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Canadian Association of Radiologists Technical Standards for Bone Mineral Densitometry Reporting

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The standards of the Canadian Association of Radiologists (CAR) are not rules but are guidelines that attempt to define principles of practice that should generally produce radiologic care. The physician and the medical physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to CAR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgement regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

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 [1–21]. In 2005, CAR, in conjunction with the Scientific Advisory Council of Osteoporosis Canada, issued a set of guidelines for the reporting of BMD test results [1]. That document set down some of the principles to be used in performing BMD and the recommended content of bone mineral densitometry reports. It also established, for the first time, a methodology for determining absolute fracture risk for individuals 50 years of age and older. Subsequent population studies have demonstrated the performance of the risk system in the Canadian population [22,23]. The intention of the CAR was to periodically update the BMD document to clarify points and to adapt to evolving data and approaches in the fields of osteoporosis and metabolic bone disease. 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 to be accredited by the CAR BMD Accreditation Program. This document is not intended to serve as a primer on bone densitometry and, for the most part, describes standards that must be met to achieve CAR BMD accreditation [24–26]. In some instances in which there is not yet consensus on the optimal approach, suggestions or options are provided, anticipating that those aspects will be discretely defined in the future versions of CAR Technical Standards for Bone Mineral Densitometry Reporting.

Information That Should Be Provided by Referring Physicians

BMD consultation requests should include patient demographics, the indication for BMD testing, factors of

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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 [1,2,9,18,19,27–34]. On follow-up scans done on patients who receive 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 [1,2,11,19,35,36]. Although this level of information is often not provided, a thorough patient history from the referring physician is to be encouraged [1,19,28].

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 older) is presented in Appendix e1 (available online at www.carjonline.org), modified from the 2005 guidelines [1,19,28,37,38]. This questionnaire can either be filled in by patients and then clarified by trained facility staff, or a history can be directly taken by facility staff. The specific items on the questionnaire are intended to collect the minimum information needed to analyse a BMD scan and to determine absolute fracture risk in those 50 years or older [1,14,27]. Additional history items that are of relevance to individual patients should also be collected, such as menopausal history, medication history, and illnesses [1,2,9,15,18,19,30,32–34,37].

BMD Report Contents

Report contents will differ, depending on whether it is an adult (age 18 years or older) or pediatric study, and whether it is a first-time or follow-up study.

Components of a First-time Adult BMD Report

The components of a first-time adult BMD report are shown in Appendix e2 [1,18,38,39].

Demographics

Demographics should include patient name, date of birth, sex, provincial health care 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 [1,18,38–40]. Weight and height should be measured at the BMD facility [41,42]. Neither values reported by the patient nor measurements provided by other medical practitioners should be used, other than in exceptional circumstances in which 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, then this should be indicated in the report.

Weight can be measured with either a mechanical or electronic scale that is medical grade [41]. Facilities are encouraged to use wall-mounted height-measuring devices, referred to as stadiometers, that use standardized positioning of patients [18,41–44]. It is also encouraged that 3 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 [41–44]. At the current time, this height measurement methodology is a recommendation and is not a requirement for accreditation.

Diagnostic Category

The current standard for reporting the diagnostic category is shown in Appendix e3 [1,14,15,40]. The diagnostic category is based on the lowest T-score for an individual from the results for the lumbar spine, total hip, trochanter, and femoral neck [1,14,45]. If the forearm is measured, then the value for the third or 33% site is used [1,14,18,45,46]. If a total body scan is done, then the total body BMD T-score may be used [1,14]. A change has been made from the 2005 CAR BMD Clinical Practice Guidelines for diagnostic categories in women [1,14]. Whereas categorization in women was previously based on a combination of menopausal status and age, the current standard is based only on age, with different terminology for women younger than 50 years old and those 50 years and older [1]. The intent is to make the categorization coherent with absolute fracture-risk determination methodology, which does not consider menopausal status [1].

