

DXA Quality Assurance

HABC

STANDARD OPERATING

PROCEDURES

University of California San Francisco

Prevention Sciences Group

Version 1.0

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DATA TRANSFER PROCEDURE

This section describes the procedures for sending BMD data, scans and other materials from the clinical centers to the DXA Reading Center.

At the end of each month, the following materials are assembled and forwarded to the DXA Reading Center:

1. DB Archive disks
2. QC printouts
3. Scan logsheets
4. Printouts of flagged scans
5. Maintenance/Repair log
6. Electronic copies of scans (on traveling optical)
7. Completed Batch Record form for each study

DATA SHIPMENT RECEIPT PROCEDURE

This section describes the procedures for handling BMD data received from the clinical centers.

1. The contents of the batch are cross checked with the Batch record form to ensure that all materials listed on the form have been received.
2. QC plots are set aside for visual review. The result of the visual review is entered in the Daily QC database. The QC plots are then filed in the respective clinic scan review folder
3. Scan printouts are kept with the batch record form and electronic copies of the scans until reviewed by the Scan Review technician.
4. Scan logsheets are filed in the appropriate Logsheets binder.

BMD DATA MANAGEMENT

This section describes methods used at the DXA Reading Center for transferring data to SAS and running SAS programs to summarize data and create final data.

There are 3 types of BMD data: Participant data, Cross-calibration data, and Longitudinal QC data. Data management for each type of data is described separately.

Participant data

1. Scan data from each clinical center is sent to the DXA Reading Center on optical disks and stored on a Hologic workstation. The database is exported to an ASCII file, and imported to SAS. This data is edited to create final BMD data.
2. Scan review data is entered in an ACCESS database and exported to SAS using StatTransfer. This data is used to identify unacceptable scans in the scan data. It's also used to check scan data for completeness.

Cross-calibration data

This data from cross-calibration phantoms is exported from the Hologic database to an ASCII data file and imported to SAS. It's used to create final BMD data and to run tables summarizing precision, accuracy, and consistency among the workstations used at the clinical centers.

Longitudinal QC data

The longitudinal data is recovered from dbarchives from clinics. It is exported from the Hologic database to ASCII data files and imported to SAS to create the QC data. It's used to run additional review of variation of daily phantom data within each workstation.

Participant Data

Scan Review Data

1. Transferring ACCESS database to SAS dataset

StatTransfer is used to create Bmdqc1.sd2 from the ACCESS BMD data table, tblScanRev.

2. Creation of SAS Data

Bmdqc1 contains scan review data for all studies at the QA Center. The following SAS programs are run to rename variables to be consistent with names used by other SAS programs (scanrev.sas), subset to HABC participants (habcrev.sas) and identify unacceptable scans.

SAS Programs: Located in Habc_sas\Bmd\Current

HABCREV.SAS Inputs scanrev.sd2 and subsets to HABC study.

3. SAS Listings for data integrity

SAS programs located in Habc_sas\Bmd\Current\Lists are run to check scan review data for duplicates, invalid id's, and correct visit assignment. These are revised as needed for a given visit.

Participant BMD Scan Data

Clinics store scans on optical disks and send scans to the DXA Reading Center every month. Scans are loaded onto a database on a Hologic Workstation at QA Center. The Hologic database is exported to an ASCII file, dbexport.dat, using the Hologic dbexport utility.

The ASCII data is imported into a SAS dataset for each type of scan (hip, whole body). Datasets for each scan type are combined to one file. This file is checked for valid HABC participants and id's, completeness, and duplicates. A subset of variables is output to a SAS file.

Queries are run to create edit lists to assure quality of data.

1. Transferring Hologic database to SAS dataset

This section describes the procedures for exporting patient data from the Hologic workstation. Scan data is exported using the Hologic dbexport utility from Hologic database to an ASCII file, dbexport.dat. This is achieved by typing the db export command with the -e flag at the DOS prompt.

Data is transferred to WHI486 via the ethernet network by dragging the file to the appropriate folder, dxadata\habc\current.

A copy of the data is also transferred to the server containing the Bmd folder where SAS programs are stored.

2. Creation of SAS Data

This section describes programs to run to create SAS data.

Dbexport.dat is input to SAS using dbimport.sas. Dbimp.sas acts as a batch program that calls dbimport.sas. Separate scan files are created. The files are combined into separate hip and whole body datasets.

The following SAS programs are run in sequence to create SAS data.

Dbimp.sas (calls dbimport.sas) creates the following SAS datasets:

Patient.sd2 contains the biographical information for the participants.

Hip.sd2 contains the hip DXA results.

W_body.sd2 contains the whole body DXA results

The dbimport.log is inspected for any errors or data problems encountered during the SAS run. The dbimport.lst is also checked.

