

ARIC MEDICATION SURVEY FORM

ID NUMBER: CONTACT YEAR: 0 1 FORM CODE: M S R VERSION: A 11/1/86

LAST NAME: INITIALS:

INSTRUCTIONS: This form should be completed in three stages. Section A should be completed at the Reception station. The transcription portion of Section B should be completed while the participant proceeds with the visit. The interview portion of Section B, as well as Sections C & D, should then be completed during the physical exam. The paper form is to be used for data collection and keyed into the data entry system as soon as possible following its completion. ID Number and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

MEDICATION SURVEY FORM (MSRA page 1 of 4)

A. RECEPTION

1. Did you bring the containers of all medications you used in the past two weeks? Yes, all **Y**
Some of them **S**
No **N**

If "Yes, all", go to Section B and begin transcription while participant proceeds with clinic visit.
If "Some of them", go to Item 3; transcribe those medications which were brought at this time.

2. Is this because you forgot, because you have not taken any medications at all in the last two weeks, or because you could not bring your medications? Took no medications **T**

Go to Item 9,
Page 4

- Forgot or was unable to bring medications **F**

"That's all right. Since the information on medications is so important we would still like to ask you about it during the interview."

3. Could we follow up on this after the visit so that we can get the information from the (other) medication labels? {Explain follow-up options.} Yes **Y**
No or not applicable **N**

{Attempt to convert refusals; indicate on Itinerary Form}

Describe method of follow-up to be used: _____

MEDICATION SURVEY FORM (MSRA page 2 of 4)

B. MEDICATION RECORDS

I. Transcription (Copy the NAME followed by the CONCENTRATION of each medication in the spaces below. Continue on second line if needed.):

II. Interview (For each medication, circle the appropriate response to the following questions.):

c. "Was this medication prescribed for you, over-the-counter, or shared?"

d. "Did you take this medication in the past 24 hours?"

4. RECORD NUMBER	a. MEDICATION NAME & CONCENTRATION	b. CODE NO.	RX (R)/ OTC (O)/ SHARED (S)/ UNKNOWN (U)	YES (Y)/ NO (N)/ UNKNOWN (U)
M1.	_____	<input type="text"/>	R O S U	Y N U
M2.	_____	<input type="text"/>	R O S U	Y N U
M3.	_____	<input type="text"/>	R O S U	Y N U
M4.	_____	<input type="text"/>	R O S U	Y N U
M5.	_____	<input type="text"/>	R O S U	Y N U
M6.	_____	<input type="text"/>	R O S U	Y N U
M7.	_____	<input type="text"/>	R O S U	Y N U
M8.	_____	<input type="text"/>	R O S U	Y N U
M9.	_____	<input type="text"/>	R O S U	Y N U
M10.	_____	<input type="text"/>	R O S U	Y N U
M11.	_____	<input type="text"/>	R O S U	Y N U

MEDICATION SURVEY FORM (MSRA page 3 of 4)

B. MEDICATION RECORDS (continued)

I. Transcription (Copy the NAME followed by the CONCENTRATION of each medication in the spaces below. Continue on second line if needed.):

II. Interview (For each medication, circle the appropriate response to the following questions.):

c. "Was this medication prescribed for you, over-the-counter, or shared?"

d. "Did you take this medication in the past 24 hours?"

4. RECORD NUMBER	a. MEDICATION NAME & CONCENTRATION	b. CODE NO.	RX (R)/ OTC (O)/ SHARED (S)/ UNKNOWN (U)				YES (Y)/ NO (N)/ UNKNOWN (U)		
M12.	_____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	R	O	S	U	Y	N	U
M13.	_____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	R	O	S	U	Y	N	U
M14.	_____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	R	O	S	U	Y	N	U
M15.	_____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	R	O	S	U	Y	N	U
M16.	_____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	R	O	S	U	Y	N	U
M17.	_____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	R	O	S	U	Y	N	U

5. Total number of medications in bag:

6. Number of medications unable to transcribe:

7. Transcriber Code Number:

MEDICATION SURVEY FORM (MSRA page 4 of 4)

C. INTERVIEW

"Now I would like to ask about a few specific medications."

8. Were any of the medications you took during the past two weeks for:
{If "Yes", verify that medication name is on medication record.}

Table with 4 columns: Question, Yes, No, Unknown. Rows include High Blood Pressure, Angina or Chest Pain, Control of Heart Rhythm, Heart Failure, Blood Thinning, Diabetes or High Blood Sugar, Stroke, Leg pain when walking.

