

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. We will document on the Medication Inventory Form the use of all over-the-counter and prescription medications taken during the 30 days before the clinic visit. We are specifically interested in how individual medications are actually taken rather than how they are prescribed or intended to be taken. We will also ask about selected medications that may have a prolonged effect on biological markers of osteoarthritis.

2. Equipment and supplies

- Medication use and inventory forms (Appendices 1, 2, and 3)
- Medication Code Database (Baseline only)
- Black ball-point pen
- Plastic bag for medications
- Medications the participant has been taking in the last 30 days

3. Detailed measurement procedures

3.1 Targeted medications

Please see appendices for targeted medications including when they were taken (e.g., ever, since menopause, past 12 months, past 6 months, past 30 days, current). Question categories are listed below:

Targeted Medication Questions	Baseline	15-month follow-up ¹	30-month follow-up
Vitamin E and C	X	X	X
Bisphosphonates	X		X
Estrogen (women only)	X		
Tamoxifen/Raloxifene (women only)			X
Testosterone (men only)			X
Medications for joint pain	X ²		X
Knee injection – steroid	X ²		X
Knee injection – hyaluronic acid			X
Calcium – at least 400 mg		X ³	
Vitamin D – at least 400 IU		X ³	
Vitamin C – at least 100 mg		X ³	
Vitamin E – at least 30 IU		X ³	

¹Cases and controls ²If diagnosed with arthritis ³Recorded on MIF

3.2 Medication Inventory Form (MIF)

The Medication Inventory Form is completed at all visits.

- The participant will have been instructed to bring with them to the clinic visit all prescription and nonprescription medications used in the preceding 30 days.
- The examiner will review all medications and transcribe the name and mark whether the medication is prescription or not on the MOST Medication Inventory Form (MIF).
- The examiner will ask the participant the duration of use and frequency that the medication is taken and mark the responses on the MIF.
- Baseline only: examiner will record the seven-digit medication code from the Medication Code Database.
- 15- and 30-month: 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 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 annual 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 visit.

3.2.1 Drug definition guidelines

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

- 1) **Current use:** All 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 eye drops, pills or tablets, solutions, creams/salves, dermal patches, and injections. It also includes sample medications dispensed by a physician and prescriptions written for another person

(usually the participant's spouse) in cases where a participant regularly takes the medication. These practices are not uncommon as a way of controlling medical costs.

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 was written for the medication and it was dispensed by a pharmacist, even if it is available without a prescription, it should be considered a prescription medication.

- 3) **Non-prescription medications:** A medication, vitamin, or dietary supplement that is purchased without a physician's prescription. This category should include herbal medications and health supplements.

3.2.2 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 medications, vitamins, and supplements handy when you complete the Medication Use Interview and Medication Inventory Form (MIF) questions.

Medication Inventory Form (in Clinic Visit Workbook)

Determine if the participant brought in ALL prescription or non-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 (including prescription and non-prescription, as well as vitamins) in the given box. Then proceed to PRESCRIPTION AND OVER-THE-COUNTER 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 brought in:” 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 or over-the-counter 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 or non-prescription medications over the last 30 days?"

The Medication Inventory Form (in the Clinic Visit Workbook) can be used as many as times as needed. 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.

If additional space is needed to record more 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.

3.2.3 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 are 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 a limited number of 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 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.

Be sure to fill in "Yes" next to "Prescription?" for prescription drugs.

3.2.4 Recording non-prescription

Non-prescription drugs are recorded in the same format as prescription drugs. Be sure to fill in "No" next to "Prescription?" for non-prescription drugs. To simplify the coding of non-prescription medications, some medications may be recorded in the following fashion:

- 1) If a cold medication is a well-known national brand, such as “Actifed,” the trade name may be used. For others, enter the name of the primary ingredients such as “Acetaminophen/Pseudoephedrine/Chlorpheniramine.” Combination medications with more than two or three components should be listed by the generic or trade name, as there are a limited number of character spaces available to record the medication name.
- 2) If an allergy medication is a well-known national brand, such as “Allerest,” the trade name may be used and the appropriate strength recorded. For other allergy preparations, enter the name of the primary ingredients such as “Pseudoephedrine/Chlorpheniramine.” Combination medications with more than two or three components should be listed by the generic or trade name, as there are a limited number of character spaces available to record the medication name.
- 3) If a pain medication is a well-known national brand, such as “Aleve,” the trade name may be used. For others, enter the name of the primary ingredients such as “Acetaminophen/Hydrocodone” or “Acetaminophen/Aspirin/Caffeine.”
- 4) Herbal medications should be recorded with the name of the herbal ingredients; avoid brand names or product names like “Herbal Prostate Supplement” or “Herbal Arthritis Pain Supplement.”

