

STUDY OF OSTEOPOROTIC FRACTURES (V4)

Protocol for Medication Inventory Form (MIF)

1. Introduction

During Visit 4 a complete and accurate list of current medication will be obtained for each participant. We are specifically interested in how individual medications are actually taken rather than how they are prescribed or intended to be taken. The participant will be instructed to bring all prescription and non-prescription medications used within the preceding four weeks (30 days) with them to the visit. The clinic staff person will review all medications and transcribe the name and current dose from the container to the MIF. The participant will then be asked how often the medication is taken, and what is the reason for use.

For the purposes of this visit, use the following definition guidelines:

- 1) "Current use." All medication taken within the four week period (30 days) prior to the visit.
- 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 four weeks prior to the visit. Prescription medication may include eye drops, pills or tablets, solutions, creams/salves, dermal patches, and injections.
- 3) "Non-prescription medication." A medication, vitamin, or dietary supplement that may be purchased without a physician's prescription.

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, calcium supplements, and bulk laxatives.

2. Procedure

A. Medication Reception (section A of MIF)

Using the script found in section A of the MIF, fill in the appropriate box.

- "Yes" box, if all medication brought in to clinic. Proceed to section B of MIF.
- "No" box, if one or more medications were not brought in. When a participant forgets to bring in one or more medications, each site is responsible for developing a mechanism to gather the information via telephone or return visit. We recommend calling the women 1-2 days after the visit to obtain the missing information.

- Took no medication. Self explanatory but ask "Are you sure you took no prescription or non-prescription medications over the last four weeks?"
- Refused. Record reason for refusal.

B. Prescription Medications (section B of MIF)

In this section record the use of prescription medications only.

a. Medication name

Record only medications used within four weeks (30 days) of the visit. Medications which were prescribed but not taken, or those taken greater than four weeks ago, are not recorded.

Print the name of each medication using capital letters onto the MIF. Either the generic or trade name may be recorded.

Some combination medications contain two or more drugs in a single pill or tablet, and if present on the label the trade name should be recorded (for example, Dyazide is a combination of hydrochlorothiazide and triamterene). If a trade name is not present, record the components of the medication separated by a slash (for example, hydrochlorothiazide/triamterene). Suppositories should include the word "suppository" in the name (for example "phenergan suppository").

If additional space is needed to record more than 15 medications, mark the box at the end of section B, and use the Supplemental MIF form.

b. Strength

Most preparations will be in milligram (mg), and these should be recorded without units. Fractions of a milligram can be recorded by a decimal fraction (for example two and one half mg would be 2.5).

When strength is not in milligrams, record the strength followed by the unit on the bottle. For example, a potassium supplement may be in milliequivalents and would be recorded as 8 mEq. Use the following abbreviations:

<u>Medication Units</u>	<u>MIF Abbreviation</u>
•milliliter	ml
•milliequivalents	mEq
•milligram per milliliter	mg/ml
•milliequivalent per milliliter	mEq/ml
•microgram	mcg
•percent	%
•units	u

Some compound medications are only available in a single dose combination, such as Dyazide, and the strength will not be indicated on the label. In these instances, place a line or slash through the strength box. Other compound medications are available in several strengths, and if the dose of individual components are listed, they should each be recorded on the MIF separated by a slash.

For example, Inderide is a combination of propranolol and hydrochlorothiazide, and comes in several strengths. If the bottle listed Inderide 80/25, then 80/25 should be recorded in the strength box. Follow the same order as listed in the name box, so that a generic combination of 25 mg of hydrochlorothiazide and 50 mg of triamterene would be listed as "hydrochlorothiazide/triamterene" under name, and "25/50" under strength.

The strength of certain types of medications must be coded in a specific way:

- The strength of solutions are frequently in percent, or mg/ml, and the strength should be recorded with the appropriate units.
- For inhalers, strength is not applicable and place a line or slash through the strength box.

c. Number taken

Ask the participant how the medication was taken over the last four weeks. Record the total number of pills or dose taken for the time period. This may differ from the number prescribed.

Circle the appropriate letter to indicate whether the dose recorded was taken per day (D), week (W), or month (M). For example, "Take three pills four times a day" would be coded as 12 with D circled.

When instructions state "take as directed" or include a range (for example, "take 1-2 pills 3-4 times a day"), ask the participant the usual number taken in the last four weeks.

Other special circumstances include:

- Complex instructions- Record the average, for example "I take one pill every other day" would be coded as "0.5" per day, and "I take 1 pill every other day, alternating with 2 pills every other day" would be code as "1.5" per day.
- Solutions- Record the total number of milliliters taken per day, week, or month, and include the units as "ml." in the number taken box. All solutions must have "ml" included in the number taken box. Use the following conversions:

1 teaspoon	=	5 ml
1 tablespoon	=	15 ml
1 ounce	=	30 ml

For example, two tablespoons of a 10% potassium chloride solution (KCl) taken twice a day would be coded as "10%" under strength, and "60 ml" per day under number taken.

