



THE INTERNATIONAL SOCIETY
FOR CLINICAL DENSITOMETRY

2007

OFFICIAL POSITIONS

of the
INTERNATIONAL SOCIETY
FOR CLINICAL DENSITOMETRY

The International Society for Clinical Densitometry (ISCD) is a not-for-profit multidisciplinary professional society with a mission to advance excellence in the assessment of skeletal health by standard setting, increasing patient awareness, continuing medical education, public policy, densitometry certification, and supporting clinical and scientific advances in the field.

With the evolution of bone densitometry, differences in technologies, acquisition techniques, reference databases, reporting methods, and terminology have developed. These differences may have adverse effects on patient care and the exchange of scientific information. To address these issues, the ISCD periodically holds Position Development Conferences, a process whereby an international panel of experts makes recommendations based on reviews of the scientific literature by the ISCD's Scientific Advisory Committee. Recommendations that are approved by the ISCD Board of Directors become Official Positions of the ISCD.

All ISCD Official Positions are for worldwide application except where otherwise noted.

These are the Official Positions of the ISCD as updated in 2007. **The Official Positions that are new or revised since 2005 are in bold type.** These Official Positions may also be viewed and downloaded as a text file or PowerPoint presentation from the ISCD Web site at www.ISCD.org.



Indications for Bone Mineral Density (BMD) Testing

- ▶ Women aged 65 and older
- ▶ Postmenopausal women under age 65 with risk factors for fracture.
- ▶ **Women during the menopausal transition with clinical risk factors for fracture, such as low body weight, prior fracture, or high-risk medication use.**
- ▶ Men aged 70 and older.
- ▶ **Men under age 70 with clinical risk factors for fracture.**
- ▶ Adults with a fragility fracture.
- ▶ Adults with a disease or condition associated with low bone mass or bone loss.
- ▶ Adults taking medications associated with low bone mass or bone loss.
- ▶ Anyone being considered for pharmacologic therapy.
- ▶ Anyone being treated, to monitor treatment effect.
- ▶ Anyone not receiving therapy in whom evidence of bone loss would lead to treatment.

Women discontinuing estrogen should be considered for bone density testing according to the indications listed above.

Reference Database for T-Scores

- ▶ Use a uniform Caucasian (non-race adjusted) female normative database for women of all ethnic groups.*
- ▶ Use a uniform Caucasian (non-race adjusted) male normative database for men of all ethnic groups.*
- ▶ The NHANES III database should be used for T-score derivation at the hip regions.

*Note: Application of recommendation may vary according to local requirements.

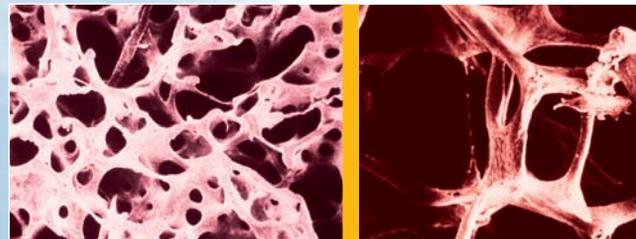
Central DXA for Diagnosis

- ▶ The WHO international reference standard for osteoporosis diagnosis is a T-score of -2.5 or less at the femoral neck.
 - The reference standard from which the T-score is calculated is the female, white, age 20-29 years, NHANES III database
- ▶ Osteoporosis may be diagnosed in postmenopausal women and in men age 50 and older if the T-score of the lumbar spine, total hip, or femoral neck is -2.5 or less:*
- In certain circumstances the 33% radius (also called 1/3 radius) may be utilized

*Note: Other hip regions of interest, including Ward's area and the greater trochanter, should not be used for diagnosis. Application of recommendation may vary according to local requirements.

