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Precision Assessment and Radiation Safety for Dual-energy X-ray Absorptiometry (DXA)

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Abstract
Measurement of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) is used to diagnose osteoporosis, assess the risk of fracture, and monitor changes in BMD over time. Since biological changes in BMD are usually small in proportion to the error inherent in the test itself, interpretation of serial BMD tests depends on knowledge of the smallest change in BMD that is beyond the range of error. This value, called the least significant change (LSC), varies according to the instrument used, the patient population being tested, the measurement site, the skill of the technologist at positioning the patient and analyzing the test, and the confidence interval used in the calculation. The precision and LSC values provided by the manufacturer cannot be applied to clinical bone densitometry centers due to differences in the patients being tested and the technologist performing the test. Since harmful errors in clinical management may occur from incorrectly interpreting serial BMD tests, it is recommended that every DXA technologist conduct a precision assessment and calculate the LSC for each measurement site and DXA instrument used. Precision assessment provides direct benefit to patients by allowing clinicians to make clinical decisions based on genuine change or stability of BMD. The patient-care benefits of precision assessment outweigh the risk of exposure to trivial doses of ionizing radiation.

Introduction
A standardized approach exists to ensure a dual-energy X-ray absorptiometry (DXA) bone densitometry center is aware of the random (non-biological) error that is inherent in all quantitative medical testing. Knowledge of this random error, called precision-error, is critical when densitometry is used for monitoring serial bone mineral density (BMD) measurements and is an essential aspect of a bone densitometry center's quality assurance program (1). Non-biological measurement variability inherent in BMD testing can obscure the typically small, but clinically important, rates of true bone loss (0.5 – 2.0%/year) that occur in adults throughout their lifetime, and suggest bone loss when there has been no real biological change. In addition, significant degrees of precision error interfere with the clinical interpretation of serial BMD studies in patients with osteopenia, osteoporosis, other bone metabolic diseases, and those requiring therapeutic intervention. To accurately interpret serial measurements, one must know the least significant change (LSC) at the facility where BMD measurements are being performed. If the measured change equals or exceeds the LSC, one is reasonably confident that true bone loss or gain has occurred in the patient and appropriate therapeutic decisions can be made. However, when the LSC has not been equaled or exceeded, the patient can be assured that the changes noted in the measurement are not statistically significant. In this way, neither patients nor practitioners are misled into abandoning an effective therapeutic regime or starting an unnecessary one due to misinterpretation of the random variability inherent in the measurements. The standardization of the technique to determine precision error for serial DXA measurements of bone density is imperative for patient care.

The International Society for Clinical Densitometry (ISCD) is a not-for-profit multidisciplinary professional society with a mission to advance excellence in the assessment of skeletal health. This is done through educational courses, scientific meetings, publications, certification in bone densitometry, and establishing international standards in the field of bone densitometry. This document summarizes the official position of the ISCD pertaining to precision assessment and radiation safety for BMD evaluation.

Methodology
The findings in this paper are the result of a review of the medical literature on precision assessment and radiation safety, analyzed by the authors, evaluated and approved by the ISCD Scientific Advisory Committee, and approved by the ISCD Board of Directors. The conclusions, based on the medical evidence and expert opinion, constitute the official public policy positions of the ISCD that are applicable worldwide.

Results

The following discussion, in question and answer format, addresses precision assessment and the radiation safety for DXA. Discussion will include the definition and utility of DXA precision assessment and radiation safety in clinical medicine with specific application to DXA precision assessment.

What is the definition of DXA precision assessment and how is it measured in clinical practice?

Although many physicians have not received formal training in statistics, a basic understanding of precision and accuracy is essential for the interpretation of serial quantitative clinical tests. Quantitative tests rarely give exactly the same result from one time to the next. The likelihood that a subject's blood pressure measured under identical conditions 24 hours apart will be within 5 mm of Hg of the first is less than 50% (2). With this inherent variability of all quantitative measurements in human subjects, a basic understanding of statistics is necessary to determine whether a difference between two measurements is due to a real biological change or simply random error.

