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National Survey of Midlife Development in the United States (MIDUS II): Biomarker Project, 2004-2009

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Medication Data

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DOCUMENTATION

for

MEDICATION DATA

in the

MIDUS II
BIOMARKER PROJECT
(P4)

University of Wisconsin ♦ Institute on Aging
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INTRODUCTION

This document provides an overview of the medication data collected in the MIDUS-II Biomarker Project (P4). It describes the protocols for collecting and recording medication data, as well as coding medications and diagnoses. It also provides information about the construction and usage of related administrative and constructed variables.

Data users are also encouraged to review the Biomarker (P4) Readme Data File Notes. This document provides information about naming conventions, as well as administrative and filter variables included in the data file. It also includes information about how we handled missing values and other issues that arose over the course of the study.   For example, there are instances when variables were added or sections of an instrument were expanded for data entry purposes to accommodate additional information provided by the respondent.

This document will be periodically revised and updated as more information is gathered, and researchers continue to work with the MIDUS-II Biomarker data. If there are suggestions or comments, please contact Gayle Love (glove@wisc.edu) or Barry Radler (bradler@wisc.edu).

TABLE OF CONTENTS

SECTION A

OVERVIEW OF DATA FILE AND COLLECTION PROTOCOLS

OVERVIEW OF DATA AND COLLECTION PROTOCOLS

The Biomarker Project (P4) includes comprehensive data about the medications study participants are taking at the time of data collection. Specifically information is recorded about the following medications types, as well as medication allergies:
- Prescription
- Over-The-Counter (OTC)
- Alternative Medications

The Medication data appear in the data file immediately following the Bone Scan data. A copy of the Medication Chart appears in Section B. The variable names have been added to the instrument in the cell where the data they represent is recorded. As described in "MIDUS II Biomarker Project (P4) Readme Data File Notes", the naming convention organizes variables according to the data type or method used for data collection. The variable names for the medication data begin with the unique 3 character set "B4X".

This data is obtained at all 3 P4 sites. The remainder of this section provides general information and also indicates where additional details can be found.

Medication Data
Respondents are instructed to bring all their medications, in the original bottles, to the GCRC (General Clinical Research Center) when they come for their visit. We ask them to do this to ensure that we are able to record medication names and dosages accurately. The Medication Chart has three pages and includes sections to record information about:

- Prescription Medications: All FDA approved medications prescribed by someone authorized/licensed under the Western medical tradition, typically a physician.

- Over the Counter Medications: Include vitamins, minerals, non-prescription pain, antacids, anti-diarrheas, fiber, lubricating eye or nose preparations etc. that the subject uses regularly and can be purchased "Over the Counter" (OTC) without a prescription.

- Alternative Medications: Include herbs, herbal blends (not including herbal teas), homeopathic remedies, and other alternative remedies. These may be purchased over the counter or they may be "prescribed" by a health care practitioner trained in a non-western tradition.

- Medication Allergies: Any medication (prescription, OTC, alternative) that the subject reports being allergic to.

During the visit project staff record the following information about medications on the medication chart:
- Medication name, dosage, and route of administration
- How often the medication is taken
- How long the participant has been taking a given medication
- Why they think they are taking the medication

In addition to the detailed medication data this section of the data file also includes the following administrative, filter, or computed variables:

- B4XPMD, B4XOMD, B4XAMD – administrative variables indicating if the respondent takes medications of the indicated type or not.

- Analyses including biomarkers typically control for medication use that might affect the observed levels. To facilitate analyses using common biomarkers pairs of summary variables were created for 4 common types of Prescription medications. Each pair includes a Yes/No variable indicating if the participant takes medication of that type and a second variable indicating the number of medications of that type that the individual takes. Details about the construction of these variables, including medication codes, can be found in the "Documentation of Scales and Composite Variables". The indicated pairs of variables were created for the indicate medication classes:

  o Blood Pressure: B4XBPD, B4XBPC
  o Cholesterol: B4XCHD, B4XCHC
  o Corticosteroids: B4XCOD, B4XCOC
  o Depression: B4XDPD, B4XDPC

These computed variables appear in the data after the variables for the prescription medication. To create similar variables for other categories of medications please refer to Appendix B in Section D which contains a list of the medication codes and category names.

Protocol for Collecting Medication Data
A standardized protocol for collecting medication data was implemented at all 3 sites. A copy of this protocol appears in Section C. See Appendix A in Section D for a sample of a completed medication chart.

Protocol for Coding Medication Data
Completed forms were sent to the University of Madison (central coordinating site) for review prior to data entry.   The review included specification of medication codes based on the medication name, as well as information about route, or reason for taking the medication, as appropriate. The medication codes were selected from our master list of medication codes derived from the UW Hospital Formulary which utilizes the American Hospital Formulary System (AHFS) Pharmacologic-Therapeutic classification system. Guidelines for assigning these codes can be found in Section 3. A list of the medication codes and corresponding category names can be found in Appendix B.

