



International Society for Clinical Densitometry 2007 Adult and Pediatric Official Positions

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ABSTRACT

The International Society for Clinical Densitometry (ISCD) periodically convenes Position Development Conferences (PDCs) in order to establish standards and guidelines for the assessment of skeletal health. The most recent Adult PDC was held July 20–22, 2007, in Lansdowne, Virginia, USA; the first Pediatric PDC was June 20–21, 2007 in Montreal, Quebec, Canada. PDC topics were selected according to clinical relevancy, perceived need for standardization, and likelihood of achieving agreement. Each topic area was assigned to a task force for a comprehensive review of the scientific literature. The findings of the review and recommendations were presented to adult and pediatric international panels of experts. The panels voted on the appropriateness, necessity, quality of the evidence, strength, and applicability (worldwide or variable according to local requirements) of each recommendation. Those recommendations that were approved by the ISCD Board of Directors become Official Positions. This is a review of the methodology of the PDCs and selected ISCD Official Positions.

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Introduction

The International Society for Clinical Densitometry (ISCD) is a professional society composed of clinicians, scientists, and technologists dedicated to enhancing knowledge and improving quality in the assessment of skeletal health. The ISCD strives to accomplish this mission through venues that include educational events, the *Journal of Clinical Densitometry*, certification in bone densitometry, and the establishment of standards and guidelines (Official Positions). New and updated Official Positions have been developed every two years since

2001 at Position Development Conferences (PDCs). The Official Positions provide a reference standard for quality control, acquisition, analysis, interpretation, and reporting of bone density tests. They have advanced the field of bone densitometry by improving the quality and consistency of bone density testing, and have focused attention on topics in need of further study.

The findings of the 2001, 2003, and 2005 PDCs have been published in the *Journal of Clinical Densitometry* [1–3] in association with publications providing supporting evidence, the rationale, and controversies, if any, for each Official Position. In 2007, separate adult and pediatric PDCs were held. The Adult PDC was on July 20–22, 2007, in Lansdowne, Virginia; the Pediatric PDC was June 20–21, 2007, in Montreal, Quebec, Canada. This is a review of the 2007 PDC

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methodology, key participants (Appendices), selected Official Positions for adults, and the complete Official Positions for children and adolescents. Executive summaries, listings of all participants, and supporting evidence are published in the *Journal of Clinical Densitometry* [4,5]. All ISCD Official Positions may be viewed and downloaded online at <http://www.iscd.org>.

Methodology

Topics for the 2007 PDC were selected according to clinical relevancy, a perceived need for standardization, and the likelihood of the expert panelists achieving agreement. Each topic area was assigned a set of clinical questions. Thereafter, an ISCD task force evaluated the medical evidence using a modification of the Cochrane review method [6]. Literature searches were conducted with electronic databases that included PubMed, EMBASE and MEDLINE. Appropriate articles were selected from the searches for further review. A report of the literature review and recommendations for Official Positions were presented to the international panels of experts at the PDCs. The expert panelists reviewed the recommendations and supporting documents, made revisions when appropriate, and at the conclusion of the PDCs proposed that some of them become ISCD Official Positions.

Assessment of potential Official Positions was done with a modification of the RAND Corporation and University of California at Los Angeles method (RAM) [7]. The RAM has been used to determine whether medical procedures or indications are expected to provide a specific health benefit, designated as “appropriate,” that exceeds the potential negative consequences by such a wide margin that the procedure or indication is worth doing, exclusive of cost. The rationale for use of the RAM for the PDC was based on its ability to combine the best available scientific evidence with the collective judgment of experts in the bone field. This method has particular utility with clinical questions for which the medical evidence does not provide a clear answer. Before the PDC, topic questions and sub-questions were converted into recommendation statements that were sent to the expert panelists for an initial “appropriateness” rating. In making its decisions, the expert panelists considered the level of the medical evidence, expert opinion, and the clinical need for a recommendation. In some instances, regulatory issues and costs received consideration. Following the initial rating, the documents supporting all task force recommendations were sent to the expert panelists for review. These statements were then edited, if necessary, according to suggestions from expert panelists. After all statements rated as “appropriate without disagreement” had been selected and all supporting evidence presented, the expert panelists performed a final rating for necessity, quality of the evidence, strength of the recommendation, and application of the recommendation. Proposed Official Positions with supportive evidence were presented at a meeting open to the public. On the final day of the PDC, the expert panelists, in closed session, determined final wording of the proposed Official Positions.

Official Positions of the ISCD

Listed are selected ISCD Official Positions, with those that are new in bold.

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
 - 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.
 - Lateral spine should not be used for diagnosis, but may have a role in monitoring.

- Hip region of interest
 - 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 region of interest
 - Use 33% radius (sometimes called one-third radius) of the non-dominant forearm for diagnosis. Other forearm regions of interest 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.

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.

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**

Method 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 and 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.

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/region of interest
- 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 region of interest 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.

Skeletal health assessment in children and adolescents (Males and Females ages 5–19)

Fracture prediction and definition of osteoporosis

1. Fracture prediction should primarily identify children at risk of clinically significant fractures, such as fracture of long bones in the lower extremities, vertebral compression fractures, or two or more long-bone fractures of the upper extremities.
2. The diagnosis of osteoporosis in children and adolescents should NOT be made on the basis of densitometric criteria alone.
- The diagnosis of osteoporosis requires the presence of both a clinically significant fracture history and low bone mass.

