

MEDICATIONS

1 Background and Rationale

The CHS Medication Form was adapted from the ARIC form. Information about medications is gathered during the Baseline Clinic Visit and the Annual Surveillance Visit. The baseline interview takes place during the Initial Home Visit; during subsequent years it is done during the Annual Surveillance Visit. The Medication Form is designed to obtain information about all prescription medicines used during the two weeks prior to the interview (home or clinic), as well as recent use of selected over-the-counter medications and supplements. The participant provides the interviewer with all medicine containers, and the interviewer transcribes information from the containers onto the data-collection form. After the information is transcribed, the interviewer queries the participant about each prescription medicine and also asks several questions regarding use of over-the-counter medications and supplements.

The Medication Form has several important purposes.

- 1.1 The data will enable us to describe medication use and any changing patterns of use over time in the elderly.
- 1.2 A knowledge of medications taken by a participant will be a factor in deciding whether a participant has prevalent cardiovascular disease at the baseline examination; for instance, participants taking nitroglycerin will in general have coronary heart disease.
- 1.3 Certain medications will be essential covariates in many CHS analyses. Over the next several years, medications such as lovastatin which is used to treat high cholesterol, are likely to become widely used. Without accounting for use of medications used to control hypertension or hyperlipidemia, meaningful interpretation of time trends in the levels of blood pressure or cholesterol are not possible. Additionally, we could not examine such variables as risk factors for atherosclerosis, stroke, and coronary heart disease.
- 1.4 Observational data can provide useful (if tentative) estimates of the effect of selected medications, such as estrogens or beta-blockers, on major disease endpoints in the elderly.

2 Definitions

- 2.1 Timeframe--All prescription medications, and selected over-the-counter medications taken within the two week period prior to the interview (home or clinic), are included.

2.2 Prescription medication--CHS Definition: a medication for which a prescription was written by a physician, dispensed by a pharmacist or physician, and taken by the participant during the two weeks prior to the interview. This includes prescription:

- O Eye drops
- O Pills or tablets
- O Creams/salves
- O Dermal patches
- O Injectables (such as insulin)

2.3 Non-Prescription Medications--one that may be purchased without a physician prescription.

NOTE: Physicians sometimes write prescriptions for medications which can be purchased without a prescription (over-the counter medicines). For example, the participant may take one aspirin a day. When the physician wrote a prescription for the aspirin, it is considered a **prescription medication**. When the physician recommended that the participant take aspirin, but did not write a prescription for it, the aspirin is not considered a prescription medication.

3 **Methods**

3.1 Baseline Home Interview

O Gathering Medicine Containers

! The participant is asked to gather all prescription medications taken in the previous two weeks; this request is made during the Telephone Contact, if one is made.

! The Home Visit Reminder Postcard mailed prior to the home interview also notes the need to have the medication containers for all prescription medications available for the interviewer.

O Reception of Medications (Section A of Medication Form)

! During the Baseline Home Interview, the interviewer inquires whether all prescription medications taken during the last two weeks are available. The responses are recorded in Item A-1.

! Script:

As you know, the Cardiovascular Health Study will be describing prescription medications its participants are using. We are particularly interested in medications your doctor prescribed for you and were filled by

a pharmacist. These include pills, dermal patches, eye drops, creams, salves, and injections. Are these all the medications that you took in the last two weeks?

! An alternative ending sentence for the script is:

Please gather all the medications that you have taken in the last two weeks.

! When the medications have not been gathered prior to the visit, or all are not available, the interviewer requests that the participant proceed with gathering them.

! When the participant has not taken any prescription medications during the previous two weeks, check "Took no medicines" on the Medications Form and proceed to Section C.

! Only medications which were actually taken during the previous two-week period are recorded. Medications prescribed by a physician, but not taken, will not be recorded. This includes instances where a physician wrote a prescription that was not filled and those that were filled but for which no medications were taken during the previous two weeks.

! When the participant refuses, the interviewer attempts conversion; when the participant still refuses, record the reason for refusal on the form and proceed to Section C of the Medications Form.

3.2 Annual Surveillance Visit

O Gathering Medicine Containers

! The participant is asked to bring all prescription medications taken during the past two weeks to the Field Center Clinic.

! The Follow-up Letter Before Surveillance Visit includes specific instructions as well as a medications carrying bag.

O Reception of Medications (Section A of Medication Form)

! When the participant arrives for the Annual Surveillance Visit, the receptionist 1) asks the participant question A-1, 2) logs receipt of the medications and 3) places the participant's CHS ID number on the Medication Bag.

! When the participant did not bring any medications to the clinic, the receptionist inquires whether the participant has taken any medications

during the past two weeks. When the participant has taken medicines but has not brought them to the clinic, the interviewer should probe for possible reasons for noncompliance.

O Unavailable Medications

- ! When a participant forgot to bring a medication(s) to the clinic, each Field Center is responsible for developing a mechanism to gather the information via telephone or field interviewer visit.
- ! When the medications are not available due to participant refusal, document the reason for refusal in the space provided on the form. Conversion attempts are made during the Exit Interview.
- ! When, following probes for completeness, the participant recalls additional prescription medications taken during the previous two weeks, the interviewer records the name with as much detail as possible, notes reasons for incompleteness in the Comment section, and plans a follow-up with phone interview or visit.