Examples of acceptable abbreviations include:

APAP for Acetaminophen
HCTZ for Hydrochlorothiazide
ASA for Aspirin
Vit for Vitamin
Multivit for Multivitamin
Min for Minerals
FA for Folic acid
Ophth for Ophthalmic
ES for Extra Strength
MS for Maximum Strength
MSM for Methylsulfonylmethane

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

4.1.1 Baseline coding

Most medications listed in the MOST MIF database will be matched to an existing medication in the on-line medication dictionary, found on the website in the Medication Codes tab. Medications, formulations, not found in the MOST medication dictionary will be identified and coded by the Coordinating Center. Medication edits for the field centers will be periodically generated for medications that seem incorrect or cannot be coded.

Medication Code Database and the appropriate digit code (up to seven digits) that corresponds to the drug will be entered into the ‘Med Code’ field on the Medication Inventory Form. If you do not find an exact match for the drug that you have recorded put ‘0’ in the ‘Med Code’ box. Please note, however, that you may find the drug by changing the order of your search. For example, ‘vitamin C & iron’ will be found if you search for vitamin C first, not iron first.

When looking for the drug code for the specified medications, be sure to find the code that corresponds to the appropriate formulation (as indicated in the drug code database). Truncate the word if it is more than 24 characters long.

4.1.2 Follow-up 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

You should show the participant the response card that indicates the choices for duration of use.

We are only interested in collecting the most recent, uninterrupted, duration of use. Therefore, if a participant was taking a specific medication from January 1995 to September 2005, discontinued the medication from September 2005 to November 2005, and began taking the medication again in January 2006, we are only interested in the duration of use from January 2006 to the present. If the participant only takes the medication once a week but has taken it for 7 years and has taken it within the last 30 days 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 Tylenol or Aspirin within the last 30 days but only takes it when they have a headache. This would be recorded as 'As Needed' for intermittent use. Any prescribed or over-the-counter medication or supplement that the participant takes for pain or arthritis, or vitamin or calcium supplement the participant takes daily or 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 three *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

- Reads script and questions about medications exactly as written on the Visit Interview (same order, same wording)
- Response options read/not read when appropriate
- Uses all mandatory response cards with the appropriate questions
- Follows skip pattern in questionnaire
- Accurately records participant's responses on questionnaire
- Participant asked if they brought in all medications used in the past 30 days
- If no medications taken, participant asked "Are you sure you took no medications over the last 30 days?"
- Records only medications used in the past 30 days
- Properly records name of medication
- Properly records route of administration of medication, if route is not oral
- Correctly enters appropriate formulation code
- Correctly codes duration of use
- Correctly codes "as needed" and "regular"
- Correctly completes form
- Reviews form for completeness

2. Vitamin E and C**Medication Use Interview**

54 Not counting multi-vitamins, are you currently taking any of the following specific vitamins every day or almost every day?

a) Vitamin E

Yes →

No

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

- Less than 100 IU
- 100 to 250 IU
- 300 to 500 IU
- 800 IU or more
- Don't know

b) Vitamin C

Yes →

No

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

- Less than 400 mg
- 400 to 700 mg
- 750 to 1,250 mg
- 1,300 mg or more
- Don't know

4. MIF



6949

**Medication Inventory
Form**

MOST ID #	Acrostic
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<i>Office Use Only</i>	



57) Did the participant bring in or identify ALL prescription and over-the-counter medications that they took during the last 30 days?

All
 Some
 None
 Took None

Total number recorded: medications
 Arrange for telephone call to complete MIF

PRESCRIPTION AND OVER-THE-COUNTER MEDICATIONS

Record the name of the prescription or non-prescription medicine and duration of use. Mark whether or not it is a prescription drug.