9. During the past two weeks, did you take any Aspirin, Alka-Seltzer, a cold medicine, or a headache powder? Yes Y, No N, Unknown U

10. During the past two weeks, did you take any [other] medication for arthritis, fever, or muscle aches and pains, (or menstrual cramps)? Yes Y, No N, Unknown U

D. ADMINISTRATIVE INFORMATION

11. Date of medications interview: Month - Day - Year

12. Interviewer Code Number: [] [] []

VERSION A 11/1/86

MEDICATION SURVEY FORM INSTRUCTIONS

I. GENERAL INSTRUCTIONS

The purpose of this component of the ARIC baseline examination is to assess medication usage in the two weeks preceding the examination date. Both prescription and non-prescription drugs are ascertained. To obtain this information the participant is asked during the home interview to bring to the field center all medications taken in the two-week period prior to the baseline examination.

The interviewer and transcriber should be familiar with and understand the document titled "General Instructions For Completing Paper Forms" prior to completing this form. ID Number, Contact Year, and Name should be completed as described in that document.

If the paper form is used for data collection, the header information of the Medication Survey Form should be completed prior to the arrival of the participant at the field center and the information keyed into the data entry system as soon as possible following its completion.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

A. Reception

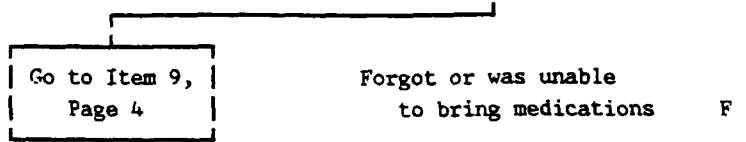
- | | | |
|--|--------------|---|
| 1. Did you bring the containers of all medications you used in the past two weeks? | Yes, all | Y |
| | Some of them | S |
| | No | N |

If "Yes, all", go to Section B and begin transcription. This can take place while participant proceeds with clinic visit. As the participant delivers the medications, indicate that they will be returned at this same station before he/she leaves. Mention that medication names will be copied from the labels, and that if required, medications will be taken out their container only in the presence of, and with approval of the participant. Finally, indicate that the Nurse or P.A. may later ask a few questions about each medication. Verify that the medications bag is clearly identified with the participant's name. Do not open the medications bag or transcribe medications until the participant has signed the informed consent.

If "Some of them", go to Item 3 to make arrangements for those medications which were not brought; transcribe those medications which were brought at this time.

If the participant has not brought any medications, question 2 is asked:

2. Is this because you forgot, because you have not taken any medications at all in the last two weeks, or because you could not bring your medications? ... Took no medications T



If the participant took no medications in the past two weeks, Section A ends here. Return the form to the participant's folder. In such cases, the interview portion of the form begins with item 9.

Question 3 is asked if the participant did take some medications in the past two weeks, but did not bring them to the field center (or only brought some of them):

"That's all right. Since the information on medications is so important we would still like to ask you about it during the interview."

3. Could we follow up on this after the visit so that we can get the information from the (other) medication labels? {Explain follow-up options.} Yes Y
- No or not applicable N

If the participant agrees to follow-up, arrangements are made for obtaining the information over the telephone or through a visit by a field interviewer. Describe the method of follow-up after item 3 on the form. If the participant did bring some of his/her medications, complete as much of the form as possible using them at this time.

In case of deliberate omission to bring medications to the field center, this is indicated on the Itinerary Sheet and conversion is attempted at a later stage during the medical review of results with the participant. Even if the participant refuses to cooperate, attempt to complete as much of the form as possible, especially items 8 through 10.

B. Medication Transcription

Open the medications carrier and remove all medications, prescriptions, and containers. Complete the transcription section, copying each medication name found on containers, prescriptions, or lists. Transcribe medication names in full (block letters if using the paper form). Include all parts of the medication name as well as numbers and/or letters that identify the strength. Copy the name first, followed by the concentration or strength of the medication, if a single concentration is listed. Examples: Chlor-Trimethon 12 mg; Teldrin 8mg; Ascorbic Acid 250 mg; Nostril 1/2%; Anacin Maximum Strength. Copy also any numbers and codes that appear to follow, or be part of the name. Examples: Anacin-3; Acerola C (100 mg); Triaminic-12; Ovrall-28; Ortho-Novum 10/11-28; Stuartnatal 1 + 1; Iletin I NPH; S-K Ampicillin; Caltrate 600 + Vitamin D. If in doubt, it is preferable to add information that may be significant and help later in identifying (and coding) a medication.

