Guideline Summary NGC-7930

Guideline Title
ACR Appropriateness Criteria® osteoporosis and bone mineral density.

Bibliographic Source(s)

Guideline Status
This is the current release of the guideline.
The appropriateness criteria are reviewed biennially and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

Scope

Disease/Condition(s)
Osteoporosis and osteoporotic fractures

Guideline Category
Diagnosis
Evaluation
Risk Assessment
Screening

Clinical Specialty
Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Radiology

Intended Users
Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

Guideline Objective(s)
To evaluate the appropriateness of bone mineral density (BMD) measurement procedures for osteoporosis

Target Population
Patients at risk of developing osteoporosis

Interventions and Practices Considered
1. Dual X-ray absorptiometry (DXA)
   - Posteroanterior (PA) spine
   - Proximal femur, femoral neck, and total hip
   - Forearm
   - Lateral spine
   - Total body composition
   - Bone mineral content (density)
   - Vertebral fracture assessment (VFA)
2. Quantitative computed tomography (QCT)
   - Spine
   - Proximal femur
3. Peripheral quantitative computed tomography (pQCT), forearm
4. Single x-ray absorptiometry/dual energy x-ray absorptiometry (SXA/DXA), heel
5. Quantitative ultrasound (QUS), heel
6. X-ray, thoracic and lumbar spine
7. Radiographic absorptiometry
8. Height by stadiometer

Major Outcomes Considered
Utility of radiologic examinations in differential diagnosis

Methodology

Methods Used to Collect/Select the Evidence
Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure
The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term “diagnostic imaging” captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.
1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.
The search strategy may be revised to improve the output as needed.

Number of Source Documents
The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence
Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key
Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis and results.
Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.
Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

**Methods Used to Analyze the Evidence**

Systematic Review with Evidence Tables

**Description of the Methods Used to Analyze the Evidence**

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the American College of Radiology (ACR) Appropriateness Criteria® Evidence Table Development document (see "Availability of Companion Documents" field).

**Methods Used to Formulate the Recommendations**

Expert Consensus (Delphi)

**Description of Methods Used to Formulate the Recommendations**

**Modified Delphi Technique**

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria (AC) topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three ratings rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is proposed as the panel’s consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

**Rating Scheme for the Strength of the Recommendations**

Not applicable

**Cost Analysis**

The guideline developers reviewed published cost analyses.

**Method of Guideline Validation**

Internal Peer Review

**Description of Method of Guideline Validation**

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

**Recommendations**

**Major Recommendations**

**ACR Appropriateness Criteria®**

**Clinical Condition: Osteoporosis and Bone Mineral Density**

**Variant 1**: Identification of low bone density and fracture risk in asymptomatic patient. Postmenopausal females, greater than 50 years of age. Females in menopausal transition (late 40s). Males greater than 50 years of age with risk factors. All races.
<table>
<thead>
<tr>
<th>Radiologic Procedure</th>
<th>Rating</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA PA spine</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>DXA proximal femur and femoral neck and total hip</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>QCT spine</td>
<td>8</td>
<td>Advantages: More sensitive than DXA for density changes in the vertebral body. QCT can be used to assess/monitor patients with extensive degenerative disc disease. Disadvantages: Higher radiation dose. WHO diagnostic criteria do not apply. Diagnosis of low bone mass is made using QCT criteria. Technically more difficult than DXA unless spiral technique is used.</td>
</tr>
<tr>
<td>X-ray thoracic or lumbar spine</td>
<td>5</td>
<td>Advantages: Useful for identifying fractures, insufficiency fractures and differentiating demineralization as local or diffuse. Disadvantages: Significant amount of bone loss occurs before osteopenia/osteoporosis is identified.</td>
</tr>
<tr>
<td>QUS heel</td>
<td>4</td>
<td>Can be used for preliminary evaluation of patients at risk for fracture. If abnormal, DXA may follow.</td>
</tr>
<tr>
<td>DXA forearm</td>
<td>3</td>
<td>Only if hip/spine or hip/hip cannot be done or patient over the table limit for weight. Primary site for patients with hyperparathyroidism.</td>
</tr>
<tr>
<td>DXA/DEXA heel</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>QCT proximal femur</td>
<td>3</td>
<td>Limited clinical experience. Currently, primarily a research tool.</td>
</tr>
<tr>
<td>pQCT forearm</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Radiographic absorptometry</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