Precision, often referred to as reproducibility, describes the ability of a quantitative measurement technique to reproduce the same numerical result when repeatedly performed in an identical fashion. In DXA, precision is the ability of a DXA system to obtain consistent BMD values upon repeated measurements of the same patient over a short time. In order to monitor bone loss or the efficacy of treatment good precision (i.e., small variations in serial measurements) is crucial.

Accuracy is defined as how well the measured value reflects the true or actual value of the object measured. Accuracy is the difference between the true and measured values compared to the true value of the quantity measured expressed in percent. The calculated value for accuracy is called the accuracy error. Typically the accuracy error of a DXA instrument is better than 10% and is sufficient for the clinical assessment of facture risk and the diagnosis of osteoporosis according to the World Health Organization (WHO) criteria (3). DXA instruments made by different manufacturers may use the same or different technologies to generate the dual photon beam and measure its attenuation, measure different sections of bone and use different software for BMD calculation. The BMD of a patient measured with DXA units of different manufacturers may differ by as much as 10-15% depending on the skeletal site scanned (*4,5*). Even if identical DXA instruments made by the same manufacturer are used to measure BMD, the manufacturer intersystem difference after primary calibration is approximately 2%, which is too large for monitoring on different DXA systems. While cross-calibration techniques can reduce the differences between DXA instruments made by different manufacturers to less than several percent, it is not recommended that serial studies be performed on instruments of different manufacturers. Nor is it recommended to use different DXA instruments made by the same manufacturer to longitudinally monitor a patient's BMD. Fortunately, most clinical situations do not involve comparison of BMD values measured on different densitometers. The more common situation is a comparison of two measurements of the same individual made at different times using the same instrument. In this scenario the precision of the measurement is more important than accuracy.

Precision and the chosen confidence interval determine the LSC in BMD which can be recognized as a statistically real change in the patient's BMD and not simply due to random errors in the measurement. Clinical DXA precision is influenced by a combination of short- and long-term variability of the scanner, patient motion, body habitus, and operator dependent factors such as patient positioning and scan analysis. Patient and operator related sources of variability are more important than the scanner variability itself with operator related factors having the most influence on the over-all precision of DXA measurements. The calculated value for precision assessment is called the precision error.

Precision error is characterized by the root mean square standard deviation (RMS SD) in g/cm^2 of a set of measurements, or the coefficient of variation (CV), the root mean square standard

deviation divided by the mean and expressed as a percentage. RMS SD is the ISCD-recommended form of expressing precision error. DXA precision in terms of RMS SD or CV is different at each of the various commonly used clinical measurement sites. Calculated precision error, %CV, has been published for the total hip (0.8-1.69%), PA spine (1.0-1.2%), femoral neck (1.11-2.2%) and trochanter (1.16-1.5%) (6-9). The least significant change in BMD that can be recognized with 95% confidence is 2.77 x CV. Thus, if a DXA instrument and operator having a combined precision of 1.0% is used to scan a patient on two occasions one year apart, the difference between the two readings must equal or exceed 2.77% (2.77 x 1%) for the referring physician to be confident that a change in BMD has actually occurred. If the precision were 2.0% a change of more that 5.6% would have to have occurred. As previously described, the poorer the precision the larger the change in BMD that is required for the change to be recognized as real. Since the rate of change of bone in normal individuals or patients being treated is small, good measurement precision is essential for detecting a clinically significant change in BMD. Achieving the best DXA precision requires the operator to carefully position the patient for scanning, analyze the scan in a consistent standardized format and routinely perform instrument quality control. Individuals who participate in a precision assessment must be representative of the bone density center's clinic population (*1,10*).

Why is precision assessment important in BMD testing?

When properly performed, bone density measurements are one of the most precise quantitative measurements in use in clinical medicine today. This high level of reproducibility permits practitioners to rely upon its results for diagnosis and to use DXA results to monitor therapy. However, no bone densitometry technique is perfectly reproducible even when the test is performed in strict accordance with the manufacturer's recommendations. In addition, the machines perform only to the level of expertise of those who operate them, which can lead to differences in precision among technologists and facilities using identical instruments. To ensure patients receive benefit from a test that uses ionizing radiation, knowledge of the reproducibility is necessary. For these reasons, the ISCD strongly recommends that each technologist and bone density facility conduct a precision assessment. Because expertise increases with experience, the ISCD recommends that technologists perform a precision assessment after they have scanned at least 100 patients. Precision assessment does not need to be repeated as long as there is no reason to believe that there has been a change in the technologist's level of competence or in the machine software and hardware (*1,10*). Individual precision assessment can be utilized to determine whether extra DXA training may be required (10).