Do not record information in the interview section at this time.

Example:

I. Transcription (Copy the NAME followed by the CONCENTRATION of each medication in the spaces below. Continue on second line if needed.):

II. Interview (For each medication, circle the appropriate response to the following questions.):

c. "Was this medication prescribed for you, over-the-counter, or shared?"

d. "Did you take this medication in the past 24 hours?"

4. RECORD NUMBER	a. <u>MEDICATION NAME & CONCENTRATION</u>	b. <u>CODE NO.</u>	RX (R)/ OTC (O)/ SHARED (S)/ UNKNOWN (U)	YES (Y)/ NO (N)/ UNKNOWN (U)
M1.	_____		R O S U	Y N U

M2.	_____		R O S U	Y N U

When listing medications, record prescription medications first; then aspirin, aspirin-containing medications, and anti-inflammatory preparations (aspirin, Alka-Seltzer, headache powders, cold medicine, medication for arthritis); then list over-the-counter preparations; list vitamins and food supplements last.

Once all names are transcribed, count the total number of different medications (including those which could not be transcribed) and enter this number in item 5. Set aside any containers which have no clear label or identification, as well as medications without containers. Names should be left blank on the form for these medications. Add the number of these medications which you were unable to transcribe, and enter this number in item 6. For example, if there were 7 medications in the bag, and you were able to transcribe 5 of them, items 5 and 6 would be completed as follows:

5. Total number of medications in bag:

6. Number of medications unable to transcribe:

Open containers to examine medications only in the presence of the participant. If necessary, make a note on the form, and let the participant know that the Nurse/P.A. will identify these medications with the participant. Enter your ARIC code number in item 7, return the medications into the medications bag, attach the MSR form to the bag, and proceed to the medication survey, or take them to the station identified for the medication survey. At no time should the medications be left unattended at the Reception area.

C. Interview

To begin the medications survey, retrieve the appropriate bag and form, verifying the participant's name. Place all medications from the bag on the desk or counter so that the participant can see each one.

Take each medication, one at a time, and verify its name and concentration transcribed on the form. Correct discrepancies following the procedure for all paper forms. Next, show the medication to the participant and ask the two questions to the right of the transcribed medication names:

- c. Was this medication prescribed for you, over-the-counter, or shared?

For the purposes of this study, a prescription medicine is one for which the participant has received from his or her physician a prescription that is filled by a pharmacist. An over-the-counter medication is one that may be purchased without a prescription from a physician. Physicians sometimes do write prescriptions for over-the-counter medicines. For example, the participant may take one aspirin a day. If the physician wrote a prescription for the aspirin, then it counts as a prescription medicine. If the physician recommended the use of an over-the-counter medicine such as aspirin but did not write a prescription for it, then the aspirin does not count as a prescription medication.

- d. Did you take this medication in the past 24 hours?

The first question (c.) is intended to clarify whether the medication was a prescription written specifically for the participant (RX), which may be obvious from the container or a prescription, a prescription written for another individual (SHARED), or a product purchased over the counter (OTC). If this cannot be determined from the container or the participant, mark the "unknown" response (UNKNOWN). Be sure to ask the participant if a product was prescribed. Even if it is normally an OTC product, or not labelled as prescription, it may have been prescribed. If the participant has indicated s/he took no medications, or only such products as vitamins, it is permissible to preface the question with an explanation. "I know you said you took no medications, but we use these questions as a memory jogger."

The second question (d.) is self-explanatory. To assist the participant in remembering, one may state the question specifying a time on the previous day. For example, "Have you taken this medication since 10:00 AM yesterday?"

Example:

I. Transcription (Copy the NAME followed by the CONCENTRATION of each medication in the spaces below. Continue on second line if needed.):

II. Interview (For each medication, circle the appropriate response to the following questions.):

- c. "Was this medication prescribed for you, over-the-counter, or shared?"
- d. "Did you take this medication in the past 24 hours?"