**Rating Scale:** 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

**Relative Radiation Level**

**Note:** Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- World Health Organization (WHO) diagnostic criteria was originally made for 65-year-old postmenopausal Caucasian women using DXA of the spine, femoral neck, and forearm, T-score.
- International Society for Clinical Densitometry (ISCD) position statements changed indications to 50-year-old males and postmenopausal females using the WHO diagnostic criteria. T-score and Z-score are used to further evaluate non-Caucasian individuals with an age-matched reference data base.
- Forearm scans are used as a primary site for evaluating hyperparathyroidism, obesity (over table limit), and as a second site if only one other is available. Preference is for two sites beginning with hip/AP spine; if spine cannot be scanned then use hip/hip; if only one hip is available then use hip/forearm or alternatively hip/total body. Total body is rarely used in adults, especially for follow-up unless total body composition is measured.
- Fracture risk assessment is part of reporting BMD and should be a combination of clinical risk factors and BMD. The comparison group should be indicated when relative fracture risk is reported.
- Any device above can predict fracture risk, but if the patient has had a DXA or QCT, the fracture risk should be based on that study. Once DXA or QCT is begun, a peripheral device should not be used if the patient is found to be at risk. Conversely, if a patient is at risk with a peripheral device then DXA (preferably for diagnosis) or QCT should be performed and followed on that specific device. Once treatment has started, fracture risk is more difficult to estimate.

**Variant 2: Follow-up. Patients demonstrated to have risk for fracture or low density.**

<table>
<thead>
<tr>
<th>Radiologic Procedure</th>
<th>Rating</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA PA spine</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>DXA proximal femur and femoral neck and total hip</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>QCT spine</td>
<td>8</td>
<td>Advantages: More sensitive than DXA for density changes in the vertebral body. QCT can be used to assess/monitor patients with extensive degenerative disc disease. Disadvantages: Higher radiation dose. WHO diagnostic criteria do not apply. Diagnosis of low bone mass is made using QCT criteria. Technically more difficult than DXA unless spiral technique is used.</td>
</tr>
<tr>
<td>DXA forearm</td>
<td>3</td>
<td>Response to treatment significantly slower. Primary site for patients with hyperparathyroidism.</td>
</tr>
<tr>
<td>DXA proximal femur</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>QCT proximal femur</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>DXA lateral spine</td>
<td>1</td>
<td>Low precision and inadequate reference database</td>
</tr>
</tbody>
</table>

**Rating Scale:** 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

**Relative Radiation Level**

**Note:** Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- BMD is compared in gm/cm² – NOT T-score or Z-score.
- QCT reported in g/cm².
- Follow-up scans are used to determine bone loss or gain in patients at risk for loss and not taking treatment to help make a decision about treatment, or in patients undergoing treatment to determine compliance, efficacy.
- An example of a patient who should have follow-up is one being treated with corticosteroids.
- An example of a patient who should have follow-up is one being treated with corticosteroids.
- The patient is followed every 2 years (postmenopausal women) until BMD stabilizes. Then follow-up can be lengthened unless risk factors or treatment changes.

**Variant 3: Identify low BMD. Premenopausal females with risk factors. Males 20 to 50 years of age with risk factors. All races.**

<table>
<thead>
<tr>
<th>Radiologic Procedure</th>
<th>Rating</th>
<th>Comments</th>
<th>RRL</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA PA spine</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DXA proximal femur and femoral neck and total hip</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>QCT spine</td>
<td>5</td>
<td>Advantages: More sensitive than DXA for density changes in the vertebral body. QCT can be used to assess/monitor patients with extensive degenerative disc disease. Disadvantages: Higher radiation dose. WHO diagnostic criteria do not apply. Diagnosis of low bone mass is made using QCT criteria. Technically more difficult than DXA unless spiral technique is used.</td>
<td></td>
</tr>
<tr>
<td>QCT proximal femur</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SXA/DXA heel</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DXA forearm</td>
<td>2</td>
<td>Only if hip/spine or hip/hip cannot be done or patient over the table limit for weight. Primary site for patients with hyperparathyroidism.</td>
<td></td>
</tr>
<tr>
<td>QUS heel</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pQCT forearm</td>
<td>2</td>
<td>Limited usage in United States.</td>
<td></td>
</tr>
</tbody>
</table>

Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.
- WHO diagnostic criteria do not apply to this group, Z-score ONLY is used (two standard deviations or more below age-matched reference database) to determine whether BMD is below expected for age.
- There are no fracture risk data for BMD in this age group.
- Peripheral devices above determine fracture risk and suggest low BMD.

**Variant 4: Follow-up to low BMD. Premenopausal females with risk factors. Males 20 to 50 years of age with risk factors. All races.**

<table>
<thead>
<tr>
<th>Radiologic Procedure</th>
<th>Rating</th>
<th>Comments</th>
<th>RRL</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA PA spine</td>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DXA proximal femur and femoral neck and total hip</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>QCT spine</td>
<td>5</td>
<td>Precision less than for PA spine. Technically demanding.</td>
<td></td>
</tr>
<tr>
<td>QCT proximal femur</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DXA lateral spine</td>
<td>2</td>
<td>Primary site for patients with hyperparathyroidism.</td>
<td></td>
</tr>
<tr>
<td>DXA forearm</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.
- BMD in gm/cm², NOT Z-score, is used for follow-up comparison.
- QCT reported in gm/cm².

