

**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 (MIF) the use of all prescription medications taken during the 30 days before the follow-up visit and all prescription medications listed on MIF Response Card #3 (Appendix 2) that were taken within the past 12 months 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)
- 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 (or identify) 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 plus the number of prescription medications listed on MIF Response Card #3 that were taken within the last 12 months, and transcribe the names.

- The examiner will have the list of prescription medications that the participant reported using at the previous clinic visit (when applicable) available on the Data from Prior Visits Report (DPV).
- 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. The formulation codes are displayed in the drop down menu 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 and/or if they were not able to adequately review and recall whether or not they took any medications listed on MIF Response Card #3 during the last 12 months, arrange for a telephone call to complete the MIF.
  - In the form, identify the number of prescription medications taken by the participant during the last 30 days, the number of prescription medications taken on MIF Response Card #3 during the last 12 months (show participant MIF Response Card #3), and the number of prescription medications you will inventory during the clinic visit interview (could be less). Make a note in the participant's chart that the participant should be called in order to complete the MIF.
  - The next contact to complete the MIF should be recorded as a repeat contact. The MIF can be submitted more than one time if needed. Do not report the same medications on the repeat form, only report the new medications on the repeat form.
- The maximum number of medications that can be entered on 1 form is 20. If the participant brought more than 20 medications, open another MIF in REDCap and mark the additional form as "Repeat exam 1."

### 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 and all prescription medications listed on MIF Response Card #3 that were taken within the last 12 months 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 (and 12 months for the prescription medications on MIF Response Card #3) prior to the visit. Prescription medications may include pills or tablets, solutions, creams/salves, gels, dermal patches, inhalers, powders, eye-drops, sprays, IUDs, implants, and injections (intravenous (IV), intramuscular (IM), or subcutaneous (SC) administration).

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

### 3.2.1 Bisphosphonate use

Script: “Have you ever / Since we spoke to you on < insert month and year> have you taken a bisphosphonate medication or injection to treat or prevent osteoporosis or to treat Paget's disease? This includes the following medications: alendronate (Fosamax), risedronate (Actonel/Atelvia), ibandronate (Boniva), or zoledronate/zoledronic acid (Reclast/Zometa).”

Interviewer note: Review Data from Prior Visits Report for previously reported bisphosphonate medication for the existing cohort. Refer to Appendix 1 for medication pronunciation. Show appropriate response card to the participant.

If “Yes:”

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

Interviewer note: Round up year at 6 months. <6 months=0 years, and 6-12 months=1 year. Record the number of years. For existing cohort 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.

### 3.2.2 Knee injections

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:”

Script: “During the past 6 months, have you had an injection of hyaluronic acid (such as, 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.”

Show appropriate response card to participant.

If “Yes:”

Script: “In which knee?”

Mark appropriate side.

Script: “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:”

Script: “In which knee?”

Mark appropriate side.

### 3.2.3 Female-only items

The following question is for female participants only. (If the participant is male, these questions will not be on display in the REDCap data collection form.)

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?”

Show appropriate response card to participant. Refer to Appendix 1 for medication pronunciation.

If “Yes:”

Script: “When was the last time you took this? If you are unsure, please make your best guess.”

Show appropriate response card. The options are: less than 1 months ago; 1 to 2 months ago; 3 to 6 months ago; more than 6 months ago. Mark appropriate option.

### 3.2.4 Vitamin D use

Script: “Not counting multiple vitamins, are you currently taking Vitamin D alone or combined with calcium and/or magnesium?”

If “Yes:”

Script: “What is the total dose per day you take most of the time?”

The options are: 100 IU; 200 to 300 IU; 400 to 800 IU; 1000 IU; 2000 or more IU. Mark appropriate option.

### 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.

Show to and review MIF Response Card #3 with the participant so they can identify if they took any of the prescription medications listed during the last 12 months.

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

- Choose the “**All**” option if all prescription medications taken in the last 30 days and all prescription medications listed on MIF Response Card #3 and taken during the last 12 months were brought in to clinic or identified.
- Choose the “**Some**” option if one or more medications were not brought in, and one or more medications were brought in and unidentified. **When a participant forgets to bring in or identify one or more medications that they have taken in the last 30 days (and 12 months for medications listed on MIF Response Card #3), 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.** Complete and submit the MIF for all available medications. 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, schedule the phone contact.
- Choose the “**None**” option if the participant took medications but did not bring these with them to the clinic visit and/or is not sure whether they took medications listed on MIF Response Card #3 during the last 12 months. 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.

- Choose the “**Took None**” option if the participant took no prescription medications in the past 30 days and no prescription medications listed on MIF Response Card #3 during the past 12 months. 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?"

Show the participant MIF Response Card #3 if it has not been reviewed yet.

Script: "Did you take any of these prescription medications during the last 12 months?"

Record the number of prescription medications the participant has taken over the past 30 days plus the number of prescription medications listed on MIF Response Card #3 the participant has taken during the past 12 months. Then record the number of prescription medications that will be entered on the MIF (i.e., the participant brought in either the medication bottle, provided a medication list, and/or identified the medication on MIF Response Card #3). If the participant took more prescription medications than they are able to provide information about, a follow-up call should be arranged to so that remaining medication information can be captured.