For each medication, staff members also ask study participants "Why are you taking it?" Responses to this question are recorded verbatim. During the pre-data entry review process project staff examined answers to this question and recorded the most appropriate diagnosis code. *Thus, the codes correspond to the participants understanding of why they are taking the medication, which may differ from the reason why it was prescribed.* The diagnosis codes are taken from the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). A master list of common diagnoses is maintained. A copy of our master list of diagnosis codes and corresponding category names can be found in Appendix C. The list was updated over the course of the study using the ICD-9 website at: http://www.eicd/EICMain.htm

SECTION B

MEDICATION CHART

MIDUS PROJECT 4: **PRESCRIPTION MEDICATION**

Site #____   ID#_____

# of prescription medications? __[B4XPM]____

Date_____

Drug code	Drug name and dosage	Route	Frequency	Taken for how long?	Why are you taking it?	Diagnosis code
[B4XPC1]	1. [B4XPDD1] [B4XPDU1]	[B4XPR1]	[B4XPF1] [B4XPFU1]	[B4XPT1] [B4XPTU1]		[B4XPDC1]
[B4XPC2]	2. [B4XPN2] [B4XPDD2] [B4XPDU2]	[B4XPR2]	[B4XPF2] [B4XPFU2]	[B4XPT2] [B4XPTU2]		[B4XPDC2]
[B4XPC3]	3. [B4XPN3] [B4XPDD3] [B4XPDU3]	[B4XPR3]	[B4XPF3] [B4XPFU3]	[B4XPT3] [B4XPTU3]		[B4XPDC3]
[B4XPC4]	4. [B4XPN4] [B4XPDD4] [B4XPDU4]	[B4XPR4]	[B4XPF4] [B4XPFU4]	[B4XPT4] [B4XPTU4]		[B4XPDC4]
[B4XPC5]	5. [B4XPN5] [B4XPDD5] [B4XPDU5]	[B4XPR5]	[B4XPF5] [B4XPFU5]	[B4XPT5] [B4XPTU5]		[B4XPDC5]
[B4XPC6]	6. [B4XPN6] [B4XPDD6] [B4XPDU6]	[B4XPR6]	[B4XPF6] [B4XPFU6]	[B4XPT6] [B4XPTU6]		[B4XPDC6]
[B4XPC7]	7. [B4XPN7] [B4XPDD7] [B4XPDU7]	[B4XPR7]	[B4XPF7] [B4XPFU7]	[B4XPT7] [B4XPTU7]		[B4XPDC7]
[B4XPC8]	8. [B4XPN8] [B4XPDD8] [B4XPDU8]	[B4XPR8]	[B4XPF8] [B4XPFU8]	[B4XPT8] [B4XPTU8]		[B4XPDC8]
[B4XPC9]	9. [B4XPN9] [B4XPDD9] [B4XPDU9]	[B4XPR9]	[B4XPF9] [B4XPFU9]	[B4XPT9] [B4XPTU9]		[B4XPDC9]
[B4XPC10]	10. [B4XPN10] [B4XPDD10] [B4XPDU10]	[B4XPR10]	[B4XPF10] [B4XPFU10]	[B4XPT10] [B4XPTU10]		[B4XPDC10]
[B4XPC11]	11. [B4XPN11] [B4XPDD11] [B4XPDU11]	[B4XPR11]	[B4XPF11] [B4XPFU11]	[B4XPT11] [B4XPTU11]		[B4XPDC11]

NON-PRESCRIPTION MEDICATION
(Over the Counter)

Site #_____   ID#_____

# of non-prescription medications? __[B4XOM]____   Date_____

Drug code	Drug name and dosage	Route	Frequency	Taken for how long?	Why are you taking it?	Diagnosis code
[B4XOC1]	1. Multiple vitamin Y N [B4XOMV] [B4XODD1] [B4XODU1]	[B4XOR1]	[B4XOF1] [B4XOFU1]	[B4XOT1] [B4XOTU1]		[B4XODC1]
[B4XOC2]	2. Calcium Y N [B4XOCS] [B4XODD2] [B4XODU2]	[B4XOR2]	[B4XOF2] [B4XOFU2]	[B4XOT2] [B4XOTU2] [B4XOTU2S]		[B4XODC2]
[B4XOC3]	3. [B4XODD3] [B4XODU3]	[B4XOR3]	[B4XOF3] [B4XOFU3]	[B4XOT3] [B4XOTU3]		[B4XODC3]
[B4XOC4]	4. [B4XODD4] [B4XODU4]	[B4XOR4]	[B4XOF4] [B4XOFU4]	[B4XOT4] [B4XOTU4]		[B4XODC4]
[B4XOC5]	5. [B4XODD5] [B4XODU5]	[B4XOR5]	[B4XOF5] [B4XOFU5]	[B4XOT5] [B4XOTU5]		[B4XODC5]
[B4XOC6]	6. [B4XODD6] [B4XODU6]	[B4XOR6]	[B4XOF6] [B4XOFU6]	[B4XOT6] [B4XOTU6]		[B4XODC6]
[B4XOC7]	7. [B4XODD7] [B4XODU7]	[B4XOR7]	[B4XOF7] [B4XOFU7]	[B4XOT7] [B4XOTU7]		[B4XODC7]
[B4XOC8]	8. [B4XODD8] [B4XODU8]	[B4XOR8]	[B4XOF8] [B4XOFU8]	[B4XOT8] [B4XOTU8]		[B4XODC8]
[B4XOC9]	9. [B4XODD9] [B4XODU9]	[B4XOR9]	[B4XOF9] [B4XOFU9]	[B4XOT9] [B4XOTU9]		[B4XODC9]
[B4XOC10]	10. [B4XODD10] [B4XODU10]	[B4XOR10]	[B4XOF10] [B4XOFU10]	[B4XOT10] [B4XOTU10]		[B4XODC10]

B3

ALTERNATIVE MEDICATIONS (herbal, homeopathic, etc.)

