Canadian Association of Radiologists
L'Association canadienne des radiologistes

CAR TECHNICAL STANDARDS FOR

BONE MINERAL DENSITOMETRY REPORTING

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1. INTRODUCTION

Bone mineral density (BMD) testing by central dual-energy x-ray absorptiometry (DXA) is the fundamental technology for the diagnosis, treatment, and monitoring of osteoporosis and is a useful adjunct in the management of other metabolic bone diseases (1–9). The CAR BMD guidelines are issued here as technical standards and represent the current expectations for BMD testing and reporting in Canada. These standards must be met in order to be accredited by the CAR BMD Accreditation Program. Changes have been made to the 2010 CAR Technical Standards for Bone Mineral Densitometry Reporting to incorporate principles from the 2010 Clinical Practice Guidelines for the Diagnosis and Management of Osteoporosis in Canada from Osteoporosis Canada: Summary (1, 2).

2. INFORMATION THAT SHOULD BE PROVIDED BY REFERRING PHYSICIANS

BMD consultation requests should include patient demographics, the indication for BMD testing, factors of relevance to scan assessment (joint replacement, bone surgery, or bone disease in scan regions), osteoporosis medication history, factors of relevance to fracture risk determination in patients 50 years of age or older (fragility fracture history, glucocorticoid history), and any other pertinent medical information (1, 2, 6, 10). On follow-up scans done on patients receiving osteoporosis drug therapy, it is particularly helpful if BMD requests indicate the scan year of primary interest for comparison, with details of current osteoporosis drug therapy and duration (2, 6, 11, 12). While this level of information is often not provided, a thorough patient history from the referring physician is to be encouraged (1, 2, 6).

3. ADULT PATIENT QUESTIONNAIRE

A template questionnaire that acquires the appropriate information necessary for BMD testing in adults (defined as those 18 years of age or over) is presented in Appendix 1 (1, 2). This can either be filled in by patients and then clarified by trained facility staff, or history can be directly taken by facility staff. The specific items on the questionnaire are intended to collect the minimum information needed to analyze a BMD scan and determine absolute fracture risk in those aged 50 and over (1, 2). Additional history items that are of relevance to individual patients should also be collected, such as menopausal history, medication history, and illnesses (1, 2, 6).

4. BMD REPORT CONTENTS

Report contents will differ depending on whether it is an adult (age 18 or over) or paediatric study that is being reported, and whether it is a baseline or follow-up study.

4.1 COMPONENTS OF A FIRST-TIME ADULT BMD REPORT

The components of a first-time adult BMD report are shown in Appendix 2 (1, 2).

4.1.1 DEMOGRAPHICS

Demographics should include patient name, date of birth, gender, provincial healthcare number or other identifier, height, weight, scan date, report date, name of the referring physician, name of the reporting physician, and BMD facility name and location (2, 6, 13). Weight and height should be measured at the BMD facility (1, 2). Neither values reported by the patient nor measurements provided by other medical practitioners should be used, other than in exceptional circumstances where it is not possible to carry out the measurements (such as if the patient cannot stand). If height or weight data were not measured directly by the BMD facility, this should be indicated in the report.

Weight can be measured with either a mechanical or an electronic scale that is medical-grade. Facilities are encouraged to use wall-mounted height measuring devices, referred to as stadiometers, and to use standardized positioning of patients (7, 14, 15). It is also encouraged that three height measurements be made, with repositioning between each measurement, and the average used as the height value. The reason for

this is that, just as with bone density quantitation, height measurements have significant precision error and this is minimized by averaging several assessments (14, 15). Currently, this height measurement methodology is a recommendation and is not a requirement for accreditation.

4.1.2 DIAGNOSTIC CATEGORY

The current standard for reporting the diagnostic category is shown in Appendix 3 (2). The diagnostic category is determined using the lowest T-score (for individuals 50 years of age or older) or Z-score (for individuals under 50 years of age) from the available results for the lumbar spine, total hip, femoral neck, 1/3 (or 33%) radius, and total body (see section 4.1.5 and Appendix 3 for details) (2). The trochanteric region and Ward's region of the proximal femur are not to be used (16). T-scores or Z-scores for diagnostic categorization should be derived using a white female reference database for women and a white male reference database for men.

4.1.3 FRACTURE RISK CATEGORY

The absolute fracture risk category should be reported for men and women 50 years of age and older when relevant history is available (1, 2). The current standard for determining absolute fracture risk uses the 2010 version of the Canadian Association of Radiologists/ Osteoporosis Canada risk tables (CAROC 2010) (1, 2). The CAROC 2010 risk tables are provided in Appendix 4 along with instructions on how to use them. This risk determination incorporates BMD results from the femoral neck, age, sex, fragility fracture history after age 40 years, and glucocorticoid history. The spine BMD T-score is also used in certain circumstances. There are several clinical circumstances in which fracture risk is deemed to be high regardless of BMD. There are also clinical circumstances where fracture risk cannot be assigned. Details are provided below. For individuals under age 50, absolute risk assessment is not available and a fracture risk category should not be reported (13, 16).

CAROC 2010 Tables

Fracture risk is determined on the CAROC 2010 tables using the femoral neck T-score. For both women and men, T-scores for fracture risk determination using CAROC 2010 are derived from a white female reference database. Note that this approach differs from that used to determine the diagnostic category for men (Section 4.1.2), where a white male reference database is used. BMD data for males will therefore need to be analyzed on both white male and white female reference databases.

Fragility Fracture History

The absolute fracture risk categories were derived using data from four types of fractures: forearm, vertebra, proximal femur, and proximal humerus (3). Fractures at these sites should generally be regarded as fragility fractures if they occur subsequent to a fall from standing or sitting heights. Generally, craniofacial fractures and fractures of the hands and feet are not considered fragility fractures. Other types of fractures have weaker relationships to osteoporosis, but may be regarded as fragility fractures if the history suggests that the fracture occurred with a degree of trauma that would not normally be expected to lead to a broken bone (2, 17). Only fractures that occurred after age 40 should be considered in determining risk (2, 17).