- Eye drops- code as any other solution, except that the number taken refers to the total number of drops used per day, week, or month. For instance if a women uses 4 drops a day in each eye of Timoptic 0.5%, it would be coded as "timoptic" under name, "0.5%" under strength, and "8 per day" under number taken.

- Inhalers- Record the total number of sprays or puffs used per day, week, or month.
- Creams, lotions- Record the total number of applications used per day, week, or month.
- Patches- Record the total number to be applied to the skin per day, week, or month.
- Powders- Record the name and strength (if appropriate) of the powdered medication, and record the total number of tablespoons used per day week or month. For example, if a participant uses 2 tablespoons per day of metamucil, it would be coded as "metamucil" under name, "2 per day" under number taken, with a slash through the strength box (as it does not apply). A woman who takes "two scoops a day" of Questran, a powdered lipid lowering drug, would have this coded as "questran" under name, "4 per day" under number taken (as the "scoop" provided with the medication is approximately two tablespoons).

d Reason for Use

Each current medication listed on the MIF must have a primary reason for use. Limit the reason for use to a single primary indication, and use the best medical indication offered by the participant. For example, if told that a medication was taken for "high blood pressure" record "high blood pressure" or "hypertension" after "reason for use." Attempt to record a medical diagnosis or condition and not simply an organ or organ system (use "chest pain" or "angina" rather than "for my heart"). Unless a more specific indication is volunteered by the participant, use "supplement" as the reason for use for vitamins, minerals, and herbal supplements.

e PRN medications (taken as needed)

Indicate whether the medication is taken on an "as needed" basis by marking yes or no in the PRN column. The strength and number taken should be completed as above for all medications taken PRN. "As needed" is not the same as "As directed." PRN is generally used for allergy, pain, or sleep medications.

When it is not possible to code the name, strength, or number prescribed for a prescription medication, write a "*" in the relevant space and explain in comments. In your comments, note the Section of the form and medication number in that section to which you are referring.

C. Non-prescription medications (section C of MIF)

This section uses the same format as the section on prescription medications.

a Medication name

Record only non-prescription medications used within four weeks (30 days) of the visit. Do not record the brand names unless it specifically describes the medication.

For example, it is acceptable to transcribe "Ex-lax" as that name specifically identifies that medication, but "Healthrite Vitamin C" should be coded at "vitamin C."

If additional space is required, mark the box at the end of Section C, and use the Supplemental MIF Form.

Certain groups of non-prescription medications may be coded without specific drug or compound name, such as:

- 1) Code multiple vitamins as "multivitamins". Any vitamin preparation with 3 or more types of vitamins should be considered a multiple vitamin. Those with additional components, such as extra calcium or extra iron, should be coded as "multivitamin/calcium" or "multivitamin/iron". Preparations with just two components (for example, one vitamin and one mineral, or two different vitamins) should be coded as combination medications, including strength. Preparations with three components should list the components but the strengths do not need to be coded.

It is not necessary to record a strength for multivitamins, even if they contain extra calcium or iron, simply place a slash through the "strength" box. Some vitamin preparations will not be easily coded, and those can be transcribed with the brand name or specific name on the label.

Examples: "Target Multiple Vitamins with B6" would be coded "multivitamins/B6," with a slash through the strength box. A combination preparation of 250 mg of calcium and 125 units of vitamin D ("Shakelee Calcium plus D") would be coded "calcium/vitamin D" with "250/125U" in the strength box.

- 2) If a cold medication is a well known national brand, such as "Actifed," the trade name may be used and the appropriate strength recorded. Other cold preparations, such as "Walgreen's Cold Medication," may be coded as "cold remedy" or "antihistamine/decongestant." Place a slash through the strength box if "cold remedy" or "antihistamine/decongestant" codes are used.
- 3) If an allergy medication is a well known national brand, such as "Allerest," the trade name may be used and the appropriate strength recorded. Other allergy preparations, may be coded as "allergy medication" or "antihistamine/decongestant." Place a slash through the strength box if "allergy medication" or "antihistamine/decongestant" codes are used.
- 4) Herbal medications, such as garlic capsules, brewer's yeast, root extracts, wheat germ, and pectins may be coded as "herbal preparations"
- 5) All oral laxatives (such as Ex-lax, Milk of Magnesia) may be coded with the trade name or simply as "laxative." If a medication is coded as "laxative", place a slash through the strength box, and record the number taken per day, week or month.

b Strength

Record strength as indicated on label. If a strength is not available or applicable, place a slash through the strength box.

c. Number taken

Follow instructions as given for prescription medications.

d. PRN medications

Indicate whether the non-prescription medication is usually taken on an "as needed" basis by marking the yes or no box in the PRN column.

When it is not possible to code the name, strength, or number prescribed for a non-prescription medication, write a "*" in the relevant space and explain in comments. In your comments, note the Section of the form and medication number in that section to which you are referring.