Learning Objectives

- Basic quality assurance measures that assess scanner performance and allow for accurate reporting of bone density results.
- Common errors on bone density scans and the impact on reported results and clinical care.
- How ICD-10 coding and legislation could impact DXA reimbursement.
Quality Assurance Concepts

• The clinician, technologist or manager need to assure that QA and phantom scans are performed, analyzed and evaluated to assure quality DXA results
  - Daily Instrument Quality Control
  - Regular phantom scanning and evaluation
  - Precision assessment
  - Cross calibration
Perform Instrument Quality Assurance Each Day Scanner is Used

- ISCD Official Position recommends routine QC
  - The Quality Control (QC) program at a DXA facility should include adherence to manufacturer guidelines for system maintenance.
- Most manufacturers require QC be run each day before patients are scanned
QA Block and Phantom Have Different Duties

- QA block validates calibration
  - GE and Norland have external devices (QA block) to validate calibration
  - Hologic uses internal hardware
- All densitometers have external phantoms to monitor BMD, BMC and area measurements
GE Lunar Quality Control Should be Run Each Day Scans are Obtained

- Software only requires every 72 hours, however best practice is to run each day scanning occurs
  - QA only requires black block be scanned
- Software will pass or fail calibration and plot cumulative block measurement
Review QA Report for Changes

- Review QA report
- BMD plot should be stable, no shift or drift
  - Note only last 12 months are plotted
- %CVs should be ~1% or less
  - Consider service if approaching 2%
Hologic Quality Control Includes Phantom Scanning

- Hologic Apex software requires QC be run every 24 hours
  - Includes an internal calibration step and external phantom scanning
- Software will pass or fail calibration and generate phantom measurements
Phantoms Scans Should Occur Regularly

- ISCD positions recommend routine phantom scanning and evaluation
  - Perform periodic (at least once per week) phantom scans for any DXA system as an independent assessment of system calibration.
  - Plot and review data from phantom scans.
  - Verify the phantom mean BMD after any service performed on the densitometer.
  - Establish and enforce corrective action thresholds that trigger a call for service.
Determine Phantom Mean and 1.5% Thresholds for BMD, BMC and Area

- Scan a phantom 10-25 times and calculate BMD, BMC and Area means for baseline comparison
  - Calculate 1.5% of mean for upper and lower limits
  - Plot values regularly (weekly or monthly) and watch for drift toward threshold limits or shift outside limits
  - An occasional irregular value is not of concern, however, steady drifts, stable shift or routine erroneous measurements should prompt service to avoid scanner shut down
Software Automatically Generates Graphs to Evaluate for Shift or Drift Over Time

- Hologic automatically calculates mean and graphs 1.5% upper and lower limits
GE Software Generates Only Trending Graphs

- Plots in percent change, not g/cm² but percent change from baseline
- Only uses one baseline measurement, does not establish a mean
- Plots by an age, not date
- Consider using graphing software to manually generate plots
Example Where GE Phantom Plots Demonstrate a Drift Unappreciated in QA Plot

- QA plot only shows one year of data
- Phantom is more similar to patient than QA block
Phantom Plot Demonstrates X-ray Tube Deterioration

- Phantom demonstrates a drift starting ~2008
  - Service determined x-ray tube starting to fail, but due to minimal decline and cost elected not to change in 2008
- Drift continues and starts to approach 1.5% threshold end of 2013
  - Service agreed to replace x-ray tube
  - Phantom returned to baseline
X-Ray Tube Affected BMC, not Area

- Bone Mineral Content followed BMD pattern before and after tube change
  - Suggesting the tube directly impacted measurement
- Area remained stable over time, demonstrating good edge detection over time

Phantom BMC Plot

Phantom Area Plot
QC has Established Accuracy, Now Need to Allow for Patient Monitoring

- Cannot monitor patient change without determining facility Least Significant Change (LSC)
  - Without LSC can only determine diagnosis
- Precision assessment incorporates three components of error, therefore requiring assessment at each facility
  - Scanner variability
  - Technologist skill
  - Patient population
ISCD Precision Assessment Position

- Each DXA facility should determine its precision error and calculate the Least Significant Change (LSC)
  - The precision error supplied by the manufacturer should not be used.
- If a DXA facility has more than one technologist, an average precision error combining data from all technologists should be used to establish precision error and LSC for the facility, provided the precision error for each technologist is within a pre-established range of acceptable performance.
ISCD Precision Assessment Position