Site #_____   ID#_____

# of alternative medications? ___[B4XAM]_____   Date_____

Drug code	Drug name and dosage	Route	Frequency	Taken how long?	Why are you taking it?	Diagnosis code
[B4XAC1]	1. [B4XADD1] [B4XADU1]	[B4XAR1]	[B4XAF1] [B4XAFU1]	[B4XAT1] [B4XATU1]		[B4XADC1]
[B4XAC2]	2. [B4XADD2] [B4XADU2]	[B4XAR2]	[B4XAF2] [B4XAFU2]	[B4XAT2] [B4XATU2]		[B4XADC2]
[B4XAC3]	3. [B4XADD3] [B4XADU3]	[B4XAR3]	[B4XAF3] [B4XAFU3]	[B4XAT3] [B4XATU3]		[B4XADC3]
[B4XAC4]	4. [B4XADD4] [B4XADU4]	[B4XAR4]	[B4XAF4] [B4XAFU4]	[B4XAT4] [B4XATU4]		[B4XADC4]

* Up to 8 alternative medications recorded in the actual data file. The variable names for record 5-8 follow the same convention as shown here for record 1-4.

MEDICATION ALLERGIES   Does R have any medication allergies? (circle one)   Yes   No [B4XM] [B4XMM]

Drug code	Drug name	Reaction
[B4XMC1]	1.	
[B4XMC2]	2.	
[B4XMC3]	3.	
[B4XMC4]	4.	

* Up to 6 medication allergies recorded in the actual data file. The variable names for record 5-6 follow the same convention as shown here for record 1-4.

SECTION C

DATA COLLECTION AND CODING PROTOCOLS

Protocol for Collecting Medication Data

Protocol for Coding Medication Names

PROTOCOL FOR COLLECTING MEDICATION DATA

The following provides instructions for administering the Medication Chart for the MIDUS II Biomarker Project (P4).

Background

Respondents are instructed to bring all their medications in the original bottles. We ask them to do this to ensure that we are able to record medication names and dosages accurately. The Medication Chart has three pages and includes sections to record information about:

Prescription Medications:
> All FDA approved medications prescribed by someone authorized/licensed under the Western medical tradition, typically physician.
>
> Note: Some vitamins (e.g. Folic Acid, Niacin /Niaspan below) are prescription strength and would be in a prescription bottle.

Over the Counter Medications:
> Include vitamins, minerals, non-prescription pain, antacids, anti-diarrheals, fiber, lubricating eye or nose preparations etc. that the subject uses regularly and can be purchased "Over the Co unter" (OTC) without a prescription.
>
> There are two notable exceptions;
> - Folic Acid is a prescription medication if the dosage is 800 mcg or more.
> - Niacin (Niaspan) is a prescription medication if the dosage is 500 mg or more.

Examples: Over the Counter (non-prescription) General Medications

Advil	Fiber supplements	Motrin
Acetaminophen APAP	Fiber Con	Naproxen
Alleve	Floride Rinse	Nasalcrom
Ascriptin	Ibuprofen	Nasal spray (saline)
Aspirin	Immodium	Pepto Bismol
Benadryl	Hydrocortisone cream	Psyllium
Citrucel	Legatrim	Sennakot
Diphenhydramine	Loperimide	Simethicone
Docusate	Lactaid	Tums
Eye drops - artificial tears	Maalox	Tylenol
Excedrine	Metamucil	

Examples: Over the Counter (non-prescription) Vitamins & Minerals

Multi vitamin	Chromium picolinate	Phosphorus
Vitamin A	Copper	Potassium
Vitamin B's	Ferrous sulfate	Protegra
Vitamin C	Folic acid	Selenium
Vitamin D	Iron	Zinc
Vitamin E	Niacin	
Calcium	Magnesium	

<u>Alternative Medications:</u>
Include herbs, herbal blends (<u>not including herbal teas</u>), homeopathic remedies, and other alternative remedies. These may be purchased OTC (over the counter) or they may be "prescribed" by a health care practitioner trained in a non-western tradition

Examples: Over the Counter (non-prescription) Vitamins & Minerals

Alfalfa	Echinacea	Lutein
Alpha lipoic Acid	Essential Fatty Acid	Lysine
Adrenal Support	Flax Seed Oil	Lymph gland cleanser
Bowel Aide	Fish Oil	Melatonin
Billberry Extract	Ginkgo biloba	MSMw/GS
Homeopathic	Garlic	Mega-chel
Cayenne	Ginseng	Nutri-calm
Chondrochondroitin	Ginger	Olive Leaf Extract
Cod liver oil	Glucosamine/	Osteobiflex
Co Q 10	glucosamine chondroitin	Primrose seed oil
Colostrum	Kava kava	St Johns wort
Cortislim	Kelp	Saw Palmetto
Cranberry Pill	Lecithin	Valerian

<u>Medication Allergies</u>
Include any medication (prescription, OTC, alternative) that the subject believes s/he is allergic to.

Instructions for Completing the Medication Chart

<u>General Guidelines:</u>
1. If a respondent is taking multiple drugs of a particular type, or to treat a particular condition, record information about all the medications. For example a respondent may take two different types of insulin, or is taking multiple medications to treat high blood pressure.
2. Additional Medications: Some respondents will take more medications than our forms allow. To accommodate these situations, Project staff should carry an extra copy of the Medication Chart and use the appropriate page to record information about additional medications. Specifically, staff should:
   a. Write "See additional sheet" at the end of the appropriate section of the chart
   b. Fill out the appropriate additional sheet and *paper clip* it to the back of the completed chart.
   c. Make sure that the "# of _____medications?" line reflects the total number of medications of that type that the respondent takes.
3. Medications Not Currently Being Taken: If the respondent brings in prescription medication that they are no longer taking, do not record it on the form (or remove it during field editing).