How is DXA precision assessment performed?

Determination of the precision error and the LSC has been described in a number of publications (*10,11*). The ISCD has an automated computer tool available at www.iscd.org that can be utilized at no charge for the calculation of the precision error and LSC.

Precision error and LSC are measured by performing two or more scans on a group of patients and then calculating the root-mean squared standard deviation of the replicate measurements. The number of patients to be scanned and the number of scans to be performed on each patient are related and are determined by a statistical concept called, *degrees of freedom* (df). The number of degrees of freedom in a precision assessment is defined as the number of measurements that independently contribute to the mean squared standard deviation of the replicate scans. Since one of the scans of a patient does not contribute independently to the calculation of the mean for that individual, the degrees of freedom for the study is determined by the following formula: (Number of measurements on each individual – 1) x (Number of individuals in the study). For example, to achieve 30 degrees of freedom if only 1 subject is measured, 31 measurements would be required to obtain 30 df. If 30 subjects are measured, then only two 2 scans of each subject must be performed, e.g., (2 scans per subject -1) x (30 subjects) = 30 df. The correct number of degrees of freedom is needed in order to assure that the estimated precision error and LSC are statistically accurate and unbiased. The ISCD recommends that when performing a short-term precision assessment study 30 degrees of freedom should be used whether 30 subjects are measured twice or 15 subjects are measured in triplicate. This number of

degrees of freedom is chosen to ensure that the upper limit for the 95% confidence interval (CI) of the precision error is no more than 34% greater than the calculated value.

What are the most common factors that affect precision assessment?
Proper positioning of the patient and proper analysis of the scan are the most important factors affecting measurement precision. The most common sources of scan-to-scan variation of the posterior-anterior (PA) spine are poor positioning, incomplete acquisition of L1-L4, inconsistent inclusion of vertebral levels and misplaced intervertebral markers. In scans of the proximal femur, variations are largely the result of poor rotation and positioning of the leg, inconsistent sizing of region of interest boxes, and improper placement of femoral neck region of interest (12-15).

Can the precision error supplied by the manufacturer be used by a DXA center?
The purpose of precision testing is to assure that individual patient's bone density studies are not misinterpreted. This can only be accomplished if the precision error accurately reflects the true precision for the facility performing the studies. Although there is some inherent error in the scanner technology, most of the variability in densitometry is introduced by variations in patient positioning and scan analysis (16). In addition, the statistical methods used to calculate the precision error can also significantly influence the results. In general, the details of manufacturers'precision assessment are not available (1).

Although there has been no systematic comparison of the precision estimates provided by all DXA manufactures to those obtained by precision studies at individual facilities, a recent study at a university bone densitometry center documented significant disagreements in precision estimates for the total hip and trochanter measurements provided by one manufactures software and the university's precision study results (8). As a result, significantly more patients were judged to have had a significant change in proximal femur density utilizing the manufacturer's precision estimates than when the actual precision of the study site was used.

Data were evaluated from a quality control center for a multicenter pharmaceutical trial in which DXA measurements of the spine and proximal femur were repeated in postmenopausal women age 50-80 (8). In 6 of the 7 investigative sites, the PA spine precision ranged from 0.969% to 2.101% and the femoral neck precision ranged from 1.475 to 3.362%. At the 7^{th} site, the average PA spine precision was 3.535% (0.230%-9.537%) and the femoral neck precision was 4.349% (0.510-14.148%). Use of the manufacturer's precision data to calculate the LSC would be clearly inappropriate for studies performed at Center 7, but would also lead to an unacceptable rate of misinterpretation of patient results in the other centers with different precision errors. The large range in precision errors among these sites argues strongly that accurate interpretation of serial measurements cannot be accomplished without knowing the precision for the facility in which they are performed. The ISCD position is that manufacturer's precision assessment data not be utilized at DXA centers. In-house precision assessment must be determined and utilized by the individual DXA center performing BMD determination (1).