Up to 20 medications can be entered on the MIF. In the rare occasions when there are more than 20 medications to be inventoried complete the initial MIF, and then open an MIF floating form in REDCap. Mark the “Repeat exam 1” option on the MIF floating form, and then enter the additional medications. If there are more medications than can be included on the first MIF repeat form, use an additional MIF floating form and mark the “Repeat exam 2” option. The MIF floating form can be used up to 3 times for repeats (repeat exam 1, repeat exam 2, repeat exam 3). Up to 80 medications can be captured using the MIF and MIF floating forms.

### 3.4 Recording prescription medication

Record only medications that the participant reports that they took in the 30 days and medications listed on MIF Response Card #3 that were taken within the 12 months prior to the clinic visit. Medications administered in the previous 30 days (and 12 months) during surgery or hospitalization will not be recorded on the MIF unless they were continued after discharge. Medications that were prescribed but not taken are not recorded.

Type the name directly onto the MIF from the medication container. Record the complete drug name exactly as written on the container, do not abbreviate. 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.

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.”

Blinded medications that are taken due to participation in a clinical trial will not be collected.

With the development of the MIF in REDCap at the 144-month follow-up clinic visit, it is no longer necessary to abbreviate medication names due to space limitations. However, the examples below are acceptable abbreviations that may be used on the MIF:

- **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”)

Also record the appropriate formulation code for each medication on the MIF (see section 3 for the formulation codes).



#### 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.

#### 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. For most medications, 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 to < 10 years' response option should be chosen from drop down list.

Some of the prescription medications listed on MIF Response Card #3 are taken infrequently and participants may not have taken the medication in the past 30 days. A participant may take a medication listed on MIF Response Card #3 every 6 months and has done so for 3 years; regardless of whether they have taken it within the past 30 days, the '3 to <5 years' response option should be chosen.

#### 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. 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. Some of the medications listed on MIF Response Card #3 are taken infrequently (e.g., every 6 months, once a year, etc.), but on a predetermined scheduled. Any medication that the participant takes on a regular basis as part of a predetermined schedule should be recorded as 'Regularly.' Daily use is not the only use that should be recorded as regular.

## 7. Quality assurance

### Training

- Read and study manual
- Attend MOST training session on techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

### 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 (or identified) all prescription medications taken in the last 30 days
- Participant asked if they have taken any prescription medications on MIF Response Card #3 during the last 12 months
- 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?" and "Have you taken any of these prescription medications during the last 12 months" while showing the participant MIF Response card #3 if the card has not already been reviewed
- Records only prescription medications used in the past 30 days and prescription medications listed on MIF Response Card #3 that were taken within the past 12 months
- 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

## 8. Data collection forms

Please see the Overview of the 144-month Follow-up Visit Operations Manual for an overview of the data collection forms, information on whether each form is in REDCap or TELEForm, and where the forms can be accessed on the study website.

**Appendix 1 Medication Pronunciation Guide**Bisphosphonate medications

Alendronate	a-LEN-droh-nate
Fosamax	FAH-SUH-MAX
Risedronate	ris-ED-roe-nate
Actonel	AK-ton-ell
Ibandronate	ih-BAN-dro-nate
Zoledronate	zoh-LED-droh-nate
Zoledronic acid	ZOE-le-DRON-ik AS-id
Reclast	REE-classt
Zometa	zoh-MAY-tuh

Breast and/or ovarian cancer medications

Tamoxifen	tuh-MOX-uh-fin
Nolvadex	NOHL-VUH-DECKS
Raloxifene	ruh-LOCKS-uh-feen
Evista	uh-VISS-tuh
Toremifene	tor-EM-eh-feen
Fareston	fuh-RES-tin
Anastrozole	an-ASS-troe-zole
Arimidex	uh-RIM-ih-decks
Exemestane	ex-e-MES-tane
Aromasin	uh-ROE-mu-sin
Letrozole	LET-roe-zole
Femara	fuh-MAR-uh

**Appendix 2 Medications to include on MIF if taken in past 12 months; these medications are listed on MIF Response Card #3**

Medication	Brand Name
<b>Ibandronate</b> <i>(Injection every 3 months)</i>	<b>Boniva<sup>®</sup></b>
<b>Teriparatide</b> <i>(Injection once daily)</i>	<b>Forteo<sup>™</sup></b>
<b>Denosumab</b> <i>(Injection every 6 months)</i>	<b>Prolia<sup>™</sup></b>
<b>Zoledronic Acid</b> <i>(Infusion once a year)</i>	<b>Reclast<sup>™</sup> / Zometa<sup>®</sup></b>
<b>Pamidronate</b> <i>(Injection)</i>	<b>Aredia<sup>®</sup></b>
<b>Estrogen Replacement Therapy (ERT)</b> <i>(Patch, tablets, creams, vaginal rings, gels, or sprays)</i>	-----
<b>Hormone Replacement Therapy (HRT) / Hormone Therapy (HT)</b> <i>(Patch, tablets, creams, IUDs, vaginal rings, gels or injection [rarely])</i>	-----
<b>Testosterone Replacement Therapy (TRT)</b> <i>(Patch, tablets, gels, injection, or implant)</i>	-----
PCSK9 Inhibitors (to lower LDL cholesterol): <b>Alirocumab or Evolocumab</b> <i>(Injection every 2 weeks)</i>	<b>Praluent<sup>®</sup> / Repatha<sup>™</sup></b>