Specific Instructions:
Collect medications from the participant after GCRC admission but before the nurse begins the admission assessments. The Medication Chart is completed in three steps. The first two are completed during the GCRC visit. The third step can be completed after the subject has left the GCRC.

An example of a completed Medication Chart can be found in Section D, Appendix A.

Step 1: *To ensure that medications are correctly organized by type*, please complete this step while GCRC nurse is conducting admission assessment or while subject is eating dinner.   Return the medications to the subject after completing this step.

Staff will ask subjects to confirm the dosage information recorded in this step, thus it will be helpful to use a pencil.

If the subject is not taking medications of a certain type, record a 0 in the space for "# of ___ medications".

For all medications the subject is taking record the following:

1. Drug name: Copy from label on bottle.

    - Many subjects are likely to be taking a multiple vitamin or calcium supplement. Therefore, the first two lines on the chart for Non-Prescription Medications are reserved for these two medications.
        - If the subject is not taking any non-prescription medications ignore these two boxes.
        - If the subject is taking non-prescription medications, circle "Yes" or "No" and fill in the appropriate information.

2. Dosage: we want to know how much of the drug they take at any given time that they take it. Copy from label on bottle and ask respondents if this is how they actually take the drug. Write the exact dosage they take. For example, if the label reads:

    - Lipitor 80mg, take half tablet once a day & the respondent confirms taking only ½ tablet daily, then record 40mg as the dosage.

    - Atenolol 20 mg, take one tablet in the morning and one at bedtime, & the respondent confirms this, then record 20 mg as the dosage.

    - Alfalfa 500mg per tablet & the respondent reports taking 6 tablets three times per day, then record 3,000 mg as the dosage.

    - Inhaled Medications: dosage information for inhalers can be listed in two forms.
        - It may be listed in the standard units (e.g. mcg, mg etc.) reflecting the total dosage for the contents of the inhaler.
        - It should also be listed in terms of the number of puffs that person should inhale reflecting the amount taken when the inhaler is used. Please be sure to record # of puffs as this is the dosage that we want to record.

Note: On rare occasions alternative medications may report dosage information in grains rather than mg, cc's, etc. This may be indicated by the word "grain" in the medication name. In those instances, record the full name of the medication, but report the dose in terms of the number of pills, tablets etc. that the respondent takes.

3. Route: this the route by which the medication is taken. The following abbreviations can be used:

PO	oral (tablets, capsules, liquid)
IM	intramuscular (Vitamin B12 shots)
SC or SQ	subcutaneous (insulin injections)
Inh	inhaled (nasal spray, asthma inhalers)
Top	topical (creams, eye drops, patches)
SL	sub-lingual (under the tongue)

4. Frequency: this tells us how often they take the dose recorded at # 2 above. The following abbreviations can be used:

QD	once daily
BID	twice a day
TID	three times a day
QID	four times a day
PRN	as needed

o Medications Taken As Needed (PRN):

PRN ONLY – This refers to PRN medications that are taken irregularly in response to an acute need (e.g. cold medicine, sleep aids, antibiotics), they are generally OTC or alternative medications, but can be prescribed.

- If a medication is taken PRN at a specific time of day, please only record "PRN". For example if the respondent takes a sleep aid in the evening as needed and both PRN and QD or at bedtime is recorded, it implies the respondent is taking the medication on both a regular schedule *and* as needed.
  - o The key piece of information is that it is taken '***as needed'***

- OTC medications taken for a single occurrence of some condition or illness that has not recurred for at least 3 months should not be recorded.
- OTC medications taken on an irregular basis for recurring conditions (e.g. eczema, sinusitis) should be recorded.

PRN Supplemental – This refers to PRN medications that are taken as needed to supplement a regularly scheduled dosage, under certain circumstances.

- In those instances record the regular dosage on a single line then repeat the information on the next line for the PRN usage. This is the only instance in which information about a single medication should appear on *two* lines.

For example, asthmatics may have an inhaler that is used daily, but could also be used PRN in emergencies. This would be recorded as follows:

1. Albuterol 2 puffs   BID ….
2. Albuterol 1 puff   PRN ……

- o Medications Taken More Than Once A Day:

  Typically, the number of times the medication is taken and the amount are standardized. Sometimes the dosage is the same every time the medication is taken, other times the dosage taken in the morning time is different from that taken later in the day. As long as the amounts and time of day are standardized, the medication and all dosage information should be recorded on the same line.

  For example someone with high Blood Pressure may be taking Altenolol twice a day, but at different dosages. This would be recorded as follows:

  1. Altenolol 50mg a.m. 100 m.g. p.m.   BID ….
  2. (next medication)

5. After recording the above information in the appropriate location for each medication the subject is taking, record the total number of medications of each type in the "# of _____ medications" line.

Step 2: This step can be performed in conjunction with the Medical History or the Physical Exam at the discretion of GCRC or Project Staff.

Review the Medication Chart with the subject. For each medication recorded on the chart:

6. Confirm that subject is taking the medication as indicated on the bottle. Sometimes the prescribed dosage is a certain amount but it is modified at the doctor's recommendation or the subject prefers not to take the recommended dose for a non-prescription or alternative medication.

7. Ask the subject how long s/he has been taking the medication, record days, months or years as appropriate.

   - If the respondent reports the year, or a month and year that they started taking a medication please convert to the appropriate number of years, months etc.

