

Position Statement

Official Positions of the International Society for Clinical Densitometry and Executive Summary of the 2007 ISCD Position Development Conference

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Abstract

The International Society for Clinical Densitometry (ISCD) convenes a Position Development Conference (PDC) every 2 yr to make recommendations for standards in the field of bone densitometry. The recommendations are based on clinically relevant issues in bone densitometry such as quality control, acquisition, analysis, interpretation and reporting. Topics for consideration are developed by the ISCD Board of Directors and its Scientific Advisory Committee. Clinically relevant questions related to each topic area are assigned to task forces for a comprehensive review of the medical literature and subsequent presentation of the reports to an international panel of experts. For this PDC, the Expert Panel included representatives of the American Society for Bone and Mineral Research, International Bone and Mineral Society and the National Osteoporosis Foundation. The recommendations of the PDC Expert Panel are then reviewed by the ISCD Board of Directors. Recommendations that are approved become Official Positions of the ISCD. The most recent PDC was held July 20–22, 2007, in Lansdowne, Virginia, USA. Topics considered included vertebral fracture assessment, technical and clinical issues relevant to dual-energy X-ray absorptiometry (DXA), and bone densitometry technologies other than central DXA. This report describes the methodology and the results of the Lansdowne, Virginia, USA 2007 PDC, and a summary of all ISCD Official Positions, including the ones recently adopted by this PDC and the 2007 Pediatric PDC held in Montreal, Quebec, Canada.

Key Words: Densitometry; dual-energy X-ray absorptiometry; official positions; osteoporosis; recommendations; standards.

Introduction

The International Society for Clinical Densitometry (ISCD) is a multidisciplinary non-profit professional organization dedicated to enhancing knowledge of bone densitometry and its application to skeletal health. ISCD accomplishes

this mission through educational venues (scientific meetings, courses, and publications), certification programs, and recommendations for the use of bone densitometry: the ISCD Official Positions. New Official Positions are considered biannually according to the PDC format. Previously established Official Positions are also re-evaluated periodically at the Position Development Conferences (PDC), as required by new developments in this field. The Official Positions are widely utilized by clinicians and technologists as a reference for quality control, acquisition, analysis, interpretation,

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and reporting. They form the basis for much of the material taught in the ISCD Bone Densitometry Courses.

Official Positions resulting from prior PDCs held biannually from 2001–2005 have previously been reported (1–18). Most recently PDCs were held in Montreal, Quebec, Canada (Pediatric PDC), on June 20–21, 2007, and in Lansdowne, Virginia, USA (Adult PDC), on July 20–22, 2007. This report describes the methodology and results of the 2007 Lansdowne, Virginia PDC and contains a summary of all ISCD Official Positions.

The Official Positions resulting from the PDC are established in order to enhance quality and clinical utility of bone densitometry worldwide. They provide clinicians, technologists and researchers with a reference standard for skeletal health assessment. Since the field of bone densitometry is new and evolving, some clinically important issues that are addressed at the PDCs are not associated with robust medical evidence. Accordingly some Official Positions are based largely on expert opinion. Despite limitations inherent in any process such as this, ISCD believes it is essential to provide clinicians and technologists with the best distillation of current knowledge in the discipline of bone densitometry, and provide an important focus for the scientific community to consider further research to resolve areas of ambiguity and/or ongoing controversy.

The ISCD wishes to acknowledge the extraordinary efforts of the PDC Task Force Chairpersons and members, who are a most distinguished group of international experts. The dedication of these individuals for the past 2 yr has been exemplary.