Fracture-risk Category

The absolute fracture-risk category should be reported for men and women 50 years of age and older [1,14,27] when relevant history is available. The current standard for determining absolute fracture risk is the method described in the 2005 CAR Clinical Practice Guidelines [1,14]. This risk determination incorporates age, BMD results, sex, fragility fracture history, and glucocorticoid history. Bone-active drug therapy will alter fracture risk if the drug is taken regularly, if it is taken correctly, and if it is achieving the desired effects [47–52]. If a patient who undergoes BMD testing for the first time is already on bone-active drug therapy, then the fracture-risk category should be provided, but a statement should be included that indicates that the risk may be lower than calculated if osteoporosis drug therapy is effective [47–52]. For individuals younger than 50 years old, absolute risk assessment is not available, and a fracture-risk category should not be reported. The World Health Organization's 10-year fracture-risk calculation system, called FRAX [53,54], may be included in some DXA software. This, however, is a country-specific risk calculator, and there is no validated Canadian FRAX model. FRAX is not to be used for determining fracture risk [53,54].

History Used for Risk Determination

For individuals 50 years of age or older, the report should state the specific history used in risk determination when either the fragility fracture status or a glucocorticoid history is positive [1−3,9,13,14,18,29−31]. 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. The absolute fracture-risk categories were originally derived by using data from 4 types of fractures: forearm, vertebra, proximal femur, and proximal humerus [1−3,9,53,54]. Fractures at these sites should generally be regarded as fragility fractures if they occur subsequent to a fall from standing or sitting heights. 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 [2,3,9,22,55]. Only fractures that occurred after age 40 years should be considered in determining risk [1,2,56].

Glucocorticoid history is considered positive if prednisone (or other glucocorticoids in terms of prednisone equivalents) was in use at a dose greater than 7.5 mg per day for more than 3 months in the prior 12 months (meaning for more than 90 total days of the preceding 365 days, not necessarily consecutive). This is a clarification of the 2005 CAR Clinical Practice Guidelines [1,30,31,57].

BMD Data

Care must be taken in all technical aspects of how scanning is performed, including adherence to manufacturer protocols, proper positioning, subregion assignment, bone tracing, determination of regions of interest, and quality assurance [18,19,40,58−67]. A minimum of 2 skeletal sites should be scanned and reported [1,15,18,19,63,67−69]. The usual sites would be the lumbar spine and the proximal femur [1,15,18,19,40,45,63,69]. When analysing the lumbar spine, L1-L4 should be used unless the decision is made to exclude 1 or 2 vertebrae because of technical artifacts [1,45,63]. A minimum of 2 vertebrae should be used. Interpretation should not be based on a single vertebra [1,45,70,71]. If a report includes graphical representation of results, then the graph must present data and reference curves for the vertebrae actually used in interpretation [1]. Consideration can be given to excluding a particular vertebra if the T-score of that vertebra is more than 1 standard deviation greater than the T-score of the vertebra with the next highest value [1,63,72]. 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 or is invalid, or if the right hip was previously measured [73,74]. Results should be reported for the total hip, femoral neck, and trochanteric region [1,14,45,67,69,75]. If either the spine or hip site is not available or invalid because of artifact, then another site should be substituted [1,14,18,19]. The nondominant forearm is the site of choice, and the midshaft of the radius (referred to as the one-third radius or 33% radius) should be reported [1,15,18,19,67]. If the nondominant forearm is not available or is invalid, then the dominant side may be used. If the wrist cannot be measured, then total body BMD can be assessed [1,19]. The head may be included or excluded when analysing the scan. If the head is excluded, then this should be noted in the report. If the spine cannot be measured, and neither forearm nor total body measurements are available, then bilateral hip measurements may be made [18,19,73]. The 2 hip measurements should be reported separately, not as an averaged value [18,73,74]. For patients whose weight exceeds the limit of the DXA equipment, bilateral forearm studies may be done unless 1 side is not available or is invalid [18].

For each skeletal site with a valid scan, reported density results should include absolute BMD (in g/cm^2 to 3 decimal places) and T-score (to 1 decimal place) [1,18,27,75]. T-scores should be derived by using the manufacturer's white female reference population database for women and the white male database for men [1,14,18,22,23]. Non-white reference databases should not be used. The reference database and version should be specified in the report [19].

Limitations

Any structural abnormalities, anatomical variants, artifacts, suboptimal positioning, or other issues that impact scan reliability and interpretation need to be considered when interpreting BMD results [1,18,19,27,58,61,65,66,70,76−88]. A judgement needs to be made as to whether they render results invalid or impact on the interpretation. Some sources of artifact (such as metal on clothes or in pockets, or recent barium or nuclear medicine studies) are preventable, and care should be taken to assess for these before scanning and either remove the source of artifact or postpone the scan to a future date [11,40,63,65,81,87,89,90]. 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 [91−94]. 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. Some manufacturer databases do not provide T-scores between the ages of 18−20 years. It is acceptable in this circumstance to provide Z-scores and to use the pediatric approach to reporting. This should be noted in the report.

