

MEDICATION INVENTORY

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1. Background and rationale

A complete and accurate list of current medication use is essential for several reasons: some medications and vitamins affect the tissues of the joints and bones; and medication use increases with increasing pain. During the follow-up visit we will ask participants targeted questions about history of bisphosphonate medication to treat osteoporosis, hyaluronic acid or steroid injections in the knees to treat arthritis, hormone and vitamin D use. We will document on the Medication Inventory Form the use of all prescription medications taken during the 30 days before the follow-up visit. We are specifically interested in how individual medications are actually taken rather than how they are prescribed or intended to be taken.

2. Equipment and supplies

- Medication History, Medication Inventory Form (MIF) (section 8)
- Black ball-point pen
- Plastic bag for medications
- All prescription medications the participant has been taking in the last 30 days

3. Detailed measurement procedures

- The examiner will ask about history of bisphosphonate, hyaluronic acid injection, steroid injection, hormone, and vitamin D use.
- The participant will have been instructed to bring with them to the clinic visit all prescription medications taken during the last 30 days.
- The examiner will review the medications brought by the participant. The examiner will record on the MOST Medication Inventory Form (MIF) the number of prescription medications the participant has taken in the last 30 days and transcribe the names.
- The examiner will have the list of prescription medications that the participant reported using at the previous clinic visit available on the Data from Prior Visits Report.
- The examiner will ask the participant the duration of use and frequency that the medication was taken, and mark the responses on the MIF. For each medication entered, the examiner will record a formulation code (as a 2-digit number). The formulation codes are found at the bottom of the Medication Inventory Form, and are listed as follows:
 - 1=oral tablet or capsule
 - 2=oral liquid
 - 3=topical liquid, lotion, or ointment
 - 4=ophthalmic
 - 5=rectal or vaginal
 - 6=inhaled
 - 7=injected
 - 8=transdermal patch

9=powder

10=nasal

- If the participant did not bring in or identify all prescription medications that they took during the last 30 days, arrange for a telephone call to complete the MIF.
- If a participant returns to the clinic for additional measurements during the follow-up visit, any new medication they report should not be recorded on the Medication Inventory Form. The MIF is intended to be a snapshot of their medication use at one point in time, the date of their original follow-up visit.

3.1 Drug definition guidelines

For the purposes of MOST, use the following definition guidelines:

- 1) **Current use:** All prescription medications taken within the last 30 days prior to the clinic visit. Do not include medications received during an overnight hospitalization, unless they are continued after discharge.
- 2) **Prescription medications:** A medication for which a prescription was written by a physician, dispensed by a pharmacist or physician, and taken by the participant during the 30 days prior to the visit. Prescription medications may include pills or tablets, solutions, creams/salves, dermal patches, inhalers, powders, eye-drops, and injections.

Some non-prescription medications may also be obtained with a prescription. For example, coated aspirin may be bought over the counter, but many physicians write a prescription for it. If a prescription is written for the medication, even if it is available without one, it should be considered a prescription medication.

When a physician recommends an over-the-counter medication, but does not write a prescription for it, it is considered non-prescription. Examples of medications frequently recommended by physicians but obtained without a prescription include vitamins, aspirin, and calcium supplements. We will not be collecting names of non-prescription medications at the visit.

3.2 Medication history

Medication History

Script: “Since we last contact you, about 2 years ago, have you taken a bisphosphonate medication to treat or prevent osteoporosis or to treat Paget’s disease? This includes the following medications: alendronate (Fosamax), risedronate (Actonel), etidronate (Didronel), clodronate, ibandronate (Boniva), pamidronate (Aredia), tiludronate (Skelid), or zoledronate/zoledronic acid (Reclast/Zometa)

Refer to response card for medication pronunciation. This card is for interviewer use only; do not show card to participants.

If “Yes:”

Ask, “For how many years did you take bisphosphonates? If you are unsure, please make your best guess.”