- ▶ Skeletal sites to measure
 - Measure BMD at both the PA spine and hip in all patients
 - Forearm BMD should be measured under the following circumstances:
 - Hip and/or spine cannot be measured or interpreted
 - Hyperparathyroidism
 - Very obese patients (over the weight limit for DXA table)

- ▶ Spine Region of Interest (ROI)
 - Use PA L1-L4 for spine BMD measurement
 - Use all evaluable vertebrae and only exclude vertebrae that are affected by local structural change or artifact. Use three vertebrae if four cannot be used and two if three cannot be used
 - BMD based diagnostic classification should not be made using a single vertebra
 - If only one evaluable vertebra remains after excluding other vertebrae, diagnosis should be based on a different valid skeletal site
 - Anatomically abnormal vertebrae may be excluded from analysis if:
 - They are clearly abnormal and non-assessable within the resolution of the system; or
 - There is more than a 1.0 T-score difference between the vertebra in question and adjacent vertebrae
 - When vertebrae are excluded, the BMD of the remaining vertebrae is used to derive the T-score
 - The lateral spine should not be used for diagnosis, but may have a role in monitoring
- ▶ Hip ROI
 - Use femoral neck, or total proximal femur whichever is lowest.
 - BMD may be measured at either hip



- There are insufficient data to determine whether mean T-scores for bilateral hip BMD can be used for diagnosis
- The mean hip BMD can be used for monitoring, with total hip being preferred
- ▶ Forearm ROI
 - Use 33% radius (sometimes called one-third radius) of the non-dominant forearm for diagnosis. Other forearm ROI are not recommended

Fracture Risk Assessment

- ▶ A distinction is made between diagnostic classification and the use of BMD for fracture risk assessment.
- ▶ For fracture risk assessment, any well-validated technique can be used, including measurements of more than one site where this has been shown to improve the assessment of risk.

Use of the Term “Osteopenia”

- ▶ The term “osteopenia” is retained, but “low bone mass” or “low bone density” is preferred.
- ▶ People with low bone mass or density are not necessarily at high fracture risk.

BMD Reporting in Postmenopausal Women and in Men Age 50 and Older

- ▶ T-scores are preferred.
- ▶ The WHO densitometric classification is applicable.

BMD Reporting in Females Prior to Menopause and in Males Younger Than Age 50

- ▶ Z-scores, not T-scores, are preferred. This is particularly important in children.

- ▶ A Z-score of -2.0 or lower is defined as “below the expected range for age”, and a Z-score above -2.0 is “within the expected range for age.”
- ▶ **Osteoporosis cannot be diagnosed in men under age 50 on the basis of BMD alone.**
- ▶ **The WHO diagnostic criteria may be applied to women in the menopausal transition.**

Z-Score Reference Database

- ▶ Z-scores should be population specific where adequate reference data exist. For the purpose of Z-score calculation, the patient’s self-reported ethnicity should be used.

Serial BMD Measurements

- ▶ Serial BMD testing can be used to determine whether treatment should be started on untreated patients, because significant loss may be an indication for treatment.
- ▶ Serial BMD testing can monitor response to therapy by finding an increase or stability of bone density.
- ▶ Serial BMD testing can evaluate individuals for non-response by finding loss of bone density, suggesting the need for reevaluation of treatment and evaluation for secondary causes of osteoporosis.
- ▶ Follow-up BMD testing should be done when the expected change in BMD equals or exceeds the least significant change (LSC).





- ▶ Intervals between BMD testing should be determined according to each patient's clinical status: typically one year after initiation or change of therapy is appropriate, with longer intervals once therapeutic effect is established.
- ▶ In conditions associated with rapid bone loss, such as glucocorticoid therapy, testing more frequently is appropriate.

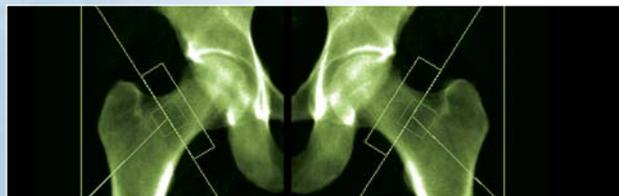
Phantom Scanning and Calibration

The Quality Control (QC) program at a DXA facility should include adherence to manufacturer guidelines for system maintenance. In addition, if not recommended in the manufacturer protocol, the following QC procedures are advised:

- ▶ Perform periodic (at least once per week) phantom scans for any DXA system as an independent assessment of system calibration.
- ▶ Plot and review data from calibration and phantom scans.
- ▶ Verify the phantom mean BMD after any service performed on the densitometer.
- ▶ Establish and enforce corrective action thresholds that trigger a call for service.
- ▶ Maintain service logs.
- ▶ Comply with government inspections, radiation surveys and regulatory requirements.

