

3.4.5 Medications

I. BACKGROUND AND RATIONALE

1. The Medications Form is designed to enable collection of data on participants' use of all types of medications, both prescription and non-prescription, including supplements. Information about participants' use of medications is collected at the initial (baseline) clinic visit and at follow-up visits. The participant is asked to bring to the clinic containers for all medications used during the two weeks prior to the visit. The interviewer then transcribes the name of each medication, its strength, and for prescription medications, frequency of administration from the containers onto the data collection form. As the information is transcribed, the interviewer queries the participant about actual usage of each medication.
2. Collecting this information will allow us to describe medication use and any changing patterns of use over time, and may help us ascertain the effect of medications on the progression of atherosclerosis in this study population. It will be important to know what medications each participant is taking, in order to assess and perhaps attempt to explain subsequent participant events and any change in the degree of disease detected at follow-up visits.

II. MATERIALS AND EQUIPMENT

Current version of the Physician's Desk Reference (PDR)

Printed list of participant's previous medications, collected at most recent prior visit.

III. DEFINITIONS

1. Time frame: All prescription and over-the-counter medications and supplements used during the *two weeks prior* to the clinic visit should be included.
2. Prescription medication: Medication for which a prescription was written by a physician or physician assistant and dispensed by a pharmacist or a physician.
3. Non-prescription or over-the-counter medication: Medication or supplements purchased without a prescription.
4. It should be noted that occasionally a physician would write a prescription for a non-prescription medication. In that case, the medication should be recorded as prescription. If, however, the physician *recommends* a medication, rather than actually writing a prescription for it, it should be recorded as non-prescription.

IV. METHODS

This is an **interviewer-administered questionnaire**. Questions should be read to the participant verbatim as they appear on the form to ensure standardization. In addition, any introductory and transitional wording should be read verbatim.

1. Obtaining medication containers. A letter is sent to the participant before the clinic visit that includes instructions regarding medication containers. The participant is asked to bring to the clinic containers for all supplements, prescription, non-prescription medications and herbal medicines taken during the two weeks prior to the clinic visit.

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2. Medication use interview. Prior to beginning the interview, place all medications in front of the participant. You will have a list of medications the participant reported at the previous exam. Check each medication brought in by the participant against this list. For each one that appears on the list, check the “Keep?” box at the left of that particular medication. ***IMPORTANT NOTE: You can only mark a medication to keep if the name and strength are identical to what appears on the list.*** Any other medications must be recorded as new medications, either in the spaces provided at the bottom of the list or on the standard Medications form.

When asking the participant about a particular medication, show the container to the participant, keeping the other medications in view. Always conclude the interview by asking the participant if any other medications have been taken during the previous two weeks. If the participant remembers other medications, record the name, strength and frequency administered for each one in as much detail as possible. *If you are unsure about the accuracy of the participant’s responses, schedule a telephone interview to verify the prescription label information.* At the end of the visit, make sure to return all medications and other personal belongings to the participant. Guidelines for completing the Medications Form follow:

Section A. Medication Reception

As you know, the Multi-Ethnic Study of Atherosclerosis will be describing all medication its participants are using, both prescription and over-the-counter. These include pills, liquid medications, skin patches, eye drops, creams, salves, inhalers (puffers), and injections, as well as cold or allergy medications, vitamins, herbal remedies, and other supplements. The letter you received about this appointment included a plastic medications bag for all your current medications and asked you to bring them to the clinic. Have you brought this bag with you? Are these all the medications that you have taken in the past two weeks?

If “yes”, ask to see the medications and record the information in the boxes in Section B of the form or in the appropriate area at the bottom of the list.

If “no”, make arrangements to obtain medications at another time but record any available information as described above as best possible by interviewing the participant for the information.

