Tips to follow for successful submissions

We have been asked to provide additional information to assist clinicians/interpreters and technologists in what we look for in reports and scans.

Clinicians/Interpreters:
Reports MUST be in agreement with the ISCD Official Positions
Be sure to check your reports for compliance with the Positions before submitting your application and follow the sections on what should/should not be included in reports (see below).

- Apply FRAX properly, if used. – must comply with ISCD-IOF Official Positions (FRAX only used with osteopenia diagnosis)
- Make sure all skeletal sites/ROI’s are identified
- **Proper** diagnosis based on WHO category and criteria:

<table>
<thead>
<tr>
<th>Normal</th>
<th>Bone density equal to –1.0 SD or higher (T-score ≥ -1.0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Bone Mass (Osteopenia)</td>
<td>Bone density between -1.0 and -2.5 SD (T-score &gt; -2.5 and &lt; -1.0)</td>
</tr>
<tr>
<td>Low Bone Mass (low bone)</td>
<td>Bone density equal to -2.5 SD or lower (T-score ≤ -2.5)</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>Bone density at least 2.5 SD below the mean for young-adult women, with history of fragility fracture (T-score ≤ -2.5)</td>
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- **Single** diagnosis based on WHO category
  The diagnosis of osteoporosis is based on the lowest site (lumbar spine, femur neck, total femur, one-third radius)
- Indicate significance and include significant change with g/cm² amount.

In addition:
1. All demographics present? (PHI removed prior to sending to ISCD)
2. Make/Model/Software Version?
3. Statement regarding technical quality & potential limitations of study?
4. Comparison scan date(s) identified?
5. Indications for scan present?
6. Fragility fracture history indicates Osteoporosis, regardless of BMD?
7. T-score and Z-score per ISCD official positions

(Use of Z-scores in men < age 50 and in premenopausal women)
WHO classification should not be applied to healthy premenopausal women. Z-scores rather than T-scores should be used especially in children.
ISCD recommendations for men age 50 and older:
(a) T-scores are preferred
(b) The WHO densitometric criteria are applicable
In men between age 20 and 50:
(a) Z-scores, not T-scores are preferred
(b) Osteoporosis cannot be diagnosed on the basis of BMD alone
(c) A Z-score of -2.0 or lower is defined as “below the expected range for age” and a Z-score above -2.0 is “within the expected range for age”.

8. Excluded ROI’s: rationale given

9. Ward’s Area not used

10. A general fracture risk statement?

11. Recommendations for the necessity and timing of the next BMD study?

Baseline DXA Report: Minimum Requirements

- Demographics (PHI removed prior to sending to ISCD).
- Requesting provider.
- Indications for the test.
- Manufacturer and model of instrument used
- Technical quality and limitations of the study, stating why a specific site or ROI is invalid or not included.
- BMD in g/cm2 for each site.
- The skeletal sites, ROI, and, if appropriate, the side, that were scanned.
- The T-score and/or Z-score where appropriate.
- WHO criteria for diagnosis in postmenopausal females and in men age 50 and over.
- Risk factors including information regarding previous non traumatic fractures.
- A statement about fracture risk. Any use of relative fracture risk must specify the population of comparison (e.g., young-adult or age-matched). The ISCD favors the use of absolute fracture risk prediction when such methodologies are established.
- A general statement that a medical evaluation for secondary causes of low BMD may be appropriate.
- Recommendations for the necessity and timing of the next BMD study.

Follow-Up DXA Report

- Statement regarding which previous or baseline study and ROI is being used for comparison.
- Statement about the LSC at your facility and the statistical significance of the comparison.
- Report significant change, if any, between the current and previous study or studies in g/cm2 and percentage.
- Comments on any outside study including manufacturer and model on which previous studies were performed and the appropriateness of the comparison.
- Recommendations for the necessity and timing of the next BMD study.
DXA Report: Items That Should not be Included

- A statement that there is bone loss without knowledge of previous bone density.
- Mention of “mild,” “moderate,” or “marked” osteopenia or osteoporosis.
- Separate diagnoses for different ROI (e.g., osteopenia at the hip and osteoporosis at the spine).
- Expressions such as "She has the bones of an 80-year-old," if the patient is not 80 years old.
- Results from skeletal sites that are not technically valid.
- The change in BMD if it is not a significant change based on the precision error and LSC.

Technologists

- **Sample Scan Images**- Look this over for example of proper imaging and positioning.
- Clearly identify your baseline and follow-up scans by writing on the top right-hand corner: “baseline/tech Smith”, “follow-up/tech Smith”.
- Follow guidelines for de-identifying patient information (no Pt. name, dob, MR# or SS#.)
- KEEP patients age on scan, but remember all patients 90+ are identified as 89+.
- Precision studies must adhere to Official position guidelines for minimum acceptable standards: Lumbar Spine: 1.9% (LSC=5.3%), Total Hip: 1.8% (LSC=5.0%), Femoral Neck: 2.5% (LSC=6.9%) Check your input numbers for mistakes. Submit your calculator pages or your own spreadsheet. We may ask for random scan printouts for verification.
- All technologists must submit a precision study.

