

Wednesday, February 16, 2005 - Saturday, February 19, 2005

Poster Presentations

Abstracts

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Title: 1 – LONGITUDINAL EVALUATION OF VERTEBRAL DEFORMITY: MORPHOMETRIC RADIOGRAPHY VERSUS MORPHOMETRIC DXA

Authors: *Marsha Zion, MS, MPH* Program Manager, Bone Quality Control Center; Helen Hayes Hospital, Felicia Cosman, MD, Associate Professor of Medicine, Columbia University, Osteoporosis Specialist, Helen Hayes Hospital; Robert Lindsay, MD, PhD, Professor of Medicine, Columbia University, Chief of Internal Medicine, Helen Hayes Hospital; Jeri Nieves, PhD, Assistant Clinical Professor of Epidemiology, Mailman School of Public Health Columbia University, Director of Bone Density Testing Helen Hayes Hospital Clinical Research Center

To compare vertebral deformity assessment by dual x-ray morphometric absorptiometry (MXA) (Lunar Expert or Prodigy) and radiographic morphometry (MRX), data were evaluated for 82 women who had both measures at baseline and at 15 months.

Subjects were participants in a trial of (1-34)h PTH and alendronate. All were 1 year postmenopausal; on alendronate >1 year; with BMD t-score < 2.5 or < 2.0 plus prior osteoporotic fracture. Radiographs were digitized at a resolution of 200 microns. Prevalent fracture was defined as at least one vertebral ratio greater than 3 SDs below the mean of a reference population (Rea 1998, Black 1991). New/worsening fracture was defined as vertebral height loss of > 20%.

Correlations for vertebral heights between methods were 0.78 to 0.81. While a greater number of vertebrae were visualized by MRX than MXA, more were visualized on Prodigy than Expert. Vertebrae that were not visualized by MXA were mostly in the T4 to T7 region. Despite that, at baseline, more vertebrae were considered fractured by MXA (194) than by MRX (92). Ninety-five vertebrae were classified as new/worsening fractures by MXA, and 9 by MRX, although some not measurable by MRX were considered fractured qualitatively. MRX/MXA agreement for prevalent fracture was moderate for Prodigy, better than for Expert or for incident fracture.

Newer MXA technology has improved visualization of the upper thoracic region, and added mid-vertebral height measurements. MXA has utility as a screening tool for prevalent fracture, and its ability to detect incident fracture should be explored further.

Title: 2 – THE INTER-OBSERVER REPRODUCIBILITY OF CRITERIA FOR VERTEBRAL BODY EXCLUSION

Authors: *Karen E Hansen, M.D.* Assistant Professor of Medicine, University of Wisconsin; Neil Binkley, MD, University of Wisconsin; Rose Christian, MD, University of Wisconsin; Nellie Vallarta-Ast, RT(R), CDT, Radiology Department, William S. Middleton Memorial VA Hospital; Diane Krueger, BS, CCRC, University of Wisconsin; Marc K Drezner, MD, University of Wisconsin; Robert Blank, MD, PhD, University of Wisconsin

Although DXA is widely used to measure vertebral BMD, its interpretation is subject to multiple confounders. In an attempt to standardize interpretation and minimize the impact of artifacts, the ISCD established criteria for vertebral exclusion. However, the inter-observer reproducibility with application of these criteria is unknown.

To study the reproducibility of the vertebral exclusion criteria, four interpreters read a set of 200 lumbar DXA scans obtained on male veterans, noting the frequency and indication(s) for vertebral body exclusion and the resulting lumbar spine T-score for each report. All data was entered into an excel database. Subsequently, we analyzed data by kappa, McNemar, chi square tests or Pearson's correlation coefficient where appropriate.

Surprisingly, agreement among interpreters was only moderate, with the majority of kappa values falling between 0.2 and 0.6. Differences in interpretation resulted from differing thresholds for recognition of focal structural defect, and to choice of excluding the upper or lower vertebral body for the criteria requiring comparison between adjacent vertebrae. Notably, the rate of vertebral body exclusion increased from L1 to L4, and each observer had a characteristic threshold for excluding vertebrae. Both trends are significant by 2-way ANOVA, with $p < 0.0001$ for vertebrae and $p = 0.0016$ for observers, without a significant interaction between vertebrae and observers.

We conclude that in spite of their apparent simplicity, the ISCD vertebral exclusion criteria are difficult to apply consistently. In principle, appropriate refinement of the exclusion criteria may significantly improve inter-observer agreement.

Title: 3 – ISCD MALE SCREENING RECOMMENDATIONS VS. OST

Authors: *Robert A. Adler, MD* Chief Endocrinology, McGuire Veterans Affairs Medical Center; *Valentina I. Petkov, MD, MPH*, Research Assistant McGuire Research Institute and Assistant Professor of Preventive Medicine and Community Health, Virginia Commonwealth University, Richmond VA; *Susan Wright, BS*, Clinical Application Coordinator, McGuire Veterans Affairs Medical Center, Richmond VA; *Melissa I Williams, Pharm D*, Assistant Professor of Pharmacy, Virginia Commonwealth University, Richmond VA

ISCD guidelines suggest DXA screening for men > 70 years. We compared the prevalence of low bone mass by age in men screened for osteoporosis (OP) using the Osteoporosis Self-assessment Tool (OST) to estimate the number of men in whom OP diagnosis would be missed if only age is used for screening.

A Computerized Patient Record System was programmed to calculate OST $\{[\text{weight (kg)} / \text{age}] * 0.2\}$ for men (N = 16,885) enrolled in Primary Care Clinics at a single Veterans Affairs Medical Center. The distribution of low bone mass in 621 men referred for BMD test due to high or moderate risk for OP by OST was applied to estimate the number of men with undiagnosed OP by age group (< or > 70 years and by decades).

In 11,306 men < 70 years, 19% were at high or moderate risk for OP by OST, while 75% of 5,579 men > 70 years had high or moderate risk OST score.

Of 621 men with DXA, 34% were < 70 years and 66 % were > 70. Prevalence of low bone mass was not different in both groups: 29.2% with OP and 51.0% with osteopenia in the younger group; 30.4% and 55.2% in the older. If only age > 70 is used for screening, 5.8% (653/11,306) men < 70 years with silent OP would be missed.

OST can be used to screen men < 70 years. Further studies will determine if men > 70 with low risk OST are unlikely to have OP.

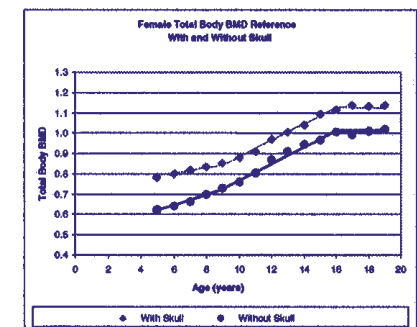
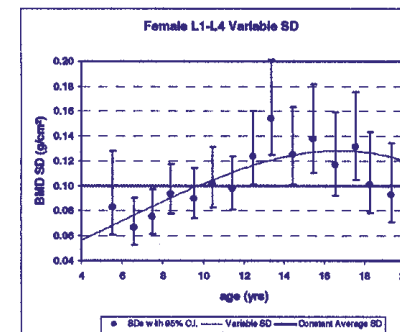
Title: 4 – PEDIATRIC DXA ENHANCEMENTS: VARIABLE STANDARD DEVIATIONS, TOTAL BODY SKULL EXCLUSION

Authors: *HS Barden, PhD* GE Healthcare, Madison, WI; *WK Wacker, GE Healthcare*, Madison, WI; *KG Faulkner, GE Healthcare*, Madison, WI

Manufacturers of DXA systems provide reference data for adult and pediatric subjects. In adults, T-score and Z-score calculation utilizes a constant standard deviation (SD) across the entire age range. A similar approach has been used in children, although variations in growth may cause SD variations with age. Also, total body (TB) reference values in adults and children include the skull. This highly cortical region constitutes a much larger proportion of TB BMD in young children than in adults, potentially compromising the sensitivity of TB BMD measurement. We evaluated pediatric BMD reference ranges, specifically use of a constant SD with age, and the impact of the skull on TB values.

We examined SDs in normal children scanned with GE Lunar DXA systems. Spine (L1-L4) SDs increased from 0.08 g/cm² at age 5 to 0.14 g/cm² at age 15, before declining to 0.12 g/cm² at age 19 years. TB SDs increased from 0.02 g/cm² at age 5 to 0.09 g/cm² at age 14 to 0.06 g/cm² at age 19 years. Skull BMD comprised nearly 45% of TB BMD at age 5 years versus 15% at age 15 in normal children. Excluding the skull from TB reference data had a significant effect on BMD and Z-scores, particularly at younger ages.

Use of variable SDs in pediatric reference ranges provide more accurate Z-scores and improved assessment of skeletal health. TB BMD excluding the skull may provide a more sensitive indication of skeletal status and greater sensitivity to small BMD changes in pediatric subjects.



Title: 5 – APPLICATION OF PRECISION ASSESSMENT RESULTS

Authors: *Robert Blank, MD* University of Wisconsin Osteoporosis Clinical Research Program; *Nellie Vallarta-Ast*, William S. Middleton Memorial Veteran's Hospital; *Karen Elver*, University of Wisconsin Hospital and Clinics; *Brenda McCarney*, University of Wisconsin Hospital and Clinics; *Diane Krueger*, University of Wisconsin Osteoporosis Clinical Research Program; *Mary Checovich*, University of Wisconsin Osteoporosis Clinical Research Program; *Xiaodan Wei*, University of Wisconsin Department of Biostatistics; *Neil Binkley*, University of Wisconsin Osteoporosis Clinical Research Program

BMD changes over time are the foundation of clinical decision making for patients with osteoporosis and other metabolic bone diseases. Interpretation of serial BMD results depends on measurement precision and least significant change (LSC). The ISCD recommends each DXA center establish precision using patients representative of their clinical population. Here, we illustrate that LSC is a more complex and subjective concept than generally appreciated.

The region being evaluated may affect precision. Vertebral body exclusion, recommended by ISCD when degenerative disease is present, decreases bone area, which should decrease precision. To determine the "penalty" arising from vertebral exclusion, we calculated precision for every subset of adjacent lumbar vertebrae in three patient populations, two were entirely female, the other largely male. Surprisingly, in men we found the L1-L3 LSC to be 0.037 g/cm² while the L1-L4 is 0.047 g/cm². It is notable that spinal degenerative disease is common in older men and degenerative changes are more frequent as one proceeds caudally. By contrast, in the two female samples, in whom spinal degenerative disease was less prevalent, the L1-3 LSC was 0.045 g/cm² and 0.035 g/cm² compared with 0.042 g/cm² and 0.027 g/cm² at L1-L4. These data suggest that degenerative disease per se reduces DXA precision.

These data support the ISCD recommendation that DXA precision be determined in a sample representative of the clinical population being measured. Additionally, they suggest that criteria for choosing the precision sample should be refined. Finally, these results suggest that the practice of applying a single LSC to individual patients with varying degrees of spinal degenerative disease requires further evaluation.

Title: 6 – DXA SOFTWARE UPGRADES WHAT DO THEY REALLY MEAN?

Authors: *Jan M Bruder, MD*, MD Associate Professor of Medicine, Division of Endocrinology, University of Texas; *Beatrice Cardenas, LVN*, University Hospital; *Glenn M Garcia, MD*, Assistant Professor of Radiology, UTHSCSA

At the 2001 ISCD position development conference, it was recommended that the lowest T-score of either the lumbar spine, total hip, femoral neck or trochanter be considered for the diagnosis of osteoporosis. It is unclear how often the T-score at the trochanter site is the lowest. However in our experience, the trochanter is seldom the lowest. Recently we noted an increase in the diagnosis of osteoporosis at the trochanter in patients referred to our clinic. This prompted us to repeat some BMDs at our facility. The referral BMDs were measured on the GE Lunar Prodigy (PA+41169) 8.10 software version. Our facility has the GE Lunar Prodigy (DF+13520) 7.53. One example was a 31 y/o premenopausal woman without risk factors for osteoporosis who suffered a compression fracture following a MVA. The diagnosis of osteoporosis was made based on the T-score of left hip trochanter of 2.7. The repeat BMD T-scores of the left trochanter was -1.3. No T-score at other sites fulfilled the criteria for osteoporosis. Binkley et al recently reported at the 2004 ASBMR meeting that the software upgrade versions 7.0 to 8.6 resulted in lower T-scores than the software prior to 7.0 at both the trochanter and femoral neck. In response to this analysis, GE Lunar has revised the software with an upgrade patch to version 8.8. The discrepancy however between the T-scores in the above example, and other examples to be presented, is left unexplained since the NHANES reference data is in both software versions. Many questions have thus been raised regarding various software versions especially as they may result in over diagnosis and treatment of patients. In addition, the marked difference in the T-scores on two GE Lunar Prodigy machines with the same reference database raises much concern.

Title: 8 – FOREARM BONE DENSITY IN PATIENTS WITH HAND OSTEOARTHRITIS

Authors: *A. G. Stern, MD* Rheumatologist, McGuire Veterans Affairs Medical Center; V. I. Petkov, MD, Research Assistant, McGuire Research Institute, Richmond VA; T. P. S. Rao, MD, Chief Rheumatology, McGuire Veterans Affairs Medical Center, Richmond VA; D. Disler, MD, Radiologist, Virginia Commonwealth University, Richmond VA Commonwealth Radiology, Richmond VA; P. Carlson, Ph D Laboratory Scientist, McGuire Veterans Affairs Medical Center, Richmond VA; R. A. Adler, MD Chief Endocrinology, McGuire Veterans Affairs Medical Center, Richmond VA and Professor of Internal and Preventive Medicine, Virginia Commonwealth University, Richmond VA

Several studies have suggested that erosive hand osteoarthritis (EOA) may be a distinct clinical entity. The objective of this study is to determine if there is a difference in forearm (FA) BMD in the two OA groups and to investigate independent predictors of FA BMD in OA subjects.

Study sample consisted of 61 Caucasian subjects (16 with EOA, 45 non-EOA). OA classification was based on hand radiographs. BMD was measured using a Hologic Delphi densitometer. We use student t-test to compare groups, ANCOVA to account for possible confounding, and multiple regression to a build predictive model. We studied as potential independent predictors age, gender, height, weight, OA group/ radiographic OA score, and C-reactive protein.

The mean age of EOA subjects was 70 (+ 7.3) years, 81% female; for non-EOA the mean age was 68 (+8.5), 67% female. There was no significant difference in FA BMD in the 2 groups: 0.559 gm/cm² (+0.099) in the EOA group and 0.567 (+0.108) in non-EOA subjects. Adjusting for covariates did not change the means. In the EOA group 6.3% had osteoporosis, 31.3% osteopenia, and 62.5% had normal T-score in the total forearm. The proportional distribution in non-EOA group was 17.8%, 22.2%, and 60.0% respectively. Independent predictors of FA BMD were gender, age and radiographic OA score, accounting for 56% of the variance.

Thus although hand EOA has distinctive clinical features it is not associated with an increased prevalence of low bone mass in the forearm.

Title: 9 – DXA PRECISION ERROR: THE IMPORTANCE OF TECHNOLOGY AND OPERATOR EXPERIENCE

Authors: *KG Faulkner, PhD* GE Healthcare, Madison, WI; LS Weynand, GE Healthcare, Madison, WI; HS Barden, GE Healthcare, Madison, WI; WK Wacker, GE Healthcare, Madison, WI

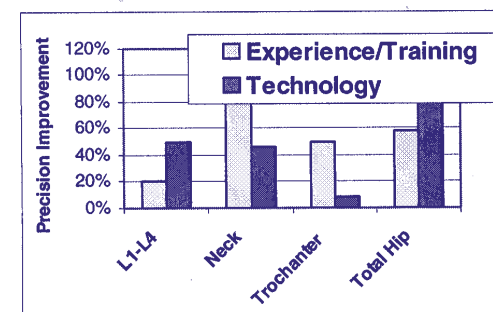
Precision error is influenced by operator and technical factors. We examined the effect of operator training/experience and DXA technology on precision by comparing values from ISCD expert sites to non-research (clinical) centers. Expert precision was reported previously for 3 research centers using both GE and Hologic fan-beam systems [1]. Clinical precision was determined at 27 centers: 17 with GE Lunar equipment (2 Prodigy Advance, 15 Prodigy), 17 with Hologic QDR (3 Discovery, 6 Delphi, 8 4500). Seven clinical centers had GE and Hologic densitometers. Each center measured 30 subjects 2X or 15 subjects 3X, using 30-second scan modes with repositioning between measurements.