Methodology

Topic Selection

Topics addressed at the 2007 PDC were selected by the ISCD Board of Directors (BOD) and Scientific Advisory Committee (SAC) according to criteria used for prior PDCs (1,2,14). Each topic selected must be judged to be clinically relevant, have a perceived need for an Official Position due to lack of overwhelming medical evidence or due to its controversial nature, and have a reasonable likelihood of achieving a consensus by the Expert Panel. Many potential topics were considered before identifying the topics that became the subject matter for the 2007 PDC. Additionally, specific questions within each topic area were selected by the Board of Directors, the Scientific Advisory Committee, and the PDC Steering Committee. The five topic areas and associated questions follow:

- Vertebral Fracture Assessment (VFA)
 - a. What are appropriate indications for VFA?
 - b. What is the most appropriate method of vertebral fracture detection with VFA?
 - c. What is the sensitivity and specificity for detection of vertebral fractures with this method?
 - d. When should additional spine imaging be performed following a VFA?

- e. What are the Reporting Obligations for Those Interpreting VFA Images?
- Dual-energy X-ray absorptiometry (DXA) Technical Issues
 - a. What are the guidelines for bone mineral density (BMD) assessment in men?
 - b. How should we classify BMD for women in the menopausal transition?
 - c. How do we define and interpret high BMD?
 - Clinical use of quantitative computed tomography (QCT) and peripheral quantitative computed tomography (pQCT) in the management of osteoporosis in the adult.
 - Quantitative ultrasound (QUS) in the management of osteoporosis.
 - Peripheral dual-energy X-ray absorptiometry (pDXA) in the management of osteoporosis.

For three non-central DXA technologies noted above, the following questions were addressed:

- a. Can QCT/pQCT, QUS and pDXA be used for fracture risk assessment?
- b. Can QCT/pQCT, QUS and pDXA be used to diagnose osteoporosis?
- c. Can QCT/pQCT, QUS and pDXA be used to initiate treatment?
- d. Can QCT/pQCT, QUS and pDXA be used to monitor treatment?
- e. How should QCT/pQCT, QUS and pDXA be interpreted and reported?
- f. What are the quality assurance and quality control (QA/QC) criteria for QCT/pQCT, QUS and pDXA?

PDC Planning

The PDC Steering Committee oversaw the planning for, and conduct of the 2007 PDC. The Steering Committee consisted of the ISCD President-elect (SB), who served as Chair. Other members of the Steering Committee consisted of the President and Past-presidents of ISCD, and a prior PDC Task Force chair. The Steering Committee identified an ISCD member to serve as Task Force chair for each topic area. Task Force members were selected from the SAC and non-SAC experts in bone densitometry and other skeletal health disciplines appropriate to each topic area. The Steering Committee asked each Task Force to consider a series of clinical or technical questions pertaining to their assigned topic. Task Force members performed a medical literature search relevant to these questions using a method modified from that utilized by the Cochrane reviews (19). The literature searches were conducted using electronic databases that included PubMed, EMBASE and MEDLINE. Appropriate articles were selected from the searches for further review. Task Force chairs and members had the option of further refining the initially posed questions. Each Task Force submitted a draft of Official Positions addressing all questions posed.

PDC Expert Panel

Concurrent with Task Force work, international experts in the field of bone densitometry and societies specific to skeletal health were contacted by the PDC Steering Committee to serve as member panelists. Twelve experts agreed to participate on the PDC Expert Panel. In addition to individuals representing many regions of the world, official representatives from The American Society for Bone and Mineral Research (ASBMR), International Society for Bone and Mineral Research (IBMS), and the National Osteoporosis Foundation (NOF) were participants on the Expert Panel. The role of the Expert Panel was to review the proposed Official Positions and supportive documents developed by the task forces and make final recommendations (see below) to the ISCD BOD.

PDC Moderators

PDC panel Moderators with experience in the RAND/UCLA Appropriateness Method (RAM) were selected by the Steering Committee. Two Moderators (JB and SS) assisted the Chair of the PDC (SB) in the development and refinement of statements derived from the initial Task Forces questions and sub-questions, and with the Chair of the PDC lead the discussion and the rating by the Expert Panel during the PDC in Lansdowne, Virginia, USA, July 20–22, 2007.

