# MEDICATION INVENTORY

We will be recording the medications that the participant has taken in the past 30 days, including both over the counter and prescription medications. We are specifically interested in how individual medications are actually taken rather than how they are prescribed or intended to be taken. For this visit, we are asking participants to bring ALL prescription and over-the counter medications (including vitamins and herbal supplements) that they took during the last 30 days. Sites may choose to include a medication worksheet in the self administered questionnaire.

## 1. Equipment and Supplies

- Medication Inventory Form
- Supplemental Medication Inventory Form
- Medication Inventory Worksheet for the SAQ
- Black ball-point pen
- Plastic Bag for Medications

## 2. Procedure for Data Collection

At the Second Sleep visit, we will collect the name of the medication used, the formulation, the duration of use (using categories), frequency (regular or intermittent) and whether the medication is prescription. In addition, for the participants who complete polysomnography, we will collect information on medication use the day prior to the in-home PSG (the field 'PSG 24 hr' is to be used ONLY if the participant completed PSG cohort and should be completed by the sleep tech when they are in the participant's home. For participants who did not complete PSG, this question should be left blank.

Sites may choose to give the participant a medication worksheet that can be completed as part of the SAQ. The participant will also be instructed to bring all prescription and non-prescription medications used within the preceding 30 days with them to the visit. A bag for the medications and instructions for bringing medications into the clinic will be sent to the participant with the SAQ prior to their clinic visit.

- Ask the participant if they took any medications (prescription or over-the-counter) in the last 30 days.
  - If participant says yes and they brought all medications taken in the last 30 days to the clinic, complete the medication inventory.
  - If the participant says yes, but they have not brought all medications to the clinic, complete the medication inventory for medications brought into the clinic and arrange for a telephone call to collect the additional information. **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 men 1-2 days after the visit to obtain the missing information. DO NOT send the data to the Coordinating Center until after you have collected all of the medication information from them over the phone.

  - If a participant lists a medication on the Medication Inventory Worksheet (part of the SAQ) but does not bring that medication in with them during the clinic visit, clinic staff should clarify if the participant was taking that medication. A follow-up call may be necessary.
  - If the participant states that they have not taken any medications in the past 30 days, ask "Are you sure you took no prescription or non-prescription medications over the last four weeks?" Indicate that they have not taken any medications in the last 30 days on the MIF data collection form.
  - Indicate if the participant refuses to provide medication information on the data collection form.
- Indicate if the participant completed PSG
- Record the total number of medications that the participant is taking in the box. You should make sure that the number recorded at the top of the page (as total number of medications listed) matches the number of medications recorded on the Medication Inventory Form and all Supplemental pages.

The recording of medications can be completed while the participant is having measurements taken or is completing other exams. The first four medications should be recorded on the Medication Inventory Form. All additional medications should be recorded on Supplemental Medication Inventory Forms, found on the MrOS website.

| If a participant takes: | You should complete: |
|---|---|
| 0-4 medications | no Supplemental Inventory Forms; only submit the main medication inventory form to the data system |
| 5-9 medications | 1 Supplemental Inventory Forms |
| 10-14 medications | 2 Supplemental Inventory Forms |
| 15-19 medications | 3 Supplemental Inventory Forms |
| and so on. | |

There is no limit to the number of Supplemental Inventory Forms that can be accepted for each participant. You will need to assign a supplement form # to each supplemental form used for each participant. **The first supplemental form used for each participant should be numbered '1'. The second supplemental form used should be numbered '2' and so on.**

Information to be collected:

a) Med Name

Record only medications used within four weeks (30 days) of the visit. Medications that were prescribed but not taken, or those taken greater than four weeks ago, should not be recorded. Medications administered in the previous 30 days during surgery, hospitalization or non-hospitalization procedure will not be recorded on the MIF unless they are continued after discharge or the procedure.

The name of the drug should be filled in, one letter per box, on the Medication Inventory Form. Dosage information is not going to be collected, so for example there will be no distinction necessary between 200mg Ibuprofen, 400 mg Ibuprofen, and 800 mg Ibuprofen. The staff member should simply record 'IBUPROFEN' in the 'Name' field.

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

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").

In general, do not record the brand names unless it specifically describes the medication. For example, it is acceptable to transcribe "Os-cal" as that name specifically identifies that medication. Manufacturer and brand names **should** be entered for OTC supplements with a large number of ingredients since the medication name alone may not adequately identify the product. For example, the name Prostate Health might be used for different products from different manufacturers, but Dr Quack's Prostate Health will positively identify it for the Coordinating Center to code.

If a participant is on a study drug, please try to determine if the study is a blinded trial. If the participant knows that they are taking an active medication, the medication name should be listed on the MIF form. However, if the participant is in a blinded study and they do not know if they are on the study drug of placebo, sites should write STUDY DRUG BLINDED as the med name. This will help limit queries as the CC reviews the medications.

Common abbreviations are acceptable, such as ASA for aspirin, HCTZ for hydrochlorothiazide, APAP for acetaminophen. But caution should be used since abbreviations like TRIAM could represent the first letters of at least three very different medications that start with those letters: TRIAMTERENE, (with or without HCTZ), TRIAMCINOLONE and TRIAMINICIN. In addition, a med entered only as VITA could be read as Vitamin A, could be a product actually called just VITA or could be the start of an incomplete entry.

b) Formulation code

The formulation code should be documented for each medication. The following codes should be used:

1 = oral tablet or capsule
2 = oral liquid
3 = applied to skin (patch, gel, lotion, topical liquid, or ointment)
4 = eye drops or eye ointment
6 = inhaled through mouth, nasal spray or nasal drops
7 = injected

Ear drops should be coded using code 3.
Suppositories should be coded using code 3.