• Every technologist should perform an in vivo precision assessment using patients representative of the clinic’s patient population.
• Each technologist should do one complete precision assessment after basic scanning skills have been learned (e.g., manufacturer training) and after having performed approximately 100 patient-scans.
• A repeat precision assessment should be done if a new DXA system is installed. A repeat precision assessment should be done if a technologist’s skill level has changed.
Conducting a Precision Assessment

- Scan 15 patients 3 times or 30 twice
  - Perform on sites used to monitor (typically hip & spine)
  - Patients should be representative of usual population
  - Patients need to stand from the table between scans to allow for repositioning (replicating serial monitoring)
  - Should apply LSC in g/cm², not percent CV%
- ISCD offers an on-line and downloadable calculator
- White paper documenting the importance of a precision assessment available on ISCD website
BMD Difference Must Exceed the LSC to Document Real Change

- Use BMD to monitor, NOT T-score
- A BMD difference must exceed the LSC to document change
- Do not report a BMD “difference” that does not exceed the LSC

Examples: Assume the LSC is 0.040 g/cm²
  - Baseline BMD = 1.000 g/cm²; follow up = 0.930 g/cm²
    - Report a decline in BMD
  - Baseline BMD = 1.000 g/cm²; follow up = 0.990 g/cm²
    - Report no change in BMD (not a 1% decline)
Cross-Calibration Required to Compare Between Instruments

- Cannot directly compare BMD between manufacturers
  - Different technology results in different measurements
  - GE and Hologic BMD differs by ~10%, T-scores are similar
- Same manufactures and like models should be cross-calibrated to compare BMD
  - Required for centers using multiple scanners, otherwise patient needs to be scanned on same instrument
ISCD Cross-Calibration Position

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

- Scan 30 patients representative of the facility’s patient population once on the initial system and then twice on the new system within 60 days.
- Measure those anatomic sites commonly measured in clinical practice, typically spine and proximal femur.
- Calculate the average BMD relationship and LSC between the initial and new machine using the ISCD DXA Machine Cross-Calibration Tool (www.ISCD.org).
- Use this LSC for comparison between the previous and new system. Inter-system quantitative comparisons can only be made if cross-calibration is performed on each skeletal site commonly measured.
ISCD Cross-Calibration Position

- Once a new precision assessment has been performed on the new system, all future scans should be compared to scans performed on the new system using the newly established intra-system LSC.
- If a cross-calibration assessment is not performed, no quantitative comparison to the prior machine can be made. Consequently, a new baseline BMD and intra-system LSC should be established.
QA Summary

- Daily QC identifies immediate mechanical issues
  - Failing daily QC requires instrument repair
- Phantom data allows long-term evaluation
  - Identify subtle measurement trends (shift or drift)
  - Allows scheduled repairs & avoids emergency shut down
  - Provides evidence of problems and increases likelihood service will be provided
- Precision assessment is necessary for monitoring
- Cross-Calibration required to compare between scanners
  - Cannot compare between manufacturers
DXA Quality Affects Clinical Care

“How often do you see a patient with a previous DXA report interpretation that is incorrect?”

Technical Errors and Manufacturer Differences Can Impact Clinical Care

- Common positioning and analysis errors
- Identify differences between Hologic and GE
- Tips to investigate unexpected results for technical problems
General Acquisition Guidelines

- Center anatomy & position straight (parallel to table)
- Include all anatomical regions of interest & landmarks
  - Spine: L5 – T12, ribs, iliac crest or sacrum
  - Hip: Greater & lesser trochanter, femur head & pelvis
- Avoid external artifacts in scan field
  - Bras, buttons, jewelry, wallets
- Patients should not move during scan
- Replicate serial scans to appropriate baseline acquisition & analysis
Ideally Acquired and Analyzed Spine

- Centered, straight & artifact free
- Iliac crest and ribs allow for correct vertebral labeling
- Intervertebral markers bisect disc space
- Edges appropriately separate bone and soft tissue
Off-center Anatomy Results in Inadequate Soft Tissue Sampling

- Green area represents region used to sample soft tissue
  - This can increase or decrease measured BMD, in this case decreased by 0.22

L1-4 BMD = 1.168

L1-4 BMD = 1.146
Demand “Clean” Scans to Eliminate a Variable when Evaluating Questionable Results