For comparison, Hologic BMD values were converted to Lunar equivalents [1,2]. Differences in average precision (RMS CV) between expert and clinical centers using the same manufacturer were considered related to operator experience/training. Differences in inter-manufacturer precision determined at expert and clinical sites were considered related to technology.

Expert precision was superior to clinical precision. Operator experience/training improved precision 20% at the spine and 50%-100% at the hip. There were significant inter-manufacturer precision differences based on technology. Use of GE Lunar technology improved precision at both expert and clinical sites by 50% at the spine, and 50%-80% at femoral neck and total hip, on average.

Both operator experience and DXA technology have a significant, independent impact on spine and hip precision. Best precision is obtained through proper training/experience and utilization of the most advanced DXA technology.

1. Shepherd (2004) IOF/WCO, Rio de Janeiro, Brazil; P115SA
2. Osteoporos Int (2001) 12:438-444



Title: 10 – EFFECTIVE DOSES FROM DXA AND VFA SCANS

Authors: *Charles R. Wilson, Ph.D., FACR* Associate Professor Radiology, Medical College of Wisconsin; *Sanford Baim, M.D.,* Associate Clinical Professor of Medicine, Medical College of Wisconsin, Milwaukee, WI; *Guillermo F. Carrera, M.D., FACR,* Professor of Radiology, Medical College of Wisconsin, Milwaukee, WI

This educational poster intends to review basic radiation dosimetry concepts as applied to dual energy x-ray absorptiometry (DXA) and vertebral fracture assessment (VFA). Information comparing radiation from DXA and VFA scans using Lunar and Hologic systems to other common diagnostic x-ray examinations will be reported. The authors will define entrance skin dose, absorbed dose, effective dose and discuss the application of the concept of effective dose for comparing the hypothetical risks associated with different x-ray examinations. The effective doses from routine DXA scans of the spine, hip, distal forearm, whole body and VFA will be compared to the effective doses from chest radiography, computed tomography of the head, chest and abdomen, lateral thoracic and lumbar spine radiography and other procedures. Information concerning typical effective doses associated with airplane travel, cosmic rays, terrestrial radiation and natural occurring radioactive materials in the environment will also be presented.

Title: 11 – IMAGE RESOLUTION OF BONE DENSITOMETERS PERFORMING VERTEBRAL FRACTURE ASSESSMENT

Authors: *L.G. Jankowski, CDT* Chief DXA Technologist, Illinois Bone and Joint Institute; *S.B. Broy MD,* Director, Osteoporosis Center, Illinois Bone and Joint Inst. Morton Grove, IL

We compared the radiographic resolution of a new high-resolution scanning mode to both conventional radiography and standard bone densitometer imaging modes currently used for vertebral fracture assessment using a standard radiographic line pair phantom.

We imaged the phantom on an 8 cm. thick acrylic plate to simulate soft-tissue, using a GE-Lunar Prodigy Advance system with ClearView software, and a Hologic QDR 4500SL with Delphi Upgrade and Image-Pro software in both standard and high-resolution (RVA) imaging modes. On the Hologic unit, the phantom was scanned in both the PA and rotated lateral gantry positions. Horizontal and vertical resolution in units of line-pairs per millimeter (lp/mm) was recorded as the smallest grouping that can be clearly visualized using manufacturer specific display software by two experienced observers.

Resolution on the Delphi varied by scan mode, line orientation, and c-arm positioning, from a high of 1.5 and 0.9 lp/mm for horizontal lines using RVA and standard PA spine modes respectively, to a low of 0.6 lp/mm for vertical lines in the lateral c-arm position in both scan modes. The Prodigy was unable to resolve the coarsest line grouping in the phantom of 0.6 lp/mm in any orientation or scan mode.

The Hologic Delphi high-resolution scan mode improves horizontal line resolution by 50% in both PA and lateral imaging and is more than three-fold better than the Prodigy. A resolution phantom of suitable design may have value in assessing and monitoring system performance, or in selecting systems suitable for VFA.

Title: 12 – BODY FATNESS AFFECTS DXA BMD MEASURES: A SIMULATION STUDY

Authors: *Ellen M. Evans*, Assistant Professor of Kinesiology and Nutritional University of Illinois at Urbana-Champaign; Renee B. Kessinger, University of Illinois at Urbana-Champaign; Tyler Fagan, University of Illinois at Urbana-Champaign

The primary purpose of this study was to assess the ability of fan-beam DXA to accurately measure BMD with changes in exogenous fat (lard) placed to simulate typical weight change in men and women. Whole body (WB), lumbar spine (LS) and proximal femur (PF) DXA scans were performed on 90 elderly (n=30; 52-81 y) and young (n=60; 18-40 y) individuals (n = 45 female, n = 45 male) of varying body size (M±SD: 26.1±4.9 kg/m²). Scans were repeated with lard packets (~1.0 thick; 10 x 7) placed over the trunk (chest and abdomen for female or abdomen for men; WB-TK) and the scanning region for PF (young females or elderly) or LS (young males or elderly). WB-TK BMD decreased (-1.1±1.3%, p<0.001) due to a minimal increase in area (+0.4±1.3%, p=0.01) and a reduction in BMC (-0.8±1.2%, p<0.001). The slight increase (+0.6±12%, p=0.001) in PF-LARD BMD was due primarily to an increase in BMC (+0.9±2.2%, p<0.001). Alternatively the reduction in LS-LARD BMD (-1.6%±1.6, p<0.001) was due primarily to a reduction in BMC (-2.2±2.5%, p<0.001). Although body morphology was not related to PF BMD error, trunk mass was related to error in LS BMD (r = -0.45, p=0.008). We conclude that on average simulated weight change: 1) has minimal impact on PF BMD and 2) has moderate impact on LS BMD, both of which are similar to DXA precision estimates. However, individual variability in measurement error was substantial and may be impacted by body thickness.

Title: 13 – FOREARM DXA AND VERTEBRAL FRACTURE ASSESSMENT (VFA): THEIR EFFECT ON THE DIAGNOSIS OF OSTEOPOROSIS

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The purpose of this study is to assess the impact of the inclusion of forearm DXA and VFA in bone density evaluation on the resultant diagnosis of osteoporosis. Recent advances in software for DXA testing have included more consistent use of forearm DXA and evaluation of fractures via Vertebral Fracture Assessment (VFA). How frequently does the inclusion of forearm DXA and VFA change patient diagnoses from either normal to osteopenia or normal or osteopenia to osteoporosis? We predict that the inclusion of forearm DXA and VFA will change overall diagnosis of osteoporosis via DXA assessment often enough to warrant notice. If so, it becomes imperative for osteoporosis referral centers to educate referring providers regarding new DXA technology. Referring providers should be aware of these newer assessment techniques and be prepared to advise their patients appropriately in light of the added information that is provided. It is important to recognize the impact of these new technologies on the diagnosis and thus potentially the treatment of low bone density and osteoporosis. Fifty consecutive patients referred to our facility for DXA will be assessed as to whether the inclusion of forearm DXA altered the diagnosis that would have been given without its inclusion. In addition to forearm DXA, included in the assessment will be the lumbar spine (L1-L4), hip (femoral neck) and presence of prevalent osteoporotic fracture as an adult. The forearm region of interest (ROI) to be assessed will be the 33% radius. At our facility, VFA is performed on all patients with DXA of the spine <2.5 and/or greater than or equal to 2 inches of height loss and/or significant back pain. Twenty consecutive patients referred for DXA who then have VFA evaluated will be assessed as to whether the addition of VFA altered the diagnosis that would have been given without its inclusion. Adding forearm bone density measurement and VFA to spine and hip will increase the diagnosis of osteoporosis.

Title: 14 – LVA INCREASES FRACTURE DETECTION AND OSTEOPOROSIS DIAGNOSIS

Authors: *John Joseph Carey, M.B.* The Center for Osteoporosis and Metabolic Bone Division; Angelo Licata, The Center for Osteoporosis and Metabolic Bone Division; Chad Deal, The Center for Osteoporosis and Metabolic Bone Division; Miriam F Delaney

Purpose

Evaluate LVA for fracture detection in a cohort of subjects with and without a fracture history

Methods

Retrospective cohort

Abstract

A cohort of subjects with recommendations on the bone mineral density report for evaluation of secondary causes of low bone mass was used for this study. 752 persons were screened over a 1 year period and 149 were eligible based on study entry criteria. All had a Z score of <-1.5 at one or more ISCD approved sites.

52 subjects had a fracture history 97 persons did not.

60 subjects had an L.V.A. performed as part of their bone mineral density scan. 20 showed definite fractures, 14 possible fractures and 23 no fractures. There was no report available for 3 examinations; these were excluded from the analysis.

36 subjects without a fracture history had an LVA 11 of whom had definite fractures, 8 had possible fractures and 17 had none. 21 subjects with a fracture history had an LVA, 9 of whom had definite fractures, 6 had possible fractures and 6 had no fracture. 6 persons with low bone mass (ISCD criteria) had LVA fractures and 7 had possible fractures.

LVA at the time of bone mineral density testing is a useful tool for fracture detection in persons without fracture history, and may increase the diagnosis of osteoporosis.

Future studies in larger populations need to be done with confirmation of fractures by other imaging procedures where there is uncertainty about the diagnosis.

Title: 15 – T-SCORE DISCORDANCE OF CONTRALATERAL FEMORA INCREASES IN WOMEN OVER THE AGE OF 65

Authors: *Raymond E. Cole, D.O.,C.C.D.* Clinical Assistant Professor of Medicine in the De; Jacob Larson, Graduate Student, School of Public Health, University of Michigan, Ann Arbor, Michigan

The AIM of this study was to determine if T-score discordance exists between right/left femora in postmenopausal women, and if it does, then does it increase with age. **METHOD:** Dual femur results from 537 women (mean age 61.2 years; SD 10.5, range 32 to 90 years) were evaluated for right and left T-score discordance at the femoral neck, trochanter, and total hip. Chi square tests determined the significance of discordance in diagnosis and treatment recommendations between women under and over 65 years old. **RESULTS:** Diagnosis (normal, osteopenia, osteoporosis) agreement differed between right/left femora in 28% of subjects at one or more sites. Discordance occurred about four times more often (3% vs. 12%) in women over age 65 compared with younger women ($p < 0.0001$) when examining discordance at any femur site. Treatment agreement differed between right/left femora in 33% of subjects at one or more sites. The percent of subjects with treatment discordance using T-score < -2 SD as the treatment indicator was nearly three times higher (23% vs. 9%) for women older than age 65 ($p < 0.001$). **CONCLUSION:** Scanning of the contralateral hip showed right vs. left femur diagnosis differences at any site in 28% of postmenopausal women and treatment differences at any site in 33% of postmenopausal women. Significantly greater discordance occurred in women over 65 years of age. Scanning of the contralateral femora improves accurate osteoporosis diagnosis and treatment classification, particularly in women over age 65.

Title: 16 – DXA BONE MINERAL DENSITY REFERENCE DATABASE FOR THE CHINESE POPULATION

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The Society for Osteoporosis and Bone Mineral Research Chinese Medical Association has recently initiated a study with GE-Lunar to establish a DXA reference database for population in mainland China. Six centers across China recruited 11,418 healthy subjects aged 20-95 years, including 7752 women and 3666 men. Each subject completed a health status questionnaire, and those with known factors affecting bone mineral density (BMD) were excluded from the study. Spine (L1-L4) and hip BMD were measured with Lunar DXA devices (GE Healthcare, Madison, WI USA). Precision of the ESP spine phantom measured at the 6 centers ranged from 0.3-0.7%. The relationship between BMD and age was assessed using various regression models, with the best-fit model used to calculate age-related reference curves. To allow the determination of T-scores, the young normal (YN) reference value was defined as the mean BMD and SD for men and women from 20 to 40 years of age:

YN BMD reference values in Chinese men and women are slightly lower than those in USA adults, though the standard deviation values are similar. In this study, a Chinese reference database for spine and hip BMD was established in a large, representative sample of normal subjects. With these locally derived reference values, it is now possible accurately determine T-scores and Z-scores for the Chinese population.

Table. The young normal (YN) BMD reference value

YN BMD (SD)	L1-L4	Neck	Trochanter	Total Femur
Female (g/cm ²)	1.110 (0.110)	0.924 (0.120)	0.758 (0.106)	0.961 (0.129)
Male (g/cm ²)	1.121 (0.114)	0.979 (0.124)	0.827 (0.121)	0.996 (0.126)

Title: 18 – TO MORPH OR NOT TO MORPH?...

Authors: *Dee Steinberg*, CDT Foundation for Osteoporosis Research and Education; Elliott N. Schwartz MD, Foundation for Osteoporosis Research and Education; Jill Steinberg, Foundation for Osteoporosis Research and Education

Aim: To evaluate the role of quantitative morphometry (QM) in the identification of vertebral compression fractures (VCF) in the clinical setting.

Using two Hologic QDR 4500A and one Lunar Prodigy densitometer, we performed 3500 DXA s including 1500 Vertebral Fracture Assessments (VFA) from 1/2/04 to 12/23/04. Our indications for performing VFA were back pain, height loss, history of VCF, > 65, steroid use, osteoporosis by WHO BMD criteria, previous fragility fracture, and secondary causes of osteoporosis.

VFA were performed by one of four central DXA technicians. An expert reader (ENS) was used to evaluate all VFA and refer all questionable VFA for QM. QM was performed by an expert technician (DS). The VFA scans were reviewed in a printed format. Scans were performed of the T4 to L4 region.

Of the 1500 VFA performed, 400 VFA (with questionable vertebral bodies) were returned for QM. Of this number, 35% subsequently proved to be normal with the remaining 65% of studies containing Grade 1, 2 and 3 fractures.

Teriparatide may alleviate back pain associated with Grade 2 and Grade 3 VCF. Therefore, it may be important to differentiate those Grades from Grade 1 fractures and to differentiate Grade 1 fractures from normal vertebral bodies. While semi-quantitative techniques are available, precise definition of grades of fracture probably requires QM classify borderline cases.

Conclusion: Selective QM of distorted vertebral bodies may have clinical relevance in therapeutic decisions. Therefore Selective QM should be considered by all centers performing VFA.

Title: 19 – DOES RECENT CALCIUM SUPPLEMENT TABLET INGESTION ALTER BONE MINERAL DENSITY MEASUREMENT?

Authors: *Diane Krueger, BS, CCRC, CDT* University of Wisconsin Osteoporosis Clinical Research; *Mary Checovich*, University of Wisconsin Osteoporosis Clinical Research Program; *Xiaodan Wei*, University of Wisconsin Department of Biostatistics; *Neil Binkley*, University of Wisconsin Osteoporosis Clinical Research Program

It is common for densitometry centers to request that patients abstain from ingesting calcium supplements prior to DXA examination to avoid interference with BMD measurement. However, it is not clear that this practice is important or necessary. This study assessed the impact of recent calcium supplement intake on lumbar spine BMD measurement and evaluated the frequency with which tablets are seen on the DXA image.

Twenty-one subjects, mean age 69 years, received baseline and two subsequent spine scans using a GE-Lunar Prodigy densitometer. Subjects were randomized to ingest one tablet of Citracal, OsCal or People's Choice calcium. Follow-up scans were performed at 15 and 30 minutes after ingestion.

Changes in L1-4 BMD greater than our facility's LSC occurred in three subjects at 15 minutes, only one of which persisted at 30 minutes. In these three subjects, a calcium tablet was visualized on only one scan, at the 30-minute timepoint. Overall, tablets were visualized on one or more scans in 38% (8/21) of subjects. Tablets were visualized in 24% of subjects at 15 minutes and 29% at 30 minutes. People's Choice calcium and OsCal were visualized in 57% while Citracal did not appear in any subject's scan. In all but one instance, there was no significant BMD change demonstrated when tablets were visualized.