**Variant 5: Diagnosis. Males and females greater than 50 years of age with advanced degenerative changes of the spine with or without scoliosis.**

<table>
<thead>
<tr>
<th>Radiologic Procedure</th>
<th>Rating</th>
<th>Comments</th>
<th>RRL</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA proximal femur and femoral neck and total hip</td>
<td>9</td>
<td>When PA spine cannot be assessed, hip/hip (bilateral) scans should be performed. However, hip and forearm are recommended for two sites, noting that in both areas, BMD changes take longer than in the spine, especially in the forearm. If only one hip is available for assessment, hip and forearm can be used.</td>
<td></td>
</tr>
<tr>
<td>QCT spine</td>
<td>9</td>
<td>Advantages: More sensitive than DXA for density changes in the vertebral body. QCT can be used to assess/monitor patients with extensive degenerative disc disease. Disadvantages: Higher radiation dose. WHO diagnostic criteria do not apply. Diagnosis of low bone mass is made using QCT criteria. Technically more difficult than DXA unless spiral technique is used.</td>
<td></td>
</tr>
<tr>
<td>DXA forearm</td>
<td>3</td>
<td>Appropriate site for patients with hyperparathyroidism.</td>
<td></td>
</tr>
<tr>
<td>QCT proximal femur</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.
Variant 6: Identify low BMD. Pediatric patients (less than 20 years of age) with risk factors.

<table>
<thead>
<tr>
<th>Radiologic Procedure</th>
<th>Rating</th>
<th>Comments</th>
<th>RRL *</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA for bone mineral content (density)</td>
<td>5</td>
<td>Use reference database from manufacturer. Traditional method of total body density (calcium) BMC used for follow-up.</td>
<td></td>
</tr>
<tr>
<td>DXA total body composition</td>
<td>5</td>
<td>Assesses total body calcium as part of the examination results. Useful in patients with chronic illness (including eating disorders) to assess for nutritional status and intervention.</td>
<td></td>
</tr>
<tr>
<td>DXA PA spine</td>
<td>5</td>
<td>Incomplete database information. Correcting apparent BMD for the patient’s height or weight is recommended.</td>
<td></td>
</tr>
<tr>
<td>QCT spine</td>
<td>5</td>
<td>Limited database. Assessment of trabecular bone in the vertebral body, independent of size; no consensus by pediatric experts.</td>
<td></td>
</tr>
<tr>
<td>DXA total hip</td>
<td>3</td>
<td>Not useful before skeletal maturity.</td>
<td></td>
</tr>
</tbody>
</table>

*Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- WHO diagnostic criteria does not apply. Z-score only is used (2 standard deviations or lower than age-matched reference database) to determine if BMD is lower than expected for age.
- Limited hip DXA database.
- Reporting method for pediatric BMD is controversial at present.

Variant 7: Follow-up. Pediatric patients (less than 20 years of age) with risk factors.

<table>
<thead>
<tr>
<th>Radiologic Procedure</th>
<th>Rating</th>
<th>Comments</th>
<th>RRL *</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA for bone mineral content (density)</td>
<td>5</td>
<td>BMC is followed, theoretical attempt to correct for changes in body size.</td>
<td></td>
</tr>
<tr>
<td>DXA total body composition</td>
<td>5</td>
<td>Used for eating disorders, failure to thrive, athletes, athletic triad, bariatric surgery assessment.</td>
<td></td>
</tr>
<tr>
<td>QCT spine</td>
<td>5</td>
<td>Advantages: More sensitive than DXA for density changes in the vertebral body. QCT can be used to assess/monitor patients with extensive degenerative disc disease. Disadvantages: Higher radiation dose. WHO diagnostic criteria do not apply. Diagnosis of low bone mass is made using QCT criteria. Technically more difficult than DXA unless spiral technique is used.</td>
<td></td>
</tr>
<tr>
<td>DXA PA spine</td>
<td>5</td>
<td>Most accurate in patients that are skeletally mature.</td>
<td></td>
</tr>
<tr>
<td>DXA total hip</td>
<td>2</td>
<td>Most accurate in patients that are skeletally mature.</td>
<td></td>
</tr>
</tbody>
</table>

*Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- Follow-up in pediatrics is not defined. Clinical decisions determine follow-up except for corticosteroid-treated patients who are scanned at the same interval at any age.
- Confounding factors in follow-up of these patients are a changing measurement area because of increasing size of bone and the method for determining if BMD change is real. QCT avoids this pitfall because of volumetric measurement.
- Very little data are available for hip DXA in children.

Variant 8: Suspected fracture, incident or prevalent, of a vertebral body based on clinical history, height loss, or patient treated with corticosteroids.

