

## STUDY OF OSTEOPOROTIC FRACTURES (V5)

### Review of Visit 5 Take-Home Questionnaire

#### 1. General

Review all sections of the take-home questionnaire for completeness. Check to see that all questions have been answered that should be answered. Do not probe further on questions that appear to be answered completely unless:

- (1) the question is answered "don't know"
- (2) there is an obvious contradiction between responses to factual questions. Most of the possible conflicts will be outlined below.
- (3) special instructions are given (below).

For "don't know" answers, check to see if the respondent understood the question by reading the question out loud to the participant in interview format. If a question has not been answered that should have been, read the question to the participant. Handle the responses in the same manner as you would any interview question.

For all open ended questions or "other" responses, if the response fits into one of the given categories, code it as such.

As always, our goal is to clarify discrepancies with the participant while she is in clinic. Thus, as outlined below, certain questions should be cross-checked while the participant is in the clinic so any discrepancies can be clarified immediately.

Many of the questions are framed "IN THE LAST TWO YEARS". We are trying to target the time period between visit 4 and visit 5. We are not using the phrase "since you last visited our clinic" because many women did not come into the clinic for Visit 4. We are not using "since you last filled out a questionnaire" because for many women this would be their fifth annual. For those women who did attend the clinic at visit 4, you may want to use their visit as a reference if they are having trouble deciding when something happened.

#### 2. Missing data

1. Draw a slash lengthwise through questions and conditional boxes that are NOT APPLICABLE (for example, questions that should be skipped because of the response to a stem question).
2. For questions where the answer is "don't know" or the participant is not able to answer the question, and there is not a "don't know" box to check, write DONT KNOW across the question in large letters.
3. When a participant refuses to answer a question, write REFUSED in large letters across the question.
4. If the participant may have information at home or may be able to get information that will help answer a question, ask if you can call her at home to get the information. If she agrees to be called at home, write CALL BACK across the question and flag this page of the questionnaire.

**3. Specific Questions for Visit 5 Take Home Questionnaire, Version 5.1**

**Q1. Name, Address, Phone Number**

Review participant's name, address, and phone number to ensure that we have the most current.

**Q2. Different mailing address in the next year or for part of the next year.**

This should include a temporary address such as winter address in Florida, or the address of children where the respondent spends a good part of the year. A place is provided to record the nature of the alternative address. If possible, record in the margin when this new address becomes effective.

**Q3. Doctor/Health Care**

If the participant has changed doctors or place of medical care, make sure a new name, address, and phone number are recorded.

**Q4. "Next of kin": Name, address, and telephone number**

Next of kin should be the relative with whom the participant has the most frequent contact, who would know her health and vital status and who would know the respondents new address if she moved. It will help to know the exact relationship of the next of kin to the participant.

**Q5-6. Name, address, and telephone number of two close friends or relatives who do not live with respondent**

A contact is someone who would know the respondents new address if she moved; it does not have to be a person who always knows her whereabouts. If a contact person has to be called to track a participant, it will help to know the contact's relationship to the participant. We will collect information on two contacts.

Questions 4 and 5: We are providing the participants with the next of kin and contacts that they indicated at visit 4. If the participant makes no changes to any of these, you might want to tactfully ask if these contacts are still alive.

The next section of questions (Q7 - 20) asks about the participant's **CURRENT lifestyle practices**.

*Review all questions following guidelines outlined in Section 1.*

**Q7. How many city blocks or their equivalent do you walk each day as part of your normal routine?**

Walking as part of the daily routine includes walking to the store because the respondent has no other way to get there, walking around a shopping mall because there is no other alternative, etc. Do not include walking up and down the aisles of the grocery store, for example, or walking around the house while cleaning. A general rule of thumb should be to include only walking of distances of a block or more at a time. This will generally be done outside or in a large shopping mall or similar setting.

**Q8. How many city blocks or their equivalent do you walk each day for exercise?**

Walking for exercise includes any regular walking by the participant done specifically for its exercise value. This would include walking to the store, the post office or senior center because she "wants the exercise." For those with irregular exercise habits or who walk for exercise every other day, add up the total blocks for a week and then divide by 7 to get a daily average. If the respondent says that city blocks in her area are much longer or shorter than the 12 to a mile indicated, convert the blocks she walks to miles and then compute blocks per day based on 12 to the mile.