Interpretation

A narrative section on interpretation and implications of BMD results should be provided. This narrative should not

be a simple restatement of data. Guidance as to therapeutic considerations can be provided within the context of Osteoporosis Canada Guidelines to the degree appropriate to the knowledge and experience of the reporting physician [2].

Recommended Follow-up Date

A recommendation should be included for the timing of the next DXA study [1,18,19,27]. Published Canadian Osteoporosis and BMD Guidelines provide some direction but do not cover all clinical scenarios. 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 [2,4,15,18–20,35,47–52,63–65]. A guide based on published recommendations but encompassing a wider range of clinical situations is provided in Appendix e4. 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, because this makes the report more readily implementable by referring physicians. For follow-up periods of less than 2 years, the month of recommended follow-up could also be included. This approach is not a requirement for accreditation at this time.

Definitions

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

- T-score: the number of standard deviations above (+) or below (−) the mean peak density.
- Fracture risk: high fracture risk is a 10-year absolute fracture risk >20%; moderate fracture risk is a 10-year absolute fracture risk in the range of 10%–20%; low fracture risk is a 10-year absolute fracture risk <10%.
- TBLH: total body less head, assessment of the entire body minus the head region.

Machine Identification

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

Components of a Follow-up Adult BMD Report

The components of a follow-up adult BMD report are shown in Appendix e5. A follow-up adult BMD report should include all of 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 that relate to measurement error, aspects of interpretation that relate density changes to the clinical situation, and definitions relevant to follow-up.

Demographics

Change in height as measured at the BMD facility should be noted [18,42,43]. In particular, height loss that exceeds 2 cm over 3 years or less should be emphasized, because this amount of height change has been shown to have a high predictive value for incident vertebral fractures that developed during the monitoring period [18,43]. A change in weight should also be noted, because this can create artifactual changes in BMD values [95,96]. 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 a 10% change in weight over the time period of monitoring. 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 by applying it to each pair of BMD measurements for which change in BMD is reported.

Fracture-risk Category

The absolute fracture-risk category should be reported for women 50 years of age and older, and for men 50 years and older, regardless of therapy that may be in use [1,14,27]. If bone-active drug therapy is in use, then the fracture-risk category should be provided, but a statement should be included that indicates that the risk may be lower than calculated if osteoporosis drug therapy is effective [1,2,15,47–52].

Changes in Density

When comparing serial assessment, the same machine should be used when possible [1,15,63], and positioning and subregion assignment must be consistent [40,59–61,63]. The same reference population database should be used for serial studies when possible [15]. If the reference database must be changed, then 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) [18,27]. The percentage change must be derived by using absolute density, not T-scores [40]. 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 (by using whichever vertebrae are considered valid, with a minimum of 2 vertebrae) and the total proximal femur [1,14,18]. Hip subregions should not be used [15,40]. 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, then change can be reported for the one-third or 33% proximal radius or for the total body BMD [15,63]. 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 [15,63]. 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 [37]. The latter BMD change is the one of greatest importance for patients on drug therapy, and also relevant to patients who started lifestyle and nutritional supplements for bone health [15,35,36,40,47−52,95,97−102]. Ideally, the comparison study of primary interest should be indicated on the requisition by the referring physician, but, if it is not provided, then the reporting physician is responsible for obtaining this information by patient history.

Statistical significance must be reported for each BMD skeletal-site comparison and indicate whether the difference is considered significant at a 95% level of confidence [1,4,5,18,61,103−108]. The manufacturer's software determination of statistical significance is not to be used [1,18,61]. 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) by using the least significant change (LSC) methodology and use this value when determining statistical significance [1,4,5,18,61,105−108]. It is permissible to apply results derived from precision testing on 1 side (forearm or hip) to serial scans done by using the opposite side of the body. A worksheet for determining precision error and LSC is available on the CAR Web site (www.car.ca). A follow-up BMD report should state the LSC in absolute values (g/cm^2, to 3 decimal places) for each skeletal site for which change is reported [1,14,18,27]. Whenever possible, the same instrument should be used for serial studies on an individual patient [1,15,63]. Comparisons between measurements done on different machines can be made only if intermachine precision between the 2 devices has been determined [18,109−111].