<table>
<thead>
<tr>
<th>Radiologic Procedure</th>
<th>Rating</th>
<th>Comments</th>
<th>RRL *</th>
</tr>
</thead>
<tbody>
<tr>
<td>DXA VFA</td>
<td>9</td>
<td>Should help treatment decision. Point of service, generally limited to T7-L4. Learning curve.</td>
<td></td>
</tr>
<tr>
<td>X-ray thoracic and lumbar spine</td>
<td>8</td>
<td>High radiation dose, high cost.</td>
<td></td>
</tr>
<tr>
<td>Height by stadiometer</td>
<td>4</td>
<td>Indicated height loss that may be related to vertebral fractures.</td>
<td></td>
</tr>
</tbody>
</table>

*Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

- Identification of incident or prevalent vertebral fracture indicates increased risk for additional vertebral or other fragility fractures in the following year and should influence therapy.
- VFA's reduced radiation, lower cost, and point of service, make it preferable to spine radiographs as an initial evaluation technique unless it is contraindicated.
Summary of Literature Review

Noninvasive measurement of bone mineral density (BMD) is a technology that benefits both the patient (as are mammography, blood pressure testing, and cholesterol measurement) and society through its potential to decrease the morbidity, mortality, and cost of fractures associated with osteoporosis through early detection and treatment.

Bone densitometry is the only technology available for accurately measuring of bone mass or predicting fracture risk. Bone measurements have been shown to predict fracture risk as well as or better than cholesterol measurements predict the risk of heart disease or blood pressure measurements predict the risk of stroke. This unique ability of bone densitometry to predict fracture risk makes it an important tool for disease prevention. Before its advent, the diagnosis of osteoporosis was based on the presence of fractures. With the advent of bone densitometry and the recognition of the relation between reductions in bone mass and increases in fracture risk, the diagnosis of osteoporosis, using World Health Organization (WHO) criteria modified by the International Society for Clinical Densitometry (ISCD) to apply to males, females going through menopausal transition near 50 years of age when rapid bone loss may occur prior to menopausal completion, and females of all races >50 years of age — can and should be made according to the level of bone mass as determined by BMD before fractures occur. Osteoporosis cannot be otherwise diagnosed by BMD in individuals less than 50 years of age using the modified WHO criteria. The only statement that can be made is that if the Z-score (the age-matched database recommended by ISCD for evaluating patients <50 years of age, including pediatric patients) is more than two standard deviations below the mean, the BMD is below the expected range for age.

Osteoporosis is a clinical diagnosis in patients <50 years of age or with the presence of a fracture. Appropriate etiologies should be investigated (secondary causes for low BMD are numerous), appropriate interventions applied, and appropriate longitudinal monitoring initiated in all age groups.

Assessment of fracture risk and an estimation of benefit from interventions designed to reduce fracture risk should be based on a patient's current relative fracture risk, as determined by measured BMD. Relative fracture risk is determined using T-score and Z-score. When reporting relative fracture risk, the reference group used must be identified. Ten-year fracture probability is currently available, released by the WHO, for reporting fracture risk and in part depends upon clinical and BMD. The FRAX® model, which is felt to limit its utility since spine and total hip measurements are considered important regions of interest (ROI) for correlating fracture risk. Limitations on the use of the FRAX® risk calculator are: 1) it should not be used for premenopausal women, 2) it should not be used for patients previously treated for osteoporosis, and 3) it should be understood that this is a beta version, not clinically validated for the US, population, although it has been endorsed by the National Osteoporosis Foundation (NOF). Since its release it has already undergone correction for risk calculation. Recent articles have also questioned the utility of the FRAX® in various populations including overweight/young people and the very elderly. Additionally, there is no weighing for fracture risk of falls. The risk assessment is meant as a guide for clinicians who are not experts in bone disease and has the caveat that it is only a guideline. It should not replace good clinical decision-making. Assessment of appropriate treatment can be made using fracture risk as long as the parameters of the fracture risk are defined.

In specific clinical circumstances, BMD can provide otherwise unobtainable information that is necessary to the clinical decision-making process. In 1999, a subcommittee of the Scientific Advisory Board of the National Osteoporosis Foundation (NOF) described four clinical situations in which knowledge of the patient's bone mass or fracture risk could affect clinical management decisions. These risks included estrogen deficiency, vertebral abnormalities or suspected osteoporosis on radiography, asymptomatic primary hyperparathyroidism, and long-term corticosteroid therapy if dosage and patient history could be modified to prevent bone loss. Numerous other potential causative factors for low bone mass can be found in the NOF Physicians Guide to Osteoporosis.

Since the NOF originally published its recommendations, clinical experience in establishing the precision of newer BMD measurement techniques has grown so that serial measurements to determine the efficacy of treatments for osteoporosis are also feasible. Also, knowledge of a patient's bone mass may affect clinical management after organ transplantation.