**Q9. Exercise to work up a sweat**

We are interested in women who on a regular basis, i.e. at least once per week, exercise vigorously enough to sweat. Record the number of times per week this occurs.

**Q10. Hours spent sleeping or lying down**

This means time spent in a fully, or almost fully, reclined position. This does not include sitting upright with the feet up, such as on an ottoman. For clarification, think of the back - if it is bent at more than 45° then consider the participant sitting up, not reclined.

**Q11. Hours spent sitting upright**

This includes all time when the participant is sitting (back bent at  $\geq 45^\circ$ ), with the feet dangling or with the feet up.

**Note: Questions 10 and 11 should not add up to more than 24 hours.**

**Q14. Stairs climbed per day.**

A flight or trip up or down stairs constitutes 10 steps. Be sure the participant is reporting flights or trips, not actual steps.

**Q15-17. Caffeine Use.**

*-all memo #638 in notes section*

The responses to these questions should be straightforward. Note that only colas or other soft drinks (such as Mountain Dew, Pepsi, Coca-cola, Tab, Dr. Pepper) containing caffeine should be included in question 33 (i.e. do not count Seven-Up or uncaffeinated colas such as Root beer). If the participant has difficulty in reporting the number of cups or cans, probe further. Stress the idea of a typical or average day. For example, for a participant who reports 2 cups of coffee per day during the week but

only 1 per day on the weekend, the quantity consumed should be recorded as 2 per day. If, after probing, the participant cannot determine the number of cups or cans, ask her to give her best guess.

### **Q18. Current Alcohol Consumption**

General issues: If anyone asks what drinking alcohol has to do with osteoporosis, simply explain that we are not suggesting that they are related, that we are simply exploring a variety of subjects that some people think might be related, that we're simply trying to learn more about what kinds of things do and do not contribute to this condition and what might help prevent it. But don't volunteer this kind of explanation unless you are asked.

If the questions are completely filled out, they do not need to be reviewed. If either of the questions are not complete, ask them both in interview format.

Some common problems that might account for incomplete questions are discussed below.

#### Frequency

If the participant writes down the precise number of times she had a drink during the past 30 days, translate it into one of the existing codes. For example, if she wrote, "5 or 6 times altogether," simply check the box for "1 or 2 days a week".

If she had difficulty answering because she "didn't drink at all some weeks but drank fairly often other weeks," probe "How about the average week during the last 30 days?" If the respondent has trouble coming up with an average per week, ask her about the frequency or actual number of drinks in the different weeks, record what she says on the questionnaire, then compute the average and record the correct answer. If in the process of answering, she describes her complete pattern for the month and the average becomes obvious, simply check the appropriate box on the basis of her more detailed answer.

#### Quantity

The question asks for the number of drinks of all types of alcohol the participant usually has on days when she drinks any alcohol.

If the participant has trouble estimating the number of drinks on days when she had alcohol, probe for the "typical day" or for "most of the days when you had a drink". Note that this question does not average in the days when she had nothing to drink. If she tells you that she drinks a quart of beer or a fifth of wine per week, record the answer verbatim so that equivalent number of drinks can be calculated later.

If the answer spans a range (i.e. "It must have been 3 or 4"), probe: "And if you had to choose one number, would you say it was probably 3 or 4?" If she reports "5 or 10", probe "Could you narrow that a little? Do you think it was closer to 5 or closer to 10?" in the hope that she will come up with a more precise number in between.

If she shows any self-consciousness about giving you a high number, it's important that you appear (and that you are) calm, non-judgmental and accepting of whatever she says and does, making her feel that you understand and are not easily shocked.

### **Q19. Do you currently smoke cigarettes?**

**Q19b. On the average, how many cigarettes did you usually smoke per day?**

Most people answer this question easily, but some who smoke only on special and/or infrequent occasions may find it hard to answer. If the respondent gives a clear answer that you cannot readily convert into a number of cigarettes per day or per week, the response should be written as given and converted to cigarettes per day before entry of the data.