- It is unknown if artifacts outside the region of interest impact BMD results
  - Do not assume artifacts are not impacting BMD
  - The presence of artifact reduces your certainty that a BMD change has, or has not occurred
There is no One Approach to Handling Internal Artifacts

- Dense artifacts should be excluded, low density artifacts can be ignored and temporary artifacts should clear
  - Gallstones should be excluded when identified as dense (bone on Hol; non-tissue on GE) (a)
  - Surgical staples have little impact (b)
  - Cannot exclude imaging contrast, must delay or repeat scan (c)
Avoid Calcium Supplementation Prior to Scanning

• Tablets visible 15-30 minutes after ingestion in ~ 50% of subjects

• Consider waiting 1-2 hrs when supplements taken

Krueger et. al., J Clin Densitom, 9:159-163, 2006
Vertebral Labeling Should be Correct

- Each vertebrae is compared to the labeled normative database to generate T-score, when mislabeled incorrect T-scores are generated
  - T-score difference of -0.8 is demonstrated between correct and incorrect labeling

L1-L4 BMD 0.896 g/cm²  
T-score = -2.4  
(labelling is one off)

L1-L4 BMD 0.798 g/cm²  
T-score = -3.2  
(correct labelling)
Or at Least Consistent

- Monitoring report identifies an L1-3 loss of -0.033 g/cm² (LSC = 0.029)
- Correct analysis of follow-up scan demonstrates a BMD increase of 0.031 g/cm²
Incorrect Edge Detection will Increase or Decrease BMD

- Edges (or mapping) inside the spine will falsely elevate BMD
  - Decreases area and includes high BMC content
- Edges outside the spine or hip will decrease BMD
  - Increases area with low density tissue

0.679 g/cm² - 4.5 T-score
0.645 g/cm² - 4.8 T-score
0.423 g/cm² - 4.7 T-score
0.448 g/cm² - 4.5 T-score
Ideally Acquired and Analyzed Femur

- Centered, straight & artifact free
- Adequate rotation; small amount of lesser trochanter visible
- Femur neck and total femur ROI appropriately placed
- Edges appropriately separate bone and soft tissue
Femur Neck Placement Challenge: Abduction and Adduction

- Femur shaft adduction generates encroachment of the greater trochanter into the femur neck space
  - Adduction will narrow space between and femur and ischium
Abduction/Adduction Generally Has Little BMD Effect, However, Note Outliers

Data presented for left femoral neck

Assume LSC ~0.030

Similar results observed at the total femur

Ozer, et. al., J Clin Densitom, 13:10-17, 2010
Panniculus Retraction May Alter FN BMD

FN BMD Pre-retraction
0.651 g/cm²

FN BMD Post-retraction
0.756 g/cm²
Panniculus Retraction May Increase or Decrease Femur BMD by Amounts > the LSC

LSC ~0.048

Binkley, et. al., J Clin Densitom, 6:199-204, 2003
Panniculus Retraction

Binkley, et. al., J Clin Densitom, 6:199-204, 2003
Femur Neck Placement Challenge: Rotation Changes Greater Troch Area

- Poor rotation positions the greater trochanter into femur neck space, increase FN BMD, less impact on total femur BMD

- FN = 1.068 g/cm²
  FN area = 4.40 cm²
  TF = 1.092 g/cm²

- FN = 1.085 g/cm²
  FN area = 4.60 cm²
  TF = 1.053 g/cm²

- FN = 1.102 g/cm²
  FN area = 5.37 cm²
  TF = 1.071 g/cm²
Femur Analysis Dependant on Scanner Manufacturer (Hologic)

- Total femur box should be aligned around femur neck, just below the lesser trochanter and just outside greater trochanter
  - Technologist has guides in the software to ensure correct placement
- Femur neck box has corner anchored on greater trochanter and other 3 should be in non-bone tissue
Femur Analysis Dependant on Scanner Manufacturer (GE-Lunar)

- Total femur is automatically determined based on femur neck box placement
- Femur neck box is placed by software using “search” option, determines narrowed area of neck and lowest BMD
  - Very large wards area (small square) indicates search or copy feature were not used
Technologist Often Needs to Adjust Auto-Analysis: Auto vs Manual Examples

- Autoanalysis (left) vs manual analysis (right)
- Copy/Compare features facilitate analysis consistency on follow-up scans

Baniak et. al. J Clin Densitom, e-pub 2013
Examples and Tips
GE Scan Modes Should be Based on Patient Size (Thin, Standard, Thick)

