

Summary of the International Society for Clinical Densitometry 2005 Position Development Conference

Neil Binkley,¹ John P Bilezikian,² David L Kendler,³ Edward S Leib,⁴ E Michael Lewiecki,⁵ and Steven M Petak⁶

BACKGROUND

THE INTERNATIONAL SOCIETY for Clinical Densitometry (ISCD) periodically convenes a Position Development Conference (PDC) for the purpose of making recommendations on quality control, acquisition, analysis, interpretation, and reporting of bone densitometry. Questions regarding relevant topics are assigned to subcommittees for a comprehensive medical literature review and presentation of a report to an international panel of experts. The expert panelists for the most recent PDC, held in Vancouver, British Columbia, Canada, in July 2005, included representatives of the American Society for Bone and Mineral Research (ASBMR) and the International Osteoporosis Foundation (IOF). Recommendations of the panel that are approved by the ISCD Board of Directors become Official Positions of the ISCD. The ISCD Official Positions are endorsed by the ASBMR and IOF. The methodology and highlights of the ISCD Official Positions^(1–13) are summarized here and may be found at www.iscd.org.

The Official Positions provide a reference for bone densitometry clinicians and technologists for quality control, acquisition, analysis, interpretation, and reporting of BMD tests. The rationale for establishing the ISCD Official Positions is based on the evolving nature of the field of bone densitometry and the clinical importance of uniformity in BMD performance and reporting. New Official Positions are considered, and previous Official Positions are re-evaluated every 2 yr at the ISCD PDC. Prior PDCs ad-

ressed issues including indications for BMD testing, selection of reference databases, precision assessment, and nomenclature. This report describes the proceedings of this PDC and contains example Positions resulting from the conference.

Official Positions of the ISCD represent an ongoing process to optimize the quality and clinical use of BMD testing. It is recognized that many of the Official Positions are associated with limited supporting medical evidence, and in fact, the need for uniformity in BMD testing methods in the setting of insufficient medical evidence is often the very reason for considering a topic at the PDC. The Official Positions serve to focus the attention of the scientific community on issues that may warrant further study. Publications of the ISCD Official Positions include recommendations for research that may serve to resolve areas of uncertainty and/or controversy. The ISCD welcomes and encourages participation of experts in the field of skeletal health assessment in selecting new topics for consideration and updating current Official Positions as appropriate.

SELECTED NEW ISCD OFFICIAL POSITIONS

Representative new ISCD Official Positions resulting from the 2005 PDC are noted below.

Cross-calibration of DXA systems

- When changing hardware, but not the entire system, or when replacing a system with the same technology (manufacturer and model), cross-calibration should be performed by having one technologist do 10 phantom scans, with repositioning, before and after hardware change.
- If a >1% difference in mean BMD is observed, contact the manufacturer for service/correction.
- Grade: Good-A-1

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.
- Grade: Poor-C-1

Dr Binkley receives research support from Merck & Co., Novartis, Roche, Aventis, and GlaxoSmithKline. He serves on the Speakers Bureau for Merck & Co., Roche, Procter & Gamble, and GlaxoSmithKline in addition to serving as a consultant to Merck & Co., Novartis, and Eli Lilly & Co. Dr Kendler serves on the advisory board and/or receives research grants from Merck & Co., Eli Lilly & Co., Novartis, Servier, Wyeth, Pfizer, Takida, NPS Pharmaceuticals, Amgen, and Zelos. Dr Lewiecki serves as a consultant to Merck & Co., Procter & Gamble, Eli Lilly & Co., Novartis, Amgen, Roche, GlaxoSmithKline, and Wyeth. He also owns stock in Procter & Gamble and GE. Dr Petak serves as a speaker for Eli Lilly & Co., Merck & Co., Procter & Gamble, Aventis, Roche, and GlaxoSmithKline. All other authors state that they have no conflicts of interest.

¹Department of Medicine, Sections of Geriatrics and Endocrinology, University of Wisconsin, Madison, Wisconsin, USA; ²Department of Medicine, College of Physicians and Surgeons, Columbia University, New York, New York, USA; ³Department of Medicine (Endocrinology), University of British Columbia, Vancouver, British Columbia, Canada; ⁴Department of Medicine, Division of Rheumatology and Clinical Immunology, University of Vermont College of Medicine, Burlington, Vermont, USA; ⁵New Mexico Clinical Research & Osteoporosis Center, Department of Medicine, University of New Mexico School of Medicine, Albuquerque, New Mexico, USA; ⁶Texas Institute for Reproductive Medicine, Houston, Texas, USA.