If, on the other hand, she says that she smoked only on special occasions (like parties or dances), probe to determine how often that happened. Intermittent smoking should be recorded in the following fashion:

- "0.5 per day" if the average use is less than one cigarette a day but more than one cigarette per week
- "0 per day" if the average use is less than one cigarette per week

For example, if a woman states that she smoked two or three cigarettes during the average week, record "0.5 per day". If, on the other hand, she indicates that her pattern has changed sharply, record the number smoked per day and the length of time she followed each pattern; for example, write "one pack per day for 7 years, 3 cigarettes per day for last 18 months." A weighted average will need to be computed before data entry.

NOTE: Q18b should be answered in cigarettes per day. Consult Table 3.1 below for converting packs per week or month into cigarettes per day. Recently, companies have begun marketing packs of cigarettes with 25 cigarettes per pack. Clarify current use of cigarettes per pack before entering the number of cigarettes smoked.

Table 3.1  
Smoking Habit Conversions

<u>Use per week</u>	<u>Cigarette use per day</u>
1/2 pack	1
1 pack	2
1 1/2 packs	4
2 packs	5
2 1/2 packs	7
3 packs	8
3 1/2 packs	10
4 packs	11
4 1/2 packs	12
5 packs	14
1 carton	28
1 1/2 cartons	42
2 cartons	56

Note: If answered in terms of a month, divide by 4 to convert to number per day.

## Q20. Living Arrangement

These questions ask about the participant's living arrangement. Living arrangement may be an indication of self-sufficiency or dependency, and changes in living arrangement may be indicative of declining health. Living arrangement also provides an estimate of potential environmental exposures and services that may affect one's health. Only one answer should be checked.

**Q20b - 1. How long have you lived alone in this current living arrangement?** This should reflect the immediate current situation. For example, if they have lived in the same house for 50 years with their husband, but he just passed away 6 months ago, then they have lived 6 months in their current living arrangement.

**Q20b - a. Who do you live with?**

More than one answer can be checked.

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**The next set of questions (Q21 - Q26) asks about events that have occurred over the LAST 12 MONTHS.**

**Falls, Self-reported health status, urine control, driving.**

Review with the participant that her answers reflect the past 12 month time period.

**Q21. Falls in the last 12 months**

Cross check any broken bones reported in 20b with fractures reported in Q26.

**Q24. Urine Control**

Many older adults experience involuntary loss of urine. We are collecting this information because incontinence is a highly prevalent condition in the elderly that has the potential to affect one's activities or way of life. In addition, incontinence affects people in different ways. If the questions are completely filled out, they do not need to be reviewed verbally with the participant. If any of the questions are not complete, ask them in interview format.

**Q24b.** At least one answer should be recorded. More than one answer is okay.

**Q25-26. Driving and accident questions.**

Driving accident questions may be sensitive to some people. It is important not to respond in any way, positively or negatively, to the information given. If all the information is filled out completely, there is no need to review it with the participant. If a participant reports more than 4 accidents, record the month, year, and time of day for these additional accidents at the bottom of the page. Send a copy of the page to Sarah Harvey at the coordinating center.

If a participant refuses to answer question 25, write REFUSED in large letters across the question.

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**The next section (Questions 27-34) deals with questions about health and activity IN THE LAST TWO YEARS (or roughly since Visit 4). Please review the questions with the participant to ensure that answers reflect this time period.**

**Q27. Fractures**

This next question asks about fractures that have been diagnosed in the last two years (since visit 4). Determine if the fracture has been previously reported by checking the fracture site and date against the list of IDs and fractures provided by the coordinating center. If the fracture was not previously reported, complete a fracture report form during the participant's visit.

**Q28-30. Medical conditions**

These next questions ask about specific medical conditions that have been diagnosed in the last two years. Try to clarify any discrepancies with the participant while she is in clinic.

**\*Q28. Spine fracture, vertebral fracture**

This question should be cross-checked with question 26. If a participant reports yes to question 27, spine fracture should be listed on question 26 and vice versa.