How is precision error measured when multiple technologists perform BMD testing?
Ideally, a patient should have follow-up scans performed by the same technologist who performed the baseline test with that technologist's precision value used to interpret the scan. In centers with multiple technologists, however, this is often impractical because the original technologist may not be available at the time of the follow-up study. Two issues arise: 1) Should the specific technologist's precision value for that technologist's studies only be used or should they be combined to calculate an average precision value for the facility, and 2) What should be done if one technologist does the first study and a different technologist does the second study?

To date there are no scientific or statistical data to indicate the most appropriate solution for these questions. Clinically, high standards for precision should be established by each facility and all technologists should be required to demonstrate the ability to meet those standards. In this case, averaging of the precision errors in a center is reasonable if the confidence intervals for the precision errors for each technologist (17) overlap indicating that the small inter-technologist

differences may not be true differences, but instead reflect the inherent uncertainty in the calculation of each technologist's precision value.

The question regarding a patient scanned by two different technologists is more complicated because inter-technologist variability is likely to be higher than within-technologist variability due to small, but systematic differences in positioning or analysis. The ISCD currently has no official position on this issue, but encourages additional research to determine the impact of this scenario on precision error. In the interim, alternatives include 1) using the mean precision estimate or 2) combining the precision scans for both technologists into one spreadsheet calculated precision assessment (1).

What is the clinical utility of DXA precision assessment in the management of osteoporosis?

DXA is used in three ways for clinical management of patients with osteoporosis:

- Diagnosis
- Assessment of fracture risk
- Measurement of BMD change due to progression of disease or response to treatment

Precision measurements are site-specific being influenced by both the instrument used and the skills of the operator(s) (11). Knowledge of precision is particularly important since the physiological changes in bone, or the changes induced by therapy, are very small. Thus to decide if a change is significant (i.e., clinically meaningful) it is important to know the magnitude of the inherent variation in measurement. If the change equals or exceeds the LSC, then this can be considered to be a genuine biological change.

Significance in this context is then a statistical measure and the usual 95% confidence limit is applied (i.e., this implies that the change has only a 5% probability of being the result of chance). Translating this into specific clinical examples:

1. A significant response to treatment:

A 67 year-old woman with a hip fracture had been diagnosed as having established osteoporosis and started on a treatment regimen.

Lumbar spine BMD--Baseline scan ..... 0.500 g/cm^2
Two years later ..... 0.542 g/cm^2
Difference ..... 0.042 g/cm^2
LSC for the lumbar spine at this DXA center ..... 0.027 g/cm^2

Conclusion: The least significant change has been exceeded (0.042 g/cm^2 compared with 0.027 g/cm^2), leading to the conclusion that there has been therapeutic response.

2. A non-significant response to treatment:

A 72 year-old woman with three thoracic vertebral fractures had been diagnosed as having established osteoporosis and started on appropriate treatment.

Lumbar spine BMD--Baseline scan ..... 0.650 g/cm^2
Two years later ..... 0.662 g/cm^2
Difference ..... 0.012 g/cm^2
LSC for the lumbar spine at this DXA center ..... 0.027 g/cm^2

Total hip BMD--Baseline scan ..... 0.597 g/cm^2
Two years later ..... 0.589 g/cm^2
Difference ..... 0.008 g/cm^2
LSC for the total hip at this DXA center ..... 0.030 g/cm^2

Conclusion: At one site (lumbar spine) the bone mineral density has increased; at the other (total hip) it has diminished in the interval. This paradox is resolved by the fact that at neither site does the change exceed the LSC (0.012 compared with

0.027 and 0.008 compared with 0.030 g/cm^2 respectively). Further follow-up would be advised.

3. A significant decrease in BMD while on treatment:

A 59 year-old woman with several risk factors for osteoporosis was diagnosed with osteoporosis and started on a treatment regimen.