Estrogen-deficient women constitute one of the largest patient populations potentially affected by these recommendations. Women are more likely to initiate preventive measures for osteoporosis if they are aware of the presence of low bone mass. BMD measurement may help an individual decide whether to begin therapy with selective estrogen receptor modulators (SERMs) for prevention in postmenopausal women, or in the case of symptoms, with hormone replacement therapy. Other therapies may be offered depending on the density and clinical factors. In general, a single bone density test can be an extremely powerful tool for patient education and compliance with lifestyle modification and drug therapy. Hence, bone density testing is currently recommended to determine whether pharmacologic intervention is indicated and to establish individual compliance and response in treated patients. The testing, if done in the immediate postmenopausal period, should be performed every 2 years until the possibility of rapid bone loss has been determined or BMD stabilizes on treatment, or, if necessary, to demonstrate continued bone loss (if it occurs) so a patient can determine whether or not to begin therapy. More frequent follow-up scans may be necessary in patients treated with corticosteroids, transplant patients, and patients treated with parathyroid hormone.

Guidelines for the Clinical Use of BMD Measurement in the Adult Population

An international panel of authorities on BMD headed by Paul D. Miller, MD, Sydney Bonnick, MD, and Clifford Rosen, MD, of the ISCD (see Appendix I for panel members) reached a consensus on the important issues that face physicians who will be ordering, performing, or interpreting BMD measurement for the diagnosis of low bone mass in the adult population. The authors developed guidelines to help physicians use BMD measurement in clinical decision-making. Official positions of the ISCD for BMD practice can be found on the ISCD Web site, www.iscd.org. The most recent position statements were developed in 2005. Many aspects of BMD measurement and reporting are covered.

The WHO guidelines define the basis for osteoporosis. The guidelines are based on using levels of low bone mass in patients who have not yet suffered fracture using dual energy x-ray absorptiometry (DXA) of the spine and femoral neck, and single photon absorptiometry (SPA) of the forearm. BMD measurement is best defined for Caucasian postmenopausal women in whom the risk of osteoporosis is greatest. In addition, the ISCD provided practical guidelines for clinicians to use which patients should be tested, where to test bone mass are required to define, what skeletal site(s) should be measured, what techniques should be used, and how clinical reports can enhance the value of BMD. These diagnostic and utilization guidelines will be followed soon by treatment and intervention guidelines. This complete compendium of information will form the basis of clinical decision-making in caring for patients with low bone mass.

Individual scanner protocols for sites to be scanned are encouraged. The protocols should be agreed upon with referring physicians and/or hospitals so that predictable study outcomes will occur. In general, two sites are measured, spine and a hip. If one of these sites cannot be measured, the protocol should outline the next site to be used. Having a protocol...
should not preclude specific requests by referring physicians who know their patients clinically and manage their care. For instance, a forearm scan may be ordered in a patient with hyperparathyroidism. If an order is not consistent with protocol and is without a reasonable clinical indication, an action plan should be developed in the protocol to ensure the scan is warranted clinically. Communication with the referring physician should be part of the protocol.

Scans of the anteroposterior (AP) spine and hip are generally performed. In the event of vertebral fracture, scans of two or three vertebral levels can be used to assess BMD. If degenerative change or multiple fractures preclude use of AP spine scan, both hips can be scanned. One manufacturer provides a dual hip positioner. If only one hip is available, hip and forearm scans are recommended. The forearm is best for evaluating hyperparathyroidism. In general, the bone loss in senile or hormonal related osteoporosis is less and slower in the forearm unless the loss is rapid or aggressive and the response to therapy is slower.

The ability of bone mass to predict future fracture risk is as valuable as cholesterol testing or blood pressure measurements are for predicting heart attack or stroke and they should be used more widely to identify at-risk patients. Osteoporosis can be diagnosed on the basis of BMD even in the absence of prevalent fractures. Diagnosing osteoporosis before a fracture occurs is important concept advancement. It is justified by the recognized inverse and exponential relationship between low bone mass and future fracture risk and by the exceedingly high risk of a second fracture once the first fracture has occurred.

The identification of individuals with high risk of fracture is performed on many types of scanners. The diagnosis of osteoporosis can only be made using WHO criteria with DXA scans. Quantitative computed tomography (QCT) can identify patients with low BMD compared to the QCT reference database and who are at risk for fracture. QCT cannot be used to diagnose osteoporosis based on the quantitative BMD value obtained, since it has never been validated for WHO criteria. It is, however, the only other technology besides DXA that is approved for following treatment.

If a patient is originally scanned on DXA but cannot be followed on that scanner and QCT is available, it can be used with the understanding that the first scan becomes the new baseline for the QCT, and follow-up is based on this baseline. Multidetector computed tomography (MDCT) has higher spatial and allows for more accurate analysis (including trabecular, total vertebral bodies, and central vertebral bodies) at the trade-off of higher radiation dose and using only two vertebral bodies (L1-L2) for analysis in an attempt to decrease radiation exposure.