Method for defining and reporting fractures on VFA

- The methodology used 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 severity of vertebral fractures may be determined using the semiquantitative (SQ) assessment criteria developed by Genant et al.⁽¹⁴⁾ Severity of deformity may be confirmed by morphometric measurement if desired.
- Grade: Fair-B-1

Spine region of interest

- 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.
- Grade: Fair-C-1

Reference database for T-scores

- The NHANES III database should be used for T-score derivation at the hip regions.
- Grade: Poor-C-1

BMD reporting in women before menopause and in men younger than 50 yr of age

- 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.”
- Grade: Poor-C-1

CONFERENCE METHODOLOGY

Topic selection

Topics addressed at the 2005 PDC were selected by the ISCD Scientific Advisory Committee with requirements that topics be clinically relevant, have a perceived need for a recommendation because of lack of overwhelming medical evidence or controversial nature, and have a reasonable likelihood of the expert panel achieving agreement. Topic areas selected for review in 2005 included technical standardization, VFA, application of the 1994 World Health Organization (WHO) classification to various skeletal sites, and application of the 1994 WHO classification to populations other than postmenopausal white women.

PDC planning

The PDC Steering Committee identified an ISCD member to serve as subcommittee chair for each of the four topic areas. Subcommittee members were selected from experts in the field appropriate to each topic area. The Steering

Committee asked each subcommittee to consider a series of clinical or technical questions pertaining to their assigned topic. Subcommittee members performed a medical literature search for these questions using a method modified from that used by the Cochrane reviews using electronic databases that included PubMed, EMBASE, and MEDLINE.⁽¹⁵⁾ Each subcommittee submitted a draft of proposed Official Positions addressing all questions posed. Concurrent with subcommittee work, international experts in the field of bone densitometry were contacted to serve as panelists. The ASBMR, the IOF, and the National Osteoporosis Foundation (NOF) were invited to have representatives on the expert panel. The role of the expert panel was to review the proposed Official Positions developed by the subcommittees and make final recommendations to the ISCD Board of Directors.

Position grading

Based on evidence quality, all 2005 PDC Official Positions were graded as follows:

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.

The strength of the recommendations were graded as follows:

Strong recommendation supported by the evidence.

Recommendation supported by the evidence.

Recommendation supported primarily by expert opinion.

Finally, the recommendations were graded according to applicability:

Worldwide recommendation.

Application of recommendation may vary according to local requirements.

The subcommittees suggested initial grading, with final grading determined by the expert panel. Because PDC topics are often selected because strong medical evidence is unavailable, but a clinical need is perceived, it is the nature of this process that the highest desirable level of evidence is not always available to support the Official Positions.

PDC conduct

The 2005 PDC general format was similar to that of prior PDCs.^(5,9) Subcommittee chairs presented reports on their topics to the expert panelists in closed session on the first day of the conference. These reports were edited by subcommittee chairs, if necessary, reflecting suggestions made by the expert panelists. The following day, each revised report was presented by the subcommittee chairs at an open meeting 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 proposed Official Positions. A separate vote was taken for each potential Official Position. Throughout the entire conference, all proceedings were audio-recorded.

Finalization of the 2005 ISCD Official Positions

An affirmative vote from two thirds of the expert panelists was required for passage of any single recommendation. In circumstances where this was not attained, no 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 and economic issues received consideration. The expert panel recognized the importance of the ongoing WHO initiative to develop validated methodologies for fracture risk reporting and modeling for cost-effective intervention thresholds. Recommendations for ISCD Official Positions were intended to be compatible with the forthcoming WHO Technical Report on these topics. After conclusion of the PDC, the Steering Committee finalized recommendation wording without changing content. These recommendations were presented to the ISCD Board of Directors for review. The Board did not alter the content or wording of proposed Official Positions. Recommendations approved by a majority vote of the ISCD Board become ISCD Official Positions. Subsequently, these Official Positions have been endorsed by the ASBMR and the IOF. A complete list of the 2005 PDC participants, financial supporters, and all ISCD Official Positions is published^(16–20) and is also available online at www.iscd.org. This website also provides a PowerPoint presentation of the Official Positions, which may be downloaded for public viewing.