In conclusion, although calcium supplements are often visualized when DXA scans are performed soon after ingestion, they rarely affect BMD. It does not appear necessary to require abstinence from calcium supplement ingestion prior to DXA examination.

Title: 21 – REANALYSIS OF GEM-BASED NORLAND STUDIES WITH ILLUMINATUS SOFTWARE

Authors: *TV Sanchez*, Senior Applications Director Norland-a CooperSurgical Company, Fort Atkinson, WI; *GJ Ekker*, Norland-a CooperSurgical Company, Fort Atkinson, WI; *RE Olszewski*, CooperSurgical Company, Fort Atkinson, WI; *RJ Rutkowski*, CooperSurgical Company, Fort Atkinson, WI

This study examines what happens when a library of studies obtained and analyzed with the traditional GEM-based Norland software is reanalyzed with Illuminatus, the new Windows-based Norland DXA application software.

A collection of 175 studies including AP Spine, Lateral Spine, Hip, Forearm, Research and Whole Body scans obtained on equipment operated with the traditional GEM-based Norland software were reanalyzed with Illuminatus software. Analysis of the scans with GEM-based Norland software and reanalysis with Illuminatus was done by the same operator (TVS). A regression analysis was completed for BMC, Area and BMD to assess the relationship between the two analyses.

Examining the regression for BMC shows a correlation coefficient of 0.9993 with a slope of 1.0026 crossing the y-intercept at 0.0086. Examining the regression for Area shows a correlation coefficient of 0.9993 with a slope of 1.0034 crossing the y-intercept at -0.3533. Finally, examining the regression for BMD shows a correlation coefficient of 0.9947 with a slope of 0.9887 crossing the y-intercept at 0.0316. In short, highly significant positive regressions were found for BMC, Area and BMD.

This study shows that reanalysis by Illuminatus does not change the BMC, Area or BMD results obtained with the GEM-based Norland software. Studies and reference sets previously obtained with GEM-based software can be directly carried forward to studies done with the Norland Illuminatus applications software.

Title: 22 – IN VIVO EVALUATION OF ILLUMINATUS, THE NEW NORLAND APPLICATIONS SOFTWARE

Authors: *KM Dudzek*, Customer Service Director Norland—a CooperSurgical Company; GJ Ekker, Norland—a CooperSurgical Company; RJ Rutkowski, Norland—a CooperSurgical Company; TW Schwalenberg, Norland—a CooperSurgical Company; TV Sanchez, Norland—a CooperSurgical Company

When significant software changes are introduced to equipment, tests should assess the impact of those changes on in vivo precision and accuracy. This study compared in vivo precision and accuracy of Illuminatus the new Windows-based Norland DXA application software with in vivo results obtained using the GEM-based Norland DXA software that has been in the field for some time.

Four to nine subjects underwent four repeated scans without repositioning with both the Illuminatus and GEM-based operating systems. AP Spine, Lateral Spine, Hip, Forearm and Whole Body scans were evaluated. All scans were done by the same operator (KMD). Precision and absolute values for results obtained by Illuminatus and the GEM-based software systems were evaluated.

Similar results were found for precision obtained by the Illuminatus and GEM-based software. Illuminatus and the GEM-based software, respectively, show precision for BMD of 0.8% and 0.9% for AP Spine, 2.6% and 2.2% for Lateral Spine, 0.7% and 0.6% for Femur, 0.9% and 1.1% for Forearm and 1.0% and 0.8% for Whole Body. Values for BMD obtained with the two software systems proved very similar. As a percent of the GEM-based result, values for BMD obtained with Illuminatus were 100.7% for AP Spine, 101.9% for Lateral Spine, 99.8% for Hip, 98.6% for Forearm and 98.6% for Whole Body.

This study shows that when the Norland DXA tables are controlled by GEM-based or Illuminatus software, both in vivo precision and absolute values obtained in these scans remain similar.

Title: 23 – CAN DXA DETECT POTENTIAL FEMORAL NECK DIAMETER THERAPEUTICAL CHANGES?

Authors: *Dr. David Kendler, MD*. Assistant Professor, University of British Columbia; Dinu, Claudia, Research Assistant, Osteoporosis Research Centre, Vancouver, BC; Robertson, Steve, CDT, Osteoporosis Research Centre, Vancouver, BC

Precise DXA measurements are crucial to the understanding of serial bone densitometry testing. Potentially, information about bone size could be obtained from DXA scans. Some studies have shown QCT-derived increases in bone area at the distal radius in postmenopausal women with osteoporosis treated with teriparatide [rhPTH(1-34)]. This effect on bone size may be associated with an improved resistance to fracture. It would be of interest if measurable changes in femoral neck size were discernable using DXA scans.

To determine the precision of hip DXA, Area and BMC were measured twice (with repositioning of the patient) in 30 postmenopausal women (age 65 ± 9 years). All patients had low bone density as defined by lumbar-spine T-score < -2 but > -3.5 . Precision error was calculated for Area and BMC (ISCD precision calculating tool) for femoral neck (FN) and total hip (TH).

Results indicated Area precision error of 3.05% at FN and 1.13% at TH; BMC precision error of 3.39% at FN and 1.30% at TH.

In the published teriparatide clinical trial (J Bone Miner Res 2003;18:539-543), radial periosteal circumference increased by 5% over 19 months of therapy. From FN Area, we can calculate the FN average diameter and approximate the FN circumference, assuming that FN is a perfect cylinder. A calculated precision error for this parameter would be 3.05% based upon the estimates of area precision error above; least significant change is 8.44%. Assuming similar changes in FN diameter as with radius diameter, the expected change of FN size would not likely be detected with DXA.

Further studies of DXA-determined bone size precision at FN are required to validate the significance of changes in these measurements.

Title: 24 – A JAPANESE WOMAN OSTEOPOROTIC IN CANADA AND NOT IN JAPAN

Authors: *Akira Itabashi, MD, PhD* Professor of Clinical Laboratory Medicine, Saitama; Sumiaki Okamoto, Oita, Japan, Okamoto Clinic

A 54 year-old Japanese woman came to our clinic who moved recently back to Japan after 5 years of residency in Canada. She had hysterectomy and ovariectomy at age 39 and was doing well since then and moved to Canada due to her husband business. Six months before she came back to Japan, she had a bone densitometry test and was diagnosed osteoporotic with lumbar T-score of -2.6 and was prescribed Fosamax. When she came to us, her lumbar spine BMD was 81% of young adult mean (YAM) (or T-score was -1.4) which was considered more than the lower limit of normal young adult in Japan. (Japanese diagnostic criteria: osteoporosis is less than 70% of YAM or less than -2.5 of T-score and osteopenia is less than 80% of YAM or less than -1.5 of T-score)

Her lumbar spine BMD may have recovered somewhat with 6 months of bisphosphonate treatment but the difference exceeded the expected increase by Fosamax. We realized that the lumbar spine BMD (L2-L4) cut-off value of -2.5 T-score is 0.804g/cm² which corresponds to 74.5% of YAM in US and Canada, while that in Japan is 0.708 g/cm² (70% of YAM and -2.4 T-score). So, if the Japanese women go back and forth between Japan and Canada, she can be diagnosed osteoporotic in Canada and normal in Japan. The YAM value is larger in US and Canada, but the standard deviation is larger in Japan. We have to be aware of these differences when using T-score.

Title: 25 – GENDER-SPECIFIC BMD REFERENCE VALUES FOR U.S WHITE CHILDREN

Authors: *Thomas L. Kelly*, Principal Scientist, Hologic, Inc. Bedford, MA; B. S. Zemel, Ph.D., Children's Hospital of Philadelphia, Philadelphia, PA; H. J. Kalkwarf, Ph.D., Cincinnati Children's Medical Center, Cincinnati, OH; J. A. Shepherd, Ph.D., University of San Francisco, San Francisco, CA; B.L. Specker, Ph.D., South Dakota State University, Brookings, SD; L. J. Moyer-Mileur, Ph.D., University of Utah, Salt Lake City, UT; H. Pan, Ph.D., Institute of Child Health, London, United Kingdom; T. J. Cole, Ph.D., Institute of Child Health, London, United Kingdom

We report on the development of age and gender-specific BMD reference values in U.S. White children from five centers in the U.S. AP Spine (n=1444), Hip (n=1047) and Whole Body (n=1948) exams were acquired in healthy children using Hologic fan beam DXA systems. All measurements were processed with version 12.1 software, which supports automatic low density analysis methods. The reference data were modeled using the LMS method1, a fitting procedure that employs cubic splines to generate centile estimates for age-related growth. Significant differences in BMD were observed between boys and girls for several age groups as assessed by a two-sided normal test (p <0.05). This finding indicates the importance of gender-specific reference values. Statistically significant skewness was observed for AP Spine BMD in girls but not in boys. Mean Z-Scores for height, weight, and BMI, calculated using CDC growth curves, were all between 0.2-0.3, indicating that the average height and weight of the study subjects was similar to the general U.S. population given the secular trend toward larger body size. BMD Z-Scores based on these reference values will help detect skeletal deficiencies in children.

Title: 26 – ASSESSMENT OF OSTEOPOROSIS RISK IN POSTMENOPAUSAL WOMEN IN SINGAPORE

Authors: *Low Siew-Leng*, Technologist Senior Lab Officer, Dept of Orthopaedic Surgery, National University Hospital of Singapore; Wong Pui-San, Dept of Orthopaedic Surgery, National University of Singapore; Das De Shamal, Dept of Orthopaedic Surgery, National University of Singapore; Wong Pui-San, Dept of Orthopaedic Surgery, Lab Officer; Das De Shamal, Dept of Orthopaedic Surgery, Professor

The Osteoporosis Self Assessment Tool for Asians (OSTA) was developed to assess the risk of osteoporosis in postmenopausal Asian women using a simple index based on age and weight. The aim of this study was to validate the OSTA index in a cohort of postmenopausal women (n = 1,476) aged 45-77 years (mean 55.9 ± 6 years). All subjects had BMD of the hip measured using a GE LUNAR DPX-L densitometer. The prevalence of osteoporosis was 4.9% (57/1174) among women aged 45-60 years and 13.9% (42/302) among women aged 61 years or older. Subjects were classified as low risk for OSTA index >1, medium risk for OSTA index between -1 and -4 and high risk for OSTA index <-4. 576 (39%) women were classified in the medium or high risk according to OSTA and among them, 78 (13.5%) had osteoporosis. Receiver operating characteristic (ROC) curves was used to assess the OSTA index and sensitivity was defined as the proportion of subjects with osteoporosis that tested positive (i.e. OSTA -1 and below). The area under the ROC curve was 0.713. Specificity of OSTA was 64% when sensitivity was 79% to detect osteoporosis in the femoral neck. OSTA index can be used in the clinical setting to identify women at high risk for osteoporosis and facilitate a more cost effective use of bone densitometry.

Title: 27 – COMPARING AP AND LATERAL SPINE BMD MEASUREMENTS IN POST-MENOPAUSAL FEMALES

Authors: *Eilish Thornton*, St. James Hospital Senior Radiographer, St. James Hospital, Dublin, IR; Miriam Casey, Cathal Walsh, J. Bernard Walsh

The ISCD position statement advises, The lateral spine should not be used for diagnosis, but may have a role in monitoring . The value of the lateral BMD measurements of L2, L3 and L4 has been under investigated, compared to the value of the AP spine measurements. These AP spine results may include aortic calcification and spinous process, which increase the BMD measurement of each vertebra.

We measured the BMD of L2, L3 and L4, in the lateral position, in 30 postmenopausal women who had been diagnosed with osteopaenia, based on the T-score in their AP lumbar spine. We wanted to investigate if the extent of their bone loss had been under diagnosed and if so, to estimate the size and variability of the differences between the two measurements.

It appears the size of the difference in the two measurements depends on the individual and to some extent the region. L3 has a bigger difference than others. The difference is not the same for all individuals. A similar analysis followed for T-scores. There is a substantial difference between AP and Lateral, and this difference is again person specific. The results show marked disagreement between the methods from a diagnostic perspective and suggests further investigation is needed to determine the most accurate method for assessing BMD in the lumbar spine.

Title: 28 – EVALUATION OF FRACTURE RISK IN IJO SUBJECTS BY MEANS OF DENSITOMETRIC MEASUREMENTS

Authors: *Roman S. Lorenc, MD, PhD* Professor of Medicine and Biochemistry, The Children's Memorial Health Institute; *Paweł Budowski*, The Children's Memorial Health Institute, Department of Biochemistry and Experimental Medicine, Warsaw, Poland; *Halina Matusik*, The Children's Memorial Health Institute, Department of Biochemistry and Experimental Medicine, Warsaw, Poland; *Michał Lebedowski*, The Children's Memorial Health Institute, Department of Rehabilitation, Warsaw, Poland

The Idiopathic Juvenile Osteoporosis (IJO), is a disease of unknown etiology, leading to low bone quality, bone deformities and fractures. In the aim of evaluation of fracture risk in IJO subjects various diagnostic approaches were compared. Study population comprised 61 IJO cases of different type and stage of the disease and 481 healthy children. Keeping in mind mechanostat approach of the skeleton, BMC of L2-L4 (SBMC), total body (TBBMC) and the lean mass (LBM) were assessed and body height (BH)/LBM, TBBMC/LBM, SBMC/LBM ratios as diagnostic indicators of musculoskeletal system calculated. All data were adjusted for age, height and weight using regression equations. Significant differences were found between adjusted TBBMC, SBMC, TBBMC/LBM and SBMC/LBM but not BH/LBM values in both healthy and IJO cases. Better adjusted logistic curves chi-squares and ROC assessed areas under the curves were found during the acute phase and for IJO girls than boys. Assessed ROC cut off values were close to those corresponding to the inflexion points of logistic curves, pointing on SBMC/LBM and TBBMC/LBM ratios as the efficient (irrespective of the phase of disease) bone quality discriminators in IJO children.

Our study pointed on significant advantage of SBMC/LBM and TBBMC/LBM ratios over typically used BMD in general assessment of bone biomechanical status in IJO cases what postulate on inclusion of these parameters into standard diagnostic procedures in pediatric study of skeletal status.

Title: 30 – VARIABILITY AROUND THE T-SCORE CUTPOINT OF -2.5 IMPACTS DIAGNOSTIC CLASSIFICATION

Authors: *Gary M. Kiebzak, PhD* Chief Research Scientist, Center for Orthopaedic Research; *Ronald C. Hamdy*, Osteoporosis Center, College of Medicine, East Tennessee State University and VAMC, Johnson City, TN; *Edith Seier*, Department of Mathematics, East Tennessee State University, Johnson City, TN; *Nelson B. Watts*, University of Cincinnati College of Medicine, Cincinnati, OH

The least significant change (LSC) value for BMD accounts for measurement variability, and determines when change in BMD is significant. Variability also exists around the T-score cutpoint -2.5, which defines osteoporosis. Our aim was to quantify the effect of variability around the T-score cutpoint of -2.5. We used BMD LSC to calculate a "T-score LSC" as: T-score LSC = BMD LSC/Hologic young normal reference SD. The T-score LSC \pm -2.5 becomes a critical range of T-scores that are not significantly different for each other. For example, T-score LSC for total hip was 0.253 T units, and critical range was -2.247 to -2.753. Upon repetitive scanning, hip classification potentially alternates between osteopenia ($>$ -2.5) and osteoporosis ($<$ -2.5) if the T-score is within the critical range. Critical T-score ranges for total hip, femoral neck and trochanter were applied to a dataset comprising 11 of 808 women with normal spines but osteoporosis in one hip (only right or only left) after each was scanned one time with DXA (Hologic). Five of 11(45%) had T-scores in both hips within the critical range. Thus, upon repetitive scanning, classification would be indeterminate, being sometimes osteopenic, sometimes osteoporotic in one or both hips. One woman (9%) would be osteoporotic in one hip all the time and the other hip none of the time; this woman would potentially be misclassified if only the normal hip was scanned. Conclusion: T-score variability influences the prevalence of osteoporosis, and impacts the decision to scan one hip or two.

