Recommendations for Bone Mineral Density Reporting in Canada

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Abstract

Objective: To propose a set of recommendations for optimal bone mineral density (BMD) reporting in postmenopausal women and older men and to provide clinicians with both a BMD diagnostic category and a useful tool to assess an individual's risk of osteoporotic fracture.

Options: The current methods of BMD reporting were reviewed. In this document, we propose that an individual's 10-year absolute fracture risk, rather than BMD alone, be used for fracture risk categorization. Consequently, age, sex, BMD, fragility fracture history, and glucocorticoid use are the basis for the approach outlined in this document.

Outcomes: An optimal BMD report as proposed in this document will provide clinicians with both a BMD diagnostic category and a useful tool to assess an individual's risk of osteoporotic fracture. A BMD report format, a checklist, and a patient questionnaire are meant to further encourage its use.

Evidence: All recommendations were developed using a consensus from clinicians and experts in the field of BMD testing and a standard method for the evaluation and citation of the supporting evidence.

Values: These recommendations were developed by a multidisciplinary working group under the auspices of the Scientific Advisory Council of the Osteoporosis Society of Canada and the Canadian Association of Radiologists.

Benefits, harm, and costs: Optimal BMD reports help the practitioner to assess an individual's risk for osteoporotic fracture and to decide whether medical therapy is warranted.

Recommendations: The BMD report should include

- patient identifiers
- dual-energy X-ray absorptiometry (DXA) scanner identifier
- BMD results expressed in absolute values (g/cm^2; 3 decimal places) and T-score (1 decimal place) for lumbar spine; proximal femur (total hip, femoral neck, and trochanter); and an alternate site (forearm BMD preferred: 1/3 radius, 33% radius or proximal radius) if either hip or spine is not valid
- a statement about any limitations due to artifacts, if present
- the fracture risk category (low, moderate, or high) as determined by using Tables 3 and 4 and by including major clinical factors that modify absolute fracture risk probability (with an indication of the corresponding absolute 10-year fracture risk of < 10%, 10–20%, or > 20%)
- a statement as to whether the change is statistically significant or not for serial measurements. The BMD centre's least significant change for each skeletal site (in g/cm^2) should be included.

Validation: Recommendations were based on consensus opinion. Since these are the first Canadian recommendations integrating clinical risk factors in a quantitative fracture risk assessment, it is anticipated that these "Recommendations for BMD Reporting in Canada" will be a work in progress and will be updated periodically to accommodate advances in this field.

The current cornerstone for the diagnosis and treatment of osteoporosis is the accurate assessment and optimal reporting of bone mineral density (BMD) results. Many factors other than low bone mass have been shown to predict the risk for future fracture; however, BMD remains the most readily quantifiable predictor of fracture risk for untreated individuals who have not yet suffered a fragility fracture. Currently, central dual-energy X-ray absorptiometry (DXA) is considered to be the preferred method for measuring BMD.

We propose a set of recommendations for optimal BMD reporting in postmenopausal women and older men. Such a report will provide clinicians with both a BMD diagnostic category and a useful tool to assess an individual's risk of osteoporotic fracture. This document complements the standards developed by the Canadian Panel of the International Society for Clinical Densitometry (ISCD) establishing the minimum requirements for acceptable performance of BMD testing in Canada.[1,2]

Previous guidelines published by the Osteoporosis Society of Canada (OSC) advised intervention based on an individual's World Health Organization (WHO) BMD diagnostic category. We propose that an individual's 10-year absolute fracture risk, rather than BMD alone, be used for fracture risk categorization. Consequently, age, sex, BMD, fragility fracture history, and glucocorticoid use are the basis for the approach outlined in this document. Initiatives are underway to integrate information about other clinical risk factors. The ability to more accurately characterize an individual's fracture risk based upon an integrated model will facilitate decision- making.

Complete Information for Reliable Results

To interpret bone densitometry results and predict fracture risk, specific information from referring physicians and patients is required. Consultation requests should include patient demographics, the reason for the BMD scan, and pertinent medical information. Referring physicians should report any patient risk factors that affect the interpretation of BMD scans, such as history of fractures, joint replacement, chronic illness, and relevant medications.

Patient Questionnaire

The patient questionnaire in Appendix 1 summarizes pertinent questions that help to ensure a valid scan and report. The patient can easily complete this questionnaire while waiting for the test.

Factors Affecting Scan Accuracy

Among other factors, proper positioning is necessary to ensure an optimal scan.[1] Consistent positioning and labelling of hip and lumbar spine regions of interest are essential when evaluating serial assessments.