Glucocorticoid History

Glucocorticoid history is considered positive if prednisone (or other glucocorticoids in terms of prednisone equivalents) was in use at a dose equal to greater than 7.5 mg per day for more than 3 cumulative months in the prior 12 months (meaning for more than 90 total days out of the preceding 365 days, not necessarily consecutive) (1, 2). Patients with hypoadrenalism on replacement glucocorticoids should not be considered to have a positive glucocorticoid history for fracture risk determination regardless of glucocorticoid dose (18).

High Risk Regardless of BMD

There are several clinical situations relating to fracture history where an individual should be classified as having high fracture risk regardless of the BMD result. These include a history of one fragility fracture and positive glucocorticoid history, history of fragility hip fracture, history of fragility vertebral fracture, and history of two or more fragility fractures (1, 2).

Use of Spine T-score

If fracture risk category has been determined to be low after determining the fracture risk category using the femoral neck T-score on the CAROC 2010 table, fracture history, and glucocorticoid history, the spine T-score is assessed. If the spine T-score is ≤ -2.5, the risk category is increased to moderate (1, 2). A white

male reference database is used for this purpose in men and a white female reference database in women.

Use of Sites Other Than Femoral Neck and Spine

Sites other than femoral neck and spine are not used to generate the fracture risk category, although they are used for determining diagnostic category (1, 2).

Undefined Clinical Scenarios

Using the approach of Osteoporosis Canada, it will not be possible to generate a fracture risk category in certain clinical scenarios (1, 2). In particular, this will occur when the femoral neck and spine are not available or when the femoral neck is not available while the spine is available but has a T-score >-2.5. In addition, there are scenarios where the fracture risk is likely higher than determined by the femoral neck, as when the spine T-score is much lower than -2.5 or T-scores of other skeletal sites are much lower than the value at the femoral neck. In these circumstances, the reporting physician should provide guidance in the interpretation section.

Use of FRAX

While FRAX (the World Health Organization fracture risk system) has validity for fracture prediction, both Osteoporosis Canada and CAR have endorsed CAROC 2010 as the method of choice for reporting BMD results (1-3, 19–26). CAROC 2010 is to be used for fracture risk reporting (1, 2).

Integrating Fracture Risk Determination Using the Osteoporosis Canada Paradigm

A flow chart of one approach to systematically integrating these principles is provided in Appendix 5.

Bone-active Therapy

Bone-active drug therapy may alter fracture risk if the drug is taken regularly, if it is taken correctly, and if it is achieving the desired effects, although some evidence suggests that fracture risk determination might remain valid in the short-term even when medications are in use (2, 27, 28). If a patient who undergoes BMD testing for the first time is already on bone-active drug therapy, the fracture risk category should be provided, but a statement should be included indicating that the risk may be lower than calculated if osteoporosis drug therapy is effective (1, 2, 28).

4.1.4 HISTORY USED FOR RISK DETERMINATION

For individuals aged 50 and over, the report should state the specific history employed in risk determination when either fragility fracture status or glucocorticoid history are positive (1, 2). This transparency allows the referring physician to understand how the fracture risk was arrived at, and allows the referring physician to provide clarification or additional information if appropriate.

4.1.5 BMD DATA

Care must be taken in all technical aspects of how scanning is performed, including adherence to manufacturer protocols, proper positioning, sub-region assignment, bone tracing, determination of regions of interest, and quality assurance (2, 6, 13). A minimum of two skeletal sites should be scanned and reported (2, 6, 9). The usual sites would be the lumbar spine and the proximal femur (2, 6, 9). When analyzing the lumbar spine, L1 to L4 should be used unless the decision is made to exclude one or two vertebrae because of technical artifacts (2, 13). A minimum of two vertebrae should be used. Interpretation should not be based on a single vertebra (2, 13). If a report includes graphical representation of results, the graph must present data and reference curves for the vertebrae actually used in interpretation (29). Consideration can be given to excluding a particular vertebra if the T-score of that vertebra is more than one standard deviation greater than the T-score of the vertebra with the next highest value (29). It is not mandatory that a high-density vertebra be excluded, but it should be evaluated for causes of artifact and a decision made as to whether it should be retained in the vertebral analysis.

For the proximal femur, the left side should be measured unless it is not available, invalid, or the right hip was previously measured (2). Results should be reported for the total hip and femoral neck (2, 13). If either the spine or hip site is not available or invalid because of artifact, another site should be substituted (2, 6, 13). The non-dominant forearm is the site of choice and the 1/3 (or 33%) radius should be reported (2, 6, 13). If the non-dominant forearm is not available or is invalid, the dominant side may be used. If the wrist cannot be measured, total body BMD can be assessed (29). The head may be included or excluded when analyzing the scan. If the head is excluded, this should be noted in the report. If the spine cannot be

measured, and neither forearm nor total body measurements are available, bilateral hip measurements may be made (6, 13, 29). The two hip measurements should be reported separately, not as an averaged value (29). When applying hip data to determine the diagnostic category or fracture risk category, the lowest of the relevant values from the two sides should be used. For patients whose weight exceeds the limit of the DXA equipment, bilateral forearm studies may be done unless one side is not available or invalid, although it will not be possible to determine fracture risk (29).

For each skeletal site with a valid scan, reported density results should include absolute BMD (in g/cm^2 to 3 decimal places) and either T-score (to one decimal place) for those 50 years or older or Z-score (to one decimal place) for those under 50 years of age (10, 13, 16, 29). For women, T-scores and Z-scores should be derived using the manufacturer's white female reference database. For men over age 50 years, T-scores used for diagnostic classification should be derived using a white male reference database; the femoral neck T-score used for risk determination should be derived from a white female reference database while the spine T-score used to alter the risk category from low to moderate if the value is <= -2.5 should be derived from a white male reference database. Both femoral neck T-scores must be reported. For men under age 50 years, Z-scores should be derived using a white male reference database. Non-white reference databases should not be used. The reference databases and versions should be specified in the report (6, 29).