Title: 31 – WOMEN WITH OSTEOPOROSIS ARE MISSED WHEN MEASURING ONLY ONE HIP

Authors: *Ronald C. Hamdy, MD* Osteoporosis Center, College of Medicine, East TN; Gary M. Kiebzak, Center for Orthopaedic Research and Education, St. Luke's Episcopal Hospital, Houston, TX; Edith Seier, Department of Mathematics, East Tennessee State University, Johnson City, TN; Nelson B. Watts, University of Cincinnati College of Medicine, Cincinnati, OH

We determined how many women with osteoporosis would be misclassified if lumbar spine and only one hip (left or right) were measured by DXA. This was a retrospective reanalysis of DXA data (Hologic) from 2,115 white women ≥ 50 yrs who had both hips scanned during the same scan session. Patients were sorted based on the WHO classification at the lumbar spine (L1-4). The number of women with osteoporosis in both hips, the left hip only, or the right hip only, was determined by lowest T-score from total hip, femoral neck, or trochanter. 808 women were normal at the spine. Of these, 8 (1.0%) were osteoporotic at both hips. However, 5 (0.62%) were osteoporotic only in the left hip ($P < 0.001$) and 6 (0.74%) only in the right hip ($P < 0.001$). 852 women were osteopenic at the spine. Of these, 93 (10.9%) were osteoporotic at both hips, 47 (5.5%) only in the left hip ($P < 0.001$), and 26 (3.1 %) only in the right hip ($P < 0.001$). We conclude that a statistically significant number of women with osteoporosis are misclassified when scanning only one hip. Although the percentages are low, the total number of women affected may be large. From a public health perspective, the practice of scanning both hips could potentially identify more women with osteoporosis and may help prevent many future hip fractures.

Title: 32 – SHOULD AGE DETERMINE DXA SITES IN MEN?

Authors: *Valentina I. Petkov, MD, MPH* Research Assistant McGuire Research Institute, Richmond, VA; Robert A. Adler, MD, Chief Endocrinology, McGuire Veterans Affairs Medical Center and Professor of Internal and Preventive Medicine, Virginia Commonwealth University, Richmond VA

Current ISCD guidelines recommend osteoporosis (OP) diagnosis to be made using the lowest of 5 DXA regions of interest (ROI): lumbar spine, total hip, femoral neck (FN), trochanter and 1/3 radius. We examined the influence of age on the contribution of each site for OP diagnosis in men.

BMD tests of 552 men referred for DXA scan due to high or moderate Osteoporosis Self-assessment tool (OST) risk were analyzed. Spine, hip and forearm were measured using a Hologic Delphi densitometer. Subjects were divided by age ($< /> 70$ years and by decades).

Among men < 70 years ($N = 191$), 60 had OP (31.4%). None of the men had OP at all 5 DXA ROI. In 14 (23.3%) OP was present only at the spine, in 10 (16.6%) only at the FN, in 5 (8%) only at 1/3 radius, and in one man only the trochanter. In the older group (> 70 years, $N = 361$) 112 had OP (31.0%). Ten (8.9%) had OP at all 5 DXA ROI. Six subjects (5.4%) had OP only in the spine, 15 (13.4%) only in the FN, and 37 (33%) only in 1/3 radius. Using other forearm sites slightly increases the prevalence of OP.

Age may be important to determine sites additional to hip. In younger men spine seems more important; in older men forearm. However DXA of all sites identified the largest number of men with OP.

Title: 33 – DXA QUALITY ASSURANCE FEEDBACK TO CLINICAL SITES IMPROVES ERROR RATES

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DXA scans of 4 anatomical sites from 1707 children ages 6- 16 years) were reviewed to describe the method of applying scan quality assurance codes that define the reason for exclusion of scans from clinical trials and the potential impact of the procedure on future trials. A set of quality assurance codes was applied to describe the reason for either partial or total exclusion of scans from the study. These include removable objects, non-removable objects, excessive x-ray noise due to morbid obesity, hand/hip overlap, anatomy outside scan region, positioning problem, motion, equipment failure, and amputation. The evaluation of the scans showed a total exclusion rate of about 0.6% (0.9% of whole body, 1.2% of forearm, and 0% spine and hip scans). The majority of exclusions were for forearm and whole body scans due to motion (65%) and positioning (21.6%). Problems associated with adults, such as pacemakers and hip replacements were not relevant and, hand/hip overlap and obesity were practically non-existent. When these codes were relayed back to the clinical sites, a marked improvement was observed in the error rate, in some cases an improvement of over 5 fold in the first year of the study.

These results will be useful in setting inclusion criteria and recruitment goals for future pediatric DXA studies and shows that QA feedback to the technologists decreases the error rate.

Title: 34 – COMPARISON OF SHORT- AND LONG-TERM PRECISION OF LUNAR PRODIGY AND HOLOGIC DELPHI SCANNERS

Author: *Thomas N. Hangartner, Ph.D.* Professor of Biomedical Engineering

Whereas short-term precision is important in setting a lower bound on accuracy of a dual-energy absorptiometry instrument, long-term precision is particularly relevant in the assessment of follow-up scans done years later. As part of the daily quality assurance, a phantom containing four blocks of bone-like material covering a density range from 0.45 to 3.0 g/cm² (Hologic units) was measured over a three-year period. The plane areas of the blocks were evaluated by sub-region analysis on two GE Lunar Prodigy and two Hologic Delphi scanners.

The short-term precision for both Delphi scanners was better than 0.6% for densities larger than 1 g/cm²; for the Prodigy scanners it was better than 0.7% for the two mid-sized blocks and 0.8% for the largest block. The precision error of the thinnest block was about 1.2% for all scanners.

The long-term performance of all scanners was influenced by necessary recalibrations, as all scanners were moved to new locations during the observation period, as well as regular scanner maintenance. The Delphi scanners showed no break points in the phantom data, only a very small but significant drift of 0.08% per year change in BMD. One of the Prodigy scanners showed a cumulative change of 4.5% compared to baseline, the other +1.5%. All individual changes refer to break points associated with service calls.

Based on this small sample of scanners, the short-term precision is similar between Prodigy and Delphi; however, the long-term precision is considerably worse for the Prodigy.

Title: 35 – VITAMIN D INADEQUACY IS A GLOBAL PROBLEM IN OSTEOPOROTIC WOMEN

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A recent study in North America found over 50% of women treated for osteoporosis have vitamin D inadequacy. This study assesses the frequency of vitamin D inadequacy among women with osteoporosis in other regions of the world.

1206 women with osteoporosis from 18 countries participated in a single visit cross-sectional study (May through September, 2004) where serum 25(OH)D and intact PTH were collected and a questionnaire about factors that could influence vitamin D was administered. Mean age was 67.7 (range 42-92) with 38% over age 70. 82% reported taking any osteoporosis therapy (including prescription osteoporosis drugs, vitamin D and/or calcium supplementation). Mean 25(OH)D concentration overall was 28.3 ng/ml and mean PTH was 29.3 pg/ml. Overall, 3% of women had 25(OH)D <9ng/ml, 11% <15 ng/ml, 26% <20ng/ml and 58% <30 ng/ml. Prevalence of vitamin D inadequacy (25(OH)D <30 ng/ml) varied by region: 53% in Europe, 82% in Middle East, 57% in Asia, 61% in Central America, 42% in South America, and 59% for Australia. Of women with 25(OH)D > 30 ng/ml, 33% reported taking a vitamin D supplement \geq 400IU daily compared to 19% of those with 25(OH)D <30 ng/ml. Vitamin D inadequacy is widespread among postmenopausal women with osteoporosis, even in countries where there is ample sunlight. In this study, conducted in 18 countries from Europe, Middle East, Asia-Pacific and Latin America, 58% of postmenopausal women with osteoporosis had vitamin D inadequacy. These results underscore the importance of increasing awareness of the need for adequate vitamin D supplementation in women with osteoporosis.

Title: 36 – PREVALENCE OF VITAMIN D INADEQUACY IN A NON-TRAUMATIC FRACTURE POPULATION

Authors: *Christine Simonelli, MD* Director, HealthEast Osteoporosis Care Service; JA Morancey, HealthEast Medical Research System; L Swanson, HealthEast Medical Research System; KK Killeen, HealthEast Medical Research System; K Grimm, HealthEast Medical Research System; TW Weiss, Merck & Co., Inc.; Y Chen, Merck & Co., Inc.

Purpose: Low serum vitamin D is a risk factor for osteoporotic fractures by directly affecting bone mineralization, muscle strength and balance. We report the prevalence of vitamin D inadequacy in a population of adults with non-traumatic fractures.

Methods: 82 adults (ages 52-97) consecutively hospitalized with hip and extremity fractures between 8/2001 and 1/2002 were recruited from two Minnesota hospitals (latitude 42 degrees). Blood specimens were collected within 48 hours of admission. Serum 25-hydroxyvitamin D [25 (OH)D] levels were performed using Diasorin 25-hydroxyvitamin D radioimmunoassay (normal values were 8-30 ng/mL). Results were available for 78 patients. Ideal serum vitamin D level was considered to be >30 ng/mL.

Results: Patients were 99% Caucasian, 63% \geq 80 years, 78% female. On admission, 9% reported using \geq 800 IU per day of vitamin D through supplements (including multivitamins) and 12% were on osteoporosis medication. The mean 25 (OH)D level was 14.2 ng/mL (SD 6.6, range 5-39). 82% of the patients had 25 (OH)D levels \geq 20 ng/mL, including 19.2% < 8 ng/mL and 97.4% of patients had 25 (OH)D levels < 30 ng/mL. Mean 25(OH)D levels did not differ by gender, age, or osteoporosis medication use. Patients who reported vitamin D supplementation \geq 800 IU/day had significantly greater mean 25 (OH)D level compared to those did not (19.0 vs. 13.7; p = 0.04).

Conclusions: Vitamin D inadequacy is common in hospitalized fracture patients, even those who reported sufficient supplementation. Significant opportunity exists to ensure adequate and persistent vitamin D intake in patients at risk for fractures.

Title: 37 – HIGH PREVALENCE OF VITAMIN D INADEQUACY AMONG NORTH AMERICAN WOMEN ON THERAPY FOR OSTEOPOROSIS

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The objective was to assess serum 25(OH)D concentrations in postmenopausal women receiving therapies to treat or prevent osteoporosis and to evaluate factors related to 25(OH)D concentration.

1554 postmenopausal, North American women were recruited between November 2003 and March 2004. A serum 25(OH)D and intact parathyroid hormone (PTH) were obtained. Factors influencing vitamin D status were assessed by questionnaire. A multivariate logistic regression model was used to analyze factors related to suboptimal (<30 ng/mL) 25(OH)D concentrations.

1536 subjects completed the study. Their mean age was 71 years and 92% were Caucasian. 35% of subjects resided at a latitude $\geq 42^\circ$ N, while 24% resided below 35° N. Mean(SD) serum 25(OH)D was 30.4 (13.2) ng/mL. Serum 25(OH)D was <20 ng/mL in 18%, <25 ng/mL in 36%, and <30 ng/mL in 52% of subjects. Suboptimal 25(OH)D concentration was present in 63% of subjects receiving <400 IU of vitamin D daily compared with 45% receiving ≥ 400 IU of vitamin D daily, $p < 0.001$. Factors significantly related in a multivariate analysis to vitamin D inadequacy (25(OH)D <30 ng/mL) included: age >80 years, race (non-Caucasian), BMI >30 kg/m², use of medications affecting vitamin D metabolism, supplementation of <400 IU vitamin D daily, lack of exercise, education level less than grade 12, and absence of previous physician counseling regarding vitamin D.

In conclusion, more than half of North American women receiving osteoporosis therapy have vitamin D inadequacy. These findings underscore the need for improved education of physicians regarding optimization of vitamin D status in postmenopausal women with osteoporosis.

Title: 38 – COMMON SCALE DEFINITELY NECESSARY FOR PATIENTS TO ACCEPT OSTEOPOROSIS TREATMENT

Author: *Akira Itabashi, MD, PhD* Professor of Clinical Laboratory Medicine, Saitama

If someone has serum cholesterol of 280mg/dl, or blood pressure of 180/100, he consults a doctor because he understands he may have a disease. Cholesterol or blood pressures are now common scales to talk about the diseases. How about osteoporosis? Do we have such a common scale? What does BMD of 0.613 g/cm² mean to the patients? Do they promptly understand that they may have osteoporosis? Actually, we need more informations such as measurement type, body sites, manufacturers, etc, and still comparisons are not easy.

Do T-scores help? As long as the spine or hip BMD is concerned, T-score can tell how low their BMD is compared with the young adults mean (YAM). But, busy physicians in other part of the world have no easy access to central DXA. If we use the peripheral devices, the T-score variation is quite large. Moreover, the concept of T-score is not easily understood by the patients or even by the physicians.

How about the percent value compared with the young adult mean (percent of YAM)? It can eliminate, although not totally, some of the discrepancies of T-score variations as is reported in the other abstract. This concept is easily understood by regular physicians and even by the patients. It can become a common scale in the osteoporotic field like serum cholesterol or blood pressure. We definitely have to seek such kind of easy scale for the advancement of prevention and treatment of osteoporosis. Then we will not have to complain underdiagnosis or undertreatment.

Title: 39 – FAILURE TO MOTIVATE ORTHOPEDIC SURGEONS AND NEUROLOGISTS TO REFER HIGH RISK PATIENTS FOR DEXA EXAM

Authors: *David R. Mandel, MD* Rheumatologist, Private Practice; Patricia L. Scott, C.D.T., David R. Mandel, MD, Inc.

Osteoporosis patients with important clinical risk factors are often not evaluated in a timely way with bone mineral density (BMD) studies for possible medical therapy. Two large groups at risk are those who have had recent fragility fractures and those who have had a hemiplegic stroke.

We initiated a study to educate local orthopedic surgeons and neurologists about these high risk patients. They were provided newsletters and medical articles about the benefits of BMD studies.

At educational conferences we invited 40 orthopedic surgeons and 20 neurologists to refer at least 6 patients over a 3-month period of time who had a fragility fracture or a hemiplegic stroke in the past year. Each physician was provided with 6 vouchers which would enable their patients to receive a free DEXA BMD study. Results of the study would then be sent to both referring physicians and the patient's primary care physician.

Only two patients were referred for BMD during the first 3 months. A follow-up letter informing the referring physicians of the small number of referrals was sent. Additional medical information and articles were also sent to encourage and motivate them. The study was continued for an additional 3 months with no additional patients referred.

These results would indicate that physicians who come in contact with patients at risk for fracture do not refer for BMD studies. Additional study is required to understand what factors encourage and impede physicians to refer their patients who are at high risk for fracture.

Title: 40 – ASSESSMENT OF HYPERTENSION AS A RISK FACTOR FOR LOW BONE MINERAL DENSITY IN ELDERLY MEN

Authors: *Gul Bahtiyar, MD* Endocrine Fellow, SUNY Downstate Medical Center, NY; Amal Farag, VA New York Harbor Healthcare Center at Brooklyn; Helena Guber, VA New York Harbor Healthcare Center at Brooklyn; Rajagopal Nikkanti, VA New York Harbor Healthcare Center at Brooklyn; Vincent Pantone, SUNY Downstate Medical Center; Deana Heller, SUNY Downstate Medical Center; Omar Murad, SUNY Downstate Medical Center; Samy I McFarlane, SUNY Downstate Medical Center

Hypertension (HTN) has been identified as a risk for low bone mineral density (BMD) in women that is associated with increased urinary calcium excretion. The objective of the study is to evaluate HTN as a risk factor for low BMD in men. In a cross sectional analysis we reviewed the charts of 887 men referred for BMD measurements at two major institutions in Brooklyn, NY. Risk factors were assessed via a questionnaire. Low BMD was defined as T-score < -1 at the lumbar spine. Of these 887 elderly men, 52.8% were white, 38.5% were black and 7.9% were Hispanic. Mean age (years) = 71.86 ± 0.38 (+ SEM) and BMI (kg/m²) = 27.3 ± 0.27. 72% had HTN. Mean systolic blood pressure (BP) = 130 ± 7 mmHg and diastolic BP = 73.8 ± 4 mmHg. 66% of the hypertensive patients had low BMD compared to 53.5% of the non-hypertensives (p < 0.002). In a logistic regression model, HTN predicted the presence of low BMD, odds ratio (OR) = 1.73 (1.2-2.4) (p < 0.01) (95% CI). After adjusting for osteoporosis risk factors, HTN remained a significant predictor for low BMD, OR = 1.7 (1.16-4.8) (p < 0.02) (95% CI). HTN appears to be an independent risk factor for low BMD in men. Since traditional risk factors such as age, family history of osteoporosis, smoking, steroids and hypogonadism only explain 40 to 60 % of men with osteoporosis, identification of non-traditional risk factors is exceedingly important for enhanced screening and development of further research in the area that leads to effective therapeutic strategies.