Habcdata.sas is run to create final hip and whole body data. ID corrections are contained in dbcorr.sas, SAS code included in whidata. Visit is assigned using SAS code included in visit.sas. HABCID and site are created by including habcid.sas. Scanid is created by including scanid.sas. Qdrfix is included to correct the qdr number of QDR 4500 workstations. Datadte is included to assign data date used to create final data. Patient name and id corrections are included in patcorr.sas. And records are deleted by including delrec.sas.

SAS Programs: Located in Habc_sas\Bmd\Current

Dbimp.sas

calls dbimport.sas.

Dbimport.sas

(provided by Peter Steiger at Hologic) Imports dbexport.dat into SAS datasets: patient, hip, w_body, sub_reg.

Habcdata.sas

Sas program that creates final hip and whole body files, hp<date> and wb<date>. ID corrections and invalid scan deletions (% include dbcorr.sas, % include delrec.sas), creates scanid variable (% include scanid), creates visit variable (% include visit.sas), qdr number corrections (% include qdrfix.sas), creates habcid

and site variables (% include habcid.sas), and patient id and name corrections (% include patcorr.sas) .

Dbccorr.sas

Corrects HABCID errors or deletes invalid scans . Included in Habbscan.sas.

Qdrfix.sas

Corrects qdr numbers of QDR 4500 hologic workstations. Included in Habbscan.sas.

Scanid.sas

Creates scanid variable based on scanf_id. It is scanid as it appears on scan printouts from the Hologic workstation. Included in Habbscan.sas.

Visit.sas

Creates visit variable based on scan_dat. It is coded 0=baseline, 12=12 month, 24=24 month , etc. Included in Habcddata.sas.

Habcid.sas

Creates habcid and site. Included in Habcddata.sas.

Datadte.sas

Creates macro variable datadte. It is used to create hp<datadte> and wb<datadte> files.

Patcorr.sas

Corrects ids and names in patient data. Included in Habcddata.sas.

3. SAS Listings for data integrity.

SAS programs located in Located in Habc_sas\Bmd\Current\Lists are run to check data for completeness, duplicates, visit assignment, and invalid id's. These are revised as needed for a given visit. These programs are run as needed, not necessarily in a particular order, but after combined BMD data and scan review data are created.

Lists are reviewed by QA Center Staff, and clinics are queried if necessary. For example, the clinic will be queried if a scan is missing and there is no documentation of a missed visit for the participant. Reviews will result in corrections to data, deletion of scans, reanalysis of scans, as necessary.

4. Annual review

At the end of each visit, a random sample of scans (5% of unreviewed scans from each clinic) will be checked for correct analysis. Outliers are also identified for review. Scans are reviewed at the DXA Reading Center as described in the section BMD Scan Review Procedure.

The SAS programs located in Habc_sas\Bmd\Annual\Lists are run to create random sample and outlier lists for review and corresponding datasets storing id's of sample.

5. Calculated Variables for Whole Body scan data

Note: lean+BMC are exported by the Hologic workstation. Lean only is calculated by subtracting BMC from lean+BMC variables.

The whole body body composition data has the following variable names (Calculated variables are in **bold**):

Region	BMC	Lean+BMC	Lean Only
Total	totbmc	totlean	ctotlean
Head	headbmc	headlean	cheadlea
Left arm	larmbmc	larmlean	clarmlea
Right arm	rarmbmc	rarmlea	crarmlea
Left leg	llegbmc	lleglea	clleglea
Right leg	rlegbmc	rleglean	crleglea
Trunk	trnkbmc	trnklean	ctrnklea

Trunk BMC is made up of the following:

Left rib BMC	lribbmc
Right rib BMC	rribbmc
Thoracic spine BMC	tspibmc
Lumbar spine BMC	lspibmc
Pelvic BMC	pelvbmc