4.1.6 LIMITATIONS

Any structural abnormalities, anatomical variants, artifacts, sub-optimal positioning, or other issues impacting on scan reliability and interpretation need to be considered when interpreting BMD results (2, 6, 10, 13). A judgment needs to be made as to whether these issues render results invalid or impact on the interpretation. Some sources of artifact are preventable and care should be taken to assess these prior to scanning (such as metal on clothes or in pockets, or recent barium or nuclear medicine studies) and either remove the source of artifact or postpone the scan to a future date. Sources of artifact relevant to the scan should be noted in the report.

Skeletal size can affect BMD readings, with larger bones producing falsely high values and smaller bones producing falsely low values (29). There is no accepted means of correcting for skeletal size, but height or weight outside the normal range should be noted and should be considered in the interpretation of results.

4.1.7 INTERPRETATION

A narrative section on interpretation and implications of BMD results should be provided. This should not be a simple re-statement of data. In individuals over age 50 years, where absolute fracture risk cannot be assigned using the Osteoporosis Canada paradigm, the reporting physician should integrate the available information and provide an indication of fracture risk where this is possible. Guidance as to therapeutic considerations can also be provided within the context of Osteoporosis Canada guidelines, to the degree appropriate to the knowledge and experience of the reporting physician (1, 2).

4.1.8 RECOMMENDED FOLLOW-UP DATE

A recommendation should be included for the timing of the next DXA study (2, 13). The timing of serial testing should be driven by the expected rate of bone loss. The intention of serial monitoring is to provide a sufficient period of time for anticipated changes in density to exceed the precision error of the DXA method, which also renders a stable density informative (1, 2, 4, 6, 13). A guide is provided in Appendix 6, although this needs to be applied in the context of local provincial health insurance plan restrictions. When indicating recommended timing of the subsequent BMD test, consideration should be given to specifying the year of recommended follow-up rather than a time interval, as this makes the report more readily implementable by referring physicians. For follow-up periods under two years, the month of recommended follow-up could also be included. This approach is not a requirement for accreditation at this time.

4.1.9 DEFINITIONS

Any terminology or abbreviation used in the report should be defined. Some examples are:

T-score: the number of standard deviations above (+) or below (-) the mean peak density.

Z-score: the number of standard deviations above (+) or below (-) the mean density for an individual of that age and gender.

Fracture Risk: high fracture risk is 10-year absolute fracture risk >20%; moderate fracture risk is 10-year absolute fracture risk in the range of 10% to 20%; low fracture risk is 10-year absolute fracture risk <10%.

TBLH: total body less head, assessment of the entire body minus the head region.

4.1.10 MACHINE IDENTIFICATION

Machine identification should include DXA brand, model, and serial number.

4.2 COMPONENTS OF A FOLLOW-UP ADULT BMD REPORT

The components of a follow-up adult BMD report are shown in Appendix 7. A follow-up adult BMD report should include all the components of a first-time adult report. In addition, items specific to follow-up also need to be described, including changes in density, statistical parameters relating to measurement error, aspects of interpretation relating density changes to the clinical situation, and definitions relevant to follow-up.

4.2.1 DEMOGRAPHICS

Change in height as measured at the BMD facility should be noted (1, 2, 13, 15). In particular, measured height loss exceeding 2 cm over three years or less should be emphasized, as this amount of height change has been shown to have a high predictive value for incident vertebral fractures having developed during the monitoring period (2, 15). This may be an indication to do spine radiographs or vertebral fracture assessment by DXA (2). Change in weight should also be noted, as this can create artifactual changes in BMD values (2, 30). There is no consensus as to what the threshold should be for flagging a change in weight as being of potential importance as a source of artifact, with some physicians using percentage change in weight and others using absolute change in weight. A suggested threshold is 10% change in weight over the period of monitoring (29). The use of this weight change threshold is only a recommendation and is not a requirement for accreditation. Each reporting physician, however, must define a weight change threshold and use it in all serial reporting, applying it to each pair of BMD measurements for which change in BMD is reported.

4.2.2 FRACTURE RISK CATEGORY

The absolute fracture risk category should be reported for men and women 50 years of age and older, regardless of therapy that may be in use (1, 2). If bone-active drug therapy is in use, the fracture risk category should be provided, but a statement should be included indicating that the risk may be lower than calculated if osteoporosis drug therapy is effective (1, 2).

4.2.3 CHANGES IN DENSITY

When comparing serial assessments, the same machine should be used when possible (2, 12, 13) and positioning and sub-region assignment must be consistent (2, 12, 13). The same reference population database should be used for serial studies when possible (29). If the reference database must be changed, this should be noted in the report. The description of density change should include the absolute density change (in g/cm^2, to 3 decimal places) and percentage change (to 1 decimal place) (10, 13, 29). Percentage change must be derived using absolute density (g/cm^2), not T-scores or Z-scores (4). An annualized rate of change may be reported, but this is optional. The skeletal sites for which changes in density are to be reported are the lumbar spine (using whichever vertebrae are considered valid, with a minimum of two vertebrae) and the total proximal femur (2, 13). Hip sub-regions should not be used (2). If either the spine or hip is not available, it is permissible to report changes at a single site. If the forearm or total body BMD is being monitored in lieu of the spine or hip, change can be reported for the 1/3 (or 33%) proximal radius or for the total body BMD (10, 29). It must be

recognized that the change profile at these sites may not parallel changes at the spine and hip, and may not correlate as well with drug responses (10, 29). This will need to be addressed in the interpretation section.

Changes in density must be reported in relation to 1) the first study on file, 2) the most recent previous study, and 3) the study done closest to the initiation of the current clinical treatment regimen (if any), if this can be ascertained. The latter BMD change is the one of greatest importance for patients on drug therapy; it is also relevant to patients who started lifestyle and nutritional supplements for bone health (1, 2). Ideally, the comparison study of primary interest should be indicated on the requisition by the referring physician, but if it is not provided, the reporting physician is responsible for obtaining this information by patient history.

