

APPENDIX B

PROCEDURE FOR THE BONE MINERAL RESULTS LETTER TO PARTICIPANTS

B.1 Procedure for the Bone Mineral Results Letter to Participants

The Women's Health Initiative (WHI) has approved the use of two letters (see attachments) that will inform participants of their bone mineral density results obtained from the Hologic Bone Densitometers used in the study. CCs will send both letters to all women specifying their results. One letter denotes the participant's results as either 'Osteoporotic' or 'non-Osteoporotic.' The second letter is a more formalized version of a procedure already in place for participant notification regarding excessive bone loss.

The purpose of this procedure is to define the determination of "Osteoporotic" and recap the procedure regarding excessive bone loss (EBL).

B.2 Osteoporotic/Non-Osteoporotic

The determination of Osteoporotic/non-Osteoporotic is based on the National Osteoporosis Foundation (NOF) guidelines. These guidelines were developed from bone densitometer scans of the hip, using the Femoral Neck measurements. WHI will use this measurement, and it is easily retrieved within the Hologic software.

At some point after analysis of the hip scan, the DXA technician should follow the following procedure:

1. At the Hologic Main Menu, select <Select>
2. Highlight the participant's name and hit the <return> or <enter> key
3. Choose <Normals> at the Hologic Main Menu screen
4. Highlight and press the <+> key on the participant's current hip scan and hit the <return> or <enter> key
5. Choose <Plot>
6. The **Reference Database** graph and table is presented
7. Check the **Total T-Score**. If this is less than -2.5 (i.e., -2.6, -2.7, -2.8 and so on) the participant is considered Osteoporotic
8. Press the <esc> key twice to exit to the Hologic Main Menu

Mark the checkbox on the form letter as Osteoporotic or non-Osteoporotic and give or send to the participant.

B.3 Excessive Bone Loss

Excessive bone loss has been monitored since the beginning of the study. See the procedure in *Volume 6, Section 10.2.2 – DXA Quality Assurance*. However, the criteria limits for percent decrease have recently changed. The following is a summary of the procedures for determining excessive bone loss (EBL).

Excessive bone loss is determined by looking at both the hip and spine scans. Either or both may show EBL. The DXA Quality Assurance Center at the University of California, San Francisco/Prevention Sciences Group (UCSF/PSG) confirms all cases of EBL. After analysis of a follow-up hip and spine scans (using the COMPARE analysis feature), the DXA technician should examine the RATE-OF-CHANGE plots for the each scan while the participant is on the table. The RATE-OF-CHANGE is retrieved using the following procedures:

1. At the Hologic Main Menu select <Select>
2. Highlight the most recent, analyzed hip or spine scan and press the <return> or <enter> key
3. Choose <Normals> at the Hologic Main Menu screen and see a list of the participant's scans
4. Use the <+> key to mark the baseline and most recent visit scan and press the <return> or <enter> key
5. Choose <Rate of Change>
6. A graph is displayed showing the data points and the normal age range. This graph also shows the annualized percentage change in BMD. On the HIP graph, use the TOTAL under the "% change/yr." column as the value for calculation. On the SPINE graph, use the value under "% change/yr." Multiply this figure by the number of years since the baseline visit (3, 6 or 9).

If this number indicates less than 10% loss from baseline to the third annual visit (AV3) or less than 12% loss from baseline to the sixth annual visit (AV6), there is no excessive bone loss. Mark the bone loss letter as 'No Excessive Bone Loss' and give or send to the participant.

If this number exceeds a 10% loss from baseline to the third annual visit (AV3) or a 12% loss from baseline to the sixth annual visit (AV6), there is a possibility of excessive bone loss. The DXA technician should then rescan the anatomical site(s) that show excessive bone loss and redo the RATE-OF-CHANGE calculations using both of the current scans and the baseline scan. If this multiplied calculation is greater than 10% at the third annual visit (AV3) or 12% at the sixth annual visit (AV6), then all printouts and electronic scans should be sent to UCSF/PSG for technical confirmation. The Quality Assurance Center may request re-analysis of the scans for better technical consistency. UCSF/PSG will make the final confirmation and send the scans back to the CC. The participant's excessive bone loss letter may then be marked as 'Excessive Bone Loss' or 'No Excessive Bone Loss' based on the final UCSF/PSG decision, and sent to the participant.

Figure B.1
Osteoporotic Bone Density Results Letter

February 16, 2012

Dear Ms., Mrs., or Mr. _____:

Thank you for your continued participation in the Women's Health Initiative. Enclosed are the results from your bone density test from your Year 3/6 clinic visit. This information is provided to all women who have had bone density testing. The World Health Organization (WHO) has developed guidelines to help doctors interpret these results and identify individuals who may be at greater risk for breaking a bone (fracture). The purpose of this letter is to help you and your doctor understand your bone density measurement.

What is a bone density measurement?

A bone density test measures how much calcium is contained in certain bones, such as the hip. In general, lower bone density and lower calcium means that the bone is weaker.

What do bone density measurements mean?

We all lose bone as we get older, but some people lose bone faster than others. Certain factors can reduce bone density, such as smoking, low calcium intake, lack of exercise, high alcohol intake, use of some medications, and some medical conditions.

Individuals with osteoporosis (brittle bones) have low bone density and weaker bones. Weaker bones are more likely to fracture during an accident (even a minor accident such as a fall). However, not all women and men with low bone density will have fractures and, occasionally, even those with high bone density will suffer a fracture.

What are my bone density results?

Your hip bone density values have been compared to that of young women and are at the level checked below:

☐ Non-Osteoporotic

☐ Osteoporotic (brittle, weak bones)

If your results are checked as "Osteoporotic," we suggest that you discuss these results with your personal physician. If you do not have a source of medical care, we can provide you with the name of a doctor who specializes in treating osteoporosis in CC's City.

If you have questions regarding these results, please contact _____ at (xxx) 555-5555.

Sincerely,

Figure B.2
Excessive Bone Loss Density Results Letter

February 16, 2012

Dear Ms., Mrs., or Mr. _____:

Thank you for your continued participation in the Women's Health Initiative. Enclosed are the results from your bone density test from your Year 3/6 clinic visit. This information is provided to all women who have had bone density testing. The World Health Organization (WHO) has developed guidelines to help doctors interpret these results and identify individuals who may be at greater risk for breaking a bone (fracture). The purpose of this letter is to help you and your doctor understand your bone density measurement.

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Individuals with osteoporosis (brittle bones) have low bone density and weaker bones. Weaker bones are more likely to fracture during an accident (even a minor accident such as a fall). However, not all women and men with low bone density will have fractures and, occasionally, even those with high bone density will suffer a fracture.

What are my bone density results?

A bone loss greater than average for a person your age may indicate an increased risk of fracture. This bone loss may also be related to other health conditions, or could result from use of certain medications. Your rate of bone loss shows:

☐ No Excessive Bone Loss

☐ Excessive Bone Loss

If your results are checked as "Excessive Bone Loss," we suggest that you discuss these results with your personal physician. If you do not have a source of medical care, we can provide you with the name of a doctor who specializes in treating osteoporosis in CC's City.

If you have questions regarding these results, please contact _____ at (xxx) 555-5555.

Sincerely,

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