Title: 41 – LOW BODY WEIGHT PREDICTS INCIDENT FRACTURE RISK AS THE RESULT OF DECREASED DXA BMD

Authors: *Richard Prince*, Associate Professor University of Western Australia; Amanda Devine, Research Officer, University of Western Australia; Ian Dick, Research Officer, University of Western Australia; Rakhshanda Naheed, Clinical Trials Clinician, University of Western Australia

Low body weight is considered to be a determinant of fracture risk but it is not certain if this is independent of bone mineral density. As part of a five year study, we examined the association of low body mass index (BMI), age at baseline and hip BMD with the risk of incident osteoporotic fracture.

1499 women mean age 75 were recruited from the whole population. Study exclusions were bone active treatment, calcium supplementation or diseases that may have prevented the subject completing the 5 year study. Of the responders, 18% were eligible and agreed to participate. Hip BMD (cv 1.0%) was measured using an Hologic 4500A. Incident X-ray verified osteoporotic fractures were ascertained 4 monthly. Study outcomes were examined using the Cox proportional hazard model to calculate hazards ratios (HR).

Low BMI, low BMD and increasing baseline age were all related to an increased risk of fracture. A 1 year increase in age was associated with a 9.8% (P<0.001) increase in 5 year fracture risk. A 1 SD reduction in BMD was associated with an increased risk of incident fracture (HR 2.64: 1.86-3.73). Patients in lowest tertile of BMI (<24.9) compared to the highest tertile (>28.6) had an increased risk of fracture (HR 1.45: 1.01-2.10). After adjustment for BMD and age, a low BMI was no longer associated with increased fracture risk (HR 0.86: 0.56-1.30).

Therefore, a low body mass index is associated with increased risk of fracture due to its association with low BMD.

Title: 42 – QUANTITATIVE HEEL ULTRASOUND IMPROVES SCREENING FOR OSTEOPOROSIS COMPARING TO FRACTURE RISK EVALUATION

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We present the role of the quantitative heel ultrasound evaluation comparing to anamnestic risk factors for osteoporosis in a transversal study. Subjects were 800 postmenopausal women with mean age of 61.6 years. All the patients risk factors were assessed through a short questionnaire (modified from IOF risk evaluation) and ultrasound quatitative (QUS) evaluation in the right heel was performed with an Achilles express Plus machine (Lunar GE). Stiffness index (SI), T score and Z score (percent and SD) were recorded. Mean SI was 77.8 with a mean T score of 1.5 SD and mean Z score of 0.4 SD. We found a significant correlation between QUS results and prevalence of fractures (p<0.03), secondary causes of osteoporosis like glucocorticoid or hyperthyroidism (p<0.01) and early menopause (p<0.05). We found no correlations between QUS results and loss of height, diarrhea or alcohol consumption. 8% women without risk factors but low SI values were shown to be osteoporotic through DXA evaluation. Comparing to anamnestic risk factors, identification of the women with low bone mass is slightly increased by the QUS evaluation.

Title: 43 – A PRACTICAL NON VERTEBRAL FRACTURE RISK SCORE COMBINING CLINICAL FACTORS AND QUS FOR 70 YEARS OLD WOMEN AND OLDER: THE SEMOF AND EPIDOS PROSPECTIVE STUDIES

Authors: *M.A. Krieg, MD, PD* Internal Medicine, University Hospital, Lausanne; D. Hans, Ph.D, PD, MBA, Nuclear Medicine, Geneva University Hospital; J. Cornuz, MD, PD, Internal Medicine, University Hospital, Lausanne; C. Ruffieux, Msc, A.M. Schott, MD, Medical Information, Hospices Civils of Lyon, Lyon, France; Prof P. J. Meunier, MD, Inserm u 403, Edouard Herriot Hospital, Lyon, France.; Prof P. Burckhardt, MD, Internal Medicine, University Hospital, Lausanne, Switzerland; and the SEMOF and EPIDOS study groups.

Many studies have shown that heel bone ultrasound (HBU) predicts non vertebral fractures in elderly women, and thus could be potentially useful as a pre-screening method. It was suggested that its association with other risk factors for osteoporosis could improve the discrimination of women at high risk for fractures but no practical combination has been developed so far.

The SEMOF study is a Swiss prospective multi-centre cohort study, in which 7 023 women aged 70 to 84 years have been included. At baseline, all the women were measured by the HBU Achilles+, and examined for their risks for osteoporosis. During a mean period of 2.8 ± 0.8 years follow-up, 349 women reported an osteoporotic hip, forearm, or humerus fracture. Each risk factor of fracture was included in a multivariate Cox model in order to establish a score of risk subcategorized as high risk (20% of false positive - specificity 80%), or low risk (20% of false negative - sensibility 80%).

HBU, age, fall last year, fracture history, and chair test are the independent predictors of fracture selected to calculate the score of risk. The application of the latter classified 22% of the women at high risk, 38% at low risk, and 40% at moderate risk. 56% of the women who reported a hip fracture were at high risk at baseline which was better than the use of HBU alone. We cross-validated our score of risk in the French prospective multi-centre cohort study, EPIDOS, in which 5 146 French women aged 75 to 84 years were recruited. Similar results were found and 63% of the women who reported a hip fracture were considered at high risk, and only 6% at low risk.

Associating heel bone ultrasound with other clinical risk factors for osteoporosis allows a good discrimination of elderly women at high risk for non vertebral fractures, from those at low risk. Current cost-effective analysis is underway to further validate such an approach for pre-screening.

Title: 44 – PREVALENT FRACTURE PREDICTS FUTURE FRACTURE RISK INDEPENDENTLY OF DXA BMD IN OLDER WOMEN

Authors: *Richard Prince*, Associate Professor Associate Professor, University of Western Australia; Amanda Devine, Research Officer, University of Western Australia; Ian Dick, Research Officer, University of Western Australia; Rakhshanda Naheed, Clinical Trials Clinician, University of Western Australia

In epidemiological studies a history of previous fracture is considered to be a determinant of future fracture risk. It is not certain if this is independent of bone mineral density.

We have examined the association of prevalent osteoporotic fracture independently and in association with BMD on the risk of 5 year incident osteoporotic fracture.

1499 women mean age 75 were recruited from the whole population. BMD was measured using an Hologic 4500A. Fractures since the age of 50 were ascertained at baseline and coded as none, 1, or >1 prevalent fractures. Incident fractures, defined as all fractures, except those of phalanges or skull, verified by x-ray, were recorded. Hazards ratio and 95% confidence intervals (HR) of the outcomes were examined using the Cox proportional hazard model.

20.2% and 7.7% of patients had sustained 1 or >1 prevalent fracture respectively after age 50. 235 individuals (16.1%) sustained 296 fractures during the study. During the study, 4.6% of patients died and 11.3% were lost to follow up. The 5 year incident fracture risk was associated with >1 prevalent fracture (HR: 1.99: 1.26 3.15) but not 1 prevalent fracture (HR 1.27 0.88 1.85). A 1 SD lower BMD was associated with an increase risk of incident fracture risk (HR 2.64: 1.86-3.73). After adjustment for BMD and age, >1 prevalent fracture remained an increased incident fracture risk (HR 1.79: 1.13 2.84).

Therefore, multiple prevalent fractures, but not one, significantly increase the risk of fracture independently of BMD.

Title: 45 – CHANGES IN VERTEBRAL FRACTURE STATUS IMPACT DXA MEASUREMENTS OF BMD

Authors: *Paul Miller, MD* Colorado Center for Bone Research; Leon Lenchik, Wake Forest School of Medicine; Peiqi Chen, PhD, Eli Lilly and Company; Derek Misurski, PhD, Eli Lilly and Company; John Krege, Eli Lilly and Company, MD

New or worsening vertebral fractures not detected during posterioranterior dual x-ray absorptiometry (DXA) assessment of bone mineral density (BMD) could result in falsely reassuring increases in follow-up lumbar spine BMD measurements. We assessed the impact of changes in fracture status on the BMD of vertebrae in postmenopausal women with osteoporosis. Lateral radiographs and DXA assessments (BMD, bone mineral content [BMC], area) were obtained at baseline and endpoint from the placebo groups of the Fracture Prevention Trial (FPT, n = 439, median 21 months observation) and the Multiple Outcomes of Raloxifene (MORE, n = 2276) Trial at three years. Vertebrae were graded using a visual semi-quantitative scale with a score of 0 for no fracture, and 1,2, and 3 for mild, moderate, and severe fracture, respectively (Genant et al. 1983). For each unit increase in fracture grade, the BMD of vertebrae increased on average by 5.4% and 6.6% in the FPT and the MORE Trial, respectively. The increase in BMD was driven by BMC, with strong positive correlations between these parameters (FPT, $r = 0.88$; MORE, $r = 0.87$). Surprisingly, there was a weak, but positive correlation between increases in BMD and area (FPT, $r = 0.32$; MORE, $r = 0.28$). In conclusion, new or worsening L1–L4 fractures increased the BMD of affected vertebrae by ~6% per unit increase in fracture grade. This was due to an increase in BMC and not a decrease in area.

Title: 46 – RISEDRONATE 15MG/DAY IS SAFE OVER WIDE RANGE OF RENAL FUNCTION

Authors: *Paul D. Miller, MD* Medical Director, Colorado Center for Bone Research; Simon H. Magowan, MD, Procter & Gamble Pharmaceuticals, Mason OH; Ian Barton, BSc, Procter & Gamble Pharmaceuticals, Egham, UK; John Beary, MD, Procter & Gamble Pharmaceuticals, Mason OH; Clifton O. Bingham III, MD NYU Hosp for Joint Diseases, New York, NY; Silvano Adami, MD, University of Verona, Verona, IT

BACKGROUND: Following oral administration, risedronate is primarily eliminated via the kidneys. Reduced drug clearance and consequent elevated serum levels could potentially increase the likelihood of adverse events.

OBJECTIVE: This analysis investigates the influence of renal function on the safety profile of risedronate 15 mg/day.

METHODS: The analysis included patients enrolled in the placebo-controlled phase III osteoarthritis clinical trials. Patients were randomized to receive placebo (N=622, female 70%: male 30%) or risedronate 15mg daily (N=609, female 71%: male 29%). For each patient, creatinine clearance was estimated using the Cockcroft-Gault methodology based on baseline serum creatinine, body weight and age. The incidence of adverse events was summarized for patients possessing a wide variety of renal function.

RESULTS: The mean age (SE) of the risedronate-treated population was 61.6 (8.6) years and 61.9 years (8.8) for the placebo. The baseline range of creatinine clearance was 37.2 to 270.0 ml/min for the risedronate arm and 31.8 to 213.1 ml/min for placebo arm. The average duration of drug exposure was 104 weeks. There was no observed relationship between AE incidence rate and baseline renal function in the two treatment groups (placebo: $R^2 = 0.001$; 15mg risedronate: $R^2 = 0.001$). The AE incidence observed was also not statistically different between the treatment groups.

CONCLUSION: This analysis shows, based on phase III clinical trial experience, that risedronate 15mg/day, which is 3 times higher than the usual dose for treatment of postmenopausal osteoporosis, demonstrates an excellent safety profile, similar to placebo, over a wide spectrum of renal function.

Title: 47 – DESIGN OF SHORT-TERM PRECISION STUDIES IN BONE DENSITOMETRY: SAMPLE SIZE DETERMINATION

Authors: *Satvinder S. Dhaliwal*, Mr Senior Lecturer, School of Public Health, Curtin University; A/Prof Richard Prince, School of Medicine & Pharmacology, University of Western Australia

Current bone densitometry literature recommends that the combination of numbers of subjects and repeat measurements per subject in the design of short-term precision study as: Number of subjects X (Number of repeat scans - 1) = 30, to ensure statistical validity. The aim of a precision study is to determine the Least Significant Change (LSC). It is the smallest difference between serial measurements above which it can be concluded that the change is statistically significant. However there is an error on this estimate. We conducted a short-term precision study of 72 unselected females (Age: 50.5±6.5y) representative of the population of patients visiting our bone densitometry facility. These subjects were scanned twice at the spine and hip using the Hologic QDR2000. Differences between total spine BMD repeat measurements were normally distributed (0 ± 0.01578). Simulation studies were then performed to quantify the variability in LSC values at the 80% and 95% level of confidence. An analytical solution was also developed which agreed very closely with the simulation approach. The sample size table for various levels of precision (95% CI) for total spine BMD LSC is:

Confidence	LSC	95% CI	No. Subjects	No. Repeat Scans	95%	± 5 mg	
73	2	95%	± 5 mg	37	3	95%	± 8 mg
29	2	95%	± 8 mg	15	3		

In practice, for a precision study of about 30 subjects scanned twice the total spine BMD LSC 95% CI is about ± 8 mg. In addition to statistical validity requirements, variability in LSC values should be considered when designing precision studies.

Title: 48 – UNIVERSAL METHOD FOR MONITORING BMD CHANGE WHEN MEASURED ON DIFFERENT DEVICES

Authors: *John A. Shepherd, Ph.D.* Assistant Professor of Radiology, University of California; Ying Lu, Associate Professor of Radiology, University of California at San Francisco, San Francisco, CA

We present a method to determine the least significant change between two measures taken on two different devices to aid the clinician in this common circumstance. Least significant change (LSC) is the minimum amount of bone mineral density (BMD) change between baseline and follow-up measures beyond statistical variation with at least 95% confidence. Mathematically, LSC from measures on a single device is 2.77 times the precision errors. It is ever more common for a physician to be presented with two BMD measures from different devices. In this case our method calculates the LSC using input from previous precision and cross-calibration studies including the sample size, regression coefficients, and the sample study mean BMD values. Using previously published total hip BMD data of a Hologic QDR-2000 upgraded to a QDR-4500, the precision of a Hologic QDR-4500 is 0.00774 g/cm². A change in BMD between two visits on the QDR-4500 alone of more than 0.0214 g/cm², i.e. the LSC, is statistically significant. We find that if the first visit occurred on the QDR-2000, then the LSC would increase to 0.0354 g/cm² for women whose baseline BMD are equal to the population mean value - a 65% increase from using just the QDR-4500. Furthermore, our LSC increases to 0.0366 g/cm² at the extremes of the clinical BMD range (0.7 g/cm² or 1.3 g/cm²), since there is less certainty in the cross calibration results at the extremes. We conclude that the LSC from two different devices is much higher than the LSC from a single device and can be practically quantified.

Title: 51 – DXA EVALUATION IN CHILDREN WITH SLIPPED EPIPHYSIS OF THE HIP

Authors: Elizabeth A. Szalay, MD Associate Professor of Pediatric Orthopaedics, UNM Carrie Tingley Hospital; David P. Huberty MD, PGY V Resident in Orthopaedics

Given that slipped capital femoral epiphysis (SCFE) is a condition seen in obese children during the preadolescent growth spurt and in children with endocrine disorders, low bone mineral density was proposed to be a factor in the disorder.

Dual energy x-ray absorptiometry (DXA) scanning of the spine and one or both hips was performed on 15 children with SCFE and on obese children without the hip disorder. All scans were performed on a Hologic Delphi W densitometer by the same technician and were interpreted by a pediatric orthopaedic surgeon certified in clinical densitometry. Z-scores were obtained using a pediatric database. Mean and standard deviation of the Z-scores were calculated, and paired T-tests were used to assess differences between sites.