Statistical significance must be reported for each BMD skeletal site comparison, indicating whether the difference is considered significant at a 95% level of confidence (2, 4, 6). The manufacturer's software determination of statistical significance is not to be used (2). Each facility must determine precision error for each DXA machine and for each skeletal site (including forearm and total body if these sites are measured by the facility and are used for serial monitoring) using the LSC (least significant change) methodology and use this value when determining statistical significance (2, 13). It is permissible to apply results derived from precision testing on one side (forearm or hip) to serial scans done using the opposite side of the body (13). A follow-up BMD report should state the LSC in absolute values (g/cm2 to 3 decimal places) for each skeletal site for which change is reported (10, 13, 29). Whenever possible, the same instrument should be used for serial studies on an individual patient (29). Comparisons between measurements done on different machines can be made only if inter-machine precision between the two devices has been determined (13, 29).

4.2.4 INTERPRETATION

The clinical implications of density change or stability must be incorporated into the interpretation section of the report (1, 2, 6, 29). This is of greatest importance for patients on osteoporosis drug therapy, where BMD is often being used to assist in monitoring drug actions (1, 2, 10). The primary BMD outcome of interest in this circumstance is the net change in density from the time that the current drug regimen was initiated (1, 11). In general, net stability or a gain in density is considered positive drug effect while net loss of density is considered evidence of drug failure (1, 11). Secondary changes in the BMD profile that may differ from the net change on a drug regimen, such as a change from the most recent prior study, also need to be considered in the interpretation (31). For serial studies in those not on osteoporosis drug therapies, there are similar implications for the effects of nutritional supplements, lifestyle changes, and exercise regimens (1, 11).

There is insufficient data at this time to define the relationship between the amount of loss and the resulting change in fracture risk, so loss of density is not incorporated into the absolute fracture risk methodology (32). The reported absolute fracture risk should not be altered because of loss in density. Rather, the implications of density loss should be discussed in the interpretation of results.

4.2.5 DEFINITIONS

LSC: least significant change = amount by which one BMD value must differ from another in order for the difference to be statistically significant at a 95% level of confidence.

4.3 COMPONENTS OF A FIRST-TIME PAEDIATRIC BMD REPORT

The paediatric population is defined as individuals under age 18 years. The components of a first-time paediatric BMD report are shown in Appendix 8. Components that are similar to the content of an adult first-time BMD report include demographics, machine identification, and limitations (1, 2, 6, 7, 13, 33). There are differences concerning BMD data and interpretation, and specific definitions apply to reporting in this age group (6, 7, 13, 33, 34). There are no guidelines on timing of follow-up studies, so a recommended follow-up date is not mandatory, although may be included at the discretion of the reporting physician (7, 29, 33). A paediatric history sheet is not provided, as there are no mandatory items incorporated into the report (as in

adult absolute risk determination), but the adult history sheet can be adapted. History that is relevant to the individual paediatric patient should be collected and may include fracture history, medications, and illnesses (7, 13, 33). Height and weight measurements in younger children require special devices and procedures (33). If these are not available, it is acceptable in younger children to use values provided by other medical practitioners. If height or weight were not measured directly by the BMD facility, this should be indicated in the report.

4.3.1 DIAGNOSTIC CATEGORY

The current standard for reporting the diagnostic category in the paediatric population is shown in Appendix 3 (2, 29). The diagnostic category is based on the lowest adjusted Z-score from the results for the lumbar spine and total body, using either bone mineral content (BMC) or BMD at the discretion of the reporting physician (6, 7, 13, 29, 33). See Section 4.3.2 for clarification of Z-score adjustment. The T-score is not to be used in paediatric reporting (7, 13, 29, 33). If either the spine or total body value is not available or invalid, this should be reported as a limitation. Forearm measurements (1/3 or 33% site) may be used if either the spine or total body value is not available, but only if a reference population database is available from which forearm Z-scores can be derived (6, 7, 13, 29, 33). Proximal femur measurements are not to be used to generate the diagnostic category in the paediatric population, although it may be clinically useful to begin measuring hip density in older adolescents in order to transition into the adult mode of monitoring (2, 13, 29, 33).

4.3.2 BMD DATA

Care must be taken in all technical aspects of how scanning is performed, including adherence to manufacturer protocols, proper positioning, sub-region assignment, bone tracing, determination of regions of interest, and quality assurance (6, 7, 13, 29, 33). Results should be reported for the lumbar spine and total body, including BMC and BMD for each site (7, 13, 29, 33). When analyzing the lumbar spine, L1 to L4 should be used unless the decision is made to exclude one or two vertebrae because of technical artifacts (2, 29). A minimum of two vertebrae should be used (2, 29). Interpretation should never be based on a single vertebra (2, 29). If a report includes graphical representation of results, the graph must present data and reference curves for the vertebrae actually used in interpretation (2, 29). Consideration can be given to excluding a particular vertebra if the Z-score of that vertebra is more than one standard deviation greater than the Z-score of the vertebra with the next highest value (29). It is not mandatory that the high-density vertebra be excluded, but it should be evaluated for causes of artifact and a decision made as to whether it should be included in the vertebral analysis. In some manufacturers' databases, Z-scores may not be available if vertebrae are excluded. In this circumstance, it is appropriate to include L1 to L4 in order to generate a Z-score, but the interpretation section must address the accuracy of the spine measurement and the ways in which the Z-score may have been perturbed by the abnormal vertebrae. For the total body measurement, the head may be included or excluded when analyzing the scan (6, 29, 33, 34). If the head is excluded, this should be noted in the report. For adolescent patients whose weight exceeds the limit of the DXA equipment, bilateral forearm studies may be done unless one side is not available or invalid, in which case a single side can be measured (29, 33, 34).