**Q31. Extended Medical History (Comorbidity)**

This list of medical conditions is a subset of those conditions asked at visit 4. We are most interested in new conditions diagnosed in the LAST TWO YEARS (since visit 4 basically). Use visit 4 as a reference if a participant is having trouble determining the timing of something.

Emphasize that a physician must have told the participant that she has or had the condition. These questions should be answered "Yes" even if the participant qualifies the response with:

- "at times"
- "slight or mild"
- "yes, but everyone my age has it"
- "yes, but it doesn't bother me" or
- "that's what my doctor says, but I don't agree (or believe him)"

This format is designed so that each participant should respond, either yes or no, to every medical condition listed. If a doctor has told her that she has a given condition, then she answers whether she is currently being treated for the condition by a doctor.

Many women will admit to some form of a given condition, but only those conditions specifically diagnosed by a physician should be recorded.

## **Definitions of listed medical conditions for EXTENDED MEDICAL HISTORY**

### **Heart attack, coronary, or myocardial infarction**

Most women will know whether they've had an MI. If you are not sure, ask if they spent several days in the hospital; people with MIs are almost always hospitalized for at least several days.

### **Angina, angina pectoris**

Characterized by chest pain, often accompanies physical effort or stress. Almost always treated with medication.

### **Congestive heart failure, enlarged heart**

Congestive heart failure (CHF) is the inability of the heart to maintain a circulation sufficient to meet the body's needs. Marked by breathlessness and abnormal retention of sodium and water, resulting in edema, with congestion in the lungs. Enlarged heart will usually be diagnosed by xray. Usually treated with low salt diet, diuretics, and other medications.

### **Stroke**

Stroke refers to neurological abnormality, including weakness, numbness, slurred speech, or partial loss of vision, which lasted at least 24 hours and was diagnosed by a physician at the time it occurred or within a few weeks. Do not include episodes of a "transient ischemic attack" or TIA, which are similar to strokes but are limited to 24 hours or less of symptoms. If the respondent says the doctor told her she had a "mini-stroke," record "yes." Stroke includes a blood clot in the brain or bleeding in the brain.

### **Diabetes, sugar diabetes, or high blood sugar**

Any confirmed diagnosis of diabetes mellitus should be recorded. Do not include elevated blood sugar during pregnancy ("gestational diabetes") if it did not persist or recur later in life. Do not include "borderline diabetes" unless the participant received a medical treatment (insulin or an oral medication) for this condition. Be sure the participant does not confuse high blood sugar with high blood pressure.

### **Parkinson's disease**

Parkinson's disease is a degenerative process of the brain which results in a characteristic tremor and gait disturbances. Most, but not all, will receive medication for this disorder.

### **Dementia or Alzheimer's disease**

Organic loss of intellectual function. Alzheimer's - progressively degenerative disease of the brain, of unknown cause.

### **Depression**

A morbid sadness, dejection, or melancholy that lasts for at least 3 months.

### **Chronic obstructive lung disease: chronic bronchitis, asthma, emphysema, COPD**

Any diagnosed chronic lung disease: bronchitis - inflammation of airway passages to and within the lungs; asthma - recurrent attacks of labored or difficult breathing; emphysema - pathologic

accumulation of air in tissues or organs. Do not include ACUTE attacks of bronchitis or upper respiratory infection.

### **Arthritis (of the various body areas)**

Many women will admit to some form of joint pain or rheumatism, but only those conditions specifically diagnosed by a physician should be recorded. If the participant has checked yes to arthritis in any specific body area, either osteoarthritis or rheumatoid arthritis should also be checked in most cases.

### **Osteoarthritis or degenerative arthritis**

Non-inflammatory degenerative joint disease, accompanied by pain and stiffness. Many women who have been diagnosed with arthritis will not be able to accurately define what type of arthritis they have. Determining if the arthritis was accompanied by inflammation or not may help to distinguish osteoarthritis (no inflammation) from rheumatoid arthritis (inflammatory).

### **Rheumatoid arthritis**

Chronic systemic disease primarily of the joints. This type of arthritis is accompanied by inflammation.

### **Arthritis (type unknown)**

This category should only be used if the participant knows she has arthritis but is not sure of the type. Try to determine the type with her by asking about whether or not she has inflammation (yes usually means it's rheumatoid). If you do not feel you can accurately determine the type, then use this category.