Interpretation

The clinical implications of density change or stability must be incorporated into the interpretation section of the report [11,40,95,97,99−101]. This is of greatest importance for patients on osteoporosis drug therapy, when BMD is often being used to assist in monitoring drug actions [8,11,15,35,40,95,98−101,111]. 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 [35,36,40,95,97,99,100]. In general, net stability or a gain in density is considered positive drug effect, whereas net loss of density is considered evidence of drug failure [35,36]. 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 [99,101,108]. For serial studies of those patients on osteoporosis drug therapies, there are similar implications for the effects of nutritional supplements, lifestyle changes, and exercise regimens [2,35].

There are 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. The reported absolute fracture risk should not be altered because of loss in density. Instead, the implications of density loss should be discussed in the interpretation of results.

Definition

- LSC: least significant change is the amount by which 1 BMD value must differ from another for the difference to be statistically significant at a 95% level of confidence.

Components of a First-time Pediatric BMD Report

Pediatric-age recommendations are an addition to the 2005 CAR guidelines. The pediatric population is defined as individuals younger than age 18 years old. An exception is made (as described in ''Components of a First-time Adult BMD Report, Limitations'') for manufacturer software that does not provide T-scores between the ages of 18 and 20 years. It is acceptable in this circumstance to provide Z-scores and to use the pediatric approach to reporting for these individuals. It should be noted in the report that results are being evaluated by using a pediatric approach.

The components of a first-time pediatric BMD report are shown in Appendix e6. Components that are similar to the content of an adult first-time BMD report include demographics, machine identification, and limitations [18,19,112]. There are differences with regard to diagnostic category, BMD data and interpretation, and specific definitions apply to reporting in this age group [18−20,112,113]. 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. A pediatric history sheet is not provided, because there are no mandatory items incorporated into the report (as in adult absolute risk determination), but the adult history sheet can be adapted. History should be collected relevant to the individual pediatric patient and may include fracture history, medications, and illnesses [18,20,21,112−128]. Height and weight measurements in younger children require special devices and procedures [41]. If these are not available, then it is acceptable in younger children to use values provided by other medical practitioners. If height or weight data were not measured directly by the BMD facility, then this should be indicated in the report.

Diagnostic Category

The current standard for reporting the diagnostic category in the pediatric population is shown in Appendix e3. The diagnostic category is based on the lowest adjusted Z-score

from the results for the lumbar spine and total body, by using either bone mineral content (BMC) or BMD at the discretion of the reporting physician [18–20,75,112,126]. See ''Components of a First-time Pediatric BMD Report, BMD Data'' for clarification of Z-score adjustment. The T-score is not to be used in pediatric reporting [18,20,75,112,116]. If either the spine or total body value is not available or is invalid, then this should be reported as a limitation. Forearm measurements (one-third or 33% site) may be used if either the spine or the total body value is not available but only if a reference population database is available from which forearm Z-scores can be derived [18–21]. Proximal femur measurements are not to be used to generate the diagnostic category in the pediatric population, although it may be clinically useful to begin measuring hip density in older adolescents to transition into the adult mode of monitoring [1,18,19,112,117].

BMD Data

Care must be taken in all technical aspects of how scanning is performed, including adherence to manufacturer protocols, proper positioning, subregion assignment, bone tracing, determination of regions of interest, and quality assurance [18,19,40,58–67]. Results should be reported for the lumbar spine and total body, including BMC and BMD for each site [18,20,112–115]. When analysing the lumbar spine, L1-L4 should be used unless the decision is made to exclude 1 or 2 vertebrae because of technical artifacts [1,45,63]. A minimum of 2 vertebrae should be used [1,45,70,71]. Interpretation should never be based on a single vertebra [1,45,70,71]. If a report includes graphical representation of results, then the graph must present data and reference curves for the vertebrae actually used in interpretation [1]. Consideration can be given to excluding a particular vertebra if the Z-score of that vertebra is more than 1 standard deviation greater than the Z-score of the vertebra with the next highest value [1,63,72]. 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. On some manufacturers' databases, Z-scores may not be available if vertebrae are excluded. In this circumstance, it is appropriate to include L1-L4 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 analysing the scan [20,112,113]. If the head is excluded, then 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 1 side is not available or is invalid, in which case a single side can be measured [112,113,118].