For each skeletal site with a valid scan, reported density results should include absolute BMD (in g/cm^2 to 3 decimal places), BMD Z-score (to 1 decimal place), and adjusted BMD Z-score (to 1 decimal place), and BMC (in g, to 2 decimal places), BMC Z-score (to 1 decimal place), and adjusted BMC Z-score (to 1 decimal place) (6, 13). The Z-score adjustment is done to correct for relative skeletal size or maturation. There is no consensus at this time as to the specific adjustment that should be made, so the nature of the adjustment is at the discretion of the reporting physician. Adjustment can be based on height, weight, body mass index, bone area, bone age, pubertal stage, lean body mass, or a combination of these parameters (6, 7, 13, 29, 34–42). The method of adjustment should be noted in the report, and if a multivariable method is used, a published reference should be provided. The assignment of diagnostic category should be based on the adjusted Z-scores using the BMC Z-score, the BMD Z-score, or the lower of the two, at the discretion of the reporting physician. Some manufacturers provide height or weight corrections as part of the DXA software. For those whose DXA software does not

provide such corrections, an approach to correcting for bone age or height age is described in Appendix 9 (7, 29, 33). Each method of correction has limitations and constraints, and these need to be considered in the interpretation (29, 33).

Bone area, corrected bone area, and area Z-scores are not required, but can be included at the discretion of the reporting physician (7, 13, 29, 33, 41). All Z-scores should be derived using a white female reference database for girls and a white male database for boys (29). Non-white reference databases should not be used The reference database and version should be specified in the report (6, 7, 29, 33). If the reference database that is used to generate Z-scores is not one provided by the manufacturer, a published reference should be provided. Z-scores may not be available for certain skeletal sites at young ages and so do not need to be reported.

4.3.3 DEFINITIONS

Any terminology or abbreviations used in the report should be defined.

4.4 COMPONENTS OF A FOLLOW-UP PAEDIATRIC BMD REPORT

The components of a follow-up paediatric BMD report are shown in Appendix 10. A follow-up paediatric BMD report should include all of the components of a first-time paediatric report. In addition, items specific to follow-up also need to be described, including changes in density, statistical parameters relating to measurement error, and aspects of interpretation relating to the changes in density.

4.4.1 CHANGES IN DENSITY

When comparing serial assessments, positioning and sub-region assignment must be consistent (29, 40, 42). The same reference population database should be used for serial studies whenever possible (13, 33). If the reference population database must be changed, this should be noted in the report. The description of density change should include the absolute density change (in g/cm^2, to 3 decimal places), percentage change (to 1 decimal place, derived using absolute density, not Z-scores), change in Z-score, and change in adjusted Z-score (13, 29). Annualized rates of change may be reported, but this is optional (29, 41). The skeletal sites for which changes in density are to be reported are the lumbar spine (using whichever vertebrae are considered valid, with a minimum of two vertebrae) and the total body (29, 33, 34). If the forearm is being monitored in lieu of the spine or total body, change can be reported for the 1/3 or 33% proximal radius (29, 34, 40). It must be recognized that the change profile at the forearm may not parallel changes at the spine and total body, and may not correlate as well with drug responses. This will need to be addressed in the interpretation section, if applicable.

Changes in density must be reported in relation to 1) the first study on file, and 2) the most recent previous study. Paediatric osteoporosis drug treatment regimens are not well defined and if information is not provided by the referring physician, it can be difficult to ascertain the timing of the BMD study corresponding to the initiation of a clinical treatment regimen. It is therefore not mandatory at this time that changes be reported in relation to the initiation of treatment. This can be provided at the discretion of the reporting physician if it is felt that an appropriate comparison study can be defined in relation to treatment.

Statistical significance must be reported for each BMD skeletal site comparison, indicating whether the difference is considered significant at a 95% level of confidence (29, 33, 43). The manufacturer's software determination of statistical significance is not to be used (13, 29). Each facility must determine precision error for each DXA machine and for each skeletal site (including forearm if this site is measured by the facility and used for serial monitoring) using the LSC methodology and use this value when determining statistical significance (13, 29, 33). It is permissible to apply results derived from precision testing of the forearm on one side to serial scans done using the opposite side of the body. Facilities are encouraged to derive precision using paediatric-age subjects, particularly facilities that perform only paediatric clinical tests. In the absence of data proving that precision differs between adults and children, however, it is acceptable at this time for all facilities to use precision derived from adult subjects (29, 33). If precision is derived using adult subjects, this should be noted in the report. A follow-up paediatric BMD report should state the LSC in absolute

values (g/cm^2 to 3 decimal places for BMD, g to 2 decimal places for BMC) for each skeletal site for which change is reported and for both BMD and BMC (13, 29). Whenever possible, the same instrument should be used for serial studies on an individual patient (29). Comparisons between measurements done on different machines can be made only if inter-machine precision between the two devices has been determined (13, 29).

There is no accepted methodology at this time for evaluating statistical significance of Z-score differences at different time points. The change in Z-score between comparison BMD studies should be noted. An opinion as to whether the difference is clinically meaningful should be incorporated into the Interpretation section. It is not necessary to report changes in either height or weight.

APPENDIX 1

PATIENT QUESTIONNAIRE

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

This document will be reviewed with you. A staff member will measure your height and weight.

Name: _____ Date: _____

Date of Birth: _____ ❒ Female ❒ Male

If you answer yes to any of the following 3 questions, please speak to the receptionist immediately:

1. Is there any chance that you are pregnant? ❒ Yes ❒ No
2. Have you had a barium enema or barium drink in the last 2 weeks? ❒ Yes ❒ No
3. Have you had a nuclear medicine scan or x-ray dye in the last week? ❒ Yes ❒ No

The following information will help us to assess your future risk for fracture.