Precision Assessment

- ▶ Each DXA facility should determine its precision error and calculate the LSC.
- ▶ The precision error supplied by the manufacturer should not be used.
- ▶ If a DXA facility has more than one technologist, an average precision error combining data from all technologists should be used to establish precision error and LSC for the facility, provided the precision error for each technologist is within a pre-established range of acceptable performance.
- ▶ Every technologist should perform an in vivo precision assessment using patients representative of the clinic's patient population.
- ▶ Each technologist should do one complete precision assessment after basic scanning skills have been learned (e.g., manufacturer training) and after having performed approximately 100 patient-scans.
- ▶ A repeat precision assessment should be done if a new DXA system is installed.
- ▶ A repeat precision assessment should be done if a technologist's skill level has changed.
- ▶ To perform a precision analysis:
 - Measure 15 patients 3 times, or 30 patients 2 times, repositioning the patient after each scan
 - Calculate the root mean square standard deviation (RMS-SD) for the group
 - Calculate LSC for the group at 95% confidence interval



- ▶ The minimum acceptable precision for an individual technologist is:
 - Lumbar Spine: 1.9% (LSC=5.3%)
 - Total Hip: 1.8% (LSC=5.0%)
 - Femoral Neck: 2.5% (LSC=6.9%)
 - Retraining is required if a technologist's precision is worse than these values
- ▶ Precision assessment should be standard clinical practice. Precision assessment is not research and may potentially benefit patients. It should not require approval of an institutional review board. Adherence to local radiologic safety regulations is necessary. Performance of a precision assessment requires the consent of participating patients.

Cross-Calibration of DXA Systems

- ▶ When changing hardware, but not the entire system, or when replacing a system with the same technology (manufacturer and model), cross-calibration should be performed by having one technologist do 10 phantom scans, with repositioning, before and after hardware change.
 - If a greater than 1% difference in mean BMD is observed, contact the manufacturer for service/correction
- ▶ When changing an entire system to one made by the same manufacturer using a different technology, or when changing to a system made by a different manufacturer, one approach to cross-calibration is:
 - Scan 30 patients representative of the facility's patient population once on the initial system and then twice on the new system within 60 days

- Measure those anatomic sites commonly measured in clinical practice, typically spine and proximal femur
- Facilities must comply with locally applicable regulations regarding DXA
- Calculate the average BMD relationship and LSC between the initial and new machine using the ISCD DXA Machine Cross-Calibration Tool (www.ISCD.org)
- Use this LSC for comparison between the previous and new system. Inter-system quantitative comparisons can only be made if cross-calibration is performed on each skeletal site commonly measured
- Once a new precision assessment has been performed on the new system, all future scans should be compared to scans performed on the new system using the newly established intra-system LSC
- ▶ If a cross-calibration assessment is not performed, no quantitative comparison to the prior machine can be made. Consequently, a new baseline BMD and intra-system LSC should be established.

BMD Comparison Between Facilities

- ▶ It is not possible to quantitatively compare BMD or to calculate a LSC between facilities without cross-calibration.



Vertebral Fracture Assessment Nomenclature

- ▶ Vertebral Fracture Assessment (VFA) is the correct term to denote densitometric spine imaging performed for the purpose of detecting vertebral fractures.

Indications for VFA

- ▶ Consider VFA when the results may influence clinical management.
- ▶ **Postmenopausal women with low bone mass (osteopenia) by BMD criteria, PLUS any one of the following:**
 - Age greater than or equal to 70 years
 - Historical height loss greater than 4 cm (1.6 in.)
 - Prospective height loss greater than 2 cm (0.8 in.)
 - Self-reported vertebral fracture (not previously documented)
 - Two or more of the following;
 - Age 60 to 69 years
 - Self-reported prior non-vertebral fracture
 - Historical height loss of 2 to 4 cm
 - Chronic systemic diseases associated with increased risk of vertebral fractures (for example, moderate to severe COPD or COAD, seropositive rheumatoid arthritis, Crohn's disease)
- ▶ **Men with low bone mass (osteopenia) by BMD criteria, PLUS any one of the following:**
 - Age 80 years or older
 - Historical height loss greater than 6 cm (2.4 in)
 - Prospective height loss greater than 3 cm (1.2 in)
 - Self-reported vertebral fracture (not previously documented)
 - Two or more of the following;