It is important to follow manufacturer-specific protocols to ensure appropriate comparisons with normative reference data.

Structural abnormalities and artifacts can significantly affect the results. There are factors independent of BMD that may decrease or increase BMD results, e.g., body weight (Table 1).

When reporting scan results, it is essential to describe whether the scan is valid with regards to positioning, artifact, and analysis.[2]

Making Results Work

The following measurements should be reported for each measured skeletal site with a valid scan:

- absolute BMD (in g/cm^2; 3 decimal places)
- T-score (1 decimal place)

All women should have T-scores derived using a white female reference database, and all men should have T-scores determined using a white male database. Other racial databases should not be used. In the absence of fracture data in nonwhite populations, results should be reported based on values extrapolated from white population databases. Z-scores should not be used in adults as they do not provide additional information.

BMD results should not be reported in terms of chronological age (e.g., "This 50-year-old woman has the bones of an 80-year-old").

The patient examination should assess:

- the lumbar spine (from L1 to L4 levels, using a minimum of 2 valid vertebrae)
- the proximal femur (using the lowest T-score of the total proximal femur, also referred to as "total hip," trochanter,

Table 1 Factors modifying bone mineral density (BMD)*

Region	Increased BMD	Decreased BMD
Hip	Excessive or inadequate internal hip rotation rotation	
	Osteoarthritis	Artifact overlying soft tissue
	Metal artifact	Lytic lesions
	Focal skeletal sclerosis	
Spine	Osteophytes	
	Focal skeletal pathology (i.e., sclerosis, metastasis, or Paget's disease)	Artifacts overlying soft tissues
	Vertebral compression fracture	Rotoscoliosis
	Vascular calcification	Laminectomy
	Metal, radiology contrast, stones, calcium tablets or other artifact overlying spine	Lytic lesions

*Extremes of body weight or significant change (more than 10%) in body weight can have unpredictable effects on BMD and affect serial measurements.

and femoral neck). Ward's area should not be included in the report, as the small amount of bone yields measurements of poor accuracy and reproducibility.

Two skeletal sites should be reported. If either the lumbar spine or hip is invalid, then the forearm should be scanned. When forearm BMD is assessed, the site in the midshaft of the radius is recommended, referred to as the 1/3 region, the 33% region, or the proximal region.

When the final report includes a graph of the patient's BMD, it should be based on the same anatomic levels that were used for numeric results; for example if L3 and L4 were excluded from spinal analysis because of degenerative artifacts, the graph should be based on the combined value for L1 and L2.

Optimal Reporting of Serial Studies

Patients often have repeat DXA studies to evaluate changes in BMD over time. This is usually done to monitor the response to a pharmacologic therapy or to document the stability of bone density in untreated patients at risk for bone loss. Depending on the clinical situation, BMD scans are usually repeated every 1 to 3 years. If used correctly, serial BMD testing can be a helpful clinical tool.

Measurement error must be considered when evaluating serial assessments. A clear understanding of the interpretation of serial measurements and the statistical principles impacting upon their interpretation is necessary to determine whether a change is real and not simply random fluctuation or artifact.[3] It is inadequate to simply use the manufacturer's default precision error, which may underestimate the precision error in the clinical setting.

Precision error must be quantified by each testing facility to ensure that follow-up testing can be interpreted reliably. Each centre should determine its precision error in absolute values (g/cm^2) so that the least significant change (LSC) can be calculated. If there are changes in staffing or instrumentation (including relocation), the precision error needs to be recalculated. In the comparison of 2 DXA examinations, the change in BMD must exceed the LSC (2.8 times the site-specific precision error for single measurements at each time point) for that centre to have 95% confidence that the change is real.

Whenever possible, the patient's initial and follow-up scans should be done on the same instrument, using the same procedure. If comparison between instruments is required (e.g., after densitometer replacement), then a formal cross-calibration of the instruments is necessary before attempting to compare patient results.

Interpreting Results

It is imperative that bone densitometry reports translate data into an estimate of fracture risk and that this provides guidance to the referring physician as to whether fracture risk is sufficiently high to warrant therapy in an untreated individual patient.

New Diagnostic Categories

In 1994, the WHO established definitions for categories of bone mineralization described as "normal, osteopenia, osteoporosis, and severe (established) osteoporosis."[4] As originally proposed, this classification applies to postmenopausal white women. There is still no consensus on how to define normal and abnormal in other patient sets.