Page of

Med # Name:

Duration of use: < 1 month 1 month to < 1 year 1 to < 3 years 3 to < 5 years ≥ 5 years Don't know

Med code: Prescription? Yes No Frequency? Int Reg

Med # Name:

Duration of use: < 1 month 1 month to < 1 year 1 to < 3 years 3 to < 5 years ≥ 5 years Don't know

Med code: Prescription? Yes No Frequency? Int Reg

Med # Name:

Duration of use: < 1 month 1 month to < 1 year 1 to < 3 years 3 to < 5 years ≥ 5 years Don't know

Med code: Prescription? Yes No Frequency? Int Reg

Med # Name:

Duration of use: < 1 month 1 month to < 1 year 1 to < 3 years 3 to < 5 years ≥ 5 years Don't know

Med code: Prescription? Yes No Frequency? Int Reg



Appendix 2 15-Month Medication Assessment

1. Vitamin E and C

Medication Use Interview

1. Not counting multi-vitamins, are you currently taking any of the following specific vitamins every day or almost every day?

a. Vitamin E

Yes No Don't know/Refused

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

- Less than 100 IU
 100 to 250 IU
 300 to 500 IU
 600 IU or more
 Don't know

b. Vitamin C

Yes No Don't know/Refused

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

- Less than 400 mg
 400 to 700 mg
 750 to 1,250 mg
 1,300 mg or more
 Don't know

Appendix 3 30-Month Medication Assessment

1. Arthritis medications – Self-Administered Questionnaire - Home

Arthritis Medications

4. Are you taking any of the following medications for joint pain or arthritis?

- ◆ Aspirin
- ◆ Advil or Motrin (Ibuprofen)
- ◆ Aleve or Naprosyn (Naproxen)
- ◆ Celebrex (Celecoxib)
- ◆ Tylenol (Acetaminophen)

Others:

- ◆ Arthrotec (Diclofenac with misoprostol)
- ◆ Cataflam (Diclofenac)
- ◆ Indocin (Indomethacin)
- ◆ Lodine (Etodolac)
- ◆ Mobic (Meloxicam)
- ◆ Orudis (Ketoprofen)
- ◆ Relafen (Nabumetone)
- ◆ Voltaren (Diclofenac)

Yes

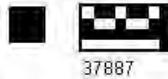
No

Don't know

Go to Page 5, Question #5.

a. How often do you take any of these medications?

- More than once a day
 - Once a day
 - Three to five times a week
 - Once or twice a week
 - Less than once a week
-



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Arthritis Medications

5. Are you taking any of the following stronger medications for joint pain or arthritis?

- ◆ Darvocet-N (Propoxyphene with acetaminophen)
- ◆ Duragesic (Fentanyl)
- ◆ Endocet (Oxycodone with acetaminophen)
- ◆ Lorcet (Hydrocodone with acetaminophen)
- ◆ MS Contin (Morphine sulfate)
- ◆ Norco (Hydrocodone with acetaminophen)
- ◆ OxyContin (Oxycodone)
- ◆ Percocet (Oxycodone with acetaminophen)
- ◆ Tylenol with codeine (Acetaminophen with codeine)
- ◆ Ultracet (Tramadol with acetaminophen)
- ◆ Ultram (Tramadol)
- ◆ Vicodin (Hydrocodone with acetaminophen)
- ◆ Vicoprofen (Hydrocodone with ibuprofen)

Yes

No

Don't know

Go to Page 6, Question #6.

a. How often do you take any of these medications?

- More than once a day
- Once a day
- Three to five times a week
- Once or twice a week
- Less than once a week

◆ Page 5 ◆

MOST Second Follow-up
Self-Administered Questionnaire - Home
KG

37887



2. Bisphosphonates

Medication History

21. Since your first visit to the MOST clinic, 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), ibandronate (Boniva), Pamidronate (Aredia), or tiludronate (Skelid).

(Examiner Note: Refer to Card #2 for pronunciation. Do Not Show Card to participants.)

Yes No Don't know/Refused

↓ ↓ ↓

21a. For how many years did you take bisphosphonates?
If you are unsure, please make your best guess.

years

**(Examiner Note:
Round up year at 6 months.
<6 months=0 years,
and 6-12 months=1 year.)**

3. Knee injections and male hormone

Medication History

Now think about the last 6 months.