- Software auto-selects scan mode based on patient height and weight
- Sometimes does not select “thin” when appropriate – resultant images on left
- When image is very “grainy” switch to thick
GE Lunar BMD in g/cm\(^2\) is \(~10\%\) Higher than Hologic
Same Patient Scanned on the Same Day

GE Lunar

L1-L4 BMD 0.889 g/cm\(^2\)
T-score = -2.4

Hologic

L1-L4 BMD 0.758 g/cm\(^2\)
T-score = -2.6
Shorter Height and Sclerotic Line Suggests Vertebral Fracture
Vertebral Bodies with Falsely Elevated BMD Due to Arthritis or Fracture Should be Excluded From Analysis

Fracture excluded with Hologic software (L1), data removed from report

Arthritis excluded with GE software, printed, but excluded from calculations
### When DXA Results are Not Expected; Review the Image

<table>
<thead>
<tr>
<th></th>
<th>Base BMD g/cm²</th>
<th>Follow-up g/cm²</th>
<th>BMD Change g/cm²</th>
<th>BMD Change %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right total femur</td>
<td>0.723</td>
<td>0.878</td>
<td>+0.155</td>
<td>+21.4</td>
</tr>
<tr>
<td>Right femur Neck</td>
<td>0.790</td>
<td>1.427</td>
<td>+0.637</td>
<td>+80.6</td>
</tr>
<tr>
<td>Left total femur</td>
<td>0.791</td>
<td>0.693</td>
<td>-0.098</td>
<td>-12.3</td>
</tr>
<tr>
<td>Left femur neck</td>
<td>0.837</td>
<td>0.719</td>
<td>-0.118</td>
<td>-14.1</td>
</tr>
</tbody>
</table>

Patient referred to specialty care; what might have caused results?
Evaluating the Images Clearly Disclose Cause for Unusual Results

Baseline

Follow-up
76 year old man referred due to osteoporosis on DXA

- FRAX generated different T-score than report
- Different database used to generate T-scores, software should always use NHANES for femur
- FRAX T-score will be ~0.5 higher than software in men as they use female database
55 year old female with congenital hip dysplasia; screening DXA resulted in referral for teriparatide consideration

Read the fine print: low percent fat in first scan suggests instrument error
Image Can Suggest When Scanner Needs Service

- Example of detector failure on GE instrument
Tissue-Typing Error Due to Positioner

GE-Lunar

- If open area of the strap slots are at the start or end of scan field, tissue typing may be incorrect and falsely elevate 1/3 radius BMD
- Bone edges are usually correct, requiring evaluation of tissue
- Most common when positioner is used backwards

Krueger et. al. J Clin Densitom, 2012 e-pub
Clothing on Forearm Can Cause Tissue-Typing Errors that Affect BMD

- The software may include clothing in soft-tissue assessment and cause error in BMD calculation; this might be an issue with other manufacturers (has not been reported)
- These errors, in many cases are likely greater than the LSC

Krueger et. al. J Clin Densitom, 2012 e-pub
Tissue-Typing Errors Impact on Radius BMD

GE-Lunar

These errors result in measurement error greater than the LSC

Krueger et. al. J Clin Densitom, 2012 e-pub
Ensure Hologic Report Contains Only Radius Measurement

Software defaults to “Radius + Ulna” make sure it’s adjusted to report only “Radius”
Use Report to Identify Instrument and Database Used: Hologic

Scan Information:
Scan Date: May 04, 2011
Scan Type: x Left Hip
Analysis: May 17, 2011 10:40
Operator: mnc
Model: Discovery C (SN 80595)
Reference curve and scores matched to White Female
Source: NHANES
Use Report to Identify Instrument and Database Used: GE

Scan Mode: Standard

Printed: 7/17/2014 2:49:44 PM
File: pese74ac8.mex

19.1% Fat = 26.7%
46.0 μGy

2 - USA (Combined NHANES (ages 20-30) / Lunar (ages 20-40)) AP Spine Reference Population (v112)

3 - Matched for Age, Weight (Females 25-100 kg) Ethnic

11 - World Health Organization - Definition of Osteoporosis and Osteopenia for Caucasian Women: Normal = T-score at or above -1.0 SD; Osteopenia = T-score between -1.0 and -2.5 SD; Osteoporosis = T-score at or below -2.5 SD; (WHO definitions only apply when a young healthy Caucasian Women reference database is used to determine T-scores.)