The new approach recommended by this committee distinguishes between postmenopausal women and all other adult groups. The diagnostic categorization is based on the lowest T-score result from the lumbar spine, the total hip, trochanter, and the femoral neck (Table 2).

Table 2 Recommended diagnostic categories based on bone densitometry

Patient group	Category	T-score values
Postmenopausal women*	Normal	Greater than or equal to –1.0 SD
	Osteopenia	Between –1.0 and –2.5 SDs
	Osteoporosis	Less than or equal to –2.5 SDs
Premenopausal women	Normal	Greater than –2.5 SDs
	Reduced bone density	Less than or equal to –2.5 SDs
Men	Normal	Greater than –2.5 SDs
	Reduced bone density	Less than or equal to –2.5 SDs

*Postmenopausal is defined as menopausal women 50 years of age; SD: standard deviation.

Absolute Fracture Risk Based on Bone Densitometry

Previous guidelines from the OSC advised intervention based on an individual's WHO category as a marker of relative fracture risk.[5] The weakness of that system is that absolute fracture risk can vary substantially within any WHO category owing to modification of risk by other factors, such as age and sex.[6]

Therefore, we now propose that age, sex, fracture history, and glucocorticoid use be incorporated into the assessment of fracture risk. The key assumptions underlying this approach are as follows: fracture risk is determined using:

- the lowest T-score from the spine, the total hip, the trochanter and the femoral neck but is based on published data for only the femoral neck
- European data, as Canadian data are not yet available
- female reference data to derive risks for both men and women
- bone densitometry results, age, and sex, but does not incorporate other potentially useful clinical risk factors that might further enhance risk stratification
- arbitrary risk categories, which may be refined as further data become available

and fracture risk estimates apply only to

- adults over age 50 years, as there are insufficient data in younger groups
- central DXA, not to other densitometric techniques
- fracture risk stratification, and not to the need for pharmacologic intervention

Additional clinical variables will be included in the absolute fracture risk estimate when the methods are more firmly established and validated.

We recommend using BMD T-scores to determine an individual's 10-year absolute fracture risk (combined risk for fractures of the hip, spine, forearm, and proximal humerus).[6] These data are derived from observed incidences of fractures as a function of age, sex, and measured BMD.

Published male data used a female reference database to produce T-scores. These were converted to corresponding male T-scores using peak bone density and standard deviation values for the femoral neck, averaging results derived separately from Hologic and GE Lunar National Health and Nutrition Examination Survey (NHANES) hip normative reference databases.

Ten-year fracture risk categories for women and men, with corresponding T-scores for each age range, are listed in Tables 3 and 4, respectively. Figures 1 and 2 illustrate the stratification into 3 risk zones for each sex. There are 3 categories for absolute risk: low (less than 10%), moderate (10 to 20%), and high (over 20%). Similar risk categories have been used for cardiovascular risk assessment.[7,8]

Clinical Factors That Modify Absolute Fracture Risk

Certain clinical factors increase fracture risk independent of BMD. The most important are the following:

- Fragility fractures after age 40 years (especially vertebral compression fractures)[9]
- Systemic glucocorticoid therapy of > 3 months' duration[10]
- The presence of either of these factors substantially elevates fracture risk. Such factors effectively increase risk categorization to the next level: from low risk to moderate risk, or from moderate risk to high risk. When both factors are present, the patient should be considered to be at high risk regardless of the BMD result.

Not all clinical risk factors for fracture are amenable to pharmacotherapy. For example, in a nonosteoporotic individual with high risk of falling, a falls prevention program could be preferred to pharmacotherapy.

How to Determine an Individual's 10-Year Absolute Fracture Risk

1. Begin with the table appropriate for the patient's sex.

2. Identify the row that is closest to the patient's age.

3. Determine the individual's fracture risk category by using the lowest T-score from the recommended skeletal sites.

Figure 1 Zones of fracture risk for women.