For patients with SCFE, the mean Z-score at each of 5 skeletal sites assessed (spine, femoral neck x 2, total hip x 2) was positive, or greater than the mean, by an average of >1 standard deviation. The control subjects as well demonstrated a bone density that was greater, not lower, than the mean. P value was .02.

This demonstrates that children with SCFE do not have low bone density, but actually show BMD that is significantly higher than expected for age and sex. Despite the fact that bone density is endocrinologically driven and that endocrinological abnormalities are implicated in SCFE, there appears to be no correlation between low bone density and SCFE.

Title: 52 – DEPRESSED VITAMIN D LEVELS AND ULTRASOUND T SCORES IN INSTITUTIONALIZED PATIENTS WITH MENTAL RETARDATION

Authors: Camille Hemlock, M.D. Medical Director, Texas Department of Aging; Ekaterina Alberts, M.D., Texas Health Foundation, Austin Texas; Nikesh Patel, PharmD, PhD, College of Pharmacy, The University of Cincinnati, Cincinnati, OH; Paul Miller, M.D., Colorado Center for Bone Research, Lakewood, CO

The purpose of the study was to evaluate serum 25-hydroxy (OH) vitamin D levels and heel ultrasound densitometry readings in patients with mental retardation at Austin State School and to characterize those with an abnormality.

Patients' respective medical charts were reviewed for demographic and clinical information. Serum 25-OH vitamin D levels were obtained (Nichols Advantage®). Vitamin D deficiency was defined as a serum 25-OH vitamin D level less than or equal to 30 nanograms per milliliter (ng/mL). Heel ultrasound T-scores were obtained with a Lunar Achilles Express in those patients who were able to cooperate with exam.

A total of 173 patients, mean (+/- standard deviation [SD]) age of 48.3 (+/- 14.2) years, were evaluated. Eighty-four (48.6%) patients were male, and a majority (n=109, 63.0%) were Caucasian. The mean (+/- SD) 25-OH vitamin D level was 26.7 (+/- 14.0) ng/mL, with 123 (71.1%) patients having serum 25-OH vitamin D levels below 30 ng/mL. Of these 123 patients, 63 (51.2%) had levels between 21 and 30 ng/mL, 46 (37.4%) between 11 and 20 ng/mL, and 14 (11.4%) below 11 ng/mL. Patients with pigmented skin and/or receiving anticonvulsants had an increased risk of having deficient serum vitamin D levels. Tube-feeding may be protective against vitamin D deficiency. T-scores were universally depressed but did not correlate with vitamin D levels. Sixty-two percent (76/123) had a diagnosed fracture, with a mean (+/-SD) of 1.4 (+/- 1.7) fractures.

Institutionalized patients with mental retardation are at risk for low bone mass and vitamin D deficiency.

Table 1. Characteristics of Patients with Vitamin D Deficiency

	21-30 ng/mL (n=63)	11-20 ng/mL (n=46)	< 11 ng/mL (n=14)
Age (y)	49.0±14.9	49.0±15.5	44.9±12.6
Caucasian*	74.6%	54.3%	35.7%
Nonambulatory	38.1%	23.9%	28.6%
Tube-fed	15.9%	2.2%	7.1%
Current or history of AED	69.8%	82.6%	64.3%
BSAP (IU/L)*	41.4±14.0 (n=45)	52.4±25.1 (n=32)	52.1±21.5 (n=13)
Vitamin D supplement (IU/day)	795.2±1073.9 (n=41)	649.3±340.0 (n=33)	571.4±292.8 (n=7)

*p<0.04.

Table 2. Characteristics of Patients Heel ultrasound t-scores

	21-30 ng/mL n=33	11-22 ng/mL n=23	< 11 ng/ml n=4
Vitamin D level			
Number of patients	n=33	n=23	n=4
Median t score	-1.80	-1.70	-3.05
Mean (+/-) standard deviation t score	t -1.88 (+/- 1.42)	t -1.73 (+/- 1.51)	t -2.73 (+/- 1.01)

p=0.4435 not statistically significant

Title: 53 – EVALUATION OF OSTEOPOROSIS WEBSITE QUALITY

Authors: *EM Lewiecki, MD* New Mexico Clinical Research & Osteoporosis Center; LA Rudolph, New Mexico Clinical Research & Osteoporosis Center, Albuquerque, NM, USA; GM Kiezbak, St. Luke's Episcopal Hospital, Houston, TX, USA

Aim. To develop and validate a measurement tool for evaluating the quality of medical websites for patients, and use the tool to test the quality of Internet patient education on osteoporosis. **Methods.** The Healthcare Website Assessment Tool (HWAT) was developed with weighted quality indicators for content, credibility, navigability, currency, and readability. Websites were selected from a Google (www.google.com) search for osteoporosis. Interobserver reliability was tested for two types of observers- physician osteoporosis experts and osteoporosis nurse educators, with results expressed as percent agreement in the scoring of each quality indicator. Validity was tested by measuring the percent agreement of nurse educators with physician experts. Website evaluation was done by an osteoporosis nurse educator for 100 websites. **Results.** Interobserver reliability testing showed 88% agreement for the physician osteoporosis experts, and 79% for the osteoporosis nurse educators. Validity testing showed 71% agreement between the physician osteoporosis experts and the osteoporosis nurse educators. The evaluated websites had scores ranging from 9 to 96 in a normal distribution, with a mean of 57 and a median of 65. Scores for the top decile of matches were significantly better than the bottom decile (P=0.008). Websites with Uniform Resource Locator (URL) suffix .org scored significantly higher than those with .com (P=0.005). **Conclusions.** A medical website quality measurement tool was developed, demonstrated to have acceptable interobserver reliability, and to discriminate variations in quality indicators for osteoporosis websites. Significant variability in website quality was observed, with higher quality scores associated with a higher level of search engine match and URL suffix.

Title: 54 – CAN AN ON-LINE OSTEOPOROSIS LECTURE INCREASE PHYSICIAN KNOWLEDGE AND IMPROVE PATIENT CARE?

Authors: *Karen E Hansen, MD* Assistant Professor of Medicine, University of Wisconsin; Elaine Rosenblatt, NP, University of Wisconsin; Matt Crowe, MD, University of Wisconsin

Background: While numerous studies have assessed whether Continuing Medical Education (CME) modalities increase physician knowledge, few studies have investigated whether such gains in knowledge improve subsequent patient care. Furthermore, few studies have looked at the internet as a mode for CME delivery.

Methods: We hypothesized that an on-line osteoporosis course would increase physician knowledge and improve subsequent patient care. Subsequently, six internists consented, and listened to an internet lecture that identified risk factors for osteoporosis and fracture, physical signs of prior fracture, and current screening guidelines for postmenopausal osteoporosis. Immediately preceding and following the course, two questionnaires assessed baseline and subsequent knowledge. To investigate change in patient care, ten new female patients > 60 years old from each participant's clinic were randomly identified, half before and half following the lecture. Each chart was scored for the following items: risk factors for fracture/osteoporosis, examination for signs of prior fracture, and appropriate screening for and treatment of osteoporosis.

Results: Physician knowledge increased significantly following the on-line lecture. The mean pre-test and post-test scores were 62.5% and 98.9% respectively (p<0.0001). Subsequently, among 49 patients, patient care scores did not show statistically significant improvement (p values >0.05).

Conclusions: We found that while physicians gained knowledge following an on-line lecture, no change in patient care was demonstrated. Visual aids, workshops, patient partner programs, or a second lecture might be more successful at improving patient care than a single, on-line lecture. Further studies are needed to determine what forms of CME translate into improved practice behaviors.

Title: 55 – TRAINING REQUIREMENTS FOR DXA TECHNOLOGISTS IN THE UNITED STATES

Authors: *Laura D Carbone, MD, MS* University of Tennessee Health Science Center; Karen D Barrow, University of Tennessee Health Science Center; Julie Vannerson, University of Tennessee Health Science Center; M David Boatright, University of Tennessee Health Science Center; Laura D Carbone, University of Tennessee Health Science Center, MD, MS; Karen D Barrow, University of Tennessee Health Science Center, MS; Julie Vannerson, University of Tennessee Health Science Center, MD; M David Boatright, University of Tennessee Health Science Center, MD; Catherine Womack, University of Tennessee Health Science Center, MD

DXA quality is dependent on the skill of the technologist. The purposes of this study were to determine, by state, the requirements for DXA operators training, knowledge of these state requirements and factors that predicted ISCD certification of DXA technologists.

The majority of states allowed either an RT or licensed/authorized certification for DXA operators (n=17) or had no certification requirements (n=16). 12 states required RT certification to operate a central DXA and 5 had state specific requirements. Among states allowing limited certification, the mean estimated cost of this was \$664.00, with a range of \$55.00 (Minnesota) to \$2640 (Tennessee).

9745 surveys including 50% (Hologic Inc.), (50% GE Lunar) and (100% Norland), users were mailed. 3188 surveys were returned (response rate 32.7%).

Those who were not current central DXA users and those in whom no information relative to state or ISCD certification was completed were excluded, (final n= 3120). Among responders who indicated that their state did not require certification (n=1661), 1084 (65.3%) were incorrect; there were requirements. There was a significant correlation between ISCD certification and number of patients scanned per week, length of operation of DXA machine, number of technologists employed within a center, and subspecialty of the practitioner.

The major findings of our study are that there is a lack of uniformity within the United States among states with respect to requirements for training of central DXA operators, DXA operators are often unaware of these state requirements and there are factors which predict ISCD certification of technologists.

Title: 56 – SURGICAL VS. MEDICAL WEIGHT LOSS: “SOFTER” AND MORE “BARREL-LIKE”

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We have shown that total body DXA derived measures of fat distribution (% truncal fat and height corrected limb fat) and skeletal muscle mass (limb lean) are predictive of total mortality for low limb lean (soft) and cardiovascular mortality for barrels (high %trunk fat, low limb fat). BARI_DXA is the first prospective study of change in body composition following laproscopic Roux-en-Y gastric bypass, with a control group of patients undergoing pre-surgical medical weight loss over a similar time.

Methods: All patients were evaluated and followed at the same facility. Total body scans were performed at baseline and three months on a LUNAR-GE PRODIGY and analyzed with ½ body custom software.

Results: Comparing the standard total body and ½ body protocol on 141 patients scanned in the 9 months prior to the current study we found good concordance within 1% for soft tissue (lean and fat). 13 subjects are included in our analysis: 8 surgical, 5 medical. Mean weight loss was similar (-11.0 (17) vs. -10.9(14) kg) but, 5/8 surgical vs. 0/5 medical subjects lost more than 6% limb lean mass (softer , p = .024) and 4/8 vs. 0/5 were more barrel like (p= .057). However, in 3 surgical patients % trunk fat favorably decreased (-2, -3.2, -10%) and limb lean mass increased (+13,+9,+5% respectively), indicating that adverse changes in body composition are likely attributable to post-operative factors. In summary, total body DXA can identify unfavorable changes in body composition after bariatric surgery and potentially serve as a diagnostic tool for timely intervention.

Title: 57 – A SURPRISING DIAGNOSE FROM A MEASUREMENT OF BONE MARKERS

Authors: *H. Kaessmann, MD* Department of Nuclear Medicine and Endocrinology; L. Rettenbacher MD; G. Galvan MD; C. Pirich MD

The usefulness of bone markers is still under debate at least for the individual patient and the routine use in an osteoporosis clinic is discussed controversially. We demonstrate the importance of a full laboratory work up when doing bone densitometry.

A 51y old lady presented to our osteoporosis unit for a DXA test because of the history of long term thyrotoxicosis. T-scores of lumbar spine and femoral neck were +0.7 SD and +0.69 SD respectively. As she was perimenopausal at this time we recommended a follow up visit 5 years later.

Eight years later she returned for another DXA test using Hologic QDR 4500W. The T-score in lumbar spine dropped to -1.70 SD, in the femoral neck to -0.15 SD representing a loss of 23% in lumbar spine. We did our complete laboratory programme including markers of bone turnover. Serum Crosslaps (10.787 pmol) and Osteocalcin (53.4 ng/ml) showed a massive high turnover situation. Thyroid hormones were thyrotoxic again, a fact that became relevant to us at a later time point. At next we performed bone scintigraphy which revealed some hot spots suspected for malignancy. Further tests were delayed until Dec. 2003 when a bone biopsy was done finally. Histology showed a metastasis of a highly differentiated follicular thyroid cancer. Further investigations confirmed the rare diagnosis of hyperthyroidism caused by functional bone metastases.

Aside from the curious circumstances which delayed diagnosis of a life threatening disease this case report demonstrates in a unique manner the value of testing bone markers in the assessment of osteoporosis.

Title: 59 – PERCENT OF YOUNG NORMALS THAN T-SCORE REDUCES DISCREPANCY AMONG DENSITOMETRIES

Authors: *Akira Itabashi, MD, PhD* Professor of Clinical Laboratory Medicine, Saitama; Sumiaki Okamoto, Okamoto Clinic

One of the major issues of diagnosing osteoporosis using WHO criteria (T-score definition) is that the T-score may be easily affected by the distribution (standard deviation) of the reference samples. For example, the same lumbar BMD value using the same manufacture machine gives us different T-score results between US and Japan. Moreover, if we measure different body sites like spine, femur, total body, forearm, fingers, calcaneus, the discrepancy of T-score is huge among the measurements. So, some women may be diagnosed osteoporotic when measured with one method, while they may be diagnosed normal when measured with other methods. This generates a tremendous confusion among physicians and also upsets many patients. Especially in Japan, so many peripheral devices are used by the clinical sites.

In Japan, we use the percent of the young adult mean (% of YAM) as a diagnostic criteria, osteoporosis as less than 70% of YAM (T-score less than -2.4, QDR L2-L4 BMD cut-off value 0.708g/cm²). We compared the age-T-score decline curves with age- % of YAM decline curves among several densitometry devices using the Japanese reference data. Although the decline curves do not coincide among the devices, we found less discrepancy among the densitometry devices when we use the percent % of YAM. It is easily accepted by the patients as well as physicians and health professionals.

We propose to introduce the percent of young normals to the regular practice.

Title: 60 – FOREARM LENGTH MEASUREMENT ERRORS AFFECT PEDIATRIC BMD

Authors: *Bo Fan, MD* Assistant Researcher, University of California San Francisco; JA. Shepherd, Assistant Professor, University of California San Francisco, San Francisco, CA; V. Gilsanz, MD, Children's Hospital of Los Angeles; M. Horlick, PhD, Columbia University; H. Kalkwarf PhD Children's Hospital of Cincinnati; J. Lappe PhD Creighton University; B. Zemel MD Children's Hospital of Philadelphia; M. Frederick PhD Clinical Trials & Surveys Corp.; K. Winer MD National Institute of Child Health and Human Development

Placement of the region of interest (ROI) for analysis of a standard forearm dual x-ray absorptiometry (DXA) scan requires a precise forearm length measurement, as placement of the ROI affects the bone mineral density (BMD) results of the scan. In longitudinal pediatric studies, this is potentially a major source of error because subjects are still growing. To determine if inaccuracy of forearm length measurement has an impact on the BMD results of the radius and to compare this to reference forearm growth rate, we studied forearm DXA scans from 1554 children, ages 6 to 16, (863 girls) who were enrolled in BMDCS at 5 clinical centers. Each subject had a baseline and a one year follow-up scan of the forearm on the Hologic Delphi. Forearm length measurements were obtained at each visit. We found that the cross-sectional growth rate in forearm length is similar between boys and girls, with a steady increase of about 9mm/year till age 10, after which the mean growth rate declines. The longitudinal change rate at 3 study sites followed a similar pattern as the cross-sectional changes. The remaining two sites showed one with significantly higher growth rate and the other with a negative growth rate. 34 of those scans were chosen for reanalysis after intentionally shortening the original forearm length by 10 mm. The change in BMD between the original and shortened length data was 0.9 and 1.5% for the mid and total radii, respectively (p<0.05).