Calculated variables

Region	Description	Code
Trunk BMC	sum of rib, spine & pelvic BMC	$trnkbmc = \text{sum}(lribbmc, rribbmc, tspibmc, lspibmc, pelvibmc)$
Head lean only	Head lean+BMC -BMC	$cheadlea = \text{headlean} - (\text{headbmc})$
Left arm lean only	Left arm lean + BMC -BMC	$clarmlea = \text{larmlean} - (\text{larmbmc})$
Right arm lean only	Right arm lean+BMC -BMC	$crarmlea = \text{rarmlean} - (\text{rarmbmc})$
Trunk lean only	Trunk lean+BMC -BMC	$ctrnklea = \text{trnklean} - (\text{trnkbmc})$
Left leg lean only	Left leg lean+BMC -BMC	$clleglea = \text{lleglean} - (\text{llegbmc})$
Right leg lean only	Right leg lean+BMC -BMC	$crleglea = \text{rleglean} - (\text{rlegbmc})$
Total lean only	Sum of head, arm, leg & trunk lean only	$ctotlean = \text{sum}(cheadlea, clarmlea, crarmlea, ctrnklea, clleglea, crleglea)$
Total fat	Sum of head, arm, leg & trunk fat	$totfat = \text{sum}(\text{headfat}, \text{larmfat}, \text{rarmfat}, \text{trunkfat}, \text{llegfat}, \text{rlegfat})$
Total lean+BMC	Sum of head, arm, leg, & trunk lean+BMC	$Totlean = \text{sum}(\text{headlean}, \text{larmlean}, \text{rarmlean}, \text{tlean}, \text{lleglean}, \text{rleglean})$
Total Mass	Sum of fat & lean+BMC	$Totmass = \text{sum}(\text{totfat}, \text{totlean})$
Total % fat	Fat as % of total mass	$Totpf = (\text{totfat}/\text{totmass}) * 100$

Longitudinal QC Data

1. Recovering QC data

This section describes the procedures for retrieving data from the Hologic dbarchive data files (QC) and exporting the QC data to an ASCII file, date.txt.

FOR EACH HOLOGIC WORKSTATION:

Dbarchives stored on floppy disks are sent from each clinic to the DXA Reading Center. Dbarchives are recovered to a database on a Hologic Workstation or equivalent PC with Hologic software. The Hologic database is exported to an ASCII file using the Hologic dbexp utility. The ASCII data is imported into a SAS dataset for each type of scan in a separate subdirectory for each workstation on the PC.

Dbarchive recovery/export is done on a dedicated PC. Hologic 9.02 files necessary for dbrecovr, dbexport, and dbexp are stored in subdirectories: c:\util, c:\menu, c:\xcdata. Data files are stored in c:\dxadata\habc in a separate subdirectory for each clinic machine.

Dbrecovr, 4. QC data, is used to recover data. Dbexp is used to export data to ASCII file, date.txt.

Data is transferred to WHI486 via the ethernet network.

2. Creation of SAS data

This section describes programs to run to create SAS data.

Data are stored in Habc\<< clinic> folders for each machine.

Qcdata.sas reads date.txt from each machine folder and creates the sas dataset, qcdata.sd2, in each machine folder. Qcdata.sas is run for all clinics at once by acting as a batch file and calling qcimp.sas. A separate listing is placed in each folder, and one log for all clinics is created.

Qctape.sas is run to combine all sites into one dataset, qcbmd.sd2. It selects only phantoms used by HABC protocol.

SAS Programs:

Qcdata.sas

Imports date.txt containing longitudinal qc data to SAS dataset qcdata.sd2.

Qcimp.sas

Runs qcdata.sas for each clinic calling qcdata.sas with % include.

Qctape.sas

Creates file, qcbmd.sd2, containing daily phantom qc data from all clinics with 1 observation/scan.

Cross Calibration QC Data

Clinics send scans to the DXA Reading Center. Scans are loaded onto a database on a Hologic Workstation at the DXA Reading Center. The Hologic database is exported to an ASCII file, dbexport.dat, using the Hologic dbexport utility (-e flag).

The ASCII data is imported into a SAS dataset for each type of scan (hip, AP spine, forearm, whole body) using dbimport.sas. A subset of variables is output to a SAS dataset.

1. Transferring Hologic database to SAS dataset

Scan data is exported using the Hologic dbexport -e utility from Hologic database to an ASCII file, dbexport.dat.

Data is transferred to WHI486 on a floppy disk to the appropriate folder, dxadata\xcal\xcal<year.>.

2. Creation of SAS Data

This sections describes programs to run to create SAS data.

Dbexport.dat is input to SAS using dbimport.sas. Separate scan files are created.

The following SAS programs are run to create SAS data.

Xchip.sas

Subsets hip to hip phantoms scanned on machines used in Habc. Outputs xchip.sd2.

Xcspine.sas

Subsets spine to spine phantoms scanned on machines used in Habc. Outputs xcspine.sd2.

Xcblock.sas

Subsets sub_reg to block phantoms scanned on machines used in Habc. Outputs xcblock.sd2.

Xchiplst.sas

Lists hip scans of hip phantom.

Xcspilst.sas

Lists spine scans of spine phantom.

Xcblocklst.sas

Lists sub_reg scans of block phantom.

The files xchip.sd2, xcspine.sd2, and xcblock.sd2 are created.

QC PLOT REVIEW PROCEDURE

This section describes the procedures for visual review of the longitudinal QC plots.