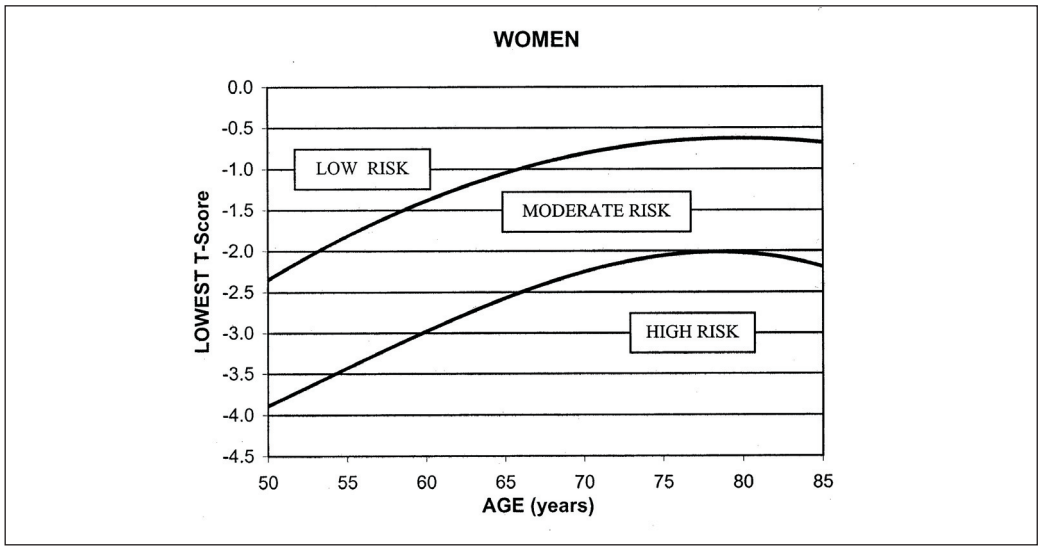
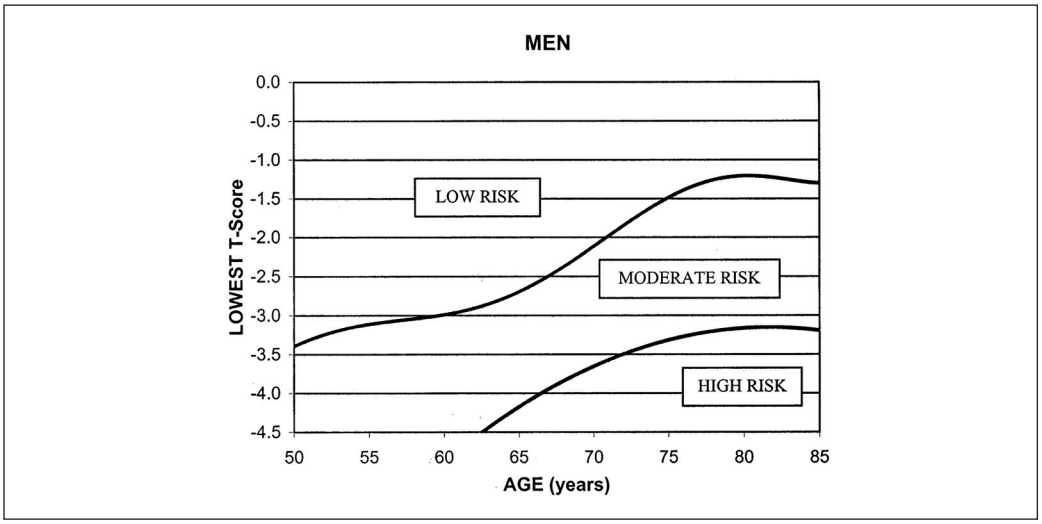


Figure 2 Zones of fracture risk for men.



4. Evaluate clinical factors that may move the patient into an even higher fracture risk category.

5. Finally, determine the individual's absolute fracture risk category.

Items to be Included in TAE BMD Report

See Appendix 2 for a checklist to guide you through the process of optimal reporting. The BMD report should include

- patient identifiers
- DXA scanner identifier
- BMD results expressed in absolute values (g/cm^2; 3 decimal places) and T-score (1 decimal place) for lumbar spine; proximal femur (total hip, trochanter, and femoral neck); and an alternate site (forearm BMD preferred: 1/3 radius, 33% radius, or proximal radius) if either hip or spine is not valid.
- a statement about any limitations due to artifacts, if present.
- the fracture risk category (low, moderate, or high) as determined by using Tables 3 and 4 and by including major clinical factors that modify absolute fracture risk probability (with an indication of the corresponding absolute 10-year fracture risk of < 10%, 10% to 20%, or > 20%).
- a statement as to whether the change is statistically significant or not for serial measurements. The BMD centre's least significant change for each skeletal site (in g/cm^2) should be included.