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 grams, to 2 decimal places), BMC Z-score (to 1 decimal place), and adjusted BMC Z-score (to 1 decimal place) [18–20,112,129]. 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 [18–20,112,113,126,127,130–134]. The method of adjustment should be noted in the report, and, if a multivariable method is used, then a published reference should be provided. The assignment of diagnostic category should be based on the adjusted Z-scores by using the BMC Z-score, the BMD Z-score, or the lower of the 2, at the discretion of the reporting physician. Some manufacturers provide height or weight corrections as part of the DXA software. For those manufacturers whose DXA software does not provide such corrections, an approach to correcting for bone age or height age is described in Appendix e7 [20,112]. Each method of correction has limitations and constraints, and these need to be considered in the interpretation [112–116].

Bone area, corrected bone area, and area Z-scores are not required but can be included at the discretion of the reporting physician [18,112,114,126,129]. All Z-scores should be derived by using a white female reference population database for girls and a white male database for boys. Non-white reference databases should not be used at this time, although they may become acceptable in the future when they are better validated. The reference database and version should be specified in the report [1,19,20,112,129]. If the reference database that is used to generate Z-scores is not one provided by the manufacturer, then 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.

Definitions

Any terminology or abbreviation used in the report should be defined. An example relevant to the pediatric report:

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

Components of a Follow-up Pediatric BMD Report

The components of a follow-up pediatric BMD report are shown in Appendix e8. A follow-up pediatric BMD report should include all of the components of a first-time pediatric report. In addition, items specific to follow-up also need to be described, including changes in density, statistical parameters that relate to measurement error, and aspects of interpretation that relate to the changes in density.

Changes in Density

When comparing serial assessments, positioning and subregion assignment must be consistent [135−137]. The same reference population database should be used for serial studies whenever possible [112,138]. If the reference population database must be changed, then 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 by using absolute density, not Z-scores), change in Z-score, and change in adjusted Z-score [18,112,113]. Annualized rates of change may be reported, but this is optional [114,139]. The skeletal sites for which changes in density are to be reported are the lumbar spine (by using whichever vertebrae are considered valid, with a minimum of 2 vertebrae) and the total body [112,113,138,139]. If the forearm is being monitored in lieu of the spine or the total body, then change can be reported for the one-third or 33% proximal radius [113,114,118]. It must be recognized that the change profile at the forearm may not parallel changes at the spine and the 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. Pediatric osteoporosis drug treatment regimens are not well defined, and, if information is not provided by the referring physician, then it can be difficult to ascertain the timing of the BMD study that corresponds to the initiation of a clinical treatment regimen. It, therefore, is not mandatory at this time that changes are reported in relation to the initiation of treatment. This can be provided at the discretion of the reporting physician if it is thought that an appropriate comparison study can be defined in relation to treatment.

Statistical significance must be reported for each BMD skeletal-site comparison and indicate whether the difference is considered significant at a 95% level of confidence [103−108,112,140,141]. The manufacturer's software determination of statistical significance is not to be used [1,18,61]. 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) by using the LSC methodology and use this value when determining statistical significance [18,61,105−108]. It is permissible to apply results derived from precision testing of the forearm on 1 side to serial scans done by using the opposite side of the body. Facilities are encouraged to derive precision by using pediatric-age subjects, particularly facilities that perform only pediatric clinical tests. In the absence of data that prove that precision differs between adults and children, however, it is acceptable at this time for all facilities to use precision derived from adult subjects [112]. If precision is derived by using adult subjects, then this should be noted in the report. A follow-up pediatric BMD report should state the LSC in absolute values (g/cm^2, to 3 decimal places for BMD; grams, to 2 decimal places for BMC) for each skeletal site for which change is reported and for both BMD and BMC [18,112]. Whenever possible, the same instrument should be used for serial studies on an individual patient [1,15,63]. Comparisons between measurements done on different machines can be made only if intermachine precision between the 2 devices has been determined [18,109−111].

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.

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Appendix e1

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? _____
8. Have you ever been treated with medication(s) for osteoporosis? ☐ Yes ☐ No
   If yes, what medication(s) and for how long?