Facilities

- All scans and reports should be de-identified, clearly marked in upper right hand corner with Clinician/Interpreter name and “baseline or follow-up”.
- Forms must be completely filled out.
- If facility has more than one tech, FAP 1140 must show *how* you arrive at your facility’s LSC values by attaching all precision calculator pages and/or your own spreadsheet with explanation (use remark section) to this form, separate from tech pages.
DXA Report Template WITH Comments

These are suggested guidelines for a DXA report. This template should be altered based on clinical judgment, any Federal, state or local regulations, and local facility preferences. Order of the report can be tailored to the institution.

Dual-Energy X-ray Absorptiometry (DXA)
A DXA scan was performed on _____ using a ______________ densitometer.

Impression:
Based on BMD diagnosis is consistent with ______________

Indication:
__________________________

Technical Quality:
__________________________

Clinical History:
__________________________

Results:
Lumbar Spine
The BMD measured in the______________ region is __________ gm/cm².
T-score (or Z-score as appropriate) = _________________

Femoral Neck
The BMD measured at the left/right femoral neck is __________ gm/cm².
T-score (or Z-score as appropriate) = _________________

Total Hip
The BMD measured at the left/right total proximal femur is __________ gm/cm².
T-score (or Z-score as appropriate) = _________________

1/3 Radius
The BMD measured at the left/right one-third radius is __________ gm/cm².
T-score (or Z-score as appropriate) = _________________

Interval Change: (if a follow-up study)
Today’s examination is compared to the technically similar prior study of __________.
In the interim, there has been no change OR a significant increase/decrease ______________, of _____ gm/cm², _____% at the __________ (skeletal site.)

At this facility, the least significant change in BMD with 95% confidence is _______ g/cm² at the L1-4 spine, _______ g/cm² at the total hip, _______ at the femoral neck and _______ g/cm² at the 1/3 radius.
**Fracture Risk:**
In this individual, the estimated 10-year risk for a hip fracture is ____% and for a major osteoporotic fracture is ____%. This fracture risk estimate was calculated using FRAX version ____ and _______ as additional clinical risk factors for fracture.

Secondary causes of bone loss should be evaluated if clinically indicated since the etiology of low BMD cannot be determined by BMD measurement alone.

**Follow-up DXA:**
Consider repeating this study in ____ years to assess bone density change or response to treatment.
Appendix: (Statements to be inserted as appropriate)

Note 1:
WHO classification: The T-score compares the patient’s BMD to the average BMD of a young adult. The criteria below are from the World Health Organization:
Normal: T-score -1.0 or above
Osteopenia/low bone mass: T-score -1.1 to -2.4
Osteoporosis: T-score -2.5 or lower
Severe or established osteoporosis: T-score -2.5 or lower plus fragility fracture

Note 2:
According to the International Society for Clinical Densitometry's 2007 consensus conference:
In women prior to menopause and men less than age 50:
• Z-scores, not T-scores are preferred. This is particularly important in children.
• A Z-score of -2.0 or lower is defined as 'below the expected range for age' and a Z-score above -2.0 is 'within the expected range for age.'
• The WHO diagnostic criteria may be applied in women in the menopausal transition.
• Osteoporosis cannot be diagnosed in men under age 50 on the basis of BMD alone.

Note 3:
Approaches to reduce osteoporosis-related fracture risk include optimizing calcium and vitamin D status and fall-prevention measures. The National Osteoporosis Foundation recommends (http://www.nof.org/hcp/practice/practice-and-clinical-guidelines/clinicians-guide) that FDA-approved medical therapies be considered in postmenopausal women and men aged ≥ 50 years with:
  a) hip or vertebral (clinical or morphometric) fracture
  b) T-score of ≤ -2.5 at the spine or hip
  c) Ten-year fracture probability by FRAX of ≥ 3% for hip fracture or ≥ 20% for major osteoporotic fracture (http://www.shef.ac.uk/FRAX/).

The American College of Rheumatology guidelines for patients receiving glucocorticoid therapy can be found at: http://www.rheumatology.org/practice/clinical/guidelines/ACR_2010_GIOP_Recomm_Clinicians_Guide.pdf

All treatment decisions require clinical judgment and consideration of individual factors including patient preferences, comorbidities, prior drug use, risk factors not captured in the FRAX model (e.g. sarcopenia, falls, vitamin D deficiency, increased bone turnover, interval significant decline in bone density) and possible under or over estimation of fracture risk by FRAX.