Lunar iDXA
ME+200024
DXA Troubleshooting when Observing Unexpected Results

- Categories to investigate potential sources for error:
  - Items related to the
    - Technologist – acquisition and analysis
    - Equipment – software and hardware
    - Patient – recent examinations and medical history
ISCD-10 Coding
Implementation Date is No Longer Oct. 2014

"On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. No. 113-93) was enacted, which said that the Secretary may not adopt ICD-10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services expects to release an interim final rule in the near future that will include a new compliance date that would require the use of ICD-10 beginning October 1, 2015. The rule will also require HIPAA covered entities to continue to use ICD-9-CM through September 30, 2015."

ICD-10 Summary

- Developed by WHO to replace ICD-9 which was out of digits for more codes
- ICD-10 provides a more defined diagnosis
  - Allows more detailed documentation; specify site and laterality
- Will not effect CPT® codes for outpatient coding
- All CPT® codes submitted to payers must be supported by the MR and reported with the appropriate ICD-10 code
- Affects all medical personal and support staff
Differences Between Systems

- ISCD-9
  - Up to 5 characters
  - Mostly numeric
  - Approximately 14,000 codes

- ISCD-10
  - Up to 7 characters
  - All codes alphanumerical
  - 1st character always a letter
  - Approximately 140,000 codes
Validate Transition Plan is Executed Appropriately

- Implementation errors will result in:
  - Claim rejections
  - Denials
  - Delays
  - Incorrect decisions based on diagnosis data
Considerations for Transition Plan

- Discuss implementation plans for your practice with payers, determine how/if ICD-10 might affect contracts
- Identify required changes to work and business practices
  - Staff training needs (both clinical and non-clinical)
- Budget for time and costs pertaining to implementation
Tools for Transition

• General reference and preparation
   CMS website –
   AACE courses and on-line material to members

• Assistance with ICD-10 Code Identification
   ICD-9 to ICD-10 Code Translator
    o Lists new codes for known ICD-9 code
    o http://www.aapc.com/icd-10/codes/
   Crosswalk Help
    o Allows you to find new or unknown codes by category
    o http://www.aapc.com/icd-10/crosswalks/
International Society for Clinical Densitometry (ISCD)

• Mission: To Advance Excellence in the Assessment of Skeletal Health
  ● Promoting education and a broad understanding of bone mass measurement and skeletal health assessment technologies
  ● Assuring proficiency and quality in skeletal health assessment through certification and accreditation
  ● Promoting appropriate patient access to bone mass measurement and skeletal health assessment technologies
  ● Supporting advances in osteoporosis diagnosis and treatment
**ISCD Certification & Accreditation**

- **Clinicians (CCD) and Technologists (CBDT)**
  - CBDT is NCAA accredited and CCD application being submitted this fall
- **Transitioning to Maintenance of Certification (2015)**
  - Annual fee includes access to on-line CME/CE and tracking of credits accumulated through ISCD
  - ISCD Membership includes Maintenance of Certification at no additional cost.
- **Facility Accreditation Program streamlined to focus on core elements**
ISCD Education

• Osteoporosis Essentials Course
  • Bone Densitometry Course updated with international content and being offered jointly with IOF

• Annual Meetings
  • 2014 held jointly with IOF
  • 2015 in Chicago includes Position Development sessions
  • 2016 in Galway Ireland – first international meeting in over 15 years

• Position Development Conference
  • Non-BMD DXA fracture risk prediction tools (TBS/HSA)
  • Central CT measures of fracture risk
    • Prevalent fracture identification/Fracture risk prediction
    • Opportunistic screening from clinical CT scans
ISCD Education

- **Online Learning**
  - Offerings for Clinician (ACCME Category 1) and Technologists (ASRT Category A)
  - Access included with Membership, nominal fee for non-members.

- **Vertebral Fracture Recognition**
  - Course redesigned to focus on DXA and other modalities for recognition

- **Fracture Liaison Services**
  - Creating educational materials to provide education outlined in a needs assessment.
ISCD Future Activities

- Continuing US and International partnerships to better impact the field
  - Promote access to skeletal health measurement through DXA Alliance and collaboration with other professional organizations
  - Joint educational activities with International Osteoporosis Foundation (IOF) and other professional societies
  - National Bone Health Alliance
    - Promote bone health and prevent disease; improve diagnosis and treatment of bone disease; and enhance bone research, surveillance and evaluation.
  - US Bone and Joint Initiative
    - Fit to a T (Know your T-score)