- Age 70 to 79 years
 - Self-reported prior non-vertebral fracture
 - Historical height loss of 3 to 6 cm
 - On pharmacologic androgen deprivation therapy or following orchiectomy
 - Chronic systemic diseases associated with increased risk of vertebral fractures (for example, moderate to severe COPD or COAD, seropositive rheumatoid arthritis, Crohn's disease)
- ▶ Women or men on chronic glucocorticoid therapy (equivalent to 5 mg or more of prednisone daily for three (3) months or longer).
 - ▶ Postmenopausal women or men with osteoporosis by BMD criteria, if documentation of one or more vertebral fractures will alter clinical management.

Methods for Defining and Reporting Fractures on VFA

- ▶ The methodology utilized for vertebral fracture identification should be similar to standard radiological approaches and be provided in the report.
- ▶ Fracture diagnosis should be based on visual evaluation and include assessment of grade/severity. Morphometry alone is not recommended because it is unreliable for diagnosis.
- ▶ **The Genant visual semi-quantitative method is the current clinical technique of choice for diagnosing vertebral fracture with VFA.**
- ▶ Severity of deformity may be confirmed by morphometric measurement if desired.

Indications for Following VFA With Another Imaging Modality

The decision to perform additional imaging must be based on each patient's overall clinical picture, including the VFA result.

- ▶ **Indications for follow-up imaging studies include:**
 - **Two or more mild (grade 1) deformities without any moderate or severe (grade 2 or 3) deformities**
 - **Lesions in vertebrae that cannot be attributed to benign causes**
 - **Vertebral deformities in a patient with a known history of a relevant malignancy**
 - Equivocal fractures
 - Unidentifiable vertebrae between T7-L4
 - Sclerotic or lytic changes, or findings suggestive of conditions other than osteoporosis

Note: VFA is designed to detect vertebral fractures and not other abnormalities.

Baseline DXA Report: Minimum Requirements

- ▶ Demographics (name, medical record identifying number, date of birth, sex).
- ▶ Requesting provider.
- ▶ Indications for the test.
- ▶ Manufacturer and model of instrument used.
- ▶ Technical quality and limitations of the study, stating why a specific site or ROI is invalid or not included.
- ▶ BMD in g/cm² for each site.
- ▶ The skeletal sites, ROI, and, if appropriate, the side, that were scanned.
- ▶ The T-score and/or Z-score where appropriate.

- ▶ WHO criteria for diagnosis in postmenopausal females and in men age 50 and over.
- ▶ Risk factors including information regarding previous non traumatic fractures.
- ▶ A statement about fracture risk. Any use of relative fracture risk must specify the population of comparison (e.g., young- adult or age-matched). The ISCD favors the use of absolute fracture risk prediction when such methodologies are established.
- ▶ A general statement that a medical evaluation for secondary causes of low BMD may be appropriate.
- ▶ Recommendations for the necessity and timing of the next BMD study.

Follow-Up DXA Report

- ▶ Statement regarding which previous or baseline study and ROI is being used for comparison.
- ▶ Statement about the LSC at your facility and the statistical significance of the comparison.
- ▶ Report significant change, if any, between the current and previous study or studies in g/cm² and percentage.
- ▶ Comments on any outside study including manufacturer and model on which previous studies were performed and the appropriateness of the comparison.
- ▶ Recommendations for the necessity and timing of the next BMD study.



DXA Report: Optional Items

- ▶ Recommendation for further non-BMD testing, such as X-ray, magnetic resonance imaging, computed tomography, etc.
- ▶ Recommendations for pharmacological and non pharmacological interventions.
- ▶ Addition of the percentage compared to a reference population.
- ▶ Specific recommendations for evaluation of secondary osteoporosis.

DXA Report: Items That Should not be Included

- ▶ A statement that there is bone loss without knowledge of previous bone density.
- ▶ Mention of “mild,” “moderate,” or “marked” osteopenia or osteoporosis.
- ▶ Separate diagnoses for different ROI (e.g., osteopenia at the hip and osteoporosis at the spine).
- ▶ Expressions such as “She has the bones of an 80-year-old,” if the patient is not 80 years old.
- ▶ Results from skeletal sites that are not technically valid.
- ▶ The change in BMD if it is not a significant change based on the precision error and LSC.