Medications that are inhaled through the nose should be coded as nasal using code 6.

c) Duration

We are only interested in collecting the most recent, uninterrupted, duration of use. Therefore, if a participant was taking a specific medication from January, 1992-Septemeber, 2001, discontinued the medication from September, 2001 to November, 2001, and began taking the medication again in January, 2002 we are only interested in the duration of use from January 2002 to the present. If the participant only takes the medication once a week but has taken it for 7 years and has taken it within the last 30 days the '>5 years' response should be filled in.

The categories for duration of use overlap on the TELEform form. The categories should be interpreted as follows:

| Category on Form | Interpretation |
|---|---|
| < 1 Month | < 1 Month |
| 1month – 1 year | greater than or equal to 1 month, but less than 1 year |
| 1 year –3 years | greater than or equal to 1 year, but less than 3 years |
| 3 years-5 years | greater than or equal to 3 years, but less than 5 years |
| > 5 years | greater than or equal to 5 years |
| Don't Know | Don't Know |

d) Use as a Sleep Medication

We are interested in if the participant is using the medication for a sleep related problem or condition. Ask this for all medications. We are not recording the reason for use in any other circumstances. If they use the medication for sleep, code as 'Yes', if not, code as 'No'. If they are not sure that they use the medication for sleep, code as 'No'.

e) Frequency

We want to record whether the medication is taken on a regular basis or taken on an as needed basis, but not on a regular schedule. For example, someone may have taken Tylenol or Aspirin within the last 30 days but only takes it when they have a headache. This would be recorded as 'int' for intermittent use. Any medication that has been prescribed to take daily or on a set schedule or any over the counter medication or vitamin/herbal that the participant takes regularly would be recorded as 'reg' for regular use. Medications can be taken on a regular basis only 1 or 2 days a week (some may even be once a month, but they take the medication or receive a therapy on a monthly schedule), any medication that the participant takes on a regular basis should be coded as 'reg'. Daily use is not the only use that should be recorded as regular.

f) Prescription

Indicate whether the medication is a prescription medication or not. The following definitions will help in determining how to code a medication:

- Prescription medication: 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.

- 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, and calcium supplements.

g) PSG-24

The technician performing the hook-up should take a copy of the Medication Inventory that was completed at the clinic visit with them to the home of the participant on the night of the PSG hook-up. Question B, 'Did participant complete Psg?', found at the top of the Medication Inventory form (page 16) should be answered 'yes'. The technician will ask the participant what medications they have taken that day and what they will take before bedtime. The technician should go through the list of the medications provided by the participant at the clinic visit and mark "yes/no" in the field 'PSG 24 hr' appropriately. The participant should also be asked if they have taken any medications that were not on the original list. If new medications were taken, record the name, duration of use, frequency, if it is used for sleep, and if it is a prescription medication. The total number of medications listed at the top of the fist page should be adjusted appropriately.

Inform the participant of this additional data collection when they are at their clinic visit so that they may have any additional medications readily available.

## 3. Transferring Data to the Coordinating Center

Once all data is recorded, the medication inventory forms (first page and supplemental pages) can be submitted to the data system. Please be sure that the number of medications listed at the top of the first page, matches the number of medications that are actually listed on the medication inventory forms.

## 4. Addressing Queries Regarding Clarification of Medication Name

As needed, (usually once a month) e-mail queries will be sent to clinics to help code the medications so they can be used in future MrOS analyses. Most of these queries will ask you

to clarify the medication name or to list the ingredients. Sometimes queries are generated because the data system did not read the medication name correctly. Clinics can clarify the medication name or correct the spelling of the medication using the MrOS web site. Sometimes a query is generated if a more complete name or list of ingredients is required to clarify the medication name. Clinics can add a list of ingredients using the MrOS web site if they will fit in the allowed field size. If the list of ingredients is too long sites should enter as much of the manufacturer's/supplier's name and product name as will fit in the spaces allowed. For example: a product named Dr Whitaker's Restful Night contains at least six ingredients and since they would not all fit on the MIF form, the med name Restful Night alone would generate an excessive number of Google hits and still might not lead to the correct product, but the full name could be abbreviated to fit and the coordinating center would do the web search to identify the ingredients and code the med.

A few things that will make addressing medication edits easier:
1) You only need to contact a participant to identify ingredients or clarify the name of prescription medications. You do not need to contact participants about ingredients in over-the-counter medications or supplements.

2) If a medication or supplement has multiple ingredients like an herbal supplement or multiple vitamin, you do not need to list all ingredients. Any vitamin, mineral or herbal preparation with three or more components may be entered as multivitamin, minerals or herbal, respectively. However, entering the full name of the product is also an option.

Those preparations with a single extra component, such as extra calcium or iron, should be coded as "multivitamins/calcium", "minerals/lutein", or "herbal/glucosamine". Preparations with just two components (for example, one vitamin and one mineral, or two different vitamins) should be coded as combination medications, as in "Saw Palmetto/Lycopene", "Vitamin B Complex/Folic Acid". Again, you can address the edit using the web site or email the Coordinating Center a list of ingredients if the web site will not accept the change.

**Quality Assurance**

- Read and study manual