3.3 Prescription Medications (Section B of Medication Form)

The field interviewer at Baseline or the receptionist at the Annual Surveillance Visit transcribes the name and dosage from each medication container onto the Medication Form using the following standard guidelines.

3.4 Transcription Process

3.4.1 Medication Name

- O Print complete names using block capital letters.
- O Record all identifying characters and numbers referring to strength.
- O Include as much identifying information as possible. When the drug name is longer than the 20 spaces available on the form, include a note in the margin ("See Comments") and record the complete name in the Comment Section on page 2.
- O Combination Drugs:

Combination medicines contain two or more drugs in a single pill or tablet. Some combination medicines such as Dyazide come in only one fixed combination (hydrochlorothiazide 25 mg and triamterene 50 mg); these combination medicines do not generally list a strength. Record DYAZIDE in the space name of medicine and leave the strength column blank.

Other combination medicines such as Inderide are available in more than one fixed dose combination (propranolol 40 mg and hydrochlorothiazide 25 mg, or propranolol 80 mg and hydrochlorothiazide 25 mg); these combination medicines generally list the strength as in "Inderide 40/25" or "Inderide 80/25." For these medicines, record INDERIDE, in the space for name, and "40/25" or "80/25" in the space provided for strength.

EXAMPLES:

! Drugs containing two or more medications:
Example: Dyazide (hydrochlorothiazide and triamptere) is recorded as:
Name: "DYAZIDE"
Strength: blank

! Variable Dosage:
Examples:
- Inderide 40/25 (40 mg Inderal, 25 mg hydrochlorothiazide) is recorded as:
Name: "INDERIDE"
Strength: "40/25"
- Inderide 80/25 (80 mg Inderal, 25 mg hydrochlorothiazide) is recorded as:
Name: "INDERIDE"
Strength: "80/25"

- O Do not record flavors of products and whether the preparations are sugar-free or sodium-free.
- O When it is not possible to transcribe the drug name, code "*" and explain in the comment section.

3.4.2 **Strength** (mg)

- O Record the strength in milligrams of each medication; left justify the strength.
- O When strength is recorded as milligrams (mg) **DO NOT** record the abbreviation "mg".
- O When strength is not recorded as milligrams (mg) record **all** numbers, digits, and characters used to denote strength; this includes:
 - ! . - decimal point,
 - ! ml - milliliter
 - ! /ml - per milliliter
 - ! mEq - milliequivalents
 - ! hr - hour,

- ! /hr - per hour and
- ! % - percent Note: When the abbreviation, "PC" (percent) is used, record percent symbol, "%."

SPECIFICS:

- ! Record strength of combination drugs where strength is separated by a "/" in this section.
- ! When the strength is given in grains (gr), convert to milligrams by multiplying by 65 milligrams per grain.
1 grain = 65 milligrams;
2 grains = 130 milligrams;
5 grains = 325 milligrams.
- ! Liquid medicines strength is often written in mg/ml (milligrams per milliliter). For example, Ampicillin 125 mg /5 ml, is recorded as:
Name: AMPICILLIN,
Strength: 125/5ML."
NOTE: Omit "mg" for milligrams.
- ! Strength for some medicines may be written as a percentage. For example: Alupent 0.6%, is recorded as:
Name: ALUPENT
Strength: 0.6%
- ! Strength for insulin is generally "U100" or "100 units per milliliter." This is often written as "100/ml" or "100U/ml." Record Insulin strength as "U100" unless another strength is listed on the label. NOTE: The other available strengths include U40, U500, and U1000; but they are rarely used.
- O When it is not possible to transcribe the strength, code "*" and explain in the comment section. This includes instances where strength is not recorded on the label.

NOTE: Do not record the quantity or number of pills/tablets dispensed as **strength**.

3.4.3 **Number Prescribed**

- O Record the total number of pills/times prescribed for the time period.
- O Circle the appropriate letter to indicate whether the prescribed administration is per "D - day", "W - week" or "M -month".

- O When the instructions include a range, record the lowest number of pills/times administered recommended. Examples:

- ! "Take 1-2 pills 3-4 times a day", code "3".
- ! "Take 1-2 pills every 4 hours while awake", code "5".
(e.g. (24 hours - 8 hours sleep)/4 = 4 pills)
- ! "Take 2-4 pills every 4 hours", code "12".

- O When it is not possible to transcribe the number prescribed per day, code "*" and explain in the Comment section.

- O SPECIFICS:

- ! When instructions indicate "Take as directed," record "1" in the number of pills prescribed per day.

- ! COMPLEX INSTRUCTIONS: record the average. For instance, code "take 1 pill every other day, alternating with 2 pills every other day" as "1.5" pills per day.

- ! PILLS, CAPSULES, or TABLETS: record the total number prescribed per day, week or month.