If either rheumatoid arthritis or osteoarthritis are checked "yes", but none of the "arthritis in specific body areas" are checked yes, then double check with the participant that her arthritis is not in any of the listed body areas.

### **Q32. Has a doctor EVER told you that you have cancer?**

For each type of cancer, indicate whether or not the participant is currently under treatment.

### **Q33. Hip pain. CLINIC USE BOX**

This question has been asked at several previous visits. We are asking it again in order to determine if ppts have new hip pain, or no longer have pain if they had it previously. We will correlate these changes in pain with changes in x-ray evidence of hip OA.

Using the clinic use box, please review in interview format the hip pain question with each participant. Emphasize each aspect of the question making sure the participant understands the complete question.

If she answered yes, probe as follows:

- a) Is the pain really in the hip, upper thigh, groin, or buttocks rather than the midthigh, knee or lower back?
- b) Did she have the pain on at least half (15) or more days of one month?
- c) Did this duration of pain occur in the past 2 years?
- d) Was this really pain or aching rather than stiffness or some other sensation?

If yes to all of the above, check Yes in clinic use box. If not yes to all of the above, check No, but do not change the ppts original answer.

If she answered No or DK, probe as follows:

- a) Have you had any hip pain that lasted more than a few days in the past two years?
- If No or DK, check corresponding category in clinic use box.
  - If yes, determine if the pain meets conditions a-d, above. If yes to all of these, check Yes in the clinic use box. CHANGE THE PPTS ORIGINAL ANSWER TO Q 32 TO YES, AND ASK PARTS 32A-D.

If the participant reports having hip pain, then determine if the pain is (was) in the right hip, and how long ago the pain occurred (parts a,b).

Repeat for left hip (parts c, d)

### **Q34. Knee Pain CLINIC USE BOX**

This question is similar to the hip pain question.

It also has a clinic use box to use in making sure the participant understands each aspect of the question.

If she answered yes, probe as follows:

- a) Is the pain really in the knee or back of the knee rather than the hip area, buttocks or back?  
b) Did she have the pain on at least half (15) or more days of one month?  
c) Was this really pain or aching rather than stiffness or some other sensation?

If yes to all of the above, check Yes in clinic use box. If not yes to all of the above, check No, but do not change the ppts original answer.

If she answered No or DK, probe as follows:

- a) Have you ever had any knee pain that lasted more than a few days?
- If No or DK, check corresponding category in clinic use box.
  - If yes, determine if the pain meets conditions a-c. If yes to all of these, check Yes in the clinic use box. CHANGE THE PPTS ORIGINAL ANSWER TO Q 33 TO YES, AND ASK PARTS 33A-D.

If the participant reports having hip pain, then determine if the pain is (was) in the right, left or both knees (parts a).

If she reports having pain in both knees, the age when the pain started (part b) is the age at the earliest time pain began in either knee.

If she reports having pain in both knees, the last time she had pain (part c) refers to the most recent pain in either knee.

### **Q35. Ankle pain question**

This question is similar to the knee pain question (Q33) on the take home.

If ppt is uncertain about the duration of the pain, ask if the pain occurred on at least half (15) or more days of one month.

- Part a If the participant reports having foot/ankle pain, then determine if the pain is (was) in the right, left or both feet or ankles. If she has foot pain on one side and ankle pain on the other, check "both."
- Part b If she reports having pain on both sides, the age when the pain started is the age at the earliest time pain began on either side.
- Part c If she reports having pain on both sides, the last time she had pain refers to the most recent pain on either side.

### **Q36. Hip Replacement**

Review completeness of the date, surgeon and hospital of all hip replacements. Approximate date is OK if she can't remember the exact month.

If the participant had hip surgery but is not sure whether she had a hip replacement, she should answer yes and answer parts a and b for that surgery.

If she had more than one hip replacement on the same side, the more recent surgery may be a revision. Obtain the date, surgeon and hospital for the earlier surgery if it occurred since baseline.

### **Q36b. Why did you have your hip replaced?**

For each hip, the participant may check more than one reason.

