



**Longitudinal Bone Mineral Density Results
for Spine and Hip Scans
from Baseline through Visit 16**

CODEBOOK

ARCHIVED DATASET 2019

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DOCUMENTATION FOR THE SWAN LONGITUDINAL BONE MINERAL DENSITY DATASET

Changes from the prior release of longitudinal bone mineral density dataset (nialbmd2018): Visit 15 and Visit 16 data has been added.

This codebook documents the Longitudinal Bone Mineral Density Dataset, which includes DXA bone scan results of spine and hip for SWAN visits from baseline to follow-up visit 16. An independent contractor – Synarc, was used for the baseline visit through visit 10 to review randomly selected or questionable DXA scans for quality control. At visits 12 through visit 16, the University of California, San Francisco (UCSF) was used in this capacity. For both the spine and hip data, there are 4 regions scanned. For the spine, the data correspond to vertebrae L1-L4. For the hip, these correspond to femoral neck, trochanter, inter-trochanter, and ward's triangle. This dataset is intended for use in longitudinal analyses looking at changes in BMD over time.

The dataset includes one record per visit per id. Since the dataset contains visits from baseline to visit 16, a participant can have between 1 and 15 records (visits 11 and 14 were interim visits with no bone scan data). Bone Density Contact Record (BDCR) flags and checks are omitted from this dataset. Although the checks and flags are omitted from the final longitudinal dataset, they are implemented in the data cleaning process, and ultimately affect the construction of the final frozen longitudinal dataset.

Note:

- Sixteen scans occurred before the actual baseline visit, resulting in a negative number for the scan day variables.
- The interim visit 11 was a non-funded visit, and quality control was not performed for this visit. Please use the data with caution. Also, the Oakland site did not participate in interim visit 11.
- No bone scans were done during interim visit 14.

Who is included in the public use dataset:

The dataset contains information for the 2365 women from the five clinical sites participating in the SWAN longitudinal bone study who had a baseline bone scan at SWAN core visits 00 through 03. The sites include Detroit, MI, Boston, MA, Oakland and Los Angeles, CA, and Pittsburgh, PA. The Oakland site did not participate in the bone study at visits 15 and 16 and the Pittsburgh site did not participate at visit 16.

The assigned participant ID has been replaced with a randomly generated ARCHID in order to protect participant privacy. The *baseline* interview date is denoted as day 0 and is used as the basis for all other dates. All other questionnaires or data collected that have a date attached have been converted to the number of days from the baseline interview.

A variable describing the race/ethnicity of participants (RACE) and study site (SITE) were added from the Screener dataset.

Missing data coding:

Original missing codes (-1: not applicable, -7: refused, -8: don't know, -9: missing) have been recoded to SAS missing codes (.B: not applicable, .D: refused, .C: don't know, and .A: missing).

Additional information:

At each scan visit, a bone density contact record (BDCR) was completed for each scan type and was stored in the BDCR datasets (for V03 to V16) and in the core datasets (V00 to V02). The bone density contact record includes questions which assist in the interpretation of scan results, and the identification of potential problem scans. Scans which were flagged were sent to Synarc for review of artifacts, technical inadequacies, or other problems. The reviews, done by scan reviewers and some by Synarc, and PIs, insure that the subject was positioned correctly, that the measured Region of Interest (ROI) was defined appropriately, and that the BMD change over time for a participant is a true change and not due to scanning problems.

Core datasets were created for visits 00, 01, and 02. After visit 02, a longitudinal dataset was created and then updated with each annual visit. Based on certain flagging criteria, a scan may have been excluded for a particular visit. However, in cases where the same conditions exist for all scans, the scan may be included in the longitudinal dataset. For example, a participant's hip scan may have been excluded because of non-removable metal jewelry present at baseline. However, every time she has been scanned the same non-removable jewelry is present in the scan. All of her scans would be included in the longitudinal dataset because the metal is present in the same location in all her scans.

At each scan visit, four spine regions are scanned, with results from the four regions combined for total bone mineral content (BMC) and total bone mineral density (BMD). Four hip regions are also scanned, with the first three regions combined for total BMC and BMD. For each region scanned, bone mineral density (BMD) is calculated as follows:

$$\text{BMD} = \frac{\text{BMC}}{\text{AREA}}$$

Scan rules:

The bone density contact record flags spine scans based upon the following criteria: excluded vertebrae, scoliosis, use of angled lines for the top or bottom of the ROI, or for the inter-vertebral markers, inability of the computer to define bone edges, visible motion or other scan artifacts, metal overlying the spine, calcium pill overlying the spine, or inability to match baseline scan. All of these flags, except metal overlying the spine, require that the bone technician send the scan to Hologic/Synarc for review and adjudication via a Data Action Sheet (DAS). *(Please note: because the contract with Synarc ended April, 2008, and sites stopped sending DASs to Synarc in the middle of Visit 10, there will be DASs that were not finalized or reviewed by Synarc).*