If “refused”, record reason for refusal in Comments Section

If “took no medicines”, *form is complete.*

1. Medication containers may be unavailable to the interviewer for a variety of reasons. Regardless of the reason, however, the interviewer should make an attempt to obtain the information necessary to complete the medication form.
2. If the participant forgets to bring medication(s) to the clinic, the interviewer is responsible for obtaining the necessary information at a second visit or by telephone interview.
3. If the participant remembers additional medication(s) taken during the previous two weeks, the interviewer should record as much information about the medication as possible at the time of the visit and then follow up with a telephone interview to check for accuracy and completeness.
4. If the medication containers are unavailable because the participant refuses to bring them to the clinic, the interviewer should document the reason for refusal in the Comment Section. The interviewer should then attempt to obtain the participant’s cooperation in

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obtaining the data, either by a second visit or by telephone.

5. If the participant brings a list of medications, instead of the medication containers, record all pertinent information from the list and note this in the Comments Section. If the interviewer has any doubt about the accuracy of the list, a follow-up telephone call should be scheduled to confirm what has been recorded.
6. Whenever medication information is collected by phone or from a list brought in by the participant instead of from the prescription container, try to verify the spelling of the name and the strength prescribed by referring to the PDR or some other source of accurate medicine listings.

Section B. Prescription Medications

1. The interviewer transcribes the name and dosage information from each medication container onto the Medications Form using the following guidelines:
2. Medication name. Print complete medication name using block capital letters. Record all characters and numbers referring to strength as well as the units. The name of each medication should be recorded *exactly* as it is written on the container. Medication names that are misspelled or otherwise recorded incorrectly will cause data entry and analysis problems because they will not match the drug database. Do not record flavors of products or whether the preparations are sugar-free or sodium-free. If the medication name is longer than the 20 spaces available on the form, transcribe as much as possible and then record the complete medication name in the Comments Section. If it is not possible to transcribe the medication name, insert an asterisk (*) and explain in the Comments Section.
3. Combination Medications contain two or more drugs. Some combination medicines, such as Dyazide, come in only one fixed combination (hydrochlorothiazide 25mg and triamterene 50mg). These combination medicines do not usually list strength. Record the name in the "Medication Name" space and leave the "Strength" column blank.

Other combination medications are available in more than one fixed dose combination. For example, Inderide, which is a combination of propranolol and hydrochlorothiazide, is available as propranolol 40mg and hydrochlorothiazide 25mg, or propranolol 80mg and hydrochlorothiazide 25mg. These combination medications usually list the strength as in "Inderide 40/25" or "Inderide 80/25." For these medications, record the name in the "Medication Name" space and the strength combination (e.g., 40/25) in the "Strength" space.

4. Strength.
 - Record the strength of each medication in milligrams (mg) whenever possible, beginning with the first space on the left in the "Strength" column.
 - When strength is in milligrams, *do not* record the abbreviation "mg;" record *only* the amount of drug (e.g., if the strength is "250 mg," record only "250").

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- When strength is not recorded as milligrams, record *all* numbers, digits, and characters used to denote strength, including:
 - milliliter (ml)
 - per milliliter (/ml)
 - milliequivalent (mEq)
 - hour (hr)
 - per hour (/hr)
 - percent (%)
 - When strength is separated by a “/” (e.g. 40/25, as in combination medications), record them in this section.
 - When strength is given in grains (gr), convert to milligrams using the following formula: (number of grains) x 65 = number of milligrams. (1 gr = 65 mg.)
 - When strength is given in micrograms (mcg or μg), convert to milligrams using the following formula: (number of micrograms) \div 1000 = number of milligrams. (1000 mcg = 1 mg.)
 - When strength is given in milligrams per milliliter (mg/ml), as is often the case with liquid medicine, record as in the following example: Ampicillin 125 mg / 5 ml is recorded as “125/5 ml.” (Note omission of “mg.”)
 - When strength is given as a percentage (%), record as such.
 - When strength is given in units (U) or units/milliliter (U/ml), as is often the case with Insulin, record as in the following examples: “100/ml” or “100U/ml.”
 - When it is not possible to record the strength, such as when it is not recorded on the medication label, record an asterisk (*) and explain in the Comments Section.
 - Note: Do not record in the “Strength” column the number or quantity of medication items (e.g., number of tablets or tablespoons). See “Number Prescribed,” below.
5. Number Prescribed. This column is designed to capture information on the number of pills (or milliliters, drops, units, etc) *prescribed* as opposed to the number actually taken. Information on the number prescribed should be taken from the medication labels.
- Record the total number of medication items (e.g., “tablets”) prescribed per the given time period (e.g., day, week, or month). Circle the appropriate letter in the “Number Prescribed” column to show whether the prescribed number is per day (D), per week (W), or per month (M).
 - If the instructions include a range in the number of medication items and/or times/day (or week or month) they are to be taken, record the lowest number of each. For example, if the label says, “take 1–2 tablets 3–4 times per day,” record as “3 tablets/day” (i.e., 1 tablet 3 times/day = 3 tablets/day); or, if the label says, “take 1–2 tablets every 4 hours while awake,” record as “5 tablets/day” (i.e., 1 tablet every 4 hours from 7 a.m. to 11 p.m.).