4.	a.	b.	c.	d.								
RECORD NUMBER	<u>MEDICATION NAME & CONCENTRATION</u>	<u>CODE NO.</u>	<u>RX (R)/ OTC (O)/ SHARED (S)/ UNKNOWN (U)</u>	<u>YES (Y)/ NO (N)/ UNKNOWN (U)</u>								
M1.		<table border="1" style="width: 100%; height: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; height: 10px;"></td> <td style="width: 10%; height: 10px;"></td> <td style="width: 10%; height: 10px;"></td> <td style="width: 10%; height: 10px;"></td> <td style="width: 10%; height: 10px;"></td> <td style="width: 10%; height: 10px;"></td> <td style="width: 10%; height: 10px;"></td> <td style="width: 10%; height: 10px;"></td> </tr> </table>									R O S U	Y N U

Repeat this process (verify name, ask the questions) for all medications. Determine from item 6 at the end of the medication transcription page whether there were any medications in the bag for which the transcriber was unable to transcribe a name. These may include unmarked containers, loose pills, and containers with more than one medication. Ask the participant to open any unmarked containers, and to handle loose pills. With the participant's help and using a PDR, attempt to identify these medications. If possible, enter the names and concentrations, and ask the two questions as above. If no unequivocal identification is possible, write UNKNOWN for the medication name and draw two horizontal lines through the boxes for the medication code number. If additional meds can be transcribed, adjust the total for item 6, "number of medications unable to transcribe" accordingly. After this has been completed for all containers, prescriptions, and medications in the bag, probe the participant on whether all medications taken in the previous two weeks are included. For any additional medications recalled by the participant, record the names and answer the questions with as much detail as possible. If there is any doubt, arrange for a phone call during which the participant can provide accurate information.

Often during an interview, the participant will recall other medications or vitamins s/he took during the past two weeks. These should be added to the list at this time, just as if they had been in the bag. The prescription or OTC nature, and whether they were used in the previous 24 hours are then recorded. However, the number of medications in the bag is not changed at this time, to alert us to the fact that the participant has provided these names from memory and ARIC staff have not transcribed these names from a written record. Item 8 is to be asked of anyone who took any medications during the past two weeks, regardless of whether or not they were brought to the clinic. In addition to the listing of individual medication names, we want to know why people may be taking medications. Ask if medications were taken in the past two weeks for the eight listed reasons. If answered affirmatively, be sure that the

name was listed, but it is not necessary to indicate which medication corresponds to which reason. Acceptable synonyms are given below:

- a. High Blood Pressure = hypertension
- b. Angina or Chest Pain = heart pains
- c. Control of Heart Rhythm = medicine for fast or irregular heart rate or heartbeats
- d. Heart Failure = congestive heart failure, not heart attack
- e. Blood Thinning = anticoagulation
- h. Leg pain when walking = claudication

For example, if the participant had taken medication for high blood pressure and claudication, record as follows:

8. Were any of the medications you took during the past two weeks for:
 {If "Yes", verify that medication name is on medication record.}

	<u>Yes</u>	<u>No</u>	<u>Unknown</u>
a. High Blood Pressure	Y	N	U
b. Angina or Chest Pain	Y	N	U
c. Control of Heart Rhythm	Y	N	U
d. Heart Failure	Y	N	U
e. Blood Thinning	Y	N	U
f. Diabetes or High Blood Sugar	Y	N	U
g. Stroke	Y	N	U
h. Leg pain when walking	Y	N	U

Items 9 and 10 are to be asked of all participants, regardless of whether they reported taking any medications during the past two weeks. The same preamble to question 8 about "jogging the memory" may also be used before questions 9 and/or 10: "I know you said you took no medications, but we use these questions as a memory jogger."

9. During the past two weeks, did you take any Aspirin,
 Alka-Seltzer, a cold medicine, or a headache powder?

Yes	Y
No	N
Unknown	U

In item 9, we ask about aspirin or aspirin containing medications because these may affect some of the hemostasis tests. Again, confirm whether the names are on the medication record.

10. During the past two weeks, did you take any [other] medication for arthritis, fever, or muscle aches and pains, (or menstrual cramps)? Yes Y

{Read bracketed "other" unless no meds were reported; include parenthetical portion for females only.} No N

Unknown U

In item 10, we ask about analgesic and anti-inflammatory medications that are not aspirin-based, because they also affect the hemostasis tests. Confirm whether the names are on the medication list. Follow the instructions provided after the question.

Review the form for completeness, and place your code in the spaces provided in item 12. Secure all medications in the bag and explain to the participant that he/she should pick it up from the Receptionist before leaving. Place the form in the participant's folder, and escort the participant to the next station. Return the medications bag to a secure place at the Reception work station.

Medication Coding at the Field Center

Each medication name is coded by trained field center personnel. This may be done after the participant has left. A (hard copy) translation dictionary is used at the field center, or matching software if done at the Coordinating Center. Only exact matches and specific spelling variants listed in the dictionary are coded, by entering the corresponding numeric code in the boxes provided on the form.