Grading of the Official Positions

All Official Positions for the 2007 PDC were rated by the Expert Panel in the following categories:

1. *Appropriateness*: Statements that the Expert Panel rated as “appropriate without disagreement” according to predefined criteria derived from the RAM (20) were referred to the ISCD BOD with a recommendation to become ISCD Official Positions (see below). A statement was defined as “appropriate” when the expected health benefit exceeded the expected negative consequences by a significant margin such that it was worth performing (20).
2. *Necessity*: Recommended Official Positions that were rated by the Expert Panel were then rated according to necessity to perform in all circumstances (see below), i.e., whether the health benefits outweighed the risks to such an extent that it must be offered to all patients (20). Necessity rating was conducted in a similar fashion as the appropriateness rating, in that each Official Position had to be rated as necessary without disagreement using similar predefined RAM criteria.
3. *Quality of evidence*:
 - Good*: Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
 - Fair*: Evidence is sufficient to determine effects on outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies.

Poor: Evidence is insufficient to assess the effects on outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

4. *Strength of recommendations*:
 - A: Strong recommendation supported by the evidence
 - B: Recommendation supported by the evidence
 - C: Recommendation supported primarily by expert opinion
5. *Application of recommendations*:
 - W: Worldwide recommendation
 - L: Application of recommendation may vary according to local requirements

Proposed ratings in all cases, except the RAM ratings for appropriateness and necessity for each of the above categories, were included in the preliminary Official Positions crafted by each Task Force. Final ratings were determined by the on site, convened Expert Panel that included appropriateness and necessity.

A rating of “appropriate” was required in order for a statement to be sent to the BOD for selection as an ISCD Official Position. Ratings of each Official Position from the 2007 PDC are expressed in the form of four characters representing quality of the evidence, strength of the recommendation, application of the recommendation, and whether it is necessary as previously described. For example, a rating “Good-A-W-Necessary” indicates that the evidence includes consistent results from well-designed, well-conducted studies in representative populations, a strong recommendation supported by the evidence, worldwide recommendation, and is necessary to perform in all instances. Since PDC topics are often selected because strong medical evidence is unavailable, it is the nature of the process that Official Positions are not always supported by the highest possible level of evidence. Nevertheless, the ISCD Official Positions encourage consistent approaches in the clinical practice of bone densitometry, and focus attention on issues that require further study.

PDC Procedures

Procedures of the 2007 PDC were different from previous PDCs (1,2,14), in that the formulation of statements from initial questions and sub-questions, rating process, and Expert Panel decisions were undertaken according to the RAM (20). The RAM has been applied worldwide for years as a mechanism to determine whether 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 is based on its ability to combine the best available scientific evidence with the collective judgment of worldwide experts in the bone field, to yield appropriate recommendations that are patient- and technology specific.

In summary, after the initial selection of topics by the BOD and SAC, the PDC Steering Committee selected five Task Force chairpersons, one for each of the five major PDC topics. Thereafter, the PDC Steering Committee and Task Force chairpersons worked collectively to select international experts as members of their respective Task Forces with the knowledge required to evaluate their assigned PDC topic. All topic questions and sub-questions that were generated by each Task Force were thoroughly researched in the scientific medical literature using the methodology previously described. Prior to the PDC meeting in Lansdowne, Virginia, USA, topic questions and sub-questions were converted into recommendation statements that were sent to the Expert Panel for an initial “appropriateness” rating. The PDC required a median “appropriateness” rating in either the upper third or lower third of the rating continuum (continuum was 1 to 9 with clusters 7–9 representing the upper third and clusters 1 to 3 representing the lower third) without “disagreement”. “Disagreement” was defined as lack of consensus being predetermined to be four or more Expert Panelists rating in extreme clusters 1–3 and 7–9. In circumstances where the median “appropriateness” rating was less than 7, no Official Position was developed. In making its decisions, the Expert Panel considered the level of the medical evidence, expert opinion and the clinical need for a recommendation. In some instances, regulatory issues received consideration. The statements rated as “appropriate” with a median score of 7 or higher without “disagreement” by the Expert Panel were designated Official Positions. The statements rated as “uncertain” with a median score between four and six or any median score with “disagreement” were further discussed at the PDC. After the initial rating the documents supporting all Task Forces recommendations were sent to the Expert Panelists for review. In brief, Task Force chairs presented reports on their topics supporting the “uncertain” statements to the Expert Panelists in closed session on the first day of the conference. These statements were then edited by Task Force chairs, if necessary, reflecting suggestions made by the Expert Panelists. Re-rating of “uncertain” statements occurred during each Task Force chairpersons presentation when the PDC Moderators felt there was a significant likelihood of change in the opinions of the Expert Panel.