- 22.** 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

<p>22a. During the past 6 months, have you had an injection of hyaluronic acid (Synvisc[®] or Hyalgan[®]) in either of your knees for treatment of your arthritis? These injections are given as a series of 3 to 5 weekly injections.</p> <p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know</p>
<p>i. In which knee?</p> <p><input type="radio"/> Right knee <input type="radio"/> Left knee <input type="radio"/> Both knees <input type="radio"/> Don't know</p>
<p>22b. During the past 6 months, have you had an injection of steroids (cortisone, corticosteroids) in either of your knees for treatment of your arthritis?</p> <p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know</p>
<p>i. In which knee?</p> <p><input type="radio"/> Right knee <input type="radio"/> Left knee <input type="radio"/> Both knees <input type="radio"/> Don't know</p>

(Male participants only. Female participants: Skip to Question #24)

- 23.** During the past 6 months, have you taken male hormone or testosterone, which is given by injection, patch, or rubbed on your skin?

Yes No Don't know/Refused

<p>23a. When was the last time you had an injection, put on a patch, or rubbed this hormone on your skin? If you are unsure, please make your best guess. (Examiner Note: Read response options.)</p> <p><input type="radio"/> Less than 1 month ago</p> <p><input type="radio"/> 1 to 2 months ago</p> <p><input type="radio"/> 3 to 6 months ago</p> <p><input type="radio"/> Don't know</p>
--

4. Women only – Tamoxifen, Raloxifene, Toremifene**Medication History**

Female participants only. Male participants: Skip to Question #31.

Now think about the past year.

- 24.** During the past year have you taken Tamoxifen (also called Novadex), Raloxifene (also called Evista), or Toremifene (also called Fareston) to treat or prevent breast or ovarian cancer?

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: REQUIRED: Read response options. Show Card #3.)

Less than 1 month ago

1 to 2 months ago

3 to 6 months ago

More than 6 months ago

Don't know

5. Vitamin E and C

- 31.** Not counting multi-vitamins, are you currently taking any of the following specific vitamins every day or almost every day?

31a. Vitamin E

Yes No Don't know/Refused

↓

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

- Less than 100 IU
- 100 to 250 IU
- 300 to 500 IU
- 600 IU or more
- Don't know

31b. Vitamin C

Yes No Don't know/Refused

↓

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

- Less than 400 mg
- 400 to 700 mg
- 750 to 1,250 mg
- 1,300 mg or more
- Don't know

6. MIF

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MOST ID #	Active
<input type="text"/>	<input type="text"/>



Medication Inventory Form

32. Did the participant bring in or identify ALL prescription and over-the-counter medications, supplements, and vitamins that they took during the last 30 days? (*Examiner Note: REQUIRED: Show Card #4 when asking about duration of use.*)

All
 Some
 None
 Took None

Total number recorded: medications
 Arrange for telephone call to complete MIF

PRESCRIPTION AND OVER-THE-COUNTER MEDICATIONS

Record the name of the prescription or non-prescription medicine, frequency of use, and formulation code. Mark whether or not it is a prescription drug.

Med # Formulation code:

Name:

Duration of use: < 1 month
 1 month to < 1 year
 1 to < 3 years
 3 to < 5 years
 ≥ 5 years
 Don't know

Prescription? Yes No
Frequency? As Needed Reg

Med # Formulation code:

Name:

Duration of use: < 1 month
 1 month to < 1 year
 1 to < 3 years
 3 to < 5 years
 ≥ 5 years
 Don't know

Prescription? Yes No
Frequency? As Needed Reg

Med # Formulation code:

Name:

Duration of use: < 1 month
 1 month to < 1 year
 1 to < 3 years
 3 to < 5 years
 ≥ 5 years
 Don't know

Prescription? Yes No
Frequency? As Needed Reg

Med # Formulation code:

Name:

Duration of use: < 1 month
 1 month to < 1 year
 1 to < 3 years
 3 to < 5 years
 ≥ 5 years
 Don't know

Prescription? Yes No
Frequency? As Needed Reg

Formulation Codes:

1=oral tablet or capsule; 2=oral liquid; 3=topical liquid, lotion, or ointment; 4=ophthalmic; 5=rectal or vaginal; 6=inhaled; 7=injectable; 8=transdermal patch; 9=powder; 10=nasal