Record the number of years in the boxes provided as a two-digit number. For example, if the participant answers “2 years,” record the number as “02”. Round the number of years up at 6 months to the nearest whole number. For example, <6 months would be recorded as “00” years, and 6 to 12 months would be recorded as “01” year. Refer to the clinic visit Data from Prior Visits Report to determine if the participant reported using a bisphosphonate at the last clinic visit and the duration of use reported.

Script: “Now think about the last 6 months. During the past 6 months, have you had any injections in either of your knees for treatment of arthritis?”

If “Yes:”

Ask, “During the past 6 months, have you had an injection of hyaluronic acid (Hyaluronan [pronounced hi_AL-yer-ah-nan], Hyalgan, Orthovisc, Supartz, or Synvisc) in either of your knees for treatment of your arthritis? These injections are given as a series of 2 to 5 weekly injections.”

If “Yes:”

Ask, “In which knee?” Mark appropriate bubble.

“During the past 6 months, have you had an injection of steroids (cortisone, corticosteroids) in either of your knees for treatment of your arthritis?”

If “Yes:”

Ask, “In which knee?” Mark appropriate bubble.

This question is for female participants only. (If male participant, skip to next question.)

Script: “During the past year have you taken Tamoxifen (also called Nolvadex), Raloxifene (also called Evista), or Toremifine (also called Fareston), Anastrozole (also called Arimidex), Exemestane (also called Aromasin), or Letrozole (also called Femara) to treat or prevent breast or ovarian cancer?”

Refer to response card for medication pronunciation. This card is for interviewer use only; do not show card to participants.

If “Yes:”

Ask, “When was the last time you took this? If you are unsure, please make your best guess.” Show response card. Mark appropriate bubble.

Ask, “Not counting multiple vitamins, are you currently taking Vitamin D alone or combined with calcium?”

If “Yes:”

Ask, “What is the total dose per day you take most of the time?” Mark appropriate bubble.

3.3 Medication reception

Collect all of the medications the participant has brought with them and put these in a container or plastic bag (if not already in the bag provided). Have all prescription medications handy when you complete the Medication Use Interview and Medication Inventory Form (MIF) questions.

Medication Inventory Form in follow-up clinic visit interview

Determine if the participant brought in ALL prescription medications that they took during the last 30 days.

- Fill in the “**All**” bubble, if all medications taken in the last 30 days were brought in to clinic or identified. Record the number of medications in the given box. Then proceed to PRESCRIPTION MEDICATIONS section of the MIF.
- Fill in the “**Some**” bubble, if one or more medications were not brought in, and one or more medications were brought in or identified. **When a participant forgets to bring in one or more medications that they have taken in the last 30 days, each site is responsible for developing a mechanism to gather the missing information via telephone. Occasionally a participant will have brought in an accurate list of the other medications and a follow-up call will not be necessary.** If you need to contact a participant at a later time because they cannot give you all of the necessary information while in the clinic, leave the “Total number recorded” blank and fill in the total number when the medication list is complete. You will need to change the “**Some**” response to “**All**” after the follow-up telephone call with the participant if all other medications are added. It is recommended that the participant be called 1 to 2 days after the visit to obtain the missing information.

DO NOT send the data to the Coordinating Center until after you have collected all of the medication information from the participant over the phone. After you have collected all medication information, put a line through the “Some” bubble and fill in the “All” bubble, circle the answer, and initial and date the correction. Record the total number of medications that the participant is taking in the box. Send all pages of the Medication Inventory Form at the same time.

- Fill in the “**None**” bubble, if the participant took medications but did not bring these with them to the clinic visit. Arrange for telephone call to complete the MIF. It is recommended that the participant be called 1 to 2 days after the visit to obtain the missing information.
- Fill in the “**Took None**” bubble, if the participant took no prescription medications in the past 30 days. If the participant did not bring or list any medications, ask:

Script: "Are you sure you took no prescription medications over the last 30 days?"

The Medication Inventory Form (MIF) can be seen in section 8 of this manual. The MIF can be used as many as times as needed to capture all of the prescription medications taken in the past 30 days. The first four medications should be recorded on the first page and the additional medications should be recorded on the subsequent pages. Be sure to write page X of total pages X if more than one page of the Medication Inventory Form are filled out and write down the Med #. If the participant did not take any medication, write down page 1 of 1 and leave the medication fields blank. After the medication names are recorded the participant should be questioned regarding duration of use and frequency.