BMD measurement provides information that can affect the management of patients. It should be performed in any patient of any age or sex when the result will influence clinical decisions. The clinical decisions that may follow the results are diverse and include whether to initiate hormonal replacement therapy, to diagnose osteoporosis in a young fracturing anemic athlete, or to monitor longitudinal changes in a patient receiving pharmacological therapy to prevent or treat osteoporosis.

Choice of the appropriate site(s) for assessing bone mass or fracture risk may vary, depending on the specific circumstances of the patient. Because bone mass is discordant in the younger, perimenopausal population, if the first skeletal site measured is normal, it may be necessary to measure a second skeletal site to make an accurate diagnosis. Measuring more than one skeletal site may also be necessary if artifacts invalidate a particular site. Decisions about which site to measure and how many sites to measure should be made by the referring physician and radiologist based on the disease history, laboratory and expert opinion pattern of interest (e.g., patient with hyperparathyroidism). In general, because cancellous bone changes more rapidly than cortical bone over time or with therapeutic intervention, cancellous bone sites (axial skeleton) may be the preferred sites to measure, though cortical bone sites (mid radius, femoral neck) may also prove valuable and independent data. Also, when performing serial measurements in patients to monitor the natural course of bone loss (or gain) or the response to pharmacological intervention, clinicians must know if the changes are real or within the precision error of a particular measurement and a particular patient.

Total body density (TBD) calcium measurement by DXA has the best precision of any site measured by this technology. It performs best in the pediatric population, but is not reimbursed. Recently pediatric bone experts have stated that densitometric assessment of the pediatric population should include TBD calcium with and without the head included since the head may affect assessment in younger individuals. Lumbar and femoral BMD may also be assessed using bone mineral apparent density (BMAD) analysis. Pediatric BMD assessment continues to be difficult, however, since there are many variables and factors to consider including: weight, Tanner stage, height, and others. The choice of reference database is also difficult since most use data from pediatric phantom studies. BMAD is not a routine determination provided by manufacturers’ databases, and there is a recommendation that local reference databases be established for pediatric populations — a difficult task that is unlikely to be successful. As with adults the reference database used should be indicated. No standard calibration phantom exists for TBD. Body composition data can also be derived from these scans.

Choice of the appropriate technique for BMD measurement in a given clinical circumstance should be based on an understanding of the strengths and limitations of the different techniques. All BMD techniques are good for identifying patients at risk for fracture. The choice of which one(s) to use for any patient should also be at the discretion of the physician. In most countries, DXA is the most widely used technique because of its low precision error, low radiation exposure, large clinical experience, and capacity to measure multiple skeletal sites. However, other techniques such as QCT, ultrasound, single x-ray absorptiometry (SXA) of the wrist or calcaneous, peripheral quantitative computed tomographic (pQCT), and hand radiographic density and CT, or hand radiographic density and CT, may offer information not assessed by DXA. Some of these lower-cost techniques may be used to identify a larger percentage of the population at risk for fracture and low bone mass. Whatever technique is used, quality control and quality assurance, including appropriate physician and technologist training, are paramount for providing competent patient assessment. In situations where DXA is not readily accessible to the target population, such as in small rural practices, QCT is the best alternative test, because body CT scanners are widely available. Although QCT (unlike DXA) can selectively evaluate high-turnover cancellous bone and is the best predictor of vertebral fracture risk, its relative disadvantages include higher radiation dose, lower precision, accuracy, and speed, and lower patient throughput because it is not performed on dedicated densitometric equipment. It should be noted that DXA scanners can be transported to facilitate patient access.

BMD technologies are not interchangeable. A patient cannot be scanned on DXA and then followed by QCT without establishing a baseline on QCT. The ISCD recommendation is to scan the patient on the same scanner as the original baseline for all follow-up scans.

Quantitative Computed Tomography

QCT was developed in the late 1970s by comparing bone to a series of standard liquids in a phantom for which bone density equivalence had been established. Most systems today use liquid or solid phantoms, although there is a phantomless system using muscle and fat in the patient as a comparative standard. In comparison to DXA, QCT provides a true volumetric measurement of bone (milligrams per cubic centimeter (mg/cm³)). It measures trabecular bone density.
Separately from cortical bone, in a two-dimensional QCT scan, the calibration phantom is placed under the patient's back while the body is scanned. A computed radiographic localizer view is obtained to determine the levels of L1 to L3, and each vertebral body is imaged with 1.0-cm section thickness. BMD is then calculated by comparing the spine scan results to the calibrated standards. While this technique is accurate, the reproducibility (precision) can be diminished by variability of slice sampling. The advent of spiral CT scanners and 3-D software that acquire true volumetric images has improved reproducibility. There is also software for measuring the hip that can evaluate cortical, trabecular, and total bone density.

The addition of hip measurement by CT greatly expands the diagnostic utility of QCT. The diagnostic utility of QCT is to identify trabecular loss early, but the WHO criteria do not apply, and osteoporosis cannot be diagnosed on the BMD value alone. Precision of QCT is approximately equal to that at DXA but is operator dependent as is the case with DXA. Patients can be identified as having low BMD and followed for treatment or bone loss.