8. Ask the subject why s/he is taking the medication. Medications are typically taken for specific reasons, but subjects sometimes take them for other atypical reasons or don't really understand why they are taking a particular medication. We want to know why they think they are taking particular medications. Record the reason the subject is taking the drug verbatim.

   - If the respondent says "The Dr. prescribed it" probe for more information (e.g. condition, symptom, prevention)!

     - o If after probing it is clear that the respondent does not know why they are taking the medication then record "Don't Know".

   - Please be sure to ask this question for ALL medications.

9. Ask the subject if s/he has any medication allergies. If 'Yes' record the medication name(s) and the nature of the reaction(s) experienced.

Step 3: Assigning Medication and Diagnosis Codes.
Designated staff, in Madison, will assign Medication and Diagnosis codes using systems developed by pharmacists and epidemiologists, respectively.

Protocol for Coding Medication Names

We maintain a master list of medication codes taken from the UW Hospital Formulary which utilizes the American Hospital Formulary System (AHFS) Pharmacologic-Therapeutic classification system. Our master list was updated in winter 2007-2008 so that codes were consistent with the AHFS re-structuring of the classification system in 2006. The UW website was checked regularly for announcements regarding modifications to the AHFS classification system. As noted below, we also regularly added new medication names and codes to our master list.

Coding Protocol
1. If the medication name appears on the master Medication list and,
    a. there is only a single code listed, write that code on the medication chart.
    b. the medication has 2 or more codes see Specific Guidelines below.

2. If the medication name <u>does not</u> appear on the master list
    a. Search for the medication on the UW Formulary Website:
        http://www.formularyproductions.com/wisconsin/
        i. If the medication name is listed on the formulary and it only has one code:
            • record the code on the medication chart
            • add the medication name and code to the list of medications to be added to the master list
        ii. If the medication name is listed on the formulary and has two or more codes, flag for review to develop more specific guidelines.

    b. If the medication name cannot be found in the formulary, there are two additional databases that can be searched. Neither site lists codes, but they do provide additional information that can be used to determine the pharmacologic-therapeutic class to which the medication belongs.

        i. MICROMEDEX which is accessed through the UW Formulary link. Access this database by:
            • Clicking on any medication in the formulary
            • Select "Micromedex Drug Information"
            • Under Main select Keyword search to look for the medication name of interest.

        ii. Medline http://medlineplus.gov/. If references to the medication name are found on Medline:
            • Review the "Why is this medication prescribed?" section
                a. If the pharmacologic-therapeutic class to which the medication belongs is specified, then go back to the UW formulary to identify the code for that class of medications.
            • Review the list of brand names at the bottom of the 'page' for that medication. It may list other names for the same medication. Sometimes those other names appear on the formulary, if so record the code on the medication chart according to above.
        iii. If references to the medication name are not found on Medline flag for additional review.

<u>Specific Guidelines for Medications having 2 or more Codes</u>
Some medications can be classified into more than one pharmacologic-therapeutic class, and will therefore have multiple codes on our master list. This happens for one of two reasons.
1. A single medication has multiple effects or usages.
   Example – Epinephrine which is a Sympathomimetic (adrenergic) agent, a Vasoconstrictor, and a Mydriatic (dilates the pupils) agent.

   The correct code to be used can be determined by looking at why the respondent thinks s/he is taking the medication, or the administration route.

2. A medication has 2 or more active ingredients having different pharmacologic effects.
   Example – Combivent (asthma medication), contains an Antimuscarinic/Antispasmodic to dilate the bronchial passages and a Sympathomimetic (adrenergic) agent to regulate heart rate.

The code to be recorded for data entry purposes, however, is the one that most closely reflects why the participant is taking the medication.

The following guidelines for selecting the appropriate code were developed based on discussion with a clinical pharmacist, others were developed after looking at active ingredients in medications with multiple formulas (e.g. Tylenol) or closer examination of the medication categories (e.g. antihistamines).

<u>Decision Rules for Specific Medications or Medication Types</u>
   Antihistamines:
   The classification system includes a variety of codes for Antihistamines. They can be used to treat allergy symptoms, coughs & colds, travel sickness, and as sleep aids.
   The general Antihistamine Drug class has codes ranging from 040000 to 049200. These include the various 1st generation antihistamines, along with 2nd generation and 'other' antihistamines. An antihistamine category also appears in the following drug classes:
   Respiratory Tract Agents (Code=480400)
   Gastrointestinal Drugs-Antiemetics (Code=562208)

   Unless there is a specific reference to one of these systems we will use the appropriate code from the Antihistamine Drug class (040000's) when assigning medication code. The specific code will be determined based on the active ingredient in the medication as follows:
   - Code = 040400 if active ingredient is Diphenhydramine, Chlorpheniramine Maleate, Pseudoephedrine/Carbinox, Pseudoephedrine/Chlorpheniramine, or a combination of 1st generation Antihistamines
     o NOTE: Psuedoephedrine HCL alone is coded as 121200 a sympathomimetic (adrenergic) agent.

   - Code = 040404 if active ingredient is Doxylamine Succinate
   - Code = 040800 if active ingredient is Loratadine (e.g. Claritin)
   - Code = 049200 if active ingredient is an antihistamine but not specifically defined as 1st or 2nd generation, or a medication includes both 1st & 2nd generation antihistamines.

If someone reports using a medication for "allergies" and it is not clear what the active ingredients are most likely use Code 529200 (EENT drugs, Misc).

Acyclovir (Zovirax):
- Code = 840406 if respondent reports taking for prevention or treatment of herpes or shingles as it is an antiviral being used as an Anti-infective for skin and mucous membranes.
- Flag for review if respondent reports taking for another reason.