### **Q37. Knee Replacement**

Review completeness of the year of all knee replacements.

If the participant had knee surgery but is not sure whether she had a knee replacement, ask how many days she stayed in the hospital after her surgery. A knee replacement requires at least several days of hospitalization. If she was not hospitalized for two days or longer, the surgery was probably not a knee replacement.

### **Q38. Back surgery**

Review completeness for most recent back surgery.

### **Q39-40. Hip, pelvis injuries, dislocation**

Review completeness of information for hip injuries, extent of injury, type of injury, and dislocation of hip.

If the ppt had more than one hip injury, answer a-d for the most severe injury. This would be the one that caused the most disability or required the most days in hospital.

A few participants may say that they have a congenital dislocation, or a hip that does not fit properly in its socket (acetabulum) due to a defect in the shape of the socket. This should be counted as a dislocated hip only if the ppt had an acute or traumatic instance of dislocation requiring treatment by a physician.

## **Reproductive Health History**

### **Q41. Birth**

If the participant has even given birth (including still births), be sure she has indicated how many were vaginal and how many were Cesarean. If she doesn't remember whether or not she had any Cesarean's, you might want to ask if she has a scar on her stomach or ever had surgery on her stomach.

Additionally, when these women were giving birth, it was quite common that "once a Cesarean, always a Cesarean". Hence, if both vaginal and Cesarean births are reported, please check the timing of these births (i.e. the Cesarean births should occur after the vaginal).

### **Q42. Hysterectomy**

If a participant reported having a hysterectomy, make sure the type and reason are recorded. If the participant doesn't remember what type she had, help her to remember by asking if she had surgery on her stomach or has a scar on her stomach. If she can't remember why she had a hysterectomy, review the categories with her, using the following definitions.

- **Fibroids or bleeding:**
  - Fibroids are benign tumors of the uterus: often can cause heavy bleeding
  - Bleeding = too much bleeding from the uterus - often there was no known reason and it is thought to be "a hormonal imbalance".
- **Pelvic pain or internal scarring:**
  - could be due to prior infection or surgery
  - adenomyosis: a benign growth of the lining of the muscle of the uterus
  - endometriosis: lining of the uterus outside the uterus causes pain and scarring
- **Drooping, bulging, or pressure of the uterus, vagina, bladder, or rectum (female parts):**
  - the participant could have all or only 1 or two of the above.
  - Uterus: it drops or prolapses
  - Bladder: it drops down and is called a cystocele
  - Rectum: it bulges out and is called a rectocele, sometimes associated with constipation
- **Cancer:** this could be ovarian, uterine, or cervical cancer
- **Surgical repair for leakage of urine; uterus removed at the same time**
  - The participant had incontinence and surgery was done to correct this. It was then decided to remove the uterus at the same time just because it was there.

### **Q43-45. Osteoporosis Medications**

Although all participants will be filling out the medication inventory form (MIF), medication questions specific to osteoporosis drugs need to be asked here in case the participant hasn't taken them in the past 30 days (the time frame for the MIF). Since osteoporosis drugs tend to be long-acting, it is important to record past use.

### **Q46-51. Vitamins, supplements, and pain medications.**

Questions 43 to 48 are to be used as flags when filling out the MIF. These are the non-prescription drugs that we are most interested in. If the participant didn't bring any of these pill bottles in to the clinic, double check with her to make sure she isn't currently taking any of them.

**Q52-57. Past Work and Occupation Questions**

Questions 51 through 56 ask about a participant's past work and occupation history. These jobs include paid work and unpaid work done as part of a family business or as farm work. If a participant answers affirmatively to any lead in question, then they should answer the follow up questions about frequency, number of years, and age when stopped.

Clinic use box for question #57 is to code the work activity reported by the participant. As of 1/9/95, you do not have code sheets for the activities so the clinic use box should be left blank. Once we send you code sheets, you should start completing the clinic use box.

**Clinic Use Boxes on back page**

Please fill out the clinic use boxes on the last page as to the type of visit and source of the information.

We have also provided boxes to help you track changes in status of your participants who are not initially full clinic visits but over the course of visit 5 upgrade their participation.