4. Have you ever had a bone density test before? ❒ Yes ❒ No

   If yes, when and where? _____
5. Have you ever had surgery of the spine or hips? ❒ Yes ❒ No
6. Have you ever broken any bones? ❒ Yes ❒ No

   If yes, please state:

Bone Broken	Age Bone Broke	Cause of Broken Bone

7. Have you taken steroid pills (such as prednisone or cortisone) for more than 3 months in the last 12 months? ❒ Yes ❒ No

   If yes, are you currently taking steroid pills? ❒ Yes ❒ No

   How long have you been taking them? _____

   What is your current dose? _____

   What is the reason you take steroid pills? _____
8. Have you ever been treated with medication(s) for osteoporosis? ❒ Yes ❒ No

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

   _____

   _____

   _____

DO NOT WRITE IN THIS BOX

Additional History

Reviewed by: _____ Signature: _____

APPENDIX 2

COMPONENTS OF A FIRST-TIME ADULT BMD REPORT

All first-time adult (age 18 or over) BMD reports should include the following components in this recommended order of presentation:

Demographics

- name
- date of birth
- sex
- provincial healthcare number or other identifier
- height
- weight
- scan date
- report date
- referring physician
- reporting physician
- facility name and location

Diagnostic Category

Fracture Risk Category (if 50 years of age or older)

History Used For Risk Determination

BMD Data

- BMD
- BMD T-score for those 50 years of age or older/ Z-score for those under age 50 years
- reference database used

Note: For men 50 years of age or older, there will be two sets of BMD T-scores and two reference databases listed – white male reference database for diagnostic categorization and white female reference database for risk determination.

Limitations

Interpretation

Recommended Follow-Up Date

Definitions

Machine Identification

- brand
- model
- serial number

APPENDIX 3

BMD DIAGNOSTIC CATEGORIES

PATIENT GROUP	CATEGORY NAME	T-SCORE VALUE	Z-SCORE VALUE
50 years and older	Normal	≥ -1.0	
	Low bone mass	Between -1 and -2.5	
	Osteoporosis	≤ -2.5	
Under age 50	Within expected range for age		>-2.0
	Below expected range for age		≤ -2.0

For adults 50 years of age and older, the diagnostic category is determined using the lowest T-score for the lumbar spine, total hip, femoral neck, 1/3 (or 33%) radius, and total body. T-scores are derived using a white female reference database for women and a white male reference database for men.

For adults aged 18 years to less than 50 years, the diagnostic category is determined using the lowest Z-score for the lumbar spine, total hip, femoral neck, 1/3 (or 33%) radius, and total body. Z-scores are derived using a white female reference database for women and a white male reference database for men.

For children, defined as being under age 18 years, the Z-scores require adjustment for one or more of height, weight, body mass index, bone area, bone age, pubertal stage, and lean body mass. The diagnostic category is determined using the lowest adjusted Z-spine for the lumbar spine and total body. Z-scores are derived using a white female reference database for girls and a white male reference database for boys.

APPENDIX 4

HOW TO DETERMINE AN INDIVIDUAL'S 10-YEAR ABSOLUTE FRACTURE RISK

1. Begin with the table appropriate for the patient's gender.
2. Identify the row that is closest to the patient's age.
3. Determine the individual's fracture risk category by using the femoral neck T-score.
4. For ages intermediate between values in the table, interpolate T-scores thresholds.
5. If either fragility fracture history or glucocorticoid history are positive, the individual is moved up to the next highest risk category.
6. Fracture risk for an individual is high regardless of the CAROC 2010 risk result when:
   - both fragility fracture history after age 40 years and glucocorticoid history are positive
   - there has been a fragility hip fracture after age 40 years
   - there has been a fragility vertebral fracture after age 40 years
   - there have been two or more fragility fracture after age 40 years.
7. If the fracture risk category is low after these steps, the lumbar spine T-score is considered (using a white male reference database for men and a white female reference database for women). If the lumbar spine T-score is ≤-2.5, risk is increased to moderate.

CAROC 2010 10-YEAR FRACTURE RISK FOR WOMEN

Femoral Neck T-score			
Age (years)	**Low risk (<10%)**	**Moderate risk (10% to 20%)**	**High risk (> 20%)**
50	Greater than -2.5	-2.5 to -3.8	Less than -3.8
55	Greater than -2.5	-2.5 to -3.8	Less than -3.8
60	Greater than -2.3	-2.3 to -3.7	Less than -3.7
65	Greater than -1.9	-1.9 to -3.5	Less than -3.5
70	Greater than -1.7	-1.7 to -3.2	Less than -3.2
75	Greater than -1.2	-1.2 to -2.9	Less than -2.9
80	Greater than –0.5	-0.5 to -2.6	Less than -2.6
85	Greater than +0.1	+0.1 to -2.2	Less than -2.2

CAROC 2010 10-YEAR FRACTURE RISK FOR MEN

Femoral Neck T-score			
Age (years)	**Low risk (<10%)**	**Moderate risk (10% to 20%)**	**High risk (> 20%)**
50	Greater than -2.5	-2.5 to -3.9	Less than -3.9
55	Greater than -2.5	-2.5 to -3.9	Less than -3.9
60	Greater than -2.5	-2.5 to -3.7	Less than -3.7
65	Greater than -2.4	-2.4 to -3.7	Less than -3.7
70	Greater than -2.3	-2.3 to -3.7	Less than -3.7
75	Greater than -2.3	-2.3 to -3.8	Less than -3.8
80	Greater than –2.1	-2.1 to -3.8	Less than -3.8
85	Greater than -2.0	-2.0 to -3.8	Less than -3.8

Values in the table are taken from the Osteoporosis Canada 2010 guidelines for the assessment of fracture risk (2).