A report format can be found in Appendix 3. Fracture risk predicted for an individual by this system applies only for a finite period of time, and that risk will change with advancing age or

Table 3 Ten-year fracture risk for women

	Lowest T-score: lumbar spine, total hip, femoral neck, trochanter		
Age (years)	Low risk (< 10%)	Moderate risk (10% to 20%)	High risk (> 20%)
50	Greater than –2.3	–2.3 to –3.9	Less than –3.9
55	Greater than –1.9	–1.9 to –3.4	Less than –3.4
60	Greater than –1.4	–1.4 to –3.0	Less than –3.0
65	Greater than –1.0	–1.0 to –2.6	Less than –2.6
70	Greater than –0.8	–0.8 to –2.2	Less than –2.2
75	Greater than –0.7	–0.7 to –2.1	Less than –2.1
80	Greater than –0.6	–0.6 to –2.0	Less than –2.0
85	Greater than –0.7	–0.7 to –2.2	Less than –2.2

Table 4 Ten-year fracture risk for men

	Lowest T-score: lumbar spine, total hip, femoral neck, trochanter		
Age (years)	Low risk (< 10%)	Moderate risk (10% to 20%)	High risk (> 20%)
50	Greater than –3.4	Less than or equal to –3.4	—
55	Greater than –3.1	Less than or equal to –3.1	—
60	Greater than –3.0	Less than or equal to –3.0	—
65	Greater than –2.7	Less than or equal to –2.7	—
70	Greater than –2.1	–2.1 to –3.9	Less than –3.9
75	Greater than –1.5	–1.5 to –3.2	Less than –3.2
80	Greater than –1.2	–1.2 to –3.0	Less than –3.0
85	Greater than –1.3	–1.3 to –3.3	Less than –3.3

with the development of new clinical risk factors. Repeat assessment is appropriate in 5–10 years in those with low risk and in 1–5 years in those with moderate risk.

Conclusion

These recommendations for BMD reporting provide the elements of an optimal BMD report. The BMD report format, a checklist, and the patient questionnaire are available for downloading on the OSC Web site (<http://www.osteoporosis.ca>).

Since these are the first Canadian recommendations integrating clinical risk factors in a quantitative fracture risk assessment, these "Recommendations for Bone Mineral Density Reporting in Canada" should be considered a work in progress. It is anticipated that they will be updated periodically to accommodate advances in this field.

These recommendations were reviewed and endorsed by the following organizations:

- Canadian Association of Nuclear Medicine
- Canadian Association of Radiologists
- Canadian Orthopaedic Association
- Canadian Panel of the International Society for Clinical Densitometry
- Canadian Rheumatology Association
- Canadian Society of Endocrinology and Metabolism
- Society of Obstetricians and Gynaecologists of Canada

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These recommendations were developed by a multidisciplinary working group under the auspices of the Scientific Advisory Council of the Osteoporosis Society of Canada and the Canadian Association of Radiologists.

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Appendix 1

Patient Questionnaire

Please complete this questionnaire while waiting for your bone mineral density test.

A technologist may review this document with you. A staff member will measure your weight and height.

Name _____

Date _____

Date of Birth _____

Female ❑ Male ❑

If you answer yes to any of the following 4 questions, please speak to the receptionist immediately:

1. Is there any chance that you are pregnant?

No ❑ Yes ❑

2. Have you had a barium x-ray in the last 2 weeks?

No ❑ Yes ❑

3. Have you had a nuclear medicine scan or x-ray dye in the last week?

No ❑ Yes ❑

4. Have you ever had surgery of the spine or hips?

No ❑ Yes ❑

The following information will help us to assess your future risk for fractures:

5. Have you ever had a bone density test before?

No ❑ Yes ❑

If yes, when and where?

_____

6. Have you broken any bones since you were 40 years old?

No ❑ Yes ❑

If yes, please state:

Bone that broke_____

Age when it broke_____

What caused the broken bone_____

_____

7. Are you currently taking steroid pills (such as prednisone or cortisone)?

No ❑ Yes ❑

If yes, how long have you been taking them? _____

What is your current dose? _____

Have you ever taken steroid pills for longer than 3 months in 1 year?

No ❑ Yes ❑

8. Please list your prescription medications:

_____

9. Have you ever been treated with medication for osteoporosis?

No ❑ Yes ❑

If yes, what medication(s) and for how long?

_____

10.For women: Do you still have periods?

No ❑ Yes ❑

If no, how old were you when they stopped?_____

Appendix 2

Bone Mineral Density Reporting: Checklist

A tool to assess the risk of osteoporotic fracture. (Based on the "Recommendations for Bone Mineral Density Reporting in Canada.")

1. Obtain information from the referring physician: Does the patient have risk factors that influence bone mineral density (BMD) results or interpretation?