- A clinically significant fracture history is one or more of the following:
 - Long bone fracture of the lower extremities
 - Vertebral compression fracture
 - Two or more long-bone fractures of the upper extremities
- Low bone mineral content or bone mineral density is defined as a BMC or areal BMD Z-score that is less than or equal to -2.0 , adjusted for age, gender and body size, as appropriate.

DXA assessment in children and adolescents with diseases that may affect the skeleton

1. DXA measurement is part of a comprehensive skeletal health assessment in patients with increased risk of fracture.
2. Therapeutic interventions should not be instituted on the basis of a single DXA measurement.
3. When technically feasible, all patients should have spine and total body less head (TBLH) BMC and areal BMD measured
 - Prior to initiation of bone-active treatment.
 - To monitor bone-active treatment in conjunction with other clinical data.
4. In patients with primary bone diseases or potential secondary bone diseases (e.g. due to chronic inflammatory diseases, endocrine disturbances, history of childhood cancer, or prior transplantation (non-renal)), spine and TBLH BMC and areal BMD should be measured at clinical presentation.
5. In patients with thalassemia major, spine and TBLH BMC and areal BMD should be measured at fracture presentation or at age 10 years, whichever is earlier.
6. In children with chronic immobilization (e.g., cerebral palsy) spine and TBLH BMC and areal BMD should be measured at fracture presentation. DXA should not be performed if contractures prevent the safe and appropriate positioning of the child.
7. The minimum time interval for repeating a bone density measurement to monitor treatment with a bone-active agent or disease processes is six months.

DXA interpretation and reporting in children and adolescents

1. DXA is the preferred method for assessing BMC and areal BMD.
2. The PA spine and TBLH are the most accurate and reproducible skeletal sites for performing BMC and areal BMD measurements.
3. Soft tissue measures in conjunction with whole body scans may be helpful in evaluating patients with chronic conditions associated with malnutrition (such as anorexia nervosa, inflammatory bowel disease, cystic fibrosis) or with both muscle and skeletal deficits (such as idiopathic juvenile osteoporosis).
4. The hip (including total hip and proximal femur) is not a reliable site for measurement in growing children due to significant variability in skeletal development and lack of reproducible regions of interest.
5. In children with linear growth or maturational delay, spine and TBLH BMC and areal BMD results should be adjusted for absolute height or height age, or compared to pediatric reference data that provide age-, gender- and height specific Z-scores.
6. An appropriate reference data set must include a sample of the general healthy population sufficiently large to characterize the normal variability in bone measures that takes into consideration gender, age and race/ethnicity.

7. When upgrading densitometer instrumentation or software, it is essential to use reference data valid for the hardware and software technological updates.
8. Baseline DXA reports should contain the following information:
 - DXA manufacturer, model and software version
 - Referring physician
 - Patient age, gender, race/ethnicity, weight and height
 - Relevant medical history including previous fractures
 - Indication for study
 - Bone age results, if available
 - Technical quality
 - BMC and areal BMD
 - BMC and areal BMD Z-score
 - Source of reference data for Z-score calculations
 - Adjustments made for growth and maturation
 - Interpretation
 - Recommendations for the necessity and timing of the next DXA study are optional.
9. Serial DXA testing
 - Should be done only when the expected change in areal BMD equals or exceeds the least significant change
 - Serial DXA reports should include the same information as for baseline testing, but additionally include:
 - Indications for follow-up scan
 - Comparability of studies
 - Interval changes in height, weight
 - BMC and areal BMD Z-scores adjusted or unadjusted for height or other adjustments
 - Percent change in BMC and areal BMD and interval change in Z-scores
 - Recommendations for the necessity and timing of the next BMD study are optional.
10. Accurate interpretation of serial DXA results requires knowledge of the LSC for all sites measured and for all technologists at the DXA testing facility.
11. Terminology
 - T-scores should not appear in pediatric DXA reports.
 - The term “osteopenia” should not appear in pediatric DXA reports.
 - The term “osteoporosis” should not appear in pediatric DXA reports without knowledge of clinically significant fracture history.
 - “Low bone mass for chronologic age” is the preferred term when BMC or BMD Z-score are less than or equal to -2.0 .

pQCT in children and adolescents

1. Reference data are not sufficient for the clinical use of pQCT for fracture prediction or diagnosis of low bone mass.
2. When the forearm is measured, the non-dominant forearm should be used.
3. Measurements sites should include the metaphysis and diaphysis.
4. Determination of the precision error, LSC, and monitoring time interval should be performed as described for DXA.
5. pQCT reports should include
 - Manufacturer, model and software version
 - Referring physician
 - Patient age, gender, race/ethnicity, weight and height
 - Relevant medical history including previous fractures
 - Indication for measurement
 - Bone age results, if available
 - Measurement site

- Limb length
- Scan acquisition and analysis parameters
- Scan technical quality
- Reference data source for Z-score calculation
- Metaphyseal total and trabecular vBMD and Z-scores
- Diaphyseal BMC, cortical vBMD, cortical thickness, cross-sectional moment of inertia, and SSI results and Z-scores.
- Adjustments made for growth and maturation
- Interpretation

Appendix A. Key 2007 Adult PDC participants

Adult PDC expert panelists

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