
SELF-ADMINISTERED QUESTIONNAIRE PROTOCOL

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 5 and visit 6. We are not using the phrase "since you last visited our clinic" because many women did not come into the clinic for Visit 5. 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 5, 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 DON'T 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 6 Self-Administered Questionnaire, Version 6.0**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 - 6: We are providing the participants with the next of kin and contacts that they indicated at visit 5. 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 - 32) 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. 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.

Q10. Hours spent sitting upright per day

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 9 and 10 should not add up to more than 24 hours.

10a) Hours per week spent watching television

Review this to make sure participant realizes that this question asks about hour per week, whereas Q10 asks about hours per day. And Q10a should just be hours spent watching television, this includes movie rentals. To double check 10 and 10a, multiply the response in Q10 by 7 (this will give hours per week). This number should be equal to or greater than the response in Q10a.

Q11 & 12. Depression questions.

These are 2 new questions that we are trying to validate as a measure of depression. We will compare the responses on these 2 questions to those on our standard 15 "mood in the past week" questions. This validation has been done in other studies, but never on women this age or this large of study.

Q13-15. Caffeine Use.

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 15 (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.

Many participants might report drinking half caffeinated/half decaffeinated coffee. In this case, ask her how many cups of half and half and then divide by 2 for your number of caffeinated cups. For example, if she says she drinks 4 cups of half/half coffee, this would be 2 cups of caffeinated coffee.

Q16. 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.

Q17. Do you currently smoke cigarettes?**Q17b. 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: Q17b should be answered in cigarettes per day. Consult Table 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 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.

Q18-32. Moods in the last week.

Standard measure of depression that we will use to validate the two earlier questions. If anyone asks what moods have to do with osteoporosis, tell them that we are exploring how all aspects of physical and mental well-being affect osteoporosis and other conditions of aging.

The next set of questions (Q33 - Q40) asks about events that have occurred over the LAST 12 MONTHS.

Sleep, Falls, and Self-reported health status.

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

Q33-38. Sleep and Nap questions.

Quantity and quality of sleep change with age. These questions are designed to determine how much each participant sleeps and whether or not she feels she gets the sleep that she needs. In addition, determining sleep and nap periods will give us an estimate of time spent inactive.

If participants say their sleeping and waking patterns vary and thus can't answer when they fall asleep and wake up, try to elicit what happens on average. Review the am/pm boxes to make sure they make sense, e.g. if someone says that she usually falls asleep at 12 pm, verify that she means 12 am (midnight) and change the response accordingly.

Q37. Nap Habits. "Regular naps" in this case, does not necessarily mean everyday, but it does mean at least once per week on a regular basis.

Q38. Sleep experiences. If not complete, help participant to determine usual pattern over the past 12 months.

Q39. Falls in the last 12 months

Cross check any broken bones reported in 39b with fractures reported in Q42.

The next section (Questions 42-52) deals with questions about health and activity IN THE LAST TWO YEARS (or roughly since Visit 5). Please review the questions with the participant to ensure that answers reflect this time period.

Q42. Fractures

This next question asks about fractures that have been diagnosed in the last two years (since visit 5). 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.

Q43-45. 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.

***Q43. Spine fracture, vertebral fracture**

This question should be cross-checked with question 42. If a participant reports yes to question 43, spine fracture should be listed on question 42 and vice versa.

Q45. Extended Medical History (Comorbidity)

This list of medical conditions is a subset of those conditions asked at visit 5. We are most interested in new conditions diagnosed in the LAST TWO YEARS (since visit 5 basically). Use visit 5 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.

Hyperthyroid: high thyroid, Grave's disease, or overactive thyroid gland?

Hyperthyroidism will almost always have been treated (by surgery, medication, or radiation treatments) if it was diagnosed. Many women who initially suffered from an overactive thyroid will later develop an underactive thyroid because of the treatment given. Do not include thyroid conditions which are not specifically associated with hyperthyroidism (such as goiter, thyroid nodule or tumor, or problems with metabolism) unless participant was told it was accompanied by an overactive thyroid.

High blood pressure or hypertension

Most women will be aware of a diagnosis of hypertension if it is present. Include treated and untreated hypertension, but do not include women who were told on one or two occasions that they had an elevated blood pressure which later returned to normal and did not require specific treatment. Include women who say they have high systolic (the upper number) blood pressure. The vast majority of women with a diagnosis of hypertension will have been treated with medications, although some will have received only dietary treatment.

Q46. Mammography.

Participant's who have had a mammogram should complete the date, location, and result information. If a participant doesn't know the answer to some of the questions, arrange to call her back at home or to contact her physician.

Q47-48. Family history of breast cancer.

Due to the possible hereditary link for breast cancer, we are interested in whether a participant's natural (blood) mother had/has breast cancer and whether any of her full (same mother and father) sisters have/had breast cancer. If yes, please get age at diagnosis for all cases.

Q49-52. 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.

Clinic Use Boxes

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 6 upgrade their participation.

QC ChecklistTake Home Questionnaire Review

- Checked for completeness
- Don't know questions reviewed with participant
- Appropriate questions cross-checked
 - Feet up - Q9 and 10 don't add up to more than 24 hours
 - Hours with feet up: $Q10 \geq Q10a$.
 - Fracture questions; Q42 and 43.
 - Clinic use boxes for type of visit and source of info