3.4 Recording prescription medication

Record only medications that the participant reports that they took in the 30 days prior to the clinic visit. Medications administered in the previous 30 days during surgery or hospitalization will not be recorded on the MIF unless they were continued after discharge. Medications that were prescribed but not taken, or those taken more than 30 days ago, are not recorded.

Copy the name directly onto the MIF from the medication container, using capital letters. Write clearly! Record the complete drug name exactly as written on the container. It is not necessary to record the name of the store or pharmacy where the medication was obtained.

Some combination medications contain two or more drugs in a single pill or tablet, and the trademarked brand name should be recorded (for example, Vicodin is a combination of acetaminophen and hydrocodone). When reporting generic medications please be sure to specify a key ingredient name. Vague names such as “pain reliever” or “nasal spray” should be avoided.

If a single trade name is not present, record the components separated by a slash (for example, acetaminophen/hydrocodone). Combination medications with more than two or three components should be listed by the generic name, as there are only 27 character spaces available to record the medication name.

Medications that are given with a tapering dose (that is, given in a maximal dose for one or more days, and then taken in successively smaller amounts over several weeks) should include the word “taper” in the name. For example, if a participant reports the use of a tapered dose of steroid, “prednisone taper” would be recorded under “Name.”

If additional space is needed to record more than four medications, use as many pages as needed of the MIF form to record the remaining medications. You can find these on the Floating Forms link on the web. Be sure to label the page number and total number of pages used.

If a participant is receiving a blinded medication as part of a clinical trial, write down the name of the study and names of the possible medications that the participant may be taking in the "Name:" fields on the MIF. Be sure to include "or" between names of the medications. For example: UI Pain Study: rofecoxib or naproxen. Since space on the form is limited, the priority will be to first record the name of the study, then the possible medications.

Due to the limited text space available on the form, do not hesitate to use abbreviations when trying to represent a complex preparation. A single slash can replace conjunction words, such as "and" or "with."

Examples of acceptable abbreviations include:

APAP for Acetaminophen

HCTZ for Hydrochlorothiazide

ASA for Aspirin

Ophth for Ophthalmic

ES for Extra Strength

MS for Maximum Strength

If a medication is not taken orally, include the route of administration or include the word "cream" or "ointment" in the name. Some common examples where the route of administration should be listed include:

- suppositories (e.g., "compazine suppository")
- eye drops (e.g., "timolol eye drops")
- injections - This includes medications administered by injection or intravenously (e.g., "vitamin B12 injection," "allergy injections," "intravenous pamidronate")
- inhalers (e.g., "proventil inhaler")
- topical preparations (e.g., "hydrocortisone ointment" or "Premarin vaginal cream")
- patches (e.g., "testosterone patch")

4. Medication coding

Most medications entered on the Medication Inventory Form will automatically be matched to an existing medication in the Coordinating Center (CC) medication/ingredient database. Medications not found in the CC database will be identified and coded by the CC medication specialist. E-mails will be sent to the field centers for assistance in identifying or clarifying names of medications that seem incorrect or cannot be identified either because of typos or errors introduced in scanning or verifying.

5. Duration of use

It is required that you show the participant a response card that lists the duration of use categories to help them report the duration of use for each drug. We are only interested in collecting the most recent duration of use. If the participant took the medication sometime in the

past, stopped using it for more than 8 weeks, and then restarted it more recently, we only want the duration of use since they last started the medication. Ask the participant, “How long have you been taking the medication since you most recently started it?” Do not confuse this with frequency of use. For example, a participant may take a medication only once a week or once a month, but has done so for 7 years and has taken it within the last 30 days – in this case, the ‘> 5 years’ response bubble should be filled in.

