

Medications

STUDY OF OSTEOPOROTIC FRACTURES (V5)

Vitamin and Supplement Question

1. Description:

This question was designed by Gladys Block, PhD of the University of California at Berkeley. The question targets key vitamin, mineral, and supplement usage, determining dose and frequency and duration of use. While originally designed for a self-report questionnaire, we have modified it somewhat to be used in an interview format.

2. Collection

Each participant was asked to bring all prescription and non-prescription medications that they have taken in the past 30 days with them to their clinic visit. Use the medication bottles the participant brought in to help you completing this question. *For any vitamins and supplements listed in the question that the participant has not brought in, ask her if she has taken any of that specific type on a regular basis (at least once per week) in the last year.*

For each vitamin and supplement that the participant takes, ask her how often she takes it (and how many each time) and ask her how long she has been taking it. Fill in the appropriate categories on the form.

In addition, we want to know if the participant's multivitamin contains minerals or not (check appropriate box on form) and if she takes Vitamin C or E, how many pills per day does she take and what are the dosages of those pills. If the correct answers can't be determined from the medication bottles, ask the participant.

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Protocol for Medication Inventory Form (MIF)

1. Introduction

During Visit 5, we will follow a similar protocol to visit 4 using the Medication Inventory Form to collect a complete and accurate list of current prescription medications for each participant. However, in contrast to Visit 4, we will only be collecting information on select over the counter medications at Visit 5. We are still specifically interested in how individual medications are actually taken rather than how they are prescribed or intended to be taken.

New at Visit 5, we will collect the number of years that a participant has taken a given medication.

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, verifying the name, dose, how the medication is taken for old medications, as well as adding any new medications.

Prior to the participant's visit, print out a report of all medications (prescription and non-prescription) that she reported taking during Visit 4. This report is part of your Visit 5 system.

Prescription medications:

- Old medications: Using the participant's Visit 4 report as a guide, verify the status and how the medication is taken for all prescription meds. Changes in dosage and how the medication is taken should be recorded directly on the form in the spaces provided. We will not be tracking changes in the reason why a particular medication is taken. If the participant no longer takes a specific medication, then mark the appropriate box on the form/report. Also, ask the participant the number of years that she has taken that specific medication. Record to the nearest half year.

- New Medications: Any new prescription medications that the participant has started taking since her previous visit should be added. This information will be recorded on the same MIF forms as used at Visit 4. Complete all information including reason for use.

Over-the-counter medications:

- Arthritis and pain medications: The over-the-counter medications that we are interested in are listed in Appendix 1, at the end of this medication protocol. These are primarily arthritis and pain medications.

- Vitamins and supplements: At Visit 5, we are primarily interested in only certain vitamins and supplements. These are listed in Appendix 2, at the end of this protocol.

For those over-the-counter medications that we are not specifically interested in at Visit 5, check the box "Not collected at Visit 5". If you are in doubt as to whether or not we care about a particular medication, go ahead and collect the information.

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. For the MIF, we are only collecting information on the non-prescription medications listed in Appendix 1. However, select vitamin and supplement information is collected as part of the clinic interview as its own specific question.

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.
- "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.
- If the participant did not bring in any Tums or calcium supplements, ask her "Do you take TUMS or any other type of calcium supplement regularly?" If she responds positively, then set up a time to call her at home to collect this information.

Medication Review

Using the participant's Visit 4 MIF report, update prescription and select non-prescription medications following the guidelines outlined below.

B. Prescription Medications

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.

Old medications: Verify the correct name, dosage, and how the medication is taken. If there are changes to be made, check the appropriate box, and record the changes in the spaces provided. Ask the participant how many years she has been taking the medication. Record this in the space provided. If the participant no longer takes a certain medication, check the appropriate box. Proceed to next medication.

New medications: Print the name of each new prescription 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").

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 new, 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").

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

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

a Medication name

Old non-prescription medications: Verify that the medication is on our target lists, Appendices 1 and 2. If it is, then verify with the participant that the name, dose, and how it is taken is still correct. Record any changes in the spaces on the form. Record the number of years the participant has taken the medication to the nearest half year. If they say, on and off for the past 2.5 years, then code this as 2.5 years.

If they are no longer taking a specific medication, check the appropriate box. If the medication is one that we are no longer interested in, then check the box for "not collecting at Visit 5".

New non-prescription medications: If a participant has started taking any of the medications listed in Appendix 1 or 2, then add these to her MIF report / form.

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. Try to use the names listed in the Appendix whenever possible.

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.

MIF Appendix 1: Non-prescription aspirin and NSAID compounds**Aspirin Compounds**

Alka-seltzer (several types)	Momentum Muscular Backache Formula
Anacin Caplets & Tablets	Norwich Extra-Strength Aspirin
Anodynos Tablets	Pain Reliever Tablets
Arthritis Pain Formula (Anacin)	Pepto-bismol
Arthritis Strength BC Powder	Presalin
Arthropan	Salatin
A.S.A. Enseals	Saleto Tablets
Ascriptin Tablets/Caplets	Sine-Off Sinus Medicine Tablets - Aspirin Formula
Aspergum	St. Joseph Adult Chewable Aspirin
BC Powder	Supac
Bayer	Synalgos Capsules
Bufferin	Therapy Bayer Aspirin Caplets
Buffets II	Tri-buffered Bufferin
Buffex	Tri-Pain Tablets
Cama Arthritis Pain Reliever	Trigesic
Cope Tablets	Uracel
Dasin Capsules	Ursinus Inlay-Tabs
Duradyne Tablets	Valesin
Easprin	Vanquish Analgesic Caplets
Ecotrin Enteric Coated Aspirin	Verin
Empirin Aspirin	Wesprin Buffered
Epromate Tablets	Zorprin
Excedrin	
4-Way Cold Tablets	
Gelpirin	
Gemnisyn	
Genprin	
Halfprin	
Magnaprin	
Measurin	
Meprobamate and Aspirin Tablets	
Midol	

**Non-steroidal anti-inflammatory
compounds (NSAIDS)**

Aches-N-Pain
Advil Ibuprofen Caplets & Tablets
Aleve
CoAdvil
Dinetapp sinus
Excedrin IB caplets/tablets
Genpril
Haltran Tablets
Ibu-tab
Ibuprin

Ibuprofen Tablets
Ibuprofen Caplets
Ibuprohm
Medipren Ibuprofen Caplets &
Tablets
Menadol
Midol 200 Advanced Pain Formula
Motrin IB Caplets and Tablets
Nuprin Ibuprofen/Analgesic Tablets
and Caplets
Pamprin-IB
Saleto-200
Trendar Ibuprofen Tablets

MIF Appendix 2: Vitamins and Supplements for Visit 5

Multiple Vitamins - any type
Vitamin A (not beta-carotene)
Beta-carotene
Vitamin C
Vitamin D
Vitamin E
Calcium supplements
TUMS
Iron supplements
Zinc supplements
Selenium supplements