Lumbar spine BMD--Baseline scan ..... 0.697 g/cm^2
Two years later ..... 0.659 g/cm^2
Difference ..... 0.038 g/cm^2
LSC for the lumbar spine at this DXA center ..... 0.027 g/cm^2

Conclusion: The least significant change has been considerably exceeded (0.038 compared with 0.027 g/cm^2) but with a decrease in bone density. The investigation for secondary causes for the statistically significant decrease in BMD resulted in a diagnosis of osteomalacia. A change in therapy was enacted due to the results of the patient's serial BMD study.

What are the radiation safety concerns for ionizing radiographic procedures?

Large doses of radiation are clearly harmful. This understanding derives chiefly from excessive or catastrophic exposures such as occurred from the explosion of nuclear devices at Hiroshima and Nagasaki (18-20). These exposures involved high doses at high dose rates. The nature of the radiation was usually a mixture of x-rays, γ-rays and particulate radiation. At the other end of the scale, attempts to identify the scale of harm from low doses of radiation have provided inconsistent data (18). Radiologists in the early days of X-ray use suffered harm that has not been documented in the second half of the 20th Century after improvement of safety practices (*21,22*).

Radiation harm consists of two kinds, consistent with our practical experience of the effects of ultra-violet radiation from the sun.

1. Deterministic or non-stochastic effects. Prolonged and unprotected sun bathing will predictably result in acute sunburn. Deterministic or non-stochastic effects occur in all individuals exposed, with their severity being a function of dose but are not observed below a certain threshold. The non-stochastic effects of radiation include skin burns, depilation and, at very high and potentially lethal doses, such syndromes as the vomiting and diarrhea of radiation sickness in its gastro-intestinal form. Such effects are almost never experienced in the medical diagnostic uses of radiation, with the exception that skin burns may occur with protracted use of fluoroscopy in interventional procedures such as angioplasty.
2. Probabilistic or stochastic effects. Many years after exposure to excessive amounts of sunlight some but not all of those exposed may develop a skin cancer. There is a high incidence of skin cancer in the Australian population, where sun exposure is high. Stochastic or probabilistic effects occur in only a fraction of those exposed. The probability but not the severity of harm increases with dose and dose rate. The commonest stochastic effects of ionizing radiation are cancers and genetic mutations.

For the purposes of protecting the safety of workers occupationally exposed to radiation, and of patients, a conservative assumption has always been used-, that there is a linear relationship between dose and detriment, with no threshold operating below which effects are not anticipated. Dose limits are imposed for radiation workers and the general population not out of respect for a threshold, which, as stated, is assumed not to exist, but to keep exposures of the same order of, or less than, the magnitude of "background" exposure.

Unlike approaches dealing with some hazards a zero-tolerance approach to radiation is not possible. We are all constantly exposed to background radiation from many sources. These include cosmic radiation arriving from space, naturally occurring isotopes (such as primordial potassium-40, which we all contain in trace amounts), and from radon produced from rocks and

soil. In addition small amounts of radioactivity persist in the environment from human activities such as weapons testing. The human dose from background radiation at sea level typically amounts to approximately 2.5 millisieverts per annum (mSv/annum) and may vary by a factor of up to four with changes in altitude, geological substrate, and the local environment (23). Several attempts to relate differences in cancer incidence to such variations in background-derived dose have failed, with one exception, to demonstrate any such relation. Background doses quoted usually exclude medical exposure or doses arising from medical procedures. Protection of individuals from radiation-induced harm, whether occupational or otherwise, depends upon three constraints:

- **Justification:** No technique or procedure involving ionizing radiation should be used unless there is a net benefit. Patients should not be exposed to ionizing radiation without potential benefit and the possibility of influencing clinical management decisions. With clinical research involving ionizing radiation, the benefit may be to society rather than the individual. Prior to participating in research involving ionizing radiation, informed consent should be obtained to ensure the patient understands that benefit is for society rather than for personal welfare.
- **Optimization:** Having decided that the irradiation of a patient is desirable, it is then necessary to optimize the procedure– that is, to use the safest procedural techniques consistent with good care. This is done by means of an approach called "ALARA" (As Low As Reasonably Achievable), through strategies such as limiting **time** of exposure, maximizing **distance** from the radiation source, and using **shielding** to reduce exposure of tissues.
- **Regulation:** Since radiation exposure may be both justifiable and optimized but potentially excessive, governments set regulatory limits on exposure. This is often done by implementing the recommendations of multinational bodies of experts, such as the International Commission on Radiological Protection (ICRP) (24). Radiation exposure, especially when used for the treatment of cancer, may be exempted from constraint when the individual benefit is potentially great. Such exposure may exceed regulatory limits but still be justifiable and optimized.