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- When it is not possible to record the number of medication items prescribed per day, record an asterisk (*) and explain in the Comments Section.
- When instructions read “take as directed,” record “1” as the number prescribed per day.
- When dosing instructions are complex (e.g., “take 1 pill every other day, alternating with 2 pills every other day”), record the *average* number per day (or week or month).

6. Number Prescribed: Specific Medications.

- Pill/Tablets/Capsules: Record the total number prescribed per day (or week or month).
- Solutions: Record the total number of milliliters prescribed per day (or week or month). Use the following conversions:
 - 1 teaspoon = 5 ml
 - 1 tablespoon = 15 ml
 - 1 ounce = 30 ml
- Eye Drops: Record the total number of drops prescribed per day (or week or month). For example, “two drops in right eye, three times a day” = 6 drops, or “one drop in each eye, twice a day” = 4 drops.
- Inhalers (puffers): Record the total number of sprays or puffs prescribed per day (or week or month).
- Insulin: Record the total number of units injected per day (or week or month).
- Creams/Lotions/Ointments: Record the total number of applications prescribed per day (or week or month).
- Patches: Record the total number to be applied to the skin per day (or week or month).
- Nitroglycerin Ointment: Record the total number of inches to be applied to the skin per day (or week or month).

7. PRN (“as needed”) Medication is generally used for allergy, pain, or sleep; sublingual nitroglycerin is also used PRN.

- Use the “PRN Medicine?” column to indicate whether the medication is prescribed to be taken on an “as needed” basis.
- Circle “Y” only when the prescription instructions state “as needed,” “when needed,” “if needed,” etc.
- Circle “N” when the prescription instructions do *not* use the words “as needed,” “when needed,” “if needed,” etc.
- The words “as directed” do *not* mean the same as “as needed.”

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8. Number Taken. This column is designed to capture information on the number of pills (or milliliters, drops, units, etc) *actually taken* as opposed to the number prescribed. Information on the number *actually taken* should come directly from the participant. People do not always take their medications as prescribed. It is important to record information about both the number prescribed and the number actually taken as accurately as possible.
- Ask the participant, **“On the average during the last two weeks, how many of these pills (or other medication items) did you take a day (or week or month).”**
 - Record the average number of pills (or other medication items) taken per day (or week or month) during the last two weeks.
 - Code “0” if none of the medication items was taken during the previous two weeks. This includes instances in which a prescription was filled but none of the medication was taken during the past 2 weeks.
 - When the number taken cannot be determined, record two asterisks (**) and explain in the Comments Section.
 - Circle the appropriate letter (D, W, M) to show whether the prescribed medication was taken per day, per week, or per month.

C. Over-the-Counter Medications

Complete this section following instructions for Section B, above, but disregarding the instructions pertaining to “Number Prescribed” and “PRN Medication.”

D. Chinese and Other Traditional Medicines

Whenever possible, *in the comment section*, record traditional medicine use in the same fashion as with other medicine i.e. name, dosage, frequency. If this is not possible, record the *purpose* of the medicine.