2. Collect completed patient questionnaire.

3. Perform and analyze BMD scan for the following sites:

   - Lumbar spine
   - Proximal femur (total hip, trochanter, and femoral neck)
   - If either hip or spine is not valid then assess forearm BMD (1/3 radius, 33% radius, or proximal radius).

   Report whether scan results are valid with regard to artifact.

4. Report for each valid site:

   - absolute BMD (in g/cm^2; 3 decimal places)
   - T-score (1 decimal place)

5. Report precision error and least significant change (LSC) in absolute values (g/cm^2) for each measurement site.

6. For serial studies, use the same dual-energy X-ray absorptiometry device and scanning procedure. Include a statement as to whether the change in BMD at each site is statistically significant or not. The BMD centre's least significant change for each skeletal site (in g/cm^2) should be included.

7. Determine the 10-year absolute fracture risk category by using Tables 3 and 4.

8. Evaluate clinical factors that may move the patient into a higher absolute fracture risk category.

9. Determine the individual's absolute fracture risk category.

Appendix 3

Bone Mineral Density Reporting: Report Format

Patient name and sex (F/M):_____

DOB: ❑❑ ❑❑ ❑❑

DD MM YY

Scan date Actual Previous First Scan

❑❑ ❑❑ ❑❑ ❑❑ ❑❑ ❑❑ ❑❑ ❑❑ ❑❑

DD MM YY DD MM YY DD MM YY

Scanner:_____

Bone mineral density (BMD)		
Lumbar spine	Levels	L1–L4
	BMD	_____ g/cm^2 (3 decimal places)
	T-Score[a]	_____ (1 decimal place)
	LSC[b]	_____ g/cm^2 (3 decimal places)
	Statistically significant change[c]?	Current vs previous scan: Y/N/NA
		Current vs first scan: Y/N/NA
Total hip	Site:	L or R
	BMD =	_____ g/cm^2 (3 decimal places)
	T-Score[a] =	_____ (1 decimal place)
	LSC[b] =	_____ g/cm^2 (3 decimal places)
	Statistically significant change[c]?	Current vs previous scan: Y/N/NA
		Current vs first scan: Y/N/NA
Femoral neck	Site:	L or R
	BMD =	_____ g/cm^2 (3 decimal places)
	T-Score[a] =	_____ (1 decimal place)
	LSC[b] =	_____ g/cm^2 (3 decimal places)
	Statistically significant change[c]?	Current vs previous scan: Y/N/NA
		Current vs first scan: Y/N/NA
Trochanter	Site:	L or R
	BMD =	_____ g/cm^2 (3 decimal places)
	T-Score[a] =	_____ (1 decimal place)
	LSC[b] =	_____ g/cm^2 (3 decimal places)
	Statistically significant change[c]?	Current vs previous scan: Y/N/NA
		Current vs first scan: Y/N/NA
Forearm*	Site:	1/3 or 33% region
	BMD =	_____ g/cm^2 (3 decimal places)
	T-Score[a] =	_____ (1 decimal place)
	LSC[b] =	_____ g/cm^2 (3 decimal places)
	Statistically significant change[c]?	Current vs previous scan: Y/N/NA
		Current vs first scan: Y/N/NA

* To be measured if either lumbar spine or hip produced invalid scans.

Limitations (list any limitations due to artifacts)

_____

Diagnostic category[d]

_____

Absolute fracture risk category[e]

_____

Comments

_____

_____

Report date: ❑❑ ❑❑ ❑❑
DD MM YY

Reported by: _____

[a]T-score: number of standard deviations above (+) or below (–) mean peak young adult bone density.

[b]LSC: least significant change; corresponds to 2.8 times the site-specific precision error for single measurements at each time point for our centre.

[c]Statistically significant change: in comparing 2 dual-energy X-ray absorptiometry examinations, the change in BMD must exceed the LSC to have 95% confidence that the change is real.

[d]Recommended diagnostic categories based on BMD for postmenopausal women: normal (T-score greater than or equal to –1), osteopenia (T-score between –1 and –2.5), and osteoporosis (T-score less than or equal to –2.5); for men and premenopausal women: normal (T-score greater than –2.5) and reduced bone density (T-score less than or equal to –2.5)

[e]Absolute fracture risk category: low (<10%), moderate (10% to 20%), or high (>20%), as determined by using Tables 3 and 4. Fracture risk predicted for an individual by this system applies only for a finite period of time, and that risk will change with advancing age or with the development of new clinical risk factors.