Advair (Diskus or HFA):
- Code = 680400 if respondent reports taking for Asthma, shortness of breath, trouble breathing, emphysema etc. as the medication is being used as an anti-inflammatory
- Flag for review if respondent reports taking for another reason.

Combivent (2 active ingredients):
- Code 120808 –Antimuscarinics/Antispasmodics –bronchodialator
  - Use this code if respondent reports taking for Asthma or COPD
- Code 121200 – Sympathomimetic (Adrenergic) agent to regulate heart rate

Eye, Ear Nose, Throat Meds: (Patanol, Levobunolol, Cosopt, Lumigan, Restasis, Econopred)
- Per Clinical pharmacist, use code 523600, code for miscellaneous EENT drugs
- Flag for review if uncertain

Hydrocodone/Acetaminophen (APAP) or Darvocet (N-100) or Propoxyphene-N/APAP: These are all opiate agonists.
- Code = 280808 if respondent reports taking for pain of any type or if it is listed under Medication Allergies
- Flag for review if respondent reports taking for another reason

Magnesium:
- Code = 401200 if respondent reports taking for general uses such as, bone health (e.g. osteopenia, bones), cramps, calcium support, good health etc.
- Code= 281292 if respondent specifically reports taking as an anti-convulsant
- Code= 560400 if respondent reports taking as an antacid
- Code= 561200 if respondent reports taking as a laxative

Metrogel:
- Code =840404 (Misc. Anti-infective) if respondent reports taking for Rosacea
- Flag for review if respondent reports taking for another reason.

NSAIDs Medications not listed on Formulary:
- Code = 280804 (CNS agent having non-steroidal anti-inflammatory effect) if medication is being used to treat pain
- Code = 520820 (EENT Prepared, anti-inflammatory agent, non-steroidal) if medication is being used to treat inflammation.

Nystatin Cream:
- Code=84040808 (Antifungal, polyenes) if respondent reports taking for rash
- Flag for review if respondent reports taking for another reason

Nystatin/Triamcinolone ointment: Combination medication with 2 or more active ingredients, no specific guidelines as yet, flag for review

Phenobarbital:
- Code =281204 if listed under Medication Allergies and there is an indication that it is used to treat convulsions.
- Code = 282404 if listed under Medication Allergies and there is an indication that it is being as an anxiolytic, sedative, or hypnotic.
- Either code may be used if listed under Medication Allergies and there is no indication as to why the person is taking it.

Procrit: no specific guidelines as yet, flag for review

Promethazine (Phenergan):
- Code = 282492 (Misc. Anxiolytics, Sedatives, and Hypnotics) if respondent reports being treated for Nausea, per judgement of Clinical Pharmacist, underlying mechanism is more like an anti-histamine (040400) but that classification wouldn't make sense to most people.
- Flag for review if respondent reports taking for another reason

Tetanus:
- Code=800400 when listed as Medication Allergy. The horse serum used for the vaccination can trigger allergic reactions.

Triamcinolone Acetonide Cream/Nasonex:
- Code =840600 if respondent reports taking for a yeast infection

Tums:
- Code =401200 if respondent reports using it as Calcium source
- Code=560400 if respondent reports using it for antacid/reflux

Tylenol:
There are several different types of Tylenol some of which have multiple active ingredients. The medication code recorded will be determined by the R's reason for taking the indicated type of Tylenol as follows:

- Code = 280892 if using Original formula, Extra Strength, or Arthritis strength for pain
- Cold formula:
    - Code = 040400 if using for hay fever (e.g. anti-histamine effect)
    - Code= 480800 if using for cough suppression
    - Code = 280892 if using for headache or sinus pain
- Allergy formula:
    - Code = 049200 if using for allergies (contains 1st & 2nd generation antihistamines as active ingredients)
    - Code = 280892 if using for headache or sinus pain

- Sinus formula:
    - Code = 481600 if using as expectorant
    - Code = 280892 if using for headache or sinus pain
- PM or Simple Sleep formulas:
    - Code=040400 if using for insomnia or as a sleep aid (anti-histamines are also prescribed as sleep aid because they can induce drowsiness).
    - Code=280892 if using these formulas to help with Pain so respondent can sleep

Synthetic Corticosteroids (Flovent, Flonase, Qvar etc.):
Use one of the following as appropriate:
- 520800 – general EENT anti-inflammatory agents -- Allergies
- 680400 – Hormones & synthetic substitutes, specifically Adrenals – Asthma, trouble breathing
- 840600 – Skin and mucous membrane agents, specifically Anti-inflammatory agents

Urocit-K 10:
- Code = 400800 (Alkalinizing agent) if respondent reports kidney stone prevention
- Flag for review if respondent reports taking for another reason

Vitamins:
- Code =882800 if respondent reports taking a vitamin supplement that contains multiple vitamins and/or minerals even if it is not specifically identified as a multi-vitamin.

Zinc:
- Code = 401200 if respondent reports taking for general uses such as nail strength, immune support, good health, etc
- Code = 842400 if Zinc is used as a lotion or cream as an emollient or protectant
- Code = 849200 if Zinc is used as a lotion or cream for non-specific purpose
- Code =882800 if respondent reports taking Zinc as part of a vitamin supplement

SECTION D

APPENDICES

Appendix A: Sample Completed Medication Chart

Appendix B: Medication Codes and Category Names

Appendix C: Diagnosis Codes and Category Names

APPENDIX A: SAMPLE OF COMPLETED MEDICATION CHART

PRESCRIPTION MEDICATION

of prescription medications? __3__

Site # __2__   ID# __12345__

Date __3/25/04__

Drug code	Drug name and dosage	Route	Frequency	Taken for how long?	Why are you taking it?	Diagnosis code
	1. Celebrex 100mg	PO	BID	2mos	arthritis	
	2. Synthroid 75mcg	PO	QD	2yrs	hypo-thyroid.	
	3. Nasonex 2sprays	inh	QD	6mos	allergies	
	4.					
	5.					
	6.					
	7.					
	8.					
	9.					
	10.					
	11.					