Dose Measurement

The history of radiation protection is littered with the measurement of radiation fluxes at different points (skin or entrance doses, equivalent doses, air doses, exit doses, etc.) and units (roentgens, radiation absorbed doses (RADs), radiation equivalent for humans (REMs) and so forth). There is some consensus, at present, that effective dose (ED) (formerly the effective dose equivalent or EDE) is a useful concept. Some have advocated its use in medicine (20). ED takes into account the actual radiation flux, the volume of tissues irradiated, the relative risk of radiation carcinogenesis in those tissues and the type(s) of ionizing radiation involved (alpha-, beta-particles; x-, and gamma-rays) each of which has a different potential to cause harm related to the intensity of the ionization each induces. ED is considered as the most appropriate of numerous alternatives (24). The tissue weighting factors recommended by the International Commission on Radiological Protection to be used in calculating the ED are as follows:

Tissue	**Weighting factor**
Bone marrow	0.12
Breast	0.15
Colon	0.12
Lung	0.12
Thyroid gland	0.03
Bone surfaces	0.03
Ovaries and testes	0.25
All other tissues	0.18
Total	1.00

The duration of exposure to ionizing radiation influences its biological effects. A given dose administered acutely may cause harm that will not be apparent from the same dose delivered to the same tissue volume over months or years. This almost certainly has to do with DNA repair which will have less opportunity to come into play in those receiving large acute doses. Evidence to support the role of DNA repair in modulating radiation harm may also be found in the exaggerated sensitivity to radiation of those patients with syndromes such as ataxia-telangiectasia characterized, among other things, by defective DNA-repair mechanisms.

Radiation Exposure Regulatory Limits

The current recommended regulatory limits for radiation exposure are as follows (24):

Occupational effective dose (5-year mean)	20 milliSv/annum
Public	1 milliSv/annum

By analogy the dose from natural background radiation in most places at sea level is approximately 2.5 milliSv/annum.

What is the risk of radiation exposure and safety concerns from a DXA precision assessment?

A routine DXA scan of the hip or spine delivers a small radiation dose to the patient. The dose to the skin, i.e., where the beam enters the patient, is less than 100 μGy (1μGy = 10^{-6} Gray), for the typical DXA unit. Although the dose to the skin is easily measured, it unfortunately does not reflect the radiation risk to the patient since only a small part of the body is exposed in a DXA scan. Also skin dose over-estimates the dose to radiation sensitive organs because of attenuation of the radiation by overlying tissue. In order to estimate the impact of a partial body irradiation on a patient, the concept of effective dose has been developed by the International Commission on Radiation Protection, ICRP (24). Effective dose is a calculated quantity and is defined as the dose to the whole body that carries the same risk as the partial body dose. Effective dose is expressed in units of rem or Sievert, Sv. Effective dose from a particular partial body irradiation such as a DXA scan is found by weighting the dose to the individual organs in the DXA scan field by factors for each organ, which are associated with the risk of cancer and the relative length of life lost. ICRP Publication 60 describes this methodology in detail (24).

The concept of effective dose has been developed to allow direct comparison of different radiographic examinations and their potential radiation risk. In other words an x-ray examination, which results in an effective dose of "X" microsievert (μSv), carries the same long-term risk as a completely different x-ray procedure that gives the same effective dose. With this concept we can now compare the risk of a DXA scan to that of a chest x-ray, mammogram or caused by naturally occurring background radiation by simply comparing their relative effective doses. Effective dose is the preferred way for expressing the patient's risk of radiation harm and is, in the opinion of ISCD, the best of numerous alternatives for measuring and comparing ionizing radiation as utilized in x-ray based bone density testing.

Using the ICRP methodology, the effective doses from DXA scans of the lumbar spine and hip are typically less than 5.0 μSv (1μSv = 10^{-6} Sv), with the total effective dose for a routine DXA clinical exam consisting of a PA lumbar and proximal femur scan being less than 10 μSv (25-28).