These data demonstrate normal forearm lengths versus age and shows that measurements of BMD are clinically insensitive to minor errors in forearm length.

Title: 61 – SCREENING FOR WOMEN WITH LOW BONE DENSITY

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The Objective: To Determine which screening questionair has a better outcome in the detection of posmenopausal women who are at risk for developing Osteoporosis using oseo densometry of the distal phalanges. Women were recruited with the following characteristics: 1)Risk factors for Osteoporosis, 2)Posmenopausal women, 3)No prior knowledge of their bone mineral density(by any method). Two questionairs, the Albrand Clinical Test and the E. Lydick Simple(score) questionair, were applied to all the women. Oseos Densometry was performed on the second phalange of the second, third and forth fingers of the non-dominant hand, using the bone density Metri Alara, Inc System. The Criteria Osteoporosis postulated by the World Health Organisation was used to classify the women. The Sensitivity, Specificity, Positive Predictive Value, Negative Predictive Value and the Precision Test were calculated for each questionair. A total of 497 women were analysed. Of these 294 resulted with a risk for developing Osteoporosis according to the Albrand Clinical Test. Using the Lydick Questionair 476 resulted with a risk for developing Osteoporosis. The Sensitivity for the Score Index was 97% and for the Albrand Index was 69%. The Specificity for the Score Index fue 9.16% and 79% for the Albrand Index. The Positive Predictive Value was 77.1% and 91% respectively for the Score Index and the Albrand Index. The Negative Predictive Value for the Score Index was 52.4% and 44% for the Albrand Score. Conclusions: The Albrand Index resulted as the best questionair for detecting posmenopausal women at risk for developing Osteoporosis.

Title: 62 – WEEKLY RISEDRONATE PREVENTS BONE LOSS IN EARLY POSTMENOPAUSAL WOMEN

Authors: *Michael R. McClung, MD* Oregon Osteoporosis Center; Junfang Li, Sanofi-Aventis, Bridgewater, NJ; David Goldman, Sanofi-Aventis, Bridgewater, NJ; Earl W. Sod, Procter & Gamble Pharmaceuticals, Mason OH; Michael Bolognese, MD Bethesda Health Research, Bethesda, MD

In the early years of menopause significant bone loss can be observed. This one-year, double blind, placebo-controlled study investigated the efficacy and safety of risedronate 35 mg dosed once a week in preventing early postmenopausal bone loss. Two hundred eighty subjects, 0.5 to 5 years post menopause, were randomly assigned to receive placebo or risedronate. Subjects also received 1000 mg elemental calcium and 400 IU vitamin D daily. Age, LS BMD at baseline, and years since last menses were not significantly different between the treatment groups. For the overall study population, these were (mean [SD]) 53.6 years [4.0], 0.99g/cm² [0.14] (T-score -0.69), and 3.3 years [1.3], respectively. The primary endpoint was the percent change in LS BMD; secondary endpoints included percent changes in total proximal femur, femoral neck and trochanter BMD and assessment of the general safety and tolerability of risedronate.

At the end of the study, LS BMD had decreased in the placebo group (-1.05%, p<0.05), and had increased in the risedronate treated group (+1.83%, p<0.05), yielding a significant difference between the risedronate and the placebo groups (2.88%, p<0.0001). Significant differences were apparent at 6 months at the lumbar spine and at 6 and 12 months at all hip measurement sites. The treatment was well tolerated, with a comparable incidence of adverse events (AEs) in the treated and placebo groups.

In conclusion, these data indicate that risedronate 35 mg once a week effectively prevents bone loss in early postmenopausal women, with tolerability and safety comparable to placebo.

Title: 63 – EFFECTS OF CYCLOOXYGENASE-2 (COX-2) SELECTIVE INHIBITOR NONSTEROIDAL ANTI-INFLAMMATORY AGENTS ON BONE MINERAL DENSITY (BMD) IN MEN AND WOMEN

Authors: *Norman Gaylis, MD*, Clinical Investigator Rheumatologist, Arthritis & Rheumatic Disease Specialists; Andrea Klemes, MD, Regional Medical Director, Procter & Gamble Pharmaceuticals; Stephanie Hunter-Banks PharmD, Senior Medical Science Liaison

To determine whether the use of COX-2 selective inhibitors is associated with a decrease in bone mineral density in men and women.

Patient charts were randomly selected with the following criteria: 1) no prior use of antiresorptive medication; 2) no concomitant use of corticosteroid therapy; 3) excluded natural or surgical menopause; 4) all patients taking COX-2 selective inhibitors for at least 6 months.

Of the 4400 charts reviewed, only 32 met the criteria for the analysis. Ninety percent were Caucasian, with an average age of 75 years (range = 44-91). The male to female ratio was 9:23 and the average time between bone density tests was 2.35 years. The average exposure time to COX-2 selective inhibitors was 1.5 years. There were no statistically significant changes in BMD at any time point of observation of the lumbar spine, hip or femoral neck. However, there was a trend towards bone loss in both the femoral neck and hip.

Based on this analysis, there is no correlation between COX-2 selective inhibitor use and bone loss in men and women of younger age. The loss of bone observed at the femoral neck and hip arguably could be because of lack of antiresorptive therapy. The aggressive approach taken to prevent osteoporosis in this practice, the high percentage of patients already being treated for osteoporosis and the use of steroids in this community's patients was a limitation in terms of the number of patients qualifying for the study's protocol.

Title: 65 – PHALANGEAL RADIOGRAPHIC ABSORPTIOMETRY: AN EFFECTIVE METHOD FOR OSTEOPOROSIS SCREENING

Authors: *C.R. Mitchell, Ph.D.* Vice President of Research and Development, Alara; R.W. Myers, M.D., Division of Nuclear Medicine, Radiological Associates of Sacramento, Sacramento, CA; F.A. Conte, M.D., Division of Nuclear Medicine, Radiological Associates of Sacramento, Sacramento, CA; D.M. King, RAC, Vice President of Regulatory Affairs, Alara Inc., Fremont, CA; Steven M. Giardina, Alara Inc., Fremont, CA

Lack of conveniently available BMD testing has been proposed as a reason for the reported under-diagnosis of osteoporosis. With appropriate T-score cut-points, peripheral BMD devices could be used for screening prior to referral to DXA, increasing the proportion of eligible individuals receiving a more definitive BMD test. The goal of this study was to evaluate results from radiographic absorptiometry of the phalanges (RA) that would provide sensitivity and specificity appropriate for identifying patients that should receive a central DXA test. In this study, 943 patients (876 females (F), mean age=59.7±10.8; 67 males (M), mean age=63.3±12.0) referred for central DXA were also tested using RA (MetriScan®, Alara Inc., Fremont, CA). The RA results were examined as a diagnostic for osteoporosis (central DXA T-score ≤ -2.5 , overall incidence in hip or spine = 12.5%) using receiver operating characteristic (ROC) analysis. For an RA T-score cut-point of -1.0 , the following correlations were obtained: F (hip only): sensitivity = 94.1%, specificity = 60.6%, 55% of false positives (FP) were osteopenic according to DXA; F (lowest of hip and L2-L4 spine): sensitivity = 86.2%, specificity = 62.2%, 66% of FP were osteopenic; M and F (hip only): sensitivity = 91.1%, specificity = 57.9%, 61% of FP were osteopenic; M and F (lowest of hip and L2-L4 spine): sensitivity = 86.9%, specificity = 60.0%, 70% of FP were osteopenic. We conclude that RA, with an appropriately chosen T-score cut-point, could be effectively used to screen patients for further study with central DXA.

Title: 66 – COMPARISON OF UPPER GASTROINTESTINAL TOLERABILITY OF ALENDRONATE AND RISEDRONATE ACROSS AGE SUBGROUPS: RESULTS FROM THE FACT STUDY

Authors: *S. Broy, MD*, Illinois Bone and Joint Institute, Morton Grove, IL; N. Binkley, MD, University of Wisconsin, Madison, WI; K. Saag, MD, University of Alabama, Birmingham, AL; M. Hochberg, MD, University of Maryland School of Medicine, Baltimore, MD; E. Chen, MD, MPH, Merck & Co., Inc.; C. Skalky, BS, Merck & Co., Inc.; A. de Papp, MD, Merck & Co., Inc.

Objectives: To evaluate upper gastrointestinal (UGI) tolerability of once-weekly (OW) alendronate and OW risedronate in a subgroup analysis of patients above and below age 65.

Methods: The FOSAMAX® ACTONEL® Comparison Trial (FACT) was a 1 year, double-blind study comparing OW alendronate and OW risedronate. Postmenopausal women with osteoporosis (BMD T-score ≤ -2.0 at the total hip, hip trochanter, femoral neck, or lumbar spine) were randomized (1:1) to OW alendronate 70 mg or OW risedronate 35 mg. Rates of UGI AEs were analyzed for standard AE categories in patients <65 and ≥ 65 years. A Breslow-Day test for interaction between treatment and age was performed for overall AEs and UGI AEs.

Results: Of 1053 patients, 545(51.8%) were <65 years and 508(48.2%) were ≥ 65 years. There were no significant interactions between treatment and age for overall AEs ($p=0.444$) or UGI AEs ($p=0.595$). There were no significant differences between treatments within each age subgroup. In the subgroup <65 years, patients treated with alendronate and risedronate had a similar rate of UGI AEs (23.6% vs 19.9%), serious UGI AEs (0% vs 0.7%), and discontinuations due to UGI AEs (1.5% vs 2.9%). In the subgroup ≥ 65 years, patients treated with alendronate and risedronate had a similar overall rate of UGI AEs (21.4% vs 20.4%), serious UGI AEs (0% vs 0.8%), and discontinuations due to UGI AEs (3.6% vs 3.1%).

Conclusions: OW alendronate 70 mg and OW risedronate 35 mg have similar UGI tolerability profiles, regardless of patients age.

Title: 67 – COSTS OF INCREASING BMD, REDUCING BIOCHEMICAL MARKERS: ALENDRONATE VS. RISEDRONATE

Authors: *Christine Simonelli, MD* Director, HealthEast Osteoporosis Care Service; Thomas W. Weiss, DrPH, Merck & Co., Inc.; Edward Mansley, Merck & Co., Inc.; Ya-Ting Chen, PhD, Merck & Co., Inc.; Douglas P. Kiel, M.D., M.P.H., Harvard Medical School Division on Aging

Background: We compared the treatment costs of increasing BMD and reducing biochemical markers of bone turnover in postmenopausal women (PMW) using data from the Fosamax Actonel Comparison Trial (FACT).

Methods: FACT is a randomized, double-blind, double-dummy trial comparing the effects of alendronate 70 mg once weekly or risedronate 35 mg once weekly in PMW with low bone mass (Rosen, 2004 in press). We assumed weekly treatment costs equal to the catalog prices: \$15.38 for alendronate and \$14.94 for risedronate. While we excluded rebates or patient co-pays from these prices, we did consider them in our sensitivity analyses. Thus, assuming 100% compliance, the estimated costs (without discounts or other adjustments) for one year of treatment were \$799.76 for alendronate and \$776.88 for risedronate. Estimates of treatment cost related to BMD and biochemical marker changes assumed no change in BMD or biochemical markers in the absence of treatment.

Results: Estimated treatment costs over one year per 1% increase in BMD and per 10% reduction in the biochemical markers for alendronate (ALN) and risedronate (RIS) are presented in the table.

Conclusion: The treatment cost to improvement in BMD or biochemical markers was 21% to 44% lower for alendronate than risedronate.

	Treatment cost per 1% increase in BMD				Treatment cost per 10% reduction in biochemical markers	
	Hip Trochanter	Femoral neck	Total Hip	Lumbar spine	NTx	CTx
Alendronate	\$235	\$500	\$364	\$216	\$151	\$108
Risedronate	\$370	\$863	\$647	\$299	\$193	\$142
Cost Ratio ALN/RIS	0.64	0.58	0.56	0.72	0.79	0.76

Title: 68 – DOES EFFECT OF LONG-TERM ALENDRONATE USE DEPEND ON FRACTURE HISTORY?

Authors: *AV Schwartz, PhD* University of California San Francisco, San Francisco, CA; A Lombardi, MD, Merck and Co., Inc., Rahway, NJ; KE Ensrud, MD, VA Medical Center, Minneapolis, MN; JA Cauley, DrPH, University of Pittsburgh, Pittsburgh, PA; RB Wallace, MD, University of Iowa, Iowa City, IA; MC Hochberg, MD, University of Maryland, Baltimore, MD; AC Feldstein, MD, Kaiser Permanente, Portland, OR; SR Cummings, MD, University of California San Francisco, San Francisco, CA; DM Black, PhD, University of California San Francisco, San Francisco, CA

Effects of long-term use and discontinuation of alendronate have been reported previously, but effects on BMD may differ depending on prior fracture experience. To determine if fracture history in women with previous alendronate use can predict the efficacy of continued use, we examined change in BMD during the 5-year FIT Long-Term Extension (FLEX) Trial.

1099 women who had previously been randomized to receive alendronate (ALN) during the Fracture Intervention Trial (FIT) were re-randomized to receive placebo (40%), ALN 5 mg (30%) or 10 mg (30%) for an additional 5 years. The randomization process for FLEX pre-specified 2 risk strata. High-risk women (n=421) had at least one morphometric vertebral fracture by the end of FIT and/or a clinical fracture during FIT. At FLEX baseline, the average age of women in the 4 groups ranged from 72 to 75 years; total hip BMD from 0.71 to 0.74 g/cm²; lumbar spine BMD from 0.87 to 0.92 g/cm²; average ALN use before FLEX was 5 years. BMD was measured annually. Differences between pooled (5 and 10 mg) ALN and placebo groups at 60 months were evaluated in 403 high-risk and 668 low-risk women.

Alendronate preserved bone at the total hip, femoral neck, and spine relative to placebo in both risk strata. Modest BMD losses at the total hip and femoral neck were seen among both high-risk and low-risk women who discontinued treatment. In this study, fracture history did not modify BMD effects of continued ALN use for up to 10 years relative to discontinuation.

Title: 69 – WHO ARE THE FAILURE? ARE LOSERS FAILURES?
Author: *Anthony Sebba, MD* Assistant Clinical Professor, University of South Florida

A decline in BMD despite treatment of osteoporosis is usually viewed as failure of therapy in clinical practice. It has been proposed by the ISCD that this may reflect non-response, which might suggest the need for re-evaluation such as a search for technical error and underlying causes. Even after excluding these there does appear to be a group of patients in whom BMD decline is noted and this group might be true biological non-responders.

The criteria for determining true non-response to antiresorptive treatments are unclear and scanty data exists for guidance. There does now exist evidence for both commonly used bisphosphonates to suggest that treated patients with a decline in BMD have a higher fracture risk than those who have an increase in BMD. It is possible that this group represents incomplete responders in terms of fracture risk rather than true drug failures.

Similarly, a patient who fractures on therapy may be a non-responder. There are limited data on this assessment but whereas an incident vertebral fracture in an untreated patient reflects an increase in future vertebral and nonvertebral fracture risk, there appears to be a differing paradigm in the treated patient. Since the development of the first anabolic agent, identifying true non-responders or partial responders to antiresorptives has become more important. It is time that we studied further the group with a decline in BMD on treatment, but there may be clues to predicting those who will not increase BMD which could be derived from already existing data

Title: 70 – BMD INCREASES WITH MONTHLY AND DAILY ORAL IBANDRONATE: MOBILE STUDY

Authors: *Paul D Miller, MD* Colorado Center for Bone Research, Lakewood, CO; E Michael Lewiecki, New Mexico Clinical Research & Osteoporosis Center, Albuquerque, NM

Oral bisphosphonates are the standard treatment in post-menopausal osteoporosis (PMO), but fracture risk reduction is limited by poor patient persistence. The MOBILE (Monthly Oral ibandronate In LadiEs) study is investigating the efficacy and safety of monthly oral ibandronate, a novel, potent bisphosphonate with proven antifracture efficacy.

MOBILE is an ongoing, double-blind, phase III, non-inferiority study comparing the efficacy and safety of monthly (50/50mg [single doses on two consecutive days], 100mg [single day], 150mg [single day]) versus daily (2.5mg) oral ibandronate in women with PMO. Changes in lumbar spine and proximal femur (total hip, trochanter and femoral neck) bone mineral density (BMD) were measured after 1 year.