D3

NON-PRESCRIPTION MEDICATION
(Over the Counter)

Site # 2   ID# 12345

# of non-prescription medications? 5

Date 3/25/04

Drug code	Drug name and dosage	Route	Frequency	Taken for how long?	Why are you taking it?	Diagnosis code
	1. Multiple vitamin (Y) N	PO	QD	5 yrs	gen health	
	2. Calcium Y (N)					
	3. aspirin 81mg	PO	QD	6mos	heart health	
	4. Vit C 500mg	PO	QD	5yrs	gen health	
	5. Tylenol 1000mg	PO	PRN	5yrs	pain or headache	
	6. Metamucil 1 Tbsp	PO	QD	6mos	fiber supplement	
	7.					
	8.					
	9					
	10.					

ALTERNATIVE MEDICATIONS (herbal, homeopathic, etc.)

Site # 2   ID# 12345

# of alternative medications? 2

Date 3/25/04

Drug code	Drug name and dosage	Route	Frequency	Taken how long?	Why are you taking it?	Diagnosis code
	1. Glucosamine Sulfate 1500mg	PO	TID	1yr	arthritis	
	2. 2caps Immune Aide	PO	BID	2yrs	allergies	
	3.					
	4.					

MEDICATION ALLERGIES   Does R have any medication allergies? (circle one)   No (Yes)

Drug code	Drug name	Reaction
	1. penicillin	hives
	2. Codeine	hallucinations
	3.	
	4.	

D5

APPENDIX B: MEDICATION CODES AND CATEGORY NAMES

APPENDIX B: Medication Codes and Category Names

The following lists all medication codes and corresponding category names in the Biomarker (P4) Medication data. The codes are taken from the UW Hospital Formulary which utilizes the American Hospital Formulary System (AHFS) Pharmacologic-Therapeutic classification system. The list is in numeric order by code to parallel the structure of the AHFS system.

Note: Most of the codes are 6 digits, but some have 8 digits due to an expansion of the AHFS system in 2006.

040000	Antihistamines
040400	First Generation Antihistamines
040800	Second Generation Antihistamines
049200	Other Antihistamines
08120604	First Generation Cephalosporins
08121292	Other Macrolides
08121608	Aminopenicillins
081218	Quinolones
081220	Sulfonamides
081224	Tetracyclines
081228	Antibacterials, Miscellaneous
08122820	Lincomycins
081408	Azoles
081604	Antituberculosis Agents
08180808	HIV Protease Inhibitors
08180820	Nucleoside and Nucleotide Reverse Transcriptase Inhibitors
081828	Neuramindase Inhibitors
081832	Nucleosides and Nucleotides
083008	Antimalarials
083600	Urinary Anti-infectives
089200	Anti-infectives, Miscellaneous
100000	Anti-neoplastic Agents
120400	Parasympathomimetic (Cholinergic) Agents

120804	Antiparkinsonian Agents
120808	Antimuscarinics/Antipasmodics
121200	Sympathomimetic (Adrenergic) Agents
121600	Sympatholytic (Adrenergic Blocking) Agents
122000	Skeletal Muscle Relaxants
129200	Autonomic Drugs, Miscellaneous
200400	AntiAnemia Drugs
200404	Iron Preparations
201204	Anticoagulants
20120408	Coumarin Derivatives
201600	Hematopoietic Agents
202400	Hemorrheologic Agents
240400	Cardiac Drugs
240404	Antiarrhythmic Agents
240408	Cardiotonic Agents
240600	Antilipemic Agents
240604	Bile Acid Sequestrants
240605	Cholesterol Absorption Inhibitors
240606	Fibric Acid Derivatives
240608	HMG-CoA Reductase Inhibitors
240816	Central a-Agonists
240820	Direct Vasodilators
241208	Nitrates and Nitrites
241292	Vasodilating Agents, Miscellaneous
242000	a-Adrenergic Blocking Agents
242400	b-Adrenergic Blocking Agents
242808	Dihydropyridines
242892	Calcium-Channel Blocking Agents, Miscellaneous
243204	Angiotensin-Converting Enzyme Inhibitors

243208	Angiotensin II Receptor Antagonists
280800	Analgesics and Antipyretics
280804	Nonsteriodal Anti-inflammatory Agents
28080408	Cyclooxygenase-2 (COX-2) Inhibitors
28080424	Salicylates
28080492	Other Nonsteroidal Anti-inflammatory Agents
280808	Opiate Agonists
280892	Analgesics and Antipyretics, Miscellaneous
281204	Barbiturates
281208	Benzodiazepines
281212	Hydantoins
281292	Anticonvulsants, Miscellaneous
281604	Antidepressants
28160416	Selective Serotonin- and Norepinephrine-reuptake Inhibitors
28160420	Selective-serotonin Reuptake Inhibitors
28160424	Serotonin Modulators
28160428	Tricyclics and Other Norepinephrine-reuptake Inhibitors
28160492	Antidepressants, Miscellaneous
28160804	Atypical Antipsychotics
28160824	Phenothiazines
282000	Anorexigenic Agents and Respiratory and Celebral Stimulants
282004	Amphetamines
282092	Anorexigenic Agents and Respiratory and Celebral Stimulants, Miscellaneous
282404	Barbiturates
282408	Benzodiazepines
282492	Anxiolytics, Sedatives, and Hypnotics, Miscellaneous
282800	Antimanic Agents
283228	Selective Serotonin Agonists
283292	Antimigraine Agents, Miscellaneous