For perspective on the magnitude of an effective dose of 10 μSv, it is informative to compare it to the effective dose humans receive from background radiation. Background radiation comes from cosmic rays and naturally occurring radioactive materials in the earth and our body. The average effective dose to an individual in the U.S. from background radiation is approximately 3000 μSv per year, or about 8 μSv per day. In Canada the effective dose from background radiation is about 20% less (29). Thus, the effective dose from a DXA scan of the hip and spine is similar to the dose we receive every day from background radiation.

The effective dose from a DXA exam (<10 μSv) is among the lowest of doses resulting from commonly used medical x-ray examinations. For example, a conventional chest x-ray examination consisting of a PA and lateral view delivers an effective dose of 60 μSv; a CT

examination of the pelvis delivers about 5,000 μSv, and a conventional mammogram delivers about 130 μSv. DXA is a low dose procedure and is acceptable for longitudinal measurements to monitor progression of bone disease and the efficacy of therapy. Recognizing that the results of precision assessment are crucial in providing a healthcare benefit to all patients being monitored the additional radiation dose involved is exceedingly small and the principle of ALARA is applicable.

What are the ISCD recommendations for patient assent while participating in a precision assessment?
Radiation doses to patients participating in a precision assessment study are several orders of magnitude below the regulatory dose limit for the general public. Moreover, the doses are within the scale of the natural variations in background radiation exposure such as occur from place to place and at different altitudes.

Although patients must be informed that they are being re-scanned for the purpose of precision assessment and be given the right to refuse, it is important to recognize that precision assessment is not research. Each patient attending the facility for bone density measurements benefits personally from the results of the precision assessment because her/his results cannot be correctly interpreted without them. In fact, one could argue that the failure to determine precision in each center places patients at unacceptable risk for misinterpretation of their results and potential therapeutic errors. Patients should be informed of the merits of precision assessment, with right of refusal, but use of a consent form is not suggested (1) (see addendum A, Precision Assessment Informational Form).

Summary
Bone densitometry centers doing serial BMD tests must do precision assessment to determine whether a BMD difference is a genuine biological change or within the range of error. Precision assessment should be performed on patients typical of those tested at the center.

Patients agreeing to participate must give verbal assent, and have the right to not participate without prejudicing their further care. As a result of their participation the patients will incur a small increment in radiation dose. No acute effects of such an exposure can be expected. While there is a small theoretical risk of cancer induction, with a latency of ten and twenty years, many studies have failed to confirm that the long-term risk is real.

Determination of the LSC by means of properly conducted precision assessment is essential to good densitometry practice. The value of precision measurements outweighs the small and entirely theoretical risk of cancer induction.

ISCD Official Public Policy Position on Precision Assessment and Radiation Safety

A. **Precision measurement and calculation of least significant change (LSC) is an essential component of a quality assurance (QA) program for bone densitometry centers.**
B. **Prior to participation in precision assessment, patients should be informed of the benefits and risks. Refusal to participate must not prejudice the further care of the patient.**
C. **Since precision assessment is not research, it should not be necessary to obtain approval from an institutional review board.**
D. **Bone densitometry centers should be aware of, and comply with, all local regulations regarding the safety of patients and staff.**

Addendum A

Precision Assessment Information for Patients

To find out if there has been a change in your bone density, a recent bone density test is compared with a previous test. For an accurate comparison, we must know when the change is greater than the normal day-to-day fluctuation in the measurement itself. This is done by doing mathematical calculations on repeat bone density measurements of the same person made on the same day. This is called a "precision assessment."

You have been asked to participate in a precision assessment. You will have your bone density measured again at the [spine and hip] [spine, hip, and forearm]. After the first scan you will need to get off the table and then back on for the additional scan(s).

The X-ray exposure involved in this is exceedingly small- typically less than the normal radiation all of us are exposed to on a daily basis. Nevertheless, you should not participate if you think you might be pregnant.

Participation is up to you. If you do not wish to participate, it will have no effect on your future treatment or benefits at [clinic name]. Please ask your doctor or nurse if you have any questions or if you do not understand why you have been asked to participate.

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