benefit from BMD screening.

The costs of osteoporosis-related fractures, both monetary and human, are substantial. However, the concern over the rapid proliferation of DXA and QCT equipment throughout the state of Minnesota is a valid concern and should be examined as to its effect on the cost of delivering health care to the state's population relative to its benefits. Recommendations

Bone densitometry is best used within the context of an individual's care and is indicated in those women who are at risk of osteoporosis and need additional information to make the decision to accept treatment for the disease. Therefore, the HTAC recommends against the use of bone densitometry as a routine screening tool for osteoporosis in all postmenopausal women in Minnesota. Additional recommendations are:

0. Women consult with their health care providers to determine their risk of developing osteoporosis.
0. All health care providers be educated about the prevention of and risk factors for osteoporosis.
0. All women in Minnesota be educated on the prevention of and risk factors for osteoporosis.
0. All health care providers be educated on the benefits and limitations of using bone densitometry in postmenopausal women.
0. The benefit of using bone densitometry to aid in women's compliance with HRT treatment be studied.
0. A cost effectiveness study using quality adjusted life years as the measure of effectiveness be undertaken.
0. Copies of this report be distributed to family practice physicians, internists, rheumatologists,
endocrinologists, geriatric professionals, obstetricians/ gynecologists and consumer groups. (See Appendix V.)

Appendix I: Bone Density Screening Techniques

**Note:** Accuracy indicates the ability to measure actual bone mineral density. Precision involves the ability to reproduce results. Sensitivity allows accurate separation of the normal population from the abnormal or fracture population.  

<table>
<thead>
<tr>
<th>METHOD</th>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SPA &amp; SXA</strong></td>
<td>Accuracy ranges between 95-98% for SXA of the heel &amp; forearm.</td>
<td>Precision error of 1-2% for the heel &amp; forearm.</td>
</tr>
<tr>
<td></td>
<td>Scanning time is 5-15 minutes. Low radiation dose (2-5 mrem)</td>
<td>Not accurate in measuring BMD of the spine &amp; hip.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not sensitive to changes in trabecular bone, which has a higher turnover rate than cortical bone.</td>
</tr>
<tr>
<td><strong>DPA</strong></td>
<td>Accuracy is 90-97% for DPA of the spine. Low radiation dose (5-10 mrem). Multiple measurement sites possible.</td>
<td>Scanning time is 20-45 minutes. Precision errors range from 1.1% to 3.7%.</td>
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<tr>
<td></td>
<td></td>
<td>Uses radioactive isotope rather than an x-ray tube.</td>
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<td></td>
<td></td>
<td>No longer being manufactured.</td>
</tr>
<tr>
<td><strong>DXA &amp; DEXA</strong></td>
<td>Most common method used. Clinical efficacy established.</td>
<td>Precision errors range between 1.2%-2.0% for the hip.</td>
</tr>
<tr>
<td></td>
<td>Accuracy ranges between 90-99% for DXA of the hip, spine &amp; forearm. Precision errors are low for the spine, ranging from 0.6% to 1.5%. Low radiation dose (&lt; 5 mrem) Sensitivity level of lateral DXA approaches that of QCT.</td>
<td></td>
</tr>
<tr>
<td><strong>QCT</strong></td>
<td>Measures true bone density volume, not just BMD per unit area.</td>
<td>Larger radiation dose (100-1000 mrem) than other methods.</td>
</tr>
<tr>
<td></td>
<td>It separately measures both cortical and trabecular bone.</td>
<td>More costly than other methods.</td>
</tr>
<tr>
<td></td>
<td>Accuracy ranges between 85-97% for QCT of the spine. Provides a 3-dimensional image.</td>
<td>Precision error ranges from 1-3% (single energy) to 3-5% (dual energy) Clinical usefulness of QCT of the hip not established.</td>
</tr>
<tr>
<td><strong>Broadband Ultrasound Attenuation (BUA)</strong></td>
<td>Measures integrity of trabecular bone. Low cost. Avoids ionizing radiation. May be effective in predicting fracture risk of the hip independent of BMD.</td>
<td>Not FDA approved for use as a bone density measurement tool.</td>
</tr>
<tr>
<td><strong>Biochemical Markers</strong></td>
<td>Used to determine the rate of trabecular bone turnover. 50% efficiency in predicting bone loss at menopause FDA approved. American College of Obstetrics &amp; Gynecology recommended for identifying cause of BMD loss. Inexpensive to perform.</td>
<td>Not proven effective in predicting fracture risk.</td>
</tr>
</tbody>
</table>