289200	Central Nervous System Agents, Miscellaneous
400800	Alkalinizing Agents
401200	Replacement Preparations
402000	Caloric Agents
402800	Diuretics
402808	Loop Diuretics
480000	Respiratory Tract Agents
480800	Antitussives
481600	Expectorants
489200	Respiratory Agents, Miscellaneous
520200	Antiallergic Agents
520404	Antibacterials
520800	Ant-inflammatory Agents
520808	Corticosteroids
520820	Nonsteroidal Anti-inflammatory Agents
521600	Local Anesthetics
523200	Vasoconstrictors
529200	EENT Drugs, Miscellaneous
560400	Antacids and Absorbents
560800	Anti-diarrhea Agents
561000	Antiflatulents
561200	Cathartics and Laxatives
561600	Digestants
562200	Antiemetics
562208	Antihistamines
562220	5-HT3 Receptor Antagonists
562292	Antiemetics, Miscellaneous
562812	Histamine H2-Antagonists
562836	Proton-pump Inhibitors

563600	Anti-inflammatory Agents
569200	GI Drugs, Miscellaneous
680400	Adrenals
680800	Androgens
681200	Contraceptives
681600	Estrogens and Anti-estrogens
681604	Estrogens
681612	Estrogen Agonists-Antagonists
682004	Biguanides
682008	Insulins
682020	Sulfonylureas
682016	Meglitinides
682028	Thiazolidinediones
682092	Anti-diabetic Agents, Miscellaneous
682400	Parathyroid
682800	Pituitary
683200	Progestins
683604	Thyroid Agents
683608	Antithyroid Agents
840404	Antibacterials
840406	Antivirals
84040808	Azoles
84040828	Polyenes
84040892	Antifungals, Miscellaneous
840492	Local Anti-infectives, Miscellaneous
840600	Anti-inflammatory Agents
840800	Antipruritics and Local Anesthetics
841600	Cell Stimulants and Proliferants
842400	Emollients, Demulcents, and Protectants

842800	Keratolytic Agents
849200	Skin and Mucous Membrane Agents, Miscellaneous
861200	Genitourinary Smooth Muscle Relaxants
861600	Respiratory Smooth Muscle Relaxants
880400	Vitamin A
880800	Vitamin B Complex
881200	Vitamin C
881600	Vitamin D
882000	Vitamin E
882400	Vitamin K Activity
882800	Multivitamin Preparations
920000	Miscellaneous Therapeutic Agents
929999	MIDUS Code Alternative Medication
930000	MIDUS Code Study Medication
940000	Devices
960000	Pharmaceutical Aids

APPENDIX C: DIAGNOSIS CODES AND CATEGORY NAMES

APPENDIX C: ICD-9 Codes and Category Names

The following lists ICD-9 codes and corresponding category names. This master list was used to determine diagnosis codes included in the Biomarker (P4) Medication data. They are listed in alphabetic order to facilitate coding from verbatim responses to the question "Why are you taking it?"

ABCESS (TOOTH)	52360
ACNE	70600
ACTINIC KERATOSIS	70200
ADD	31400
ADHD	31400
ADDISONS DISEASE	25540
ADRENAL DISORDER	25590
ALLERGY	47700
ALTITUDE SICKNESS	99320
ANEMIA (low blood count)	28590
ANGINA	41300
ANXIETY	30000
ARRYTHMIA	42790
ARTHRALGIA (joint pain)	71940
ARTHRITIS	71500
ASTHMA	49300
ATRIAL FIBRILLATION	42731
BACK PAIN	72450
BACTERIAL INFECTION	04190
BIPOLAR DISORDER	29640
BLEPHARITIS	03730
BLADDER CANCER	18890

BLADDER- NEUROGENIC	59564
BLOOD CLOT	45390
BLOOD PRESSURE/ HYPERTENSION	40100
BLOOD THINNER	28630
BONES/BONE HEALTH/ BONE STRENGTH	73300
BPH (enlarged prostate)	60001
BREAST CANCER	17490
BRONCHITIS	49000
BURSITIS (Hip)	72650
CANCER	23990
CARPAL TUNNEL	35400
CATARACT	36641
CHEST PAIN	41300
CHOLESTEROL PROBLEMS	27200
CHRONIC PAIN	72920
CHROHNS DISEASE	55590
CIRRHOSIS	57140
CLL (chronic leukemia)	20410
COLD SORES	05409
COLDS/FLU	46590
COLITIS	55690
COLON CANCER	15390
CONGESTION	47220
CONJUCTIVITIS	37230

CONSTIPATION	56400
COPD	49600
CORONARY ART. DISEASE	41400
COUGH	47210
CONGESTIVE HEART FAILURE	42800
DEPRESSION	31100
DERMATITIS (rash)	69200
DIABETES	25000
DIABETES (kidney problems)	25040
DIARRHEA	55890
DIGESTIVE PROBLEMS	53630
DIVERTICULOSIS	56210
DIZZINESS	78040
DRUG ADDICTION	30490
DRY EYES	37515