After 1 year, lumbar spine BMD increased by 4.3%, 4.1% and 4.9% in the 50/50mg, 100mg and 150mg monthly groups, respectively, and 3.9% in the daily group. All monthly doses were at least as effective as daily ibandronate and 150mg monthly demonstrated superiority ($p=0.002$). Monthly ibandronate regimens also produced substantial and comparable increases in proximal femur BMD. The increases observed in total hip BMD were 2.2%, 2.7% and 3.1% for the monthly groups, respectively, and 2% for the daily group. The incidence of related adverse events leading to withdrawal was low (range: 5.1-7.3%) and balanced between the treatment arms. No upper GI safety concerns were identified.

Monthly oral ibandronate may be a safe and effective alternative to current daily and weekly oral bisphosphonate regimens in PMO, which could help address current poor-persistence issues in PMO.

Title: 71 – COMPARISON OF ONCE-WEEKLY ALENDRONATE AND ONCE-WEEKLY RISEDRONATE IN THE OSTEOPOROTIC SUBGROUP FROM THE FACT STUDY

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The objective was to evaluate once weekly (OW) alendronate compared to OW risedronate in FACT study patients with osteoporosis at baseline.

FACT was a 12 month study of 1053 postmenopausal women with T-scores ≤ -2 at total hip, hip trochanter, femoral neck, or lumbar spine. 641 women had osteoporosis defined by a T-score ≤ -2.5 at any BMD site or a history of clinical fracture at the hip, spine, or wrist since age 45. Subjects were assigned to OW alendronate 70 mg (N=313) or risedronate 35 mg (N=328). Primary endpoint was treatment difference on percent change from baseline in hip trochanter BMD at 12 months.

Tests for interaction between treatment effect and baseline osteoporosis status were not significant at 12 months at any BMD site, indicating consistency of larger response with alendronate, regardless of baseline T-score or history of osteoporotic fracture. Within the osteoporotic subgroup, alendronate produced significantly greater increases than risedronate in hip trochanter BMD at 12 months (3.7% vs 2.1%, $p < 0.001$) and a greater percent of subjects with measured maintenance or gain in BMD ($\geq 0\%$) (86.4% vs 67.9%, $p < 0.001$). Increases were also significantly greater ($p < 0.001$) at the total hip and lumbar spine at 12 months. Significant differences were seen as early as 6 months.

In conclusion, in the subgroup of osteoporotic women in FACT, treatment with OW alendronate 70 mg produced significantly greater gains in hip and spine BMD and a greater percentage of patients with measured maintenance or gain in BMD than OW risedronate 35 mg.

Title: 73 – LIMITATIONS OF OBSERVATIONAL DATA IN COMPARING TREATMENTS

Authors: *Thomas J. Schnitzer, M.D., Ph.D.* Director, Office of Clinical Research and Training; Rene Rizzoli, University Hospital Cantonal, Geneva, Switzerland; P. Sambrook, University of Sydney, Sydney, Australia

Recent studies using medical claims data suggest that differences in fracture risk, gastrointestinal (GI) event profiles, and resource utilization may exist for bisphosphonates (BPs). We used evidence-based medicine principles to evaluate and rate these studies, and compared findings from other types of studies, using the evidence-based medicine hierarchy. Prior reviews of evidence were also consulted.

Administrative claims data analyses have the least validity for comparing two or more agents; results of head-to-head clinical trials have the most validity. The primary difficulties with analyses of claims data are that patients were not randomly assigned to treatment, and patients and physicians were not blinded to treatment assignment, so there is no way to assure comparability of groups. Many potential sources of bias exist such analyses, and matching may not effectively control this. Severity of disease information is not available in claims data, so the risk of future fracture may differ widely between groups. A classic example is that of hormone replacement therapy, which, in observational studies, appeared to prevent cardiovascular disease, but was later proven in a large randomized controlled trial to increase risk.

Randomized clinical trials are the highest level of scientific evidence. Randomized trials have not demonstrated significant differences in GI events between different BPs or between BP and placebo. Observational studies of fracture outcomes are also inconsistent with results from randomized trials. Analyses of medical claims and other studies without randomization and blinding should be viewed with caution because they may not be adequate to address a cause-effect relationship.

Title: 74 – IMPACT OF NURSE PRACTITIONER (NP) CONSULTATION ON OSTEOPOROSIS EVALUATION AND TREATMENT

Authors: Julie Morancey, RA., MA Research Assistant, HealthEast Osteoporosis Care; Christine Simonelli, Director, HealthEast Osteoporosis Care; Kathryn Grimm, Research Asst., HealthEast Medical Research Institute

This study documented frequency of DXA completion, calcium, vitamin D, and osteoporosis medication use in patients who had a NP consult for osteoporosis while hospitalized with a fragility fracture. We previously described the HealthEast post-fracture orthopedist-generated NP program. The NP saw patients at least 6 months prior to the telephone contact. Data on 44 patients was collected, 2 patients were deceased and 7 patients could not be reached. Eleven (26%) recalled the NP visit while in the hospital. 34 (81%) were using some form of calcium and vitamin D supplement and 23 (68%) of those had increased both their calcium and vitamin D since discharge. Eleven (26%) patients had a DXA prior to fracture and 12 (29%) had DXA following their fracture. A total of 18 (43%) had a DXA at some point. Before fracture, 9(21%) were on treatment with a bisphosphonate or SERM. After fracture, more patients (19,45%, $p<.021$) were placed on a bisphosphonate, SERM, calcitonin or teriparatide. At follow-up, 17(40%) were still on osteoporosis treatment. Almost all patient (89%) who were started on a medication after their fracture adhered to therapy for at least 6 months. Neither age nor place of residence influenced rate of medication use. Under our current post-fracture protocol, patients have increased calcium, vitamin D and prescription medication use compared with their pre-fracture state and report a high rate of drug adherence at 6 months. This increase in osteoporosis management may be more a reflection of the NP consultation chart notes than the bedside education.

Title: 75 – BMD INCREASES WITH EXTENDED INTERVAL IBANDRONATE INJECTION: DIVA 1-YEAR RESULTS

Authors: E. Michael Lewiecki, MD, FACP Osteoporosis Director, New Mexico Clinical Research; Paul Miller, Clinical Practitioner, Colorado center for bone research

Bisphosphonates are standard treatment for postmenopausal osteoporosis (PMO), but the procedures for oral administration and side effects limit the populations in which they can be used. Ibandronate, a potent, nitrogen-containing bisphosphonate, can be given orally or by rapid i.v. injection (15-30 seconds), with extended dosing intervals. The DIVA (Dosing IntraVenous Administration) study is comparing the efficacy and safety of extended-interval ibandronate injection with the proven daily regimen.

DIVA is an ongoing, double-blind, double-dummy, phase III, non-inferiority study involving 1,395 women with PMO. Participants were randomized to receive either extended-interval ibandronate injections (2mg, every two months or 3mg, every three months) or 2.5mg daily oral ibandronate. The primary endpoint was mean percentage change from baseline in lumbar spine bone mineral density (BMD) after 1 year.

After 1 year, lumbar spine BMD increased by 5.1%, 4.8% and 3.8% in the 2mg/2mo, 3mg/3mo and 2.5mg daily arms, respectively. Non-inferiority (1% margin) and superiority ($p<0.001$) to the daily regimen was demonstrated for both i.v. regimens. Substantial and comparable increases in hip BMD (all sites) were also observed with the i.v. regimens, which were greater than those seen with the 2.5mg daily regimen. Drug-related adverse events (AEs), including renal AEs, were low and balanced across treatment arms.

These findings demonstrate that extended-interval ibandronate injections are at least as effective and as well tolerated as daily oral ibandronate in women with PMO. The extended-interval injections offer an effective, safe and practical alternative when oral bisphosphonates cannot be used.

Title: 76 – SUSTAINED REDUCTION OF VERTEBRAL FRACTURE RISK AFTER DISCONTINUATION OF RISEDRONATE

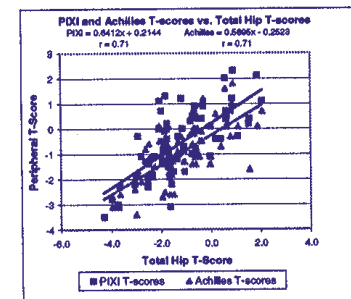
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Although a number of different properties affect bone strength and determine fracture reduction during treatment for osteoporosis, the contribution of each component is not clearly understood. It is also not known how long the effects of treatment would persist and how changes in surrogate markers such as BMD and bone turnover markers relate to fracture risk after discontinuation of treatment. Patients who received risedronate 5 mg daily (N=398) or placebo (N=361) during the VERT-NA study stopped therapy after 3 years and were reassessed one year later. Supplementation with calcium and vitamin D was continued. One year later, urinary NTX and bone alkaline phosphatase increased significantly in the former risedronate patients and were no different from controls. BMD decreased in the spine, femoral neck and trochanter in the former risedronate users but remained higher than in controls. Despite return of bone turnover markers to placebo levels and the decrease in BMD, the incidence of new vertebral fractures was significantly lower in the former risedronate group compared with former placebo users (6.5% and 11.6%, respectively, RR 0.53 [0.32, 0.89], $p=0.016$, Cox proportional hazard model). Thus, patients treated with risedronate for 3 years have a protection against fracture that persists for at least one year after treatment is stopped but changes in surrogate markers are of little value in assessing the persistence of the anti-fracture effect.

Title: 77 – COMPARISON OF TWO HEEL MEASUREMENT DEVICES: PREDICTION OF SPINE/HIP T-SCORES

Authors: *PK Burke, MD* Osteoporosis Diagnostic and Treatment Center, Richmond, VA; GN Burke, Osteoporosis Diagnostic and Treatment Center, Richmond, VA; WK Wacker, GE Healthcare, Madison, WI; KG Faulkner, GE Healthcare, Madison, WI

Bone mineral density (BMD) measured at spine and femur sites with DXA represents the gold standard for identifying osteoporotic subjects. Peripheral devices that measure the calcaneus, however, are more portable, less expensive and may be cost-effective for identifying at-risk individuals who otherwise might be missed. We examined the correlation of quantitative ultrasound (QUS) and DXA at the calcaneus from two peripheral devices and evaluated their ability to identify subjects with osteoporosis at the spine or hip. Seventy-four women (mean age 63.5 yrs, range 20-84) were measured at the spine and hip with a GE Lunar Prodigy and at the heel with Lunar PIXI (DXA) and Lunar Achilles (QUS) devices. Stiffness Index was used as the QUS measurement value. Correlation between calcaneal DXA and QUS T-scores was $r=0.80$. Correlations between peripheral T-scores and the lowest T-score among spine, femur neck, and femur total were nearly identical: PIXI $r=0.66$, Achilles $r=0.67$. Correlations also were nearly identical for total femur T-score alone ($r=0.71$ for both devices). Receiver-operator-characteristic (ROC) analysis showed slightly better performance of Achilles over PIXI in identifying osteoporosis at the spine or hip. Area under the curve (AUC) was 0.75 (0.61, 0.86) for PIXI and 0.79 (0.67, 0.89) for Achilles T-scores. The AUC for identifying osteoporotic or osteopenic subjects at the spine or femur was nearly identical for both devices: 0.84 (0.72, 0.91) for PIXI, 0.83 (0.70, 0.91) for Achilles T-scores. We conclude that the PIXI and Achilles devices are similar in ability to predict BMD at the spine or hip.



Title: 78

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The purpose was to identify bone health promotion behaviors and BMD scores among postmenopausal women. The study involved development and psychometric testing of a questionnaire for identification of osteoporosis risk factors, self-reported bone health behaviors, and perceived benefits and barriers to bone health behaviors. Several questionnaires are available to clinicians to quantify osteoporosis risk factors, yet the questionnaires stop short of exploring patient perceptions of susceptibility to osteoporosis, perceptions of the benefits of calcium supplementation and exercise, and their perceptions of barriers to health promoting behaviors. The Bone Health Questionnaire is intended for use by clinicians at the time of BMD testing.

The Bone Health Questionnaire was evaluated by a panel of content experts and psychometricians. Focus group interviews were conducted with postmenopausal women to further validate the questionnaire. 300 postmenopausal women between the ages of 30 and 80 participated in the study. Each participant completed the Bone Health Questionnaire and had peripheral BMD testing.

48% of the participants had low BMD scores. Multiple risk factors were identified in the sample, yet 75% had no previous screening for osteoporosis. Calcium intake and exercise behaviors did not meet guidelines for osteoporosis prevention. There were statistically significant positive relationships between perceived benefits of health promotion behaviors and reported calcium and exercise behaviors. There were statistically significant negative relationships between barriers to health promotion behaviors and reported behaviors.

The Bone Health Questionnaire can be used to personalize patient education at the time of BMD testing.

Title: 79 – PILOT STUDY OF A BRIEF INTERVENTION TO INCREASE BONE HEALTH KNOWLEDGE

Author: The Florida Osteoporosis Board - [osteoporosisflorida.org]

Despite increased attention to osteoporosis in the popular media, many individuals are unaware of their risk for the disease or have failed to take preventive action. The purpose of this pilot study was to test the effectiveness of a brief intervention at point of service for primary care offices in promoting bone health awareness and preventive behaviors. A pamphlet was developed that describes: fracture risk; osteoporosis/osteopenia; determinants of fracture risk; T-score interpretation; preventive strategies; and treatment parameters. Pre- and post-intervention categorical data was collected on eleven (N=11) women regarding: patient perception of bone health knowledge; understanding of fracture risk; likelihood of discussing bone health with primary care provider; patient perception of adequacy of intervention in promoting preventive behaviors; calcium and Vitamin D requirements; and awareness of osteopenia versus osteoporosis. Data were collected immediately prior to reading the pamphlet and immediately following the intervention. Significant increases in all measurement categories were noted following the brief educational intervention. Brevity of reading material was well received by participants.

Although this was an extremely small sample, the pilot study indicates that a brief written intervention may be successful in increasing bone health awareness and preventive behaviors. The study will be repeated on a larger scale to include both genders and post-intervention will be collected at repeated intervals to assess retention of knowledge.

Title: 82 – COMPARISON OF BMD AT CENTRAL AND PERIPHERAL SITES AND ITS RELATIONSHIP TO FRACTURE: EVIDENCE FROM NATIONAL OSTEOPOROSIS RISK ASSESSMENT (NORA)

Authors: *PD Miller*¹, YT Chen², S Sajjan², SK Brennehan²; ¹Colorado Center for Bone Research, Lakewood, CO; ²Merck & Co., Inc., West Point, PA

Bone mineral density (BMD) measurements at central and peripheral skeletal sites have been shown to predict risk of fracture. It is not known whether BMD at central sites is more predictive of fracture than those at peripheral sites. We compared BMD measurements at 3 skeletal sites – hip, total spine and distal radius – on the same individuals to determine the extent to which measurements concur and are able to identify women who would have an incident osteoporotic fracture within three years of measurement. Data were from the Specialist Arm of NORA. BMD T-scores were calculated using the young adult reference database provided by each manufacturer. Self-reported fractures occurring within three years were identified by follow-up surveys. 685 women with baseline BMD measurements at all 3 sites were included. Of these women, 133, 163, and 201 had T-scores ≤ -2.5 at the femoral neck, total spine, and distal radius, respectively. Of the 306 women who were osteoporotic at any site, 51 (17%) were osteoporotic at all 3 sites, 89 (29%) at 2 of 3 sites and 166 (54%) at only one site. 45 women reported osteoporosis-related fractures (hip, spine, rib, and wrist/forearm): 29 (64%) of who had a T-score ≤ -2.5 at any site. Similar proportions of women reporting fractures had T-scores ≤ -2.5 at a single site: femoral neck (36%), total spine (31%), and distal radius (33%). We conclude that both central and peripheral BMD T-scores ≤ -2.5 identify women at increased risk for fracture. However, a T-score > -2.5 at a single site does not necessarily rule-out osteoporosis at another site.