_____

_____

_____

Do not write in this box

Additional History

_____

_____

_____

_____

_____

_____

_____

_____

_____

Reviewed by: _____ Signature: _____

Appendix e2

Components of a First-time Adult Bone Mineral Density (BMD) Report

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

Demographics

- name
- date of birth
- sex
- provincial health care 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
- reference database used

Limitations

Interpretation

Recommended Follow-up Date

Definitions

Machine Identification

- brand
- model
- serial number

Appendix e3

Bone Mineral Density Diagnostic Categories

Patient group	Category name	T-score value	Adjusted Z-score value
Women 50 y or older	Normal	≥ -1.0	
	Osteopenia	Between -1 and -2.5	
	Osteoporosis	≤ -2.5	
Women younger than age 50 y	Normal	> -2.5	
	Reduced	≤ -2.5	
Men	Normal	> -2.5	
	Reduced	≤ -2.5	
Children[a]	Normal		> -2.0
	Reduced		≤ -2.0

[a] Defined as being younger than age 18 years; adjusted Z-score indicates adjustment for one or more of height, weight, body mass index, bone area, bone age, pubertal stage, and lean body mass.

Appendix e4

Recommended Timing of Follow-up Bone Mineral Density (BMD) Tests

Expected rate of BMD change	Clinical example	Timing of follow-up
Very high	Moderate-to-high dose glucocorticoids, anabolic agent	6–12 mo
High	Osteoporosis drug therapy initiated or changed, low-to-moderate dose glucocorticoids	1–2 y
Moderate	Therapy with nutritional supplements or lifestyle improvements	2–3 y
Low	Stability documented on nutritional supplements or lifestyle improvements and with no change in clinical status; drug therapy shown to be effective	3–5 y
Very low	Normal results or low fracture risk, and no clinical risks	Not indicated

Appendix e5

Components of a Follow-up Adult Bone Mineral Density (BMD) Report

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

Demographics

- name
- date of birth
- sex
- provincial health care number or other identifier
- height
- weight

- scan date
- report date
- referring physician
- reporting physician
- facility name and location

Diagnostic Category

Fracture-risk Category

History Used for Risk Determination

BMD Data

- BMD
- BMD T-score
- reference database used

Changes in Density

- BMD change
- percentage BMD change
- statistical significance
- least significant change

Limitations

Interpretation

Recommended Follow-up Date

Definitions

Machine Identification

- brand
- model
- serial number

Appendix e6

Components of a First-time Pediatric Bone Mineral Density (BMD) Report

All first pediatric (younger than age 18 years old) BMD reports should include the following components in this recommended order of presentation:

Demographics

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

Diagnostic Category

BMD Data

- bone mineral content (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 e7

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, then change birthdate to ''adjusted birthdate'' in the dual-energy x-ray absorptiometry (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 the bone age does not differ from chronological age by more than 1 year, then this should be noted in the report and a bone age–adjusted Z-score need not be reported.

Example:

Male with birthdate: January 10, 2003. DXA scan date July 10, 2010. Chronological age on scan date: 7 years 6 months. Z-scores derived by using chronological age.

Bone age by wrist radiographs: 5 years 6 months. Adjusted birthdate is assigned as January 10, 2005. Bone age–adjusted Z-scores are derived by using bone age.

Report for each skeletal site includes bone mineral density (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 bone mineral content (BMC) (in grams 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'' by using growth charts for the child's sex (available at www.cdc.gov/GrowthCharts).
3. Measure height 3 times and use the average value as patient height.
4. By using the patient's height on the vertical axis of the Centers for Disease Control (CDC) growth chart, locate where this height line intersects the 50th percentile growth curve. By extrapolating to the horizontal axis, determine the age that corresponds to the point on the 50th percentile growth curve. This is the patient's ''height age.''
5. If the height age differs from the chronological age by more than 1 year, then change birthdate to ''adjusted birthdate'' in the 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, then this should be noted in the report, and a height age–adjusted Z-score need not be reported.

Example:

Female with birthdate: January 10, 1999. DXA scan date July 10, 2010. Chronological age on scan date: 11 years 6 months. Z-scores derived by using chronological age.

Height is measured 3 times by using a stadiometer with repositioning between measurements: 134.4 cm, 133.8 cm, 135.3 cm; the average height is 134.5 cm.

On CDC Growth Chart ''Stature-for-age percentiles: girls, 2–0 years,'' a height of 134.5 cm corresponds to an age of 9 years 3 months at the 50th percentile.

Adjusted birthdate assigned as April 10, 2001. Height age-adjusted Z-scores are derived by using height age.

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

Appendix e8

Components of a Follow-up Pediatric Bone Mineral Density (BMD) Report

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

Demographics

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

Diagnostic Category

BMD Data

- bone mineral content (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 least significant change (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