After all statements rated as “appropriate without disagreement” had been selected and all supporting evidence presented, the Expert Panel performed a final rating for necessity, quality of the evidence, strength of the recommendation, and application of the recommendation. The following day, the proposed Official Positions with supportive evidence were presented by the Task Force chairs at a meeting open to the public and attended by ISCD members, representatives from companies with interests in bone health and skeletal assessment, and other individuals with interest in bone disease and densitometry. All participants were encouraged to provide comments and suggestions to the expert panelists. On the third day, the Expert Panelists, in closed session, determined final wording of the proposed Official Positions.

Selection of the 2007 ISCD Official Positions

Following completion of the PDC, the Steering Committee finalized recommendation wording without changing content. These recommendations were then presented to the ISCD BOD for review and voting. The BOD did not alter the content or wording of the proposed Official Positions. Recommendations approved by a majority vote of the ISCD BOD became ISCD Official Positions and are summarized below. The five accompanying papers from the Task Forces provide background, detailed rationale, and published references, which led to these Official Positions. A text file and downloadable PowerPoint presentation of the ISCD Official Positions can be found at the ISCD Web site (www.ISCD.org).

Participants

All 2007 PDC participants are listed in [Appendix 1](#).

Financial Support

Financial support for the 2007 PDC was received in the form of unrestricted grants from The Alliance for Better Bone Health (P&G Pharmaceuticals & Sanofi-Aventis Pharmaceuticals), Amgen Pharmaceuticals, Eli Lilly & Company, Hologic, Inc., Merck Human Health, and Wyeth Pharmaceuticals. These grantors had no role in the selection of PDC topics, participants or ratings for the final ISCD Official Positions.

Cumulative ISCD Official Positions

A summary of the ISCD Official Positions, combining those from the 2001, 2003 and 2005 PDCs with those resulting from this 2007 PDC held in Lansdowne Virginia, USA and the 2007 Pediatric PDC held in Montreal, Quebec, Canada, is provided in [Appendix 2](#).

New ISCD Official Positions

The new ISCD Official Positions resulting from the 2007 PDC are summarized below. It should be noted for a number of Task Force topic questions the Expert Panel could not reach a median score sufficient to rate the associated recommendations as appropriate. This occurred for the DXA Technical Issues Task Force (How do we define and interpret high BMD?) and the VFA Task Force (What are the medical-legal responsibilities of interpreting VFA scans?). This does not imply that the questions were unimportant, but rather the existing supportive scientific information at the time of the PDC was insufficient for the Expert Panel to rate them as “appropriate without disagreement”.

Vertebral Fracture Assessment

Indications for Vertebral Fracture Assessment (VFA)

- Postmenopausal women with low bone mass (osteopenia) by BMD criteria, PLUS any one of the following:

- Age greater than or equal to 70 yr
- 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 yr
 - 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 chronic obstructive pulmonary disorder (COPD) or chronic obstructive airways disease (COAD), seropositive rheumatoid arthritis, Crohn's disease)

Grade: Fair-B-W-Necessary
- Men with low bone mass (osteopenia) by BMD criteria, PLUS any one of the following:
 - Age 80 yr 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 yr
 - 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)

Grade: Fair-C-W
- Women or men on chronic glucocorticoid therapy (equivalent to 5 mg or more of prednisone daily for 3 mo or longer).

Grade: Fair-B-W-Necessary
- Postmenopausal women or men with osteoporosis by BMD criteria, if documentation of one or more vertebral fractures will alter clinical management.