Appendix II: Equipment Costs and Average Charge Per Scan
### Bone Densitometry as a Screening Tool for Osteoporosis in Postmenopausal Women

Published on Diagnostic Imaging (http://www.diagnosticimaging.com)

<table>
<thead>
<tr>
<th>TECHNIQUE</th>
<th>EQUIPMENT COSTS</th>
<th>AVERAGE SCAN CHARGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPA</td>
<td>$20,000 - $30,000</td>
<td>$50 - $150 (forearm &amp; heel)</td>
</tr>
<tr>
<td>DPA</td>
<td>$30,000 - $65,000</td>
<td>$150 - $300 (spine, hip &amp; total body)</td>
</tr>
<tr>
<td>DXA</td>
<td>$60,000 - 100,000</td>
<td>$150 - $300 (spine &amp; femur)</td>
</tr>
<tr>
<td>QCT</td>
<td>$5,000 - $15,000 (for software to adapt an existing CT scanner)</td>
<td></td>
</tr>
</tbody>
</table>

### Appendix III: Treatments for Osteoporosis

<table>
<thead>
<tr>
<th>TREATMENT</th>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
<th>ANNUAL COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormone Replacement Therapy (HRT)</td>
<td>Accepted treatment for menopausal symptoms. FDA approved preventive treatment for osteoporosis. Reduces risk of heart disease. Prevents further bone loss. Preventive effect of HRT does not decrease over time with long term use.</td>
<td>Benefits disappear after stopping treatment. Does not promote remineralization of bone. Increased risk of breast cancer-unknown. Increased risk of endometrial cancer demonstrated. May cause menstrual bleeding. Low long term compliance rate.</td>
<td>$400.00</td>
</tr>
<tr>
<td>Bisphosphonates e.g. alendronate (Fosamax)</td>
<td>FDA approved for treatment and prevention of osteoporosis. Inhibits bone resorption. No added risk of endometrial cancer or bleeding as with HRT. Three year clinical trials have demonstrated decreases in the rate of hip, spine and wrist fractures.</td>
<td>Lacks cardioprotective effects of HRT. Does not relieve menopausal symptoms. Risk of esophageal ulcers occurring if medication not taken as directed, and in women with achalasia, dismotility disease, and severe dyspeptic disease.</td>
<td>$650.00</td>
</tr>
<tr>
<td>Calcitonin</td>
<td>FDA approved treatment for osteoporosis. Inhibits bone resorption. May reduce the incidence of spine fractures. Increases in spinal bone mass observed.</td>
<td>Side effects occur in 15-20% of patients, including nausea and flushing. Side-effects are not as severe with use of nasal calcitonin.</td>
<td>Nasal: $650 Injection: $2,000</td>
</tr>
<tr>
<td>Calcium Supplements &amp; Vitamin D</td>
<td>Up to 2000 mg daily can reduce the rate of bone loss after menopause. In combination, Calcium and vitamin D may increase bone mass and decrease fracture risk.</td>
<td>Role of vitamin D alone in persons without vitamin D deficiency is unknown.</td>
<td>$50</td>
</tr>
<tr>
<td>Exercise</td>
<td>Weight bearing exercise may indirectly decrease the risk of fracture by promoting better balance, muscle strength and mobility.</td>
<td>The most beneficial exercise program has yet to be established.</td>
<td>$50</td>
</tr>
</tbody>
</table>

### Appendix IV: Guidelines from other sources

According to the National Osteoporosis Foundation,¹ ³ ⁸ ⁹ BMD measurements are justified in four
cases:

0. In estrogen-deficient women (hypoestrogenia), to diagnose significantly low bone mass in order to make decisions about hormone replacement therapy.
0. In patients with vertebral abnormalities or low bone mass due to x-ray exposure (roentgenographic osteopenia), to diagnose spinal osteoporosis in order to make decisions about further diagnostic evaluation and therapy.
0. In patients receiving long-term exposure to corticosteroids, to diagnose low bone mass in order to adjust therapy.
0. In patients with primary asymptomatic hyperparathyroidism, to diagnose low bone mass in order to identify those at risk of severe skeletal disease who may be candidates for surgical intervention.

The World Health Organization (WHO), whose criteria for bone density screening is commonly used by physicians, recommends screening women who are within 5 years of menopause to stratify risk and offer intervention. However, there is no need to test women who elect to take long-term HRT, nor is there a need to screen women when the results of the test will not change their decision to accept (or reject) a treatment. For women who are identified as being at intermediate risk, another test several years later may be valuable. The U.S. Preventive Services Task Force (USPSTF) has concluded that:

0. Recommendations against routine bone densitometry may be made on the grounds that it is inconvenient, costly and there are no universally accepted criteria for initiating treatment based on bone density measurements.
0. Direct evidence of benefits is not yet established. However, selective screening may be appropriate for high-risk women who would consider HRT only if they knew they were at high-risk for osteoporosis or fracture.
0. Preventive measures related to fracture risk, such as dietary calcium and vitamin D intake, weight-bearing exercise, smoking cessation and education to reduce the risk of falls and the severity of fall-related injuries are recommended.23

The American Association of Clinical Endocrinologists (AACE) recommends that bone density measurements occur in the following cases:

0. For risk assessment in perimenopausal or post menopausal women who are concerned about osteoporosis and willing to accept interventions;
0. In women with x-ray findings that suggest the presence of osteoporosis;
0. In women beginning or receiving long term glucocorticoid therapy, provided intervention is an option;
0. For perimenopausal or postmenopausal women with asymptomatic primary hyperparathyroidism in whom evidence of skeletal loss may result in parathyroidectomy;
0. For women undergoing treatment for osteoporosis, as a tool for monitoring therapeutic response.40

Appendix V: Distribution Plan
Bone Densitometry as a Screening Tool for Osteoporosis in Postmenopausal Women will be sent to the following associations and organizations:

Academy of Osteopathic Directors of Medical Education
American Academy of Family Physicians
American Academy of Osteopathy
American Aging Association
American Association of Retired Persons
American Association for Women Radiologists
American College of Medicine
American College of Obstetricians and Gynecologists
American College of Osteopathic Obstetrics and Gynecologists
American College of Physicians
American College of Radiology
American College of Rheumatology
American Federation for Aging Research
American Foundation for Aging Research
American Geriatrics Society
American Gynecological and Obstetrical Society
American Healthcare Radiology Administrators
American Medical Directors Association
American Osteopathic College of Radiology
American Registry of Clinical Radiography Technologists
American Senior Citizens Association
American Society on Aging
American Society for Bone and Mineral Research
American Society of Clinic Radiologists
American Society of Internal Medicine
American Society of Radiologic Technologists
Association of Professors of Gynecology and Obstetrics
Association of University Radiologists
Center for the Study of Pharmacy and Therapeutics for the Elderly
Council on Resident Education in Obstetrics and Gynecology
Endocrine Society
Family and Health Section of the National Council on Family Relations
Gerontological Society of America
International Society for Clinical Laboratory Technology
Interstate Postgraduate Medical Association of North America
Minnesota Radiological Society
Minnesota Society of Radiologic Technologists
National Association of Orthopaedic Technologists
National Board for Certification of Orthopaedic Technologists
National Geriatrics Society
National Osteoporosis Foundation
North American Menopause Society
Orthopedic Research Society
Radiological Society of North America
Society for Gynecologic Investigation
Society of General Internal Medicine
Society of Teachers of Family Medicine
Special Constituency Section for Aging and Long Term Care Services