Trabecular bone is metabolically more active than cortical bone, and is the most sensitive indicator of early bone loss and vertebral fracture risk. There is a strong association between vertebral fracture and spinal trabecular BMD as measured by QCT. QCT has been shown to be able to discriminate between healthy, postmenopausal women and those with vertebral fractures. Spinal trabecular BMD also correlates with trochanteric fracture risk. QCT may be useful in patients with severe scoliosis, facet disease, or hypertrophic arthropathy, in whom DXA scans of the spine will yield spuriously elevated density. It may also be more accurate for obese or exceedingly small individuals for whom the assumptions made in DXA calculations regarding soft tissue may be inaccurate.

Areal measurement of BMD versus true volumetric measurement may also affect the accuracy of areal BMD calculations due to their dependence on body size. Increased bone marrow fat content in the very elderly may exaggerate diminished bone density on QCT, as a single energy measurement (SEQCT). This uncertainty related to fat is far lower than the expected biological variation in the normal population. Also the normal database of SEQCT accounts for most variability of marrow fat with age. Radiation dosage from QCT, although higher than the dosage from pencil-beam DXA, is still quite modest when the scan is performed correctly. Increased radiation exposure with increased versatility of assessment using MDCT was discussed earlier.

Peripheral BMD Measurements

Peripheral BMD measurements, including radiographic absorptiometry (RA) and peripheral DXA and QCT (pDXA and pQCT), are becoming more readily available as techniques to identify people at risk from fracture and low bone mass. Peripheral quantitative ultrasound (QUS), in particular, has low cost, portability, ease of use, and lack of ionizing radiation. An international consensus group has reviewed the technology, and standards have been established to define patients at risk based on standard or modified T-scores obtained with this technology.

Peripheral QUS can assess fracture risk in a manner similar to other peripheral BMD measures. Its capacity for assessing rates of change for monitoring response to therapy has not yet been established. Because it does not measure BMD but rather speed of sound, which may be a parameter of a different quality of bone strength, it may yield additional information regarding fracture risk. However, without specific guidelines to determine whether central testing is necessary, patients with low bone mass may be missed because their peripheral scans are normal. QUS should be used only in screening appropriate patients – postmenopausal and elderly individuals who have not had a DXA and are unable to reach a DXA scanner easily because of rural location. This technology is used most frequently in health fair or other screening events, and if a patient is identified as having an increased risk of fracture he or she should be referred for DXA to confirm the risk of fracture and provide a diagnosis. The DXA then establishes a baseline, and follow-up can be performed. QUS can have false negatives and positives depending on the technology and its age. If a patient has multiple risk factors for fracture or low BMD he or she should be referred for DXA evaluation even if QUS is within normal limits. The use of QUS should be extremely limited, given the number of DXA scanners available.

Peripheral QCT measures cortical and/or trabecular bone in the ultradistal radius and tibia. It may provide information regarding bone strength and may be particularly beneficial in the pediatric population because it measures BMD independently of bone size and with low radiation exposure. Patients at high risk with intermediate levels of peripheral BMD probably have axial measurements in addition. However, more research is necessary to define the optimal algorithms for selecting peripheral versus central BMD measures as well as for selecting appropriate diagnostic and treatment thresholds for all types of densitometry methods and for all manner of patients.

BMD testing should be accompanied by a clinical interpretation. The computer printout data provided by BMD equipment manufacturers do not fully provide the type of clinical information that the primary care physician needs in order to direct patient care. BMD results have wide implications for clinical decisions in the care of patients with low bone mass and may lead to broader diagnostic and therapeutic interventions than can be provided by blood pressure measurements or blood chemistry results. A brief narrative report that correlates the BMD measurement to a technologist-obtained patient questionnaire database can allow the referring physician interpreting the results to suggest wider diagnostic and intervention possibilities. In pediatric patients with risk factors for low bone mass, it is mandatory that DXA scans be performed using specialized pediatric software provided by the equipment manufacturer.

BMD in Men

Recent recognition of osteoporosis as a significant health problem in men, usually related to secondary causes and worsening with age, has raised awareness for the need to assess this population for BMD in the appropriate setting. Prior to age 50, only the Z-score should be used. After age 50, the T-score is used with WHO criteria for diagnosis. Reference databases should be male.