Grade: Good-C-W-Necessary

Recommendations for Interpretation, Reporting and Follow-Up of VFA Studies

- The Genant visual semi-quantitative method is the current clinical technique of choice for diagnosing vertebral fracture with VFA.

Grade: Good-B-W-Necessary
- VFA reports should comment on the following
 - Unevaluable vertebra
 - Deformed vertebra, and whether or not the deformities are consistent with vertebral fracture
 - Unexplained vertebral and extra-vertebral pathology

Grade: Good-C-W-Necessary

- Reasonable 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

Grade: Fair-C-W-Necessary

DXA Technical Issues

- BMD testing in men under age 70 should only be performed in the presence of clinical risk factors for fracture.

Grade: Fair-B-W-Necessary
- Osteoporosis cannot be diagnosed in men under age 50 on the basis of BMD alone.

Grade: Fair-B-W-Necessary
- BMD testing in women during the menopausal transition should only be done if there is a clinical risk factor for fracture, such as low body weight, prior fracture or high-risk medication use.

Grade: Fair-C-W-Necessary
- The world health organization (WHO) diagnostic criteria may be applied to women in the menopausal transition.

Grade: Fair-B-W-Necessary

Technologies Other Than Central DXA

General Recommendations

The following general recommendations 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 published in the Journal of Clinical Densitometry.

- For QCT, pQCT, QUS, and pDXA, bone density measurements from different devices cannot be directly compared.

Grade: Good-A-W-Necessary
- For QCT, pQCT, QUS, and pDXA, different devices should be independently validated for fracture risk prediction by prospective trials or by demonstration of equivalence to a clinically validated device.

Grade: Good-B-W-Necessary
- The WHO diagnostic classification cannot be applied to T-scores from measurements other than DXA at the femur neck, total femur, lumbar spine, or one-third (33%) radius because those T-scores are not equivalent to T-scores derived by DXA.

Grade: Good-A-W-Necessary
- For QCT, pQCT, QUS, and pDXA, device-specific education and training should be given to the operators and interpreters prior to clinical use.

Grade: Good-A-W-Necessary

- Quality control procedures should be performed regularly.
Grade: Good-A-W-Necessary
- For QCT, pQCT, QUS, and pDXA, the report should combine the following standard elements (a list of appropriate technical items for QCT and pQCT are provided in the full text documents published in the Journal of Clinical Densitometry):
 - 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
Grade: Fair-C-W-Necessary
- For QCT, pQCT, QUS, and pDXA, the report may include the following optional item:
 - Recommendations for pharmacological and non pharmacological interventions.
Grade: Fair-C-W

QCT and pQCT

- With single slice QCT, L1-L3 should be scanned; with 3D QCT, L1-L2 should be scanned.
Grade: Fair-B-W-Necessary
- Spinal trabecular BMD as measured by QCT has at least the same ability to predict vertebral fractures as anterior/posterior (AP) spinal BMD measured by central DXA in postmenopausal women. There is lack of sufficient evidence to support this position for men.
Grade: Fair-B-W-Necessary
- There is lack of sufficient evidence to recommend spine QCT for hip fracture prediction in either women or men.
Grade: Good-A-W-Necessary
- 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.
Grade: Fair-B-W-Necessary
- 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.

Grade: Fair-B-W-Necessary

- Trabecular BMD of the lumbar spine, measured by QCT, can be used to monitor age-, disease- and treatment-related BMD changes.
Grade: Fair-B-W-Necessary
- Trabecular and total BMD of the ultra distal radius, measured by pQCT, can be used to monitor age-related BMD changes.
Grade: Fair-B-W
- 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
Grade: Fair-C-W-Necessary
- 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
Grade: Fair-C-W-Necessary

QUS

- The only validated skeletal site for the clinical use of QUS in osteoporosis management is the heel.
Grade: Good-A-W-Necessary
- 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.
Grade: Good-A-W-Necessary
- Discordant results between heel QUS and central DXA are not infrequent and are not necessarily an indication of methodological error.
Grade: Good-A-W-Necessary
- 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 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 published in the Journal of Clinical Densitometry.)
Grade: Fair-C-W-Necessary

- 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 published in the Journal of Clinical Densitometry.)