Appendix VI: Public Comments on Preliminary HTAC Report
A preliminary version of this report was released for public comment on May 19, 1997. Comments received may have resulted in additions, revisions or deletions to the report. Therefore, the page and paragraph numbers referenced in the following written comments may not coincide with the page numbers in this final report. Appendix VII: Summary of Public Testimony

The Minnesota Health Care Commission took testimony on June 18, 1997 regarding HTAC's final report, Bone Densitometry as a Screening Tool for Osteoporosis in Postmenopausal Women. A summary of that testimony follows.

**Russell E. Walker, Director of Product Development, OsteoGram Analysis Center.**

OsteoGram is a physiological laboratory providing computer analysis of x-rays by Radiographic Absorptiometry. OsteoGram is a division of the Bone Measurement Institute, a non-profit subsidiary of Merck & Co., Inc.

Mr. Walker thanked the Commission for the opportunity to speak, noting that overall, HTAC's report on bone densitometry is “a valuable and informative document that should help to educate the Minnesota health care community.” However, Mr. Walker stated that the report contains “outdated and inaccurate information” on one bone densitometry technology, radiographic absorptiometry (RA). Citing recent research, Mr. Walker asserted the following:
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0. RA can precisely and accurately assess bone loss associated with osteoporosis, and can reliably predict fracture risk in women with the disease.
0. As currently used, RA does not expose patients to unsafe levels of radiation.

Minnesota is the only state which does not allow the use of the non-screen film employed by RA, thus restricting access to a safe, effective and low cost diagnostic tool. It was Mr. Walker's opinion that Minnesota should amend its administrative rules to allow RA's use in the state.

Christine Simonelli, M.D., Osteoporosis Services, HealthEast Medical Research Institute.

Dr. Simonelli is a practicing physician in Minnesota.
Dr. Simonelli made the following points during her testimony before the Commission:

0. Osteoporosis is a major public health problem which will continue to grow as our populations ages.
0. Bone densitometry is needed to stratify women at risk for the disease into high- and intermediate-risk groups to offer therapy or prevention.
0. The relationship between bone density and fracture risk is well established.
0. Although dual-energy x-ray absorptiometry (DXA) remains the “gold standard” in bone densitometry, it is not readily accessible due its cost and availability in Minnesota.
0. Radiographic absorptiometry (RA) is a viable, low-cost alternative when DXA is not available.
0. RA is precise and accurate and agrees with the results of other bone density measurement methods.
0. RA is a safe, reliable and clinically accepted tool for the diagnosis of osteoporosis.

Based on the above information, Dr. Simonelli asserted that RA should be an alternative that is available to clinicians in Minnesota.

Joel E. Gray, Ph.D., Consultant, Medical Physics and Imaging Sciences.

Dr. Gray's education and experience includes photographic sciences, physics, physiology, anatomy, radiographic imaging, and epidemiology.
Dr. Gray was in agreement with HTAC's findings that radiographic absorptiometry (RA) is a technique which uses outdated technology and is a less than optimal diagnostic tool with relatively high radiation exposures. According to Dr. Gray:

0. CRA exposes the patient to 88 times more radiation than dual-energy x-ray absorptiometry (DXA)-530 mR versus 6 mR.
0. The radiation exposure from RA is equivalent to 35 chest x-rays and 4 mammographic images.
0. There is no such thing as “safe limits” where exposure to x-ray radiation is concerned. Any x-ray exposure results in increased risk for disease.
0. RA technology does not have to use non-screen film if a wedge is included in the image and the equipment is calibrated appropriately.
0. Although the literature shows a correlation between measurements obtained using RA of the forearm and DXA of the hip and spine, this does not mean they are equivalent.

It was Dr. Gray's opinion that Minnesota is not behind other states which currently allow the use of non-screen film employed by RA, but was in the forefront by banning its use.

References:
References


Bone Densitometry as a Screening Tool for Osteoporosis in Postmenopausal Women


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