NOTES

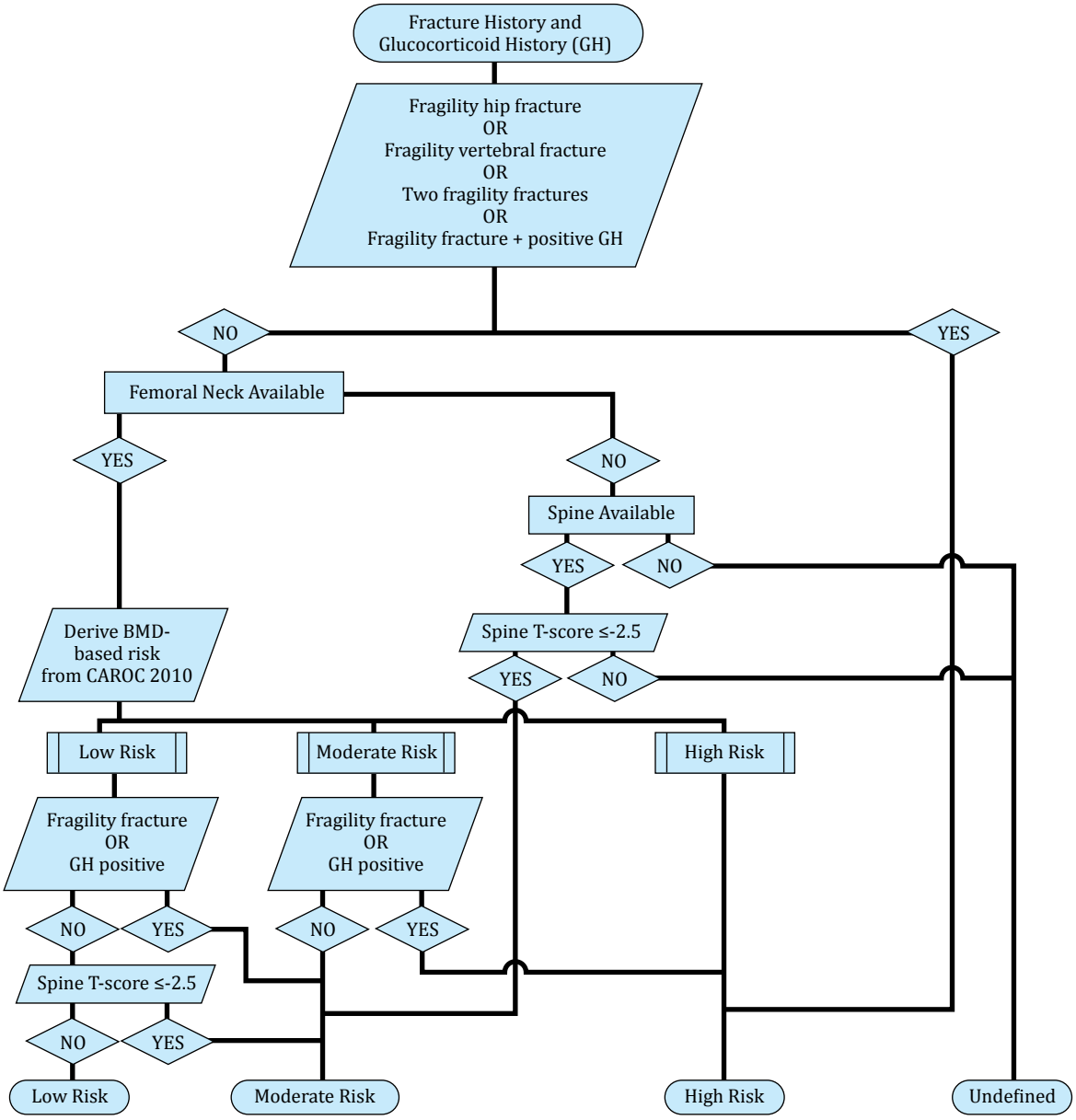
For both women and men, the femoral neck T-score used to determine fracture risk must be derived using a white female reference database. If the femoral neck T-score produces a low risk of fracture and a spine T-score of -2.5 or less is used to assign fracture risk, the spine T-score is derived from a white female reference database for women and a white male reference database for men.

Fractures of the forearm, vertebra, proximal femur, and proximal humerus are usually fragility fractures if they occurred subsequent to a fall from a standing or sitting height. Generally, craniofacial fractures and fractures of the hands and feet are not considered fragility fractures. Other types of fractures may be regarded as fragility fractures if the history suggests that the fracture occurred with a degree of trauma that would not normally be expected to lead to a broken bone.

Glucocorticoid history is considered positive if prednisone (or other glucocorticoids in terms of prednisone equivalents) was in use at a dose equal to or greater than 7.5 mg per day for more than three cumulative months in the prior 12 months. Patients with hypoadrenalism on replacement glucocorticoids should not be considered to have a positive glucocorticoid history for fracture risk determination regardless of glucocorticoid dose.

APPENDIX 5

THE OSTEOPOROSIS CANADA APPROACH TO DETERMINING AN INDIVIDUAL'S 10-YEAR ABSOLUTE FRACTURE RISK



GH = glucocorticoid history (≥ 7.5 mg/day prednisone or equivalent for 3 cumulative months in prior year)

Initial risk category using CAROC 2010 (2) is derived from the T-score for the femoral neck.

For both women and men, the femoral neck T-score used to determine fracture risk must be derived using a white female reference database. If the femoral neck T-score produces a low risk of fracture and a spine T-score of -2.5 or less is used to assign fracture risk, the spine T-score is derived from a white female reference database for women and a white male reference database for men.

APPENDIX 6

RECOMMENDED TIMING OF FOLLOW-UP BMD TESTS

EXPECTED RATE OF BMD CHANGE	CLINICAL EXAMPLE	TIMING OF FOLLOW-UP
Very High	Moderate to high dose glucocorticoids, anabolic agent	6 to 12 months
High	Osteoporosis drug therapy initiated or changed, low to moderate dose glucocorticoids	1 to 3 years
Moderate	Therapy with nutritional supplements or lifestyle improvements	1 to 3 years
Low	Stability documented on nutritional supplements or lifestyle improvements and with no change in clinical status; drug therapy shown to be effective	3 to 5 years
Very Low	Normal results or low fracture risk, and no clinical risks	5 to 10 years

In some jurisdictions, the timing of follow-up may be restricted by provincial health insurance plans. In these circumstances, follow-up recommendations need to be applied in the context of local restrictions.