BMD in Premenopausal Women and Children

Specific reasons for evaluating premenopausal women and children should exist before performing the density measurement. Potential for misdiagnosis exists. Corticosteroid treatment, eating disorders, anorexia nervosa and genetic disorders are among the reasons to evaluate this group. Reporting of their BMD is recommended. Due to the utility of DXA and QCT is ongoing. Appropriate age-matched and pediatric databases are required, but these have limited data at this time. In 2007 the ISCD held the first pediatric position development conference with International experts. The recommendations are reflected in the appropriateness tables. The limited position statements are indicative of the difficulty in performing, evaluating, and reporting pediatric densitometry. Measurements of the bone mineral content of the spine and weight-bearing sites and of spine and areal BMD are recommended for patients 5 to 19 years of age. Reporting results may include bone age using the hand, and corrections using height and height age for the scans are made when there is linear growth or maturation delay of an individual patient. DXA is the preferred method of assessment. A position regarding use of QCT was not provided.

Vertebral Fracture Assessment
Vertebral fracture assessment (VFA) is a relatively new application for DXA scanners that allows evaluation for occult fractures of the spine at the time the patient is being evaluated for BMD. The term VFA is used to identify the assessment for billing, approved by Medicare, since manufacturers have used several other proprietary names for the same technique.

Vertebral fractures are the most common osteoporotic fractures. Traditionally radiographs of the thoracic and lumbar spine are used to identify compression fracture if fracture is suspected. The radiation dose and cost of radiographs are significantly higher than those of VFA. The problem is that up to 70% of osteoporotic compression fractures are asymptomatic. The importance of identifying them is that their number and severity are predictors of the likelihood of future fractures. The identification of fracture also changes the acuity of treatment for osteoporosis. Many patients with fractures have an osteopenic BMD, but the presence of a fracture changes the diagnosis to osteoporosis. Prevention of further fracture is cost effective.

Less severe grade 1 fractures may be difficult to identify, and if only one is present, there is much less risk of subsequent fracture. Grades 2 and 3 fractures are readily identified. The technique is usually limited to T7-L4; however, the overwhelming majority of the osteoporotic fractures occur at these levels.

Criteria for use of VFA include: documented height loss of greater than 2 cm or reported height loss of 4 cm since age 21; history of a fracture after age 50, treatment with long term steroids; undocumented history of back pain suspicious for vertebral fracture. (For ISCD position statements see www.iscd.org 5.)

The evaluation for VFA uses the Genant semiquantitative analysis technique with morphometry, semi-automated, as an adjunct in difficult cases.

Summary of Key Recommendations

- BMD measurement is used to identify patients with low bone density and increased fracture risk.
- DXA is the gold standard and the only BMD technology for which WHO criteria for diagnosis of osteoporosis, originally for postmenopausal Caucasian women over age 65, can be used. ISCD has expanded the diagnostic category to include patients over age 50 of any race or gender (ISCD position statement).
- The sites that are used for diagnosis are the AP spine, femoral neck (ISCD includes total hip, and forearm [distal one-third radius]).
- Follow-up for treatment can be performed using DXA and QCT only.
- All other measurements (pDXA, pQCT, Sxa, Qus) are peripheral and for identifying individuals at risk for fracture and low BMD.
- Hyperparathyroidism is an exception to routine BMD testing where the forearm is essential for diagnosis. Another exception is pediatric patients. DXA can measure their spine BMD, but total body calcium is preferred because it helps reduce the problem of following patients with growing bones.

T-scores are used for men and women >50 of age or menopause to make a diagnosis and assess fracture risk. Z-scores are used for all individuals <50 years of age to determine low bone density. Fracture risk is not assessed based on BMD in individuals >50 years of age. No agreed-upon fracture risk assessment exists. WHO and NOF will, in the near future, provide a 10-year absolute fracture risk model that will be available for DXA software. Vertebral fracture assessment can be performed with DXA at the point of service at a lower cost and with less radiation than radiographs. Identification of a prevalent vertebral fracture has an independent risk for future fracture in the following year. Each additional fracture significantly raises the risk of another osteoporotic fracture.


Abbreviations

- AP, anterior-posterior
- BMD, bone mineral density
- DXA, dual x-ray absorptiometry
- QCT, quantitative computed tomography
- PA, posterior-anterior
- pQCT, peripheral quantitative computed tomography
- Sxa, single x-ray absorptiometry
- Qus, quantitative ultrasound
- VFA, vertebral fracture assessment
- WHO, World Health Organization

Relative Radiation Level Designations

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<th>Relative Radiation Level</th>
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<th>Pediatric Effective Dose Estimate Range</th>
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*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation,
Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate bone mineral density (BMD) measurement procedures to evaluate patients at risk for osteoporosis or to diagnose osteoporosis

Potential Harms

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see "Availability of Companion Documents" field).

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient’s clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient’s condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

- Getting Better
- Living with Illness
- Staying Healthy

IOM Domain

- Effectiveness

Identifying Information and Availability

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**Financial Disclosures/Conflicts of Interest:**
Not stated

**Guideline Status:**
This is the current release of the guideline.


The appropriateness criteria are reviewed biennially and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

**Guideline Availability:**

**Availability of Companion Documents:**
The following are available:

**Patient Resources:**
None available

**NGC Status:**
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