REFERENCES

1. Lenchik L, Leib ES, Hamdy RC, Binkley NC, Miller PD, Watts NB 2002 Executive summary International Society for Clinical Densitometry position development conference Denver, Colorado July 20-22, 2001. *J Clin Densitom* 5(Suppl):S1–S3.
2. The Writing Group for the ISCD Position Development Conference 2004 Executive summary. *J Clin Densitom* 7:7–12.
3. The Writing Group for the ISCD Position Development Conference 2004 Diagnosis of osteoporosis in men, premenopausal women and children. *J Clin Densitom* 7:17–26.
4. The Writing Group for the ISCD Position Development Conference 2004 Indications and reporting for dual-energy X-ray absorptiometry. *J Clin Densitom* 7:37–44.
5. The Writing Group for the ISCD Position Development Conference 2004 Introduction, methods and participants. *J Clin Densitom* 7:13–15.
6. The Writing Group for the ISCD Position Development Conference 2004 Nomenclature and decimal places in bone densitometry. *J Clin Densitom* 7:45–49.
7. Leib ES, Lewiecki EM, Binkley N, Hamdy RC 2004 Official positions of the International Society for Clinical Densitometry. *J Clin Densitom* 7:1–5.
8. The Writing Group for the ISCD Position Development Conference 2004 Technical standardization for dual-energy X-ray absorptiometry. *J Clin Densitom* 7:27–36.
9. Leib ES, Lenchik L, Bilezikian JP, Maricic MJ, Watts NB 2002 Position statements of the International Society for Clinical Densitometry: Methodology. *J Clin Densitom* 5(Suppl):S5–S10.
10. Hamdy RC, Petak SM, Lenchik L 2002 Which central dual X-ray absorptiometry skeletal sites and regions of interest should be used to determine the diagnosis of osteoporosis? *J Clin Densitom* 5(Suppl):S11–S17.
11. Binkley N, Schmeer P, Wasnich RD, Lenchik L 2002 What are the criteria by which a densitometric diagnosis of osteoporosis can be made in males and non-Caucasians? *J Clin Densitom* 5(Suppl):S19–S27.
12. Lenchik L, Kiebzak GM, Blunt BA 2002 What is the role of serial bone mineral density measurements in patient management? *J Clin Densitom* 5:S29–S38.
13. Miller PD, Njeh CF, Jankowski LG, Lenchik L 2002 What are the standards by which bone mass measurement at peripheral skeletal sites should be used in the diagnosis of osteoporosis? *J Clin Densitom* 5(Suppl):S39–S45.
14. Genant HK, Wu CY, Van Kuijk C, Nevitt MC 1993 Vertebral fracture assessment using a semiquantitative technique. *J Bone Miner Res* 8:1137–1148.
15. Anonymous 2002 Cochrane Reviews Handbook, vol. 4.1.5. The Cochrane Collaboration, Oxford, UK.
16. Binkley N, Bilezikian JP, Kendler DL, Leib ES, Lewiecki EM, Petak SM 2006 Official Positions of the International Society for Clinical Densitometry and Executive Summary of the 2005 Position Development Conference. *J Clin Densitom* 9:4–14.
17. Shepherd JA, Lu Y, Wilson K, Fuerst T, Genant H, Hangartner TN, Wilson C, Hans PDD, Leib ES 2006 Cross-calibration and minimum precisions standards for dual-energy X-ray absorptiometry: The 2005 ISCD Official Positions. *J Clin Densitom* 9:31–36.
18. Hans PDD, Downs RW, Duboeuf F, Greenspan S, Jankowski L, Kiebzak GM, Petak SM 2006 Skeletal sites for osteoporosis diagnosis: The 2005 ISCD Official Positions. *J Clin Densitom* 9:15–21.
19. Leslie WD, Adler RA, Fuleihan GE, Hodsmann A, Kendler DL, McClung M, Miller PD, Watts N 2006 Application of the 1994 WHO Classification to Populations other than postmenopausal Caucasian women: The 2005 ISCD Official Positions. *J Clin Densitom* 9:22–30.
20. Vokes T, Bachman D, Baim S, Binkley N, Broy S, Ferrar L, Lewiecki EM, Richmond B, Schousboe J 2006 Vertebral Fracture Assessment: The 2005 ISCD Official Positions. *J Clin Densitom* 9:37–46.

Address reprint requests to:

Neil Binkley, MD
2870 University Avenue, Suite 100
Madison, WI 53705, USA
E-mail: nbinkley@wisc.edu

Received in original form December 13, 2006; revised form December 13, 2006; accepted February 1, 2007.