1. Enter the batch number and date received on the QC logsheet
2. Check plots for signs of drift, check for outliers, check the CV. If there appears to have been a noticeable shift, check the Maintenance and Repair logs for that clinical center. A change in the longitudinal QC can sometimes be traced to a repair done on the QDR at about the time the shift appears on the plot.
3. If the change in longitudinal QC is considered significant enough to require intervention, contact the clinical center and Hologic.
4. Enter the results of the visual inspection in the Daily QC database.

BMD SCAN REVIEW PROCEDURE

This section describes the guidelines for determining correct scan analysis.

The Hologic QDR 4500 manual should be used as a reference.

Upon receipt of a data shipment, the scan printouts are checked as follows:

1. Hip scan

Check ROI for the following: inferior line ten (10) lines below the level of the Lesser trochanter or two times the length of the Greater trochanter; lateral line five (5) lines from the bone edge of the Gtr. trochanter; superior line five (5) lines above the femoral head or just above the acetabulum; medial line five (5) lines out from the femoral head or just to the side of the acetabulum.

Check bone map for accuracy.

Check position of midline. Determine if neck notch needs to be filled or ischium deleted to give correct placement.

Check position of the femoral neck box. One corner rests on the “notch” of the Gtr. trochanter, the other three are in soft tissue. Determine if bone editing of the ischium is required.

Check placement of trochanteric line.

Check for artifacts (metal, implants, movement, calcium deposits).

Determine if COMPARE mode required and/or used.

If the scan is a “follow up” scan, check that the ROI is the same size as the baseline scan and that ROI placement matches the baseline scan.

2. Whole Body

Check for proper positioning of participant.

Check for presence of tissue bar.

Check for tissue bar analysis.

Check for correct placement of subregions.

Check for artifacts, implants or prostheses.

Reanalyzed scans are checked to see that the reanalysis instructions were followed correctly and that the scans are now correctly analyzed.

SCAN REVIEW ACTION PROCEDURE

This section describes the steps taken to correct any improper scanning/analysis techniques to ensure accurate and consistent results.

1. Questionable scans are viewed on the DXA workstation and manipulated to verify appropriate analysis procedures.
2. Problems and/or inconsistencies with protocol are noted directly on the scan printout.

For all scans requiring reanalysis, the annotated printouts are returned to the study site with specific instructions for reanalysis. A printout showing the correct analysis is attached if considered necessary or helpful to the QDR operator doing the reanalysis. A copy of the annotated scan is kept in the clinic scan review folder at the quality assurance center.

Upon receipt of the reanalyzed scans, they are checked for compliance with the DXA Reading Center's reanalysis instructions. If found to be acceptable, the scans are filed with the other flagged scans from that batch; if the scans are still incorrectly analyzed, the scans are again returned to the clinical center with further reanalysis instructions. The Scan Review database is updated accordingly.

A manual review of the clinic file is performed periodically to check for outstanding (> 2 months) scans. The clinic is then reminded that the reanalysis of these scans is overdue.

EXCESSIVE BONE LOSS REVIEW PROCEDURE

This section describes the procedures for reviewing scans of participants with suspected excessive bone loss.

1. The clinical centers send in scans of participants with suspected excessive bone loss as described in the study manual.
2. A visual review of the scans is then undertaken to check for any technical problems that may have influenced the BMD measurements. Possible sources of error include QDR malfunction, operator error acquiring scan, incorrect scan analysis. Other information which may be used to evaluate the likelihood of excessive bone loss include: participant medical history (if available), obesity, weight loss.
3. The Excessive Bone Loss form is then completed, signed and dated. A photocopy of the form is made; the original is sent back to the QDR operator at the clinic and the photocopy is filed in the HABC EBL binder. The date that the form was sent back to the clinic is noted on the form.
4. A list of confirmed and unconfirmed cases of EBL is maintained in a Microsoft Excel file. The filename is HABC_EBL and is located in the HABC folder on the PowerMac 7200.

SYSTEM CROSS CALIBRATION PROCEDURE

This section describes the process of system cross calibration (x-cal). The purpose is to gain information on system calibration of multiple clinical centers simultaneously.

A Gold Standard Phantom of a hip, lumbar spine and block is distributed to the clinical centers for scanning in order to obtain specific calibration data. Machine specific protocols are sent to the clinical centers with the phantoms. The phantom scans are archived by the center and a copy of the scans sent to the QA center. The scans are then loaded into a x-cal database and a Scan Review Technician analyzes the block phantom scans. Printouts of the hip and spine phantom scans are reviewed to check analysis technique. All phantom scans are then archived to the xcal optical.

Data from the phantom scans is exported so that it can be analyzed in SAS and checked for precision, accuracy and consistency among the various clinical centers.