APPENDIX 7

COMPONENTS OF A FOLLOW-UP ADULT BMD REPORT

All follow-up adult (age 18 or over) BMD reports should include the following components in this recommended order of presentation:

Demographics

- name
- date of birth
- sex
- provincial healthcare number or other identifier
- height
- weight
- scan date
- report date
- referring physician
- reporting physician
- facility name and location

Diagnostic Category

Fracture Risk Category (if 50 years of age or older)

History Used For Risk Determination

BMD Data

- BMD
- BMD T-score for those 50 years of age or older/ Z-score for those under age 50 years
- reference database used
- Note: for men 50 years of age or older, there will be two sets of femoral neck BMD T-scores and two reference databases listed – white male reference database for diagnostic categorization and white female reference database for risk determination.

Changes in Density

- BMD change
- percentage BMD change
- statistical significance
- LSC

Limitations

Interpretation

Recommended Follow-up Date

Definitions

Machine Identification

- brand
- model
- serial number

APPENDIX 8

COMPONENTS OF A FIRST-TIME PAEDIATRIC BMD REPORT

All first-time paediatric (under age 18) BMD reports should include the following components in this recommended order of presentation:

Demographics

- name
- date of birth
- sex
- provincial healthcare number or other identifier
- height
- weight
- scan date
- report date
- referring physician
- reporting physician
- facility name and location

Diagnostic Category

BMD Data

- BMC
- BMC Z-score
- adjusted BMC Z-score
- BMD
- BMD Z-score
- adjusted BMD Z-score
- reference database used

Limitations

Interpretation

Definitions

Machine Identification

- brand
- model
- serial number

APPENDIX 9

METHOD FOR ADJUSTING Z-SCORE FOR BONE AGE OR HEIGHT AGE

Z-SCORE ADJUSTMENT FOR BONE AGE

1. Determine Z-score for all scan sites based on chronological age.
2. Perform wrist radiographs and derive bone age.
3. Use point estimate of bone age to determine "adjusted birthdate" for patient.
4. If bone age differs from chronological age by more than 1 year, change birthdate to "adjusted birthdate" in DXA program and determine adjusted Z-scores for all scan sites.
5. Report for all scan sites the Z-scores based on chronological age and the bone age-adjusted Z-scores. If bone age does not differ from chronological age by more than 1 year, this should be noted in the report and a bone age-adjusted Z-score need not be reported.

EXAMPLE

Male with birthdate: January 10, 2005. DXA scan date July 10, 2012. Chronological age on scan date: 7 years 6 months. Z-scores derived using chronological age.

Bone age by wrist radiographs: 5 years 6 months. Adjusted birthdate assigned as January 10, 2007. Bone-age adjusted Z-scores derived using bone age.

Report for each skeletal site includes BMD (in g/cm^2 to 3 decimal places), BMD Z-score (to 1 decimal place) and bone age-adjusted BMD Z-score (to 1 decimal place), and BMC (in g to 2 decimal places), BMC Z-score (to 1 decimal place) and bone age-adjusted BMC Z-score (to 1 decimal place).

Z-SCORE ADJUSTMENT FOR HEIGHT AGE

1. Determine Z-score for all scan sites based on chronological age.
2. Determine "height age" using growth charts for the child's gender (available at www.cdc.gov/GrowthCharts).
3. Measure height three times and use the average value as patient height.
4. Using the patient's height on the vertical axis of the CDC growth chart, locate where this height line intersects the 50^{th} percentile growth curve. Extrapolating to the horizontal axis, determine the age corresponding to the point on the 50^{th} percentile growth curve. This is the patient's "height age".
5. If height age differs from chronological age by more than 1 year, change birthdate to "adjusted birthdate" in DXA program and determine adjusted Z-scores for all scan sites.
6. Report for all scan sites the Z-scores based on chronological age and the height age-adjusted Z-scores. If height age does not differ from chronological age by more than 1 year, this should be noted in the report and a height age-adjusted Z-score need not be reported.

EXAMPLE

Female with birthdate: January 10, 2001. DXA scan date July 10, 2012. Chronological age on scan date: 11 years 6 months. Z-scores derived using chronological age.

Height measured 3 times using stadiometer with re-positioning between measurements: 134.4 cm, 133.8 cm, 135.3 cm; average height 134.5 cm.

On CDC Growth Chart "Stature-for-age percentiles: Girls, 2 to 20 years", a height of 134.5 cm corresponds to an age of 9 years 3 months at the 50^{th} percentile.

Adjusted birthdate assigned as April 10, 2003. Height age-adjusted Z-scores derived using height age.

Report for each skeletal site includes BMD (in g/cm^2 to 3 decimal places), Z-score (to 1 decimal place) and height age-adjusted Z-score (to 1 decimal place), and BMC (in g to 2 decimal places), BMC Z-score (to 1 decimal place), and height age-adjusted BMC Z-score (to 1 decimal place).

APPENDIX 10

COMPONENTS OF A FOLLOW-UP PAEDIATRIC BMD REPORT

All follow-up paediatric (under age 18 years) BMD reports should include the following components in this recommended order of presentation:

Demographics

- name
- date of birth
- sex
- provincial healthcare number or other identifier
- height
- weight
- scan date
- report date
- referring physician
- reporting physician
- facility name and location

Diagnostic Category

BMD Data

- BMC
- BMC Z-score
- adjusted BMC Z-score
- BMD
- BMD Z-score
- adjusted BMD Z-score
- reference database used

Changes in Density

- BMC change
- percentage BMC change
- change in BMC Z-score
- statistical significance of BMC change
- BMC LSC
- BMD change
- percentage BMD change
- change in BMD Z-score
- statistical significance of BMD change
- BMD LSC.

Limitations

Interpretation

Definitions

Machine Identification

- brand
- model
- serial number

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