The bone density contact record flags hip scans based upon the following criteria: painted hip, bone mapping inaccuracy, inability to separate the femoral neck from the pelvis or greater trochanter, inability to view the bottom of the less trochanter, femoral neck box size less than 12mm, size of the ROI, placement of lines down the middle of the femoral neck, visible motion, scan artifact, or non-correctable anatomy, or metal overlying the hip. All of these flags, except metal overlying the hip and inability to see the bottom of the lesser trochanter, require that the bone technician send the scan to Hologic/Synarc for review and adjudication.

For both spine and hip scans, If metal exists in the same location at all visits, then the scans will be retained in the dataset and are considered to be comparable over time.

The SWAN protocol requires that the left hip be scanned unless one of the following is true.

- Subject's left leg is missing, artificial, partly paralyzed, or totally paralyzed;
- Subject's left hip is artificial;
- Subject's left hip cannot be, but her right hip can be, internally rotated by the necessary amount;
- Subject has ever fractured her left hip or left femur; or
- Subject's right hip was used for her baseline SWAN scan.

For some scans, if the conditions are similar over visit and change in BMD is thought reasonable, the scan will be included in the dataset.

Created Variables:

AGE: Two age variables (**SPSCNAGE**, **HPSCNAGE**) were created using scan dates and participant date of birth.

SCAN DAY: Date of scan variables (**SPSCNDAY**, **HPSCNDAY**) are given in days from interview date at baseline. Note that for 5 participants, interview completion dates at baseline were not available and alternative dates were substituted either from the Self-Administered Questionnaire-A or Physical Measures completion dates at baseline.

SPINE: The total spine BMD variable **CAL_SPBMDT** is edited for longitudinal use with the cross-calibration factors applied at Oakland and Pitt for visit 08 and later, and the cross-calibration factors applied at Boston starting from January 27, 2010.

HIP: The total hip BMD variable **CAL_HPBMDDT** is edited for longitudinal use with the cross-calibration factors applied at the Oakland and Pittsburgh sites for visit 08 and later, and the cross-calibration factors were applied at Boston during Visit 12.

MACHINE: Two variables were used to indicate the scan machine model used (**SPSCMODE**, **HPSCMODE**). The QDR 2000 was used at the Oakland and Pittsburgh sites prior to Visit 08, and the QDR 4500 at the Detroit, Boston, and Los Angeles sites, and at the Pittsburgh and Oakland sites from visit 08 forward.

A flag variable, **BMDFLG**, has the following values

- 1 = spine scan was not reanalyzed (Synarc recommended to reanalyze the scan but the site did not do so)
- 2 = hip scan was not reanalyzed;
- 3 = spine DAS was not sent out (according to protocol a DAS was supposed to be sent to Synarc)
- 4 = hip DAS not sent out
- 5 = if PI recommended for spine exclusion.

LISTING OF CREATED VARIABLES IN THE DATASET

| Variable | Label | Code |
|-------------|--|--|
| ARCHID | Study ID Number | |
| VISIT | Visit Number | '00' = Baseline to '16' = Visit 16 |
| RACE | Race/Ethnicity | 1= Black 2= Chinese/Chinese American 3= Japanese/Japanese American 4= White Non-Hispanic 5= Hispanic |
| SITE | Site | 11= Detroit, MI 12= Boston, MA 13= Chicago, IL 14= Oakland, CA 15= Los Angeles, CA 16= Newark, NJ 17= Pittsburgh, PA |
| SPSCNAGE | Age at spine scan | |
| HPSCNAGE | Age at hip scan | |
| SPSCNDAY | Spine scan day | # of days since baseline (day 0) |
| HPSCNDAY | Hip scan day | # of days since baseline (day 0) |
| SPSCNTIM | Spine scan time | |
| SPSCMODE | Spine scan machine model | 5 = 2000 machine 11= 4500 machine |
| HPSCNTIM | Hip scan time | |
| HPSCMODE | Hip scan machine model | 5 = 2000 machine 11= 4500 machine |
| BMDFLG | Scan flag | 1 = Spine not Reanalyzed 2 = Hip not Reanalyzed 3 = Spine DAS not sent 4 = Hip DAS not sent 5 = PI recommended for Spine Exclusion |
| CAL_SPBMDT | Total Spine BMD w/cross calibrations applied | |
| CAL_HPBMDDT | Total Hip BMD w/cross calibrations applied | |