6. Frequency of use

We want to record whether the medication is taken on a regular basis or taken on an as needed basis, but not on a regular schedule. For example, someone may have taken prescription Motrin within the last 30 days but only takes it when their knee hurts. This would be recorded as ‘As Needed’ for intermittent use. Any prescribed medication that the participant takes on a set schedule would be recorded as ‘Reg’ for regular use. Medications can be taken on a regular basis only 1 or 2 days a week. Some may even be taken once a month, but on a predetermined schedule. Any medication that the participant takes on a regular basis as part of a predetermined schedule should be recorded as ‘Reg.’ Daily use is not the only use that should be recorded as regular.

7. Quality assurance

Training

- Read and study manual

Certification

- Completes training requirements.
- Sends in two *mock* sets of Medication Inventory Forms
- Observation and evaluation of two *actual* sets of Medication Inventory Forms by the Study Coordinator or their designate.

7.1 Quality assurance checklist

- Participant asked if they brought in all prescription medications taken in the last 30 days.
- Participant asked how often medication is taken
- If no medications taken, participant asked: "Are you sure you took no prescription medications over the last 30 days?"
- Records only prescription medications used in the past 30 days
- Properly records duration of use and uses response card
- Properly records name of medication
- Properly records formulation code
- Correctly codes "as needed" and "regular"

- Reviews form for completeness
- Correctly completes form



Visit	MOST ID #	Acrostic
<input type="radio"/> 60-month <input type="radio"/> 84-month	<input type="text"/>	<input type="text"/>



Medication History

Now think about the last 6 months.

52. During the past 6 months, have you had any injections in either of your knees for treatment of arthritis?

- Yes No Don't know/Refused

52a. During the past 6 months, have you had an injection of hyaluronic acid (Hyaluronan [*pronounced hi-AL-yer-ah-nan*], Hyalgan, Orthovisc, Supartz, or Synvisc) in either of your knees for treatment of your arthritis? These injections are given as a series of 2 to 5 weekly injections.

Yes No Don't know

i. In which knee?

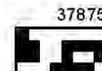
Right knee Left knee Both knees Don't know

52b. During the past 6 months, have you had an injection of steroids (cortisone, corticosteroids) in either of your knees for treatment of your arthritis?

Yes No Don't know

i. In which knee?

Right knee Left knee Both knees Don't know




 21851

Visit	MOST ID #	Acrostic
<input type="radio"/> 60-month <input type="radio"/> 84-month	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>


MOST

Medication History

Female participants only. Male participants: Skip to Page 28, Question #55.

Now think about the past year.

53. During the past year have you taken Tamoxifen (also called Nolvadex), Raloxifene (also called Evista), or Toremifene (also called Fareston), Anastrozole (also called Arimidex), Exemestane (also called Aromasin), Letrozole (also called Femara) to treat or prevent breast or ovarian cancer?
(Examiner Note: Refer to Card #23 for pronunciation. Do NOT show card to participants.)

Yes
 No
 Don't know/Refused

a. When was the last time you took this? If you are unsure, please make your best guess.
(Examiner Note: Read response options. REQUIRED: Show Card #24.)

Less than 1 month ago
 1 to 2 months ago
 3 to 6 months ago
 More than 6 months ago
 Don't know

Pregnancy/Menopause

54. Have you been through menopause or change of life?

Yes
 No
 Don't know/Refused

Review Data from Prior Visits Report.
 If participant is age 55 to 60 years old, administer a pregnancy test.



Visit	MOST ID #	Acroslic
<input type="radio"/> 60-month <input type="radio"/> 84-month	<input type="text"/>	<input type="text"/>



Medication Use

55. Not counting multi-vitamins, are you currently taking Vitamin D alone or combined with calcium?

- Yes No Don't know/Refused

What is the total dose per day you take most of the time?

- 100 IU
- 200 to 300 IU
- 400 to 800 IU
- 1000 IU
- 2000 or more IU
- Don't know



Examiner Note: STOP interview. Please answer the following question based on your judgment of the participant's responses to this questionnaire.

56. On the whole, how reliable do you think the participant's responses to this questionnaire are?

- Very reliable
- Fairly reliable
- Not very reliable
- Don't know