Grade: Good-B-W-Necessary

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

Grade: Good-A-W-Necessary

pDXA

- 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.

Grade: Fair-B-W-Necessary

- 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.

Grade: Good-A-W-Necessary

- 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 published in the Journal of Clinical Densitometry.)

Grade: Fair-B-W-Necessary

- 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 published in the Journal of Clinical Densitometry.)

Grade: Fair-B-W-Necessary

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

Grade: Good-A-W-Necessary

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Appendix 1.

2007 PDC Participants and Support Staff

Note: Disclosure for the PDC Steering Committee, Task Force chairpersons, Expert Panelists and Moderators is available at www.ISCD.org.

2007 PDC Expert Panelists

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Appendix 2.*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. This is accomplished by improving knowledge and quality of densitometry among healthcare professionals, educating and certifying clinicians and technologists, increasing patient awareness and access to densitometry, 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 task forces associated with the ISCD 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.

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Indications for Bone Mineral Testing (BMD)

- 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.

Note: 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 yr 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.

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 Measurement

- 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 1 yr 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 patient’s 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 ten 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 d.
 - 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 least significant change between the initial and new machine using the ISCD DXA Machine Cross Calibration Tool (www.ISCD.org).
 - Use this least significant change for comparison between 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 least significant change.
- 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 least significant change 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 yr
 - 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 yr
 - 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 yr 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 yr
 - 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 3 mo 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-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 region of interest (ROI) is invalid or not included.
- BMD in g/cm^2 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 nontraumatic 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: Minimum Requirements

- 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/cm^2 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 regions of interest (e.g., osteopenia at the hip and osteoporosis at the spine).
- Expressions such as "She has the bones of an 80-yr-old," if the patient is not 80 yr 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/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.

Skeletal Health Assessment in Children and Adolescents (Males and Females ages 5–19)

Fracture Prediction and Definition of Osteoporosis

- 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.
- 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 mineral content or bone mineral density.
 - 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

- DXA measurement is part of a comprehensive skeletal health assessment in patients with increased risk of fracture.
- Therapeutic interventions should not be instituted on the basis of a single DXA measurement.
- 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.
- 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.
- In patients with thalassemia major, spine and TBLH BMC and areal BMD should be measured at fracture presentation or at age 10 yr, whichever is earlier.
- 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.
- The minimum time interval for repeating a bone density measurement to monitor treatment with a bone-active agent or disease processes is 6 mo.

DXA Interpretation and Reporting in Children and Adolescents

- DXA is the preferred method for assessing BMC and areal BMD.
- The PA spine and TBLH are the most accurate and reproducible skeletal sites for performing BMC and areal BMD measurements.
- 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).
- 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.
- 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.
- 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.
- When upgrading densitometer instrumentation or software, it is essential to use reference data valid for the hardware and software technological updates.
- 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.
- 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.
- Accurate interpretation of serial DXA results requires knowledge of the LSC for all sites measured and for all technologists at the DXA testing facility.
- 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 mineral content or bone mineral density for chronologic age” is the preferred term when BMC or BMD Z-scores are less than or equal to -2.0 .

pQCT in Children and Adolescents

- Reference data are not sufficient for the clinical use of pQCT for fracture prediction or diagnosis of low bone mass.
- When the forearm is measured, the non-dominant forearm should be used.
- Measurements sites should include the metaphysis and diaphysis.

- **Determination of the precision error, LSC, and monitoring time interval should be performed as described for DXA.**
- **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**
- **Quality control procedures should be performed as described for central DXA.**

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

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 of interest
SSI: strain strength index
TBLH: total body less head
VFA: vertebral fracture assessment
vBMD: volumetric BMD
WHO: World Health Organization.