- ! SOLUTIONS: record the total number of milliliters taken per day, week or month. NOTE:

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

- ! EYE DROPS: record the total number of drops prescribed per day, week or month. Examples:

- Two drops in right eye, three times a day = 6
 - One drop in each eye, twice a day = 4

- ! INHALERS: record the total number of sprays or puffs prescribed per day, week or month.

- ! INSULIN, record the total number of units injected per day, week or month.

- ! CREAMS, LOTIONS, and OINTMENTS: record the total number of applications prescribed per day, week or month.

- ! PATCHES: record the total number to be applied to the skin per day, week or month.

- ! NITROGLYCERIN OINTMENT: record the total number of inches to be applied to the skin per day, week or month.

3.4.4 **PRN Medicine**

- O Indicate whether the medication is prescribed to be taken on an As needed@ basis.
- O Circle "Y" only when the prescription instructions indicates As needed@, Awhen needed", Aif needed", or a synonym.

! The words, As directed@, do not mean the same as "as needed."

! PRN is generally used for allergy, pain or sleep medications, or some form of sublingual nitroglycerin.

- O Circle "N" when the prescription instructions do not use the words As needed@, Awhen needed@, Aif needed@, or a synonym.

3.5 **Part 2 - Medication Use Interview**

- O Prior to beginning the interview, place all medications in front of the participant.
- O When asking about a medication, show the bottle to the participant keeping other medications in view. Following the inquiry for a medication, place the bottle off to the side (Baseline Home Interview) or return the bottle to the Medication Bag (Annual Surveillance Visit).
- O Conclude the interview with a probe regarding completeness of the prescription medications taken during the previous two weeks.
- O When, following probes for completeness, the participant recalls additional prescription medications taken during the previous two weeks, record the name, strength and dose with as much detail as possible and explain in the Comment section.
- O When doubt exists regarding recall accuracy, make arrangements to telephone the participant to verify the prescription label information.

3.5.1 **Number Taken per Day**

- O Script: On the average during the last two weeks, how many of these pills did you take a day/week/month.
- O Record the total number of pills taken on average each day/week/month during the last two weeks.

- O Circle the appropriate letter to indicate whether the prescribed administration was taken per "D - day", "W - week" or "M -month".
- O Code "0" when none of the pills were taken during the previous two weeks. This includes instances where a prescription was filled but none of the medications were taken during the past 2 weeks.
- O When the number taken cannot be determined, code "***" and explain in the Comment section.

3.5.2 **Number Unable to Transcribe**

- O Record the number of medications where complete transcription was not possible. This includes:
 - ! Medications with non-readable, missing labels
 - ! Medications whose containers were not available for transcription

3.6 **Selected Over-the-Counter Medications and Supplements (Section C of Medication Form)**

This section may repeat some information gathered in Section B; however, it is important to record the information in both sections. For example, when a participant takes aspirin as a prescription medicine (using the CHS definition), record the details of the prescription in Section B. In addition, interviewer should ask the questions regarding aspirin contained in Section C. This may also occur for medicines such as nitroglycerin.

- O Items 1 to 4--Aspirin or Fish Oil Supplements The participant is asked whether aspirin or fish oil supplements were taken during the previous two weeks.
 - ! When the participant used aspirin or fish oil supplements during the previous two weeks.

Script: On about how many days during the last two weeks did you take these medications (supplements)?
 - ! Record the total number of days (not pills) on which the medicine was taken during the last two weeks.
- O Items 5 to 8--Antihistamines, Sleeping Pills, Laxatives, Calcium Supplements The participant is asked whether any of these over-the-counter medications are taken one or more times a week.
 - ! Script: Are you taking any of the following?

- O Items 9 and 10--Flu and Pneumovax Shots The participant is asked questions regarding flu shots and shots given to prevent pneumococcal pneumonia.
 - ! Check "Yes", when the flu shot was received within the past year.
 - ! Check "Yes" when a pneumovax shot was received at any time during the participant's life.
- O Item 11--Nitroglycerin prescription The participant is asked whether a physician has prescribed nitroglycerin during the past year.

NOTE: The time frame for this question is ONE YEAR. The question refers to any form of nitroglycerin, including nitroglycerin pills which are swallowed, nitroglycerin patches, and nitroglycerin ointment.

The data collected are used to identify whether a physician prescribed nitroglycerin during the last year, NOT whether the participant actually took the medicine. This question is the one exception to the rule that our primary interest is in the participant's medicine taking behavior.

3.7 **Return of Medications**

The medications are returned to the participant at the end of the home interview or, at the Annual Surveillance Visit, along with other personal belongings as part of the Exit Interview procedure.

3.8 **Training Materials**

The following training materials have been prepared for transcribing section B of the Medication Form. The first section entitled "Medications Form: Sample Participants, Apr 1989," consists of xeroxed copies of prescription labels for 9 sample participants (cases 1-4 and 6-10). The second section entitled "Medications Form: Completed Sample Forms, April 1989," includes a typescript of how the medication names, strength of the medicine, and the number of pills prescribed per day should be transcribed for each sample participant (cases 1-4 and 6-10).