

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.

1. Equipment and Supplies

- Medication Inventory Form
- Supplemental Medication Inventory Form
- Medication Code Database (on MrOS Website)
- Computer
- Black ball-point pen
- Plastic Bag for Medications

2. Procedure for Data Collection

At the MrOS sleep visit, we will collect the name of the medication used, the duration of use (using categories), frequency (regular or intermittent), whether the medication is prescription, and if the medication is used for sleep. In addition, for the participants that completed 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 that did not complete PSG, this question should be left blank.

The participant will 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 they 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 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 (Page 16 of the Clinic Exam Forms). All additional medications should be recorded on Supplemental Medication Inventory Forms, found on the MrOS website.

<u>If a participant takes:</u>	<u>You should complete:</u>
0-4 medications	no Supplemental Inventory Forms; none should be submitted to the data system
5-9 medications	1 Supplemental Inventory Forms
10-14 medications	2 Supplemental Inventory Forms
15-19 medications and so on.	3 Supplemental Inventory Forms

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.

In late September 2004, updated versions of the medication forms were introduced in the MrOS Sleep study. Both sets of forms will be accepted by the data system, but clinics should use the same version for the main MIF page and supplemental pages. Version numbers should not be mixed and matched.

a) Med 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. 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 'Drug Name' field and use this name when looking for the medication code in the database.

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”).

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 "Os-cal" as that name specifically identifies that medication.

NOTE: If version 1 of the medication inventory form is being used please note that there is a small number of medications that we need to know the formulation for (tablet, cream, liquid, etc.). The medications requiring this extra information are asthma medications, nitroglycerin, sex hormones, eye medications, and cortocosteroids. These medications come in various formulations. For example for asthma medication a participant may either have albuterol tablets or albuterol inhalational solution or for sex hormones a participant may be taking premarin tablets or premarin injections. For these medications the drug name should be recorded as usual and then followed by the formulation, a letter indication may be used for the formulation (ex. T-tablet, C-cream) if space on the medication inventory form is an issue. The letter used to indicate the formulation should be something that will make sense to whoever looks up the drug code in the database to complete the ‘med code’ field. When looking for the drug code for the specified medications be sure to find the code that corresponds to the appropriate formulation (as indicated in the drug code database). A list of the groups of medications where a formulation is required is included in Table 1.

b) Med code

When convenient for clinic staff, the name of all medications listed should be looked-up in the Medication Code Database found on the MrOS website. The appropriate 7 digit code that corresponds to the drug should be entered into the ‘Med Code’ field on the Medication Inventory Form. If you do not find an exact match for the drug that you have entered put ‘0000000’ in the ‘Med Code’ box. If the participant indicates that they are part of a clinical trial and don’t know if they are on the study drug or placebo, Study Drug as the medication name and enter ‘0000000’ as the code. The Med Code field is present of version 1.0 of the Medication Inventory Form and Supplemental Medication Inventory Form. If using version 2.0 of the forms, this field is not listed and is not required.

Formulation code

The formulation code should be documented for each medication that is recorded on version 2.0 of the Medication Inventory Form and Supplemental Medication Inventory Form. The following codes should be used:

1 = oral tablet or capsule	4 = ophthalmic
2 = oral liquid	5 = rectal or vaginal
3 = topical liquid, lotion, or ointment	6 = inhaled

7 = injected

9 = powder

8 = transdermal patch

10 = nasal

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-September, 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:

<u>Category on Form</u>	<u>Interpretation</u>
< 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 first 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 (any follow-up information, PSG information, and medication code), the medication inventory forms (first page and supplemental pages) can be submitted to the data system. DO NOT fax the medication inventory form in until the PSG has been performed. 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 Edits Regarding Clarification of Medication Name or Ingredient List

Occasionally edits will be posted to the web site that will help us code the medications so they can be used in future MrOS analyses. Most of these edits will ask you to clarify the medication name or to list the ingredients. Sometimes the edit is 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. Sometime an edit is generated if the list of ingredients is required to clarify the medication name. Clinics can add a list of ingredients using the MrOS web site. In some cases, the web site may not allow the proper change to be made because the list of ingredients is too long. When errors occur, clinics may email the list of ingredients directly to Lewis Nusgarten at the Coordinating Center (lnusgarten@psg.ucsf.edu). If you send a list of ingredients to Lewis, you should not address the edit. Once Lewis has received the ingredients from you, he will address the edit.

A few things that will make this process a little bit easier:

- 1) You only need to contact a participant to identify ingredients 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 coded as a multivitamin, minerals or herbal, respectively. You can address the edit using the web site or send an email to Lewis if the web site will not accept the change.

Those preparations with a single extra component, such as extra calcium or iron, should be coded as "multivitamins/calcium", "minerals/lutien", 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 Lewis a list of ingredients if the web site will not accept the change.

Quality Assurance

- Read and study manual
- Practice looking up medication codes in the Access database

Table 1. Medications requiring indication of formulation in medication name field on version 1 of medication forms.

ASTHMA		EYE MEDS	
2014004	ALBUTEROL INHALATION SOLUTION	264012	ATROPINE OPHTHALMIC
2014005	ALBUTEROL TAB	264018	ATROPINE SULFATE OPHTHALMIC
2014002	VENTOLIN INHALER	264025	ATROPINE SULFATE INJECTION
2014009	VENTOLIN TAB		
305003	CROMOLYN INHALER	CORTICOSTEROID	
305008	INTAL INHALER	183020	CORTEF INJ
305005	INTAL CAPS	183069	HYDROCORTONE TAB
109007	ISOPROTERENOL TABS	755001	TERRA-CORTRIL OINTMENT
710001	ISOPROTERENOL SULF/CALCIUM IODIDE SYRUP	755003	TERRA-CORTRIL AEROSOL
291002	ISOPROTERENOL INHALER	755002	TERRA-CORTRIL OPHTH/OTIC
748003	ISOPROTERENOL/PHENYLEPHRINE HCL INHALER	259009	DIAMOX INJ
730001	ISUPREL COMPOUND ELIXIR	259006	DIAMOX TABS/CAPS
109005	ISUPREL INJ	210007	DIETHYLSTILBESTROL TABS
109004	ISUPREL TABS	210017	DIETHYLSTILBESTROL LOTION
		210016	DIETHYLSTILBESTROL VAGINAL SUPP
		178005	CORTISONE INJ
SEX HORMONES		178001	CORTISONE TAB
212036	PREMARIN CREAM TOPICAL	178003	CORTISONE ACETATE OPHTH
212028	PREMARIN TAB	193024	TRIAMCINOLONE CREAM
212034	PREMARIN INJECTION	537002	TRIAMCINOLONE INJ
212032	PREMARIN VAGINAL CREAM	193014	TRIAMCINOLONE TAB
7058001	PREMARIN VAGINAL CREAM W/FOLIC ACID	184021	HYDROCORTONE INJ
836009	PREMARIN W/METHYLTESTOSTERONE TABS	183069	HYDROCORTONE TAB
9999651	PREMPHASE TABS		
1337001	PREMPRO TABS	NITROGLYCERIN	
1116003	TESTOSTERONE CYPIONATE INJECTION	165001	ANGIBID CAPS
1015002	TESTOSTERONE ENANTHATE INJECTION	165046	DEPONIT TRANSDERMAL NITROGLYCERIN
3792001	TESTOSTERONE TOPICAL	3615025	MINITRAN PATCH
662002	TESTOSTERONE PROPIONATE BUCCAL TAB	3615026	NITREK TRANSDERMAL
		3615001	NITRO/TRANSDERM
416013	CLIMARA TRANSDERMAL	165018	NITRO-BID TOPICAL
416020	VIVELLE TRANSDERMAL	3615002	NITRODISC TRANSDERMAL NITROGLYCERIN
416005	ESTRACE TABS	3615005	NITRO-DUR TRANSDERMAL NITROGLYCERIN
416009	ESTRACE VAGINAL CREAM	165052	NITROGARD TRANSMUCOSAL NITROGLYCERIN
213001	OGEN VAGINAL CREAM	165002	NITROGLYCERIN TOPICAL
213011	OGEN TAB	165025	NITROL TOPICAL
416002	ESTRADIOL TRANSDERMAL	165041	NITROLINGUAL
462004	ESTRADIOL CYPIONATE INJECTION	165040	NITRONG SUSTAINED RELEASE CAPS
2020003	ESTRATEST TAB	165015	NITROPRN TABS
212039	ESTROGEN CREAM	165017	NITROSPAN CAPS
1337004	ESTROGEN/MEDROXYPROGESTERONE TAB	165024	NITRO-TD CAP
836010	ESTROGENS AND METHYLTESTOSTERONE TAB	165030	NTG INJECTION
211005	ESTERIFIED ESTROGENS TAB	165036	TL-NITRO SR CAPS
742001	ESTROGENS/MEPROBAMATE TAB	3615011	TRANSDERM-NITRO
332001	ESTRONE TAB	165057	NITROQUICK SUBLINGUAL TABS
213012	ESTROPIPATE TAB	165007	NITROSTAT SUBLINGUAL TABS
9999762	ESTROVEN CAPS		
7078001	ESTROVIS TAB		
212021	CONJUGATED ESTROGENS TAB		
212007	CONJUGATED ESTROGENS CREAM		
212008	CONJUGATED ESTROGENS INJECTION		
212018	CONJUGATED ESTROGENS VAGINAL CREAM		
211005	ESTERIFIED ESTROGENS TAB		
265011	EPINEPHRINE HCL INJ		
266014	PRIMATENE INHALER		
604003	PRIMATENE TABS		