Components of a VFA Report

- ▶ Patient identification, referring physician, indication(s) for study, technical quality and interpretation.
- ▶ A follow-up VFA report should also include comparability of studies and clinical significance of changes, if any.
- ▶ **VFA reports should comment on the following:**
 - Unevaluable vertebrae
 - Deformed vertebrae, and whether or not the deformities are consistent with vertebral fracture
 - Unexplained vertebral and extra-vertebral pathology
- ▶ Optional components include fracture risk and recommendations for additional studies.

General Recommendations for Non Central DXA Devices: QCT, pQCT, QUS, and pDXA

The following general recommendations for QCT, pQCT, QUS, and pDXA are analogous to those defined for central DXA technologies. Examples of technical differences amongst devices, fracture prediction ability for current manufacturers and equivalence study requirements are provided in the full text documents printed in the *Journal of Clinical Densitometry*[®].

- ▶ Bone density measurements from different devices cannot be directly compared.
- ▶ Different devices should be independently validated for fracture risk prediction by prospective trials, or by demonstration of equivalence to a clinically validated device.



- ▶ T-scores from measurements other than DXA at the femur neck, total femur, lumbar spine, or one-third (33%) radius cannot be used according to the WHO diagnostic classification because those T-scores are not equivalent to T-scores derived by DXA.
- ▶ Device-specific education and training should be provided to the operators and interpreters prior to clinical use.
- ▶ Quality control procedures should be performed regularly.

Baseline Non Central DXA Devices (QCT, pQCT, QUS, pDXA) Report: Minimum Requirements

- ▶ Date of test
- ▶ Demographics (name, date of birth or age, sex)
- ▶ Requesting provider
- ▶ Names of those receiving copy of report
- ▶ Indications for test
- ▶ Manufacturer, and model of instrument and software version
- ▶ Measurement value(s)
- ▶ Reference database
- ▶ Skeletal site/ROI
- ▶ Quality of test
- ▶ Limitations of the test including a statement that the WHO diagnostic classification cannot be applied to T-scores obtained from QCT, pQCT, QUS, and pDXA (other than one-third (33%) radius) measurements
- ▶ Clinical risk factors
- ▶ Fracture risk estimation

- ▶ A general statement that a medical evaluation for secondary causes of low BMD may be appropriate
- ▶ Recommendations for follow-up imaging

Note: A list of appropriate technical items is provided in the QCT and pQCT sections of the full text documents printed in the *Journal of Clinical Densitometry*®.

Non Central DXA Devices (QCT, pQCT, QUS, pDXA) Report: Optional Items

- ▶ Report may include the following optional item:
 - Recommendations for pharmacological and non pharmacological interventions

QCT and pQCT

- ▶ Acquisition
 - With single-slice QCT, L1-L3 should be scanned; with 3D QCT, L1-L2 should be scanned
- ▶ Fracture Prediction
 - Spinal trabecular BMD as measured by QCT has at least the same ability to predict vertebral fractures as AP spinal BMD measured by central DXA in postmenopausal women. There is lack of sufficient evidence to support this position for men
 - There is lack of sufficient evidence to recommend spine QCT for hip fracture prediction in either women or men
 - pQCT of the forearm at the ultra-distal radius predicts hip, but not spine, fragility fractures in postmenopausal women. There is lack of sufficient evidence to support this position for men

▶ Therapeutic Decisions

- Central DXA measurements at the spine and femur are the preferred method for making therapeutic decisions and should be used if possible. However, if central DXA cannot be done, pharmacologic treatment can be initiated if the fracture probability, as assessed by QCT of the spine or pQCT of the radius using device specific thresholds, and in conjunction with clinical risk factors, is sufficiently high

▶ Monitoring

- Trabecular BMD of the lumbar spine measured by QCT can be used to monitor age, disease, and treatment-related BMD changes
- Trabecular and total BMD of the ultra-distal radius measured by pQCT can be used to monitor age-related BMD changes

▶ Reporting

- For QCT using whole body CT scanners the following additional technical items should be reported:
 - Tomographic acquisition and reconstruction parameters
 - kV, mAs
 - Collimation during acquisition
 - Table increment per rotation
 - Table height
 - Reconstructed slice thickness, reconstruction increment
 - Reconstruction kernel

▶ For pQCT using dedicated pQCT scanners, the following additional technical items should be reported:

- Tomographic acquisition and reconstruction parameters
- Reconstructed slice thickness

- Single / multi-slice acquisition mode
- Length of scan range in multi-slice acquisition mode

QUS

▶ Acquisition

- The only validated skeletal site for the clinical use of QUS in osteoporosis management is the heel

▶ Fracture Prediction

- Validated heel QUS devices predict fragility fracture in postmenopausal women (hip, vertebral, and global fracture risk) and men over the age of 65 (hip and all non-vertebral fractures), independently of central DXA BMD
- Discordant results between heel QUS and central DXA are not infrequent and are not necessarily an indication of methodological error
- Heel QUS in conjunction with clinical risk factors can be used to identify a population at very low fracture probability in which no further diagnostic evaluation may be necessary. (Examples of device-specific thresholds and case findings strategy are provided in the full text documents printed in the *Journal of Clinical Densitometry*®.)

▶ Therapeutic Decisions

- Central DXA measurements at the spine and femur are preferred for making therapeutic decisions and should be used if possible. However, if central DXA cannot be done, pharmacologic treatment can be initiated if the fracture probability, as assessed by heel QUS, using device specific thresholds and in conjunction with clinical risk

factors, is sufficiently high. (Examples of device-specific thresholds are provided in the full text documents printed in the *Journal of Clinical Densitometry*®.)

Monitoring

- QUS cannot be used to monitor the skeletal effects of treatments for osteoporosis

pDXA

Fracture Prediction

- Measurement by validated pDXA devices can be used to assess vertebral and global fragility fracture risk in postmenopausal women, however its vertebral fracture predictive ability is weaker than central DXA and heel QUS. There is lack of sufficient evidence to support this position for men
- Radius pDXA in conjunction with clinical risk factors can be used to identify a population at very low fracture probability in which no further diagnostic evaluation may be necessary. (Examples of device-specific thresholds and case findings strategy are provided in the full text documents printed in the *Journal of Clinical Densitometry*®.)

Diagnosis

- The WHO diagnostic classification can only be applied to DXA at the femur neck, total femur, lumbar spine and the one-third (33%) radius ROI measured by DXA or pDXA devices utilizing a validated young-adult reference database

Therapeutic Decisions

- Central DXA measurements at the spine and femur are the preferred method for making therapeutic

decisions and should be used if possible. However, if central DXA cannot be done, pharmacologic treatment can be initiated if the fracture probability, as assessed by radius pDXA (or DXA) using device specific thresholds and in conjunction with clinical risk factors, is sufficiently high. (Examples of device-specific thresholds are provided in the full text documents printed in the *Journal of Clinical Densitometry*®.)

Monitoring

- pDXA devices are not clinically useful in monitoring the skeletal effects of presently available medical treatments for osteoporosis

DXA Nomenclature

- DXA - not DEXA.
- T-score - not T score, t-score, or t score
- Z-score - not Z score, z-score, or z score

DXA Decimal Digits

Preferred number of decimal digits for DXA reporting:

- BMD: 3 digits
(example, 0.927 g/cm²)
- T-score: 1 digit
(example, -2.3)
- Z-score: 1 digit
(example, 1.7)
- BMC: 2 digits
(example, 31.76 g)
- Area: 2 digits
(example, 43.25 cm²)
- % reference database: Integer
(example, 82%)

Notes

Glossary

BMC - bone mineral content

BMD - bone mineral density

DXA - dual-energy X-ray absorptiometry

ISCD – International Society for Clinical Densitometry

LSC - least significant change

NHANES III - National Health and Nutrition Examination Survey III

PA - posterior anterior

pDXA – peripheral dual-energy x-ray absorptiometry

pQCT – peripheral quantitative computed tomography

QC - quality control

QCT - quantitative Computed Tomography

QUS - quantitative Ultrasound

ROI – region(s) of interest

SSI - strain strength index

TBLH - total body less head

VFA - Vertebral Fracture Assessment

vBMD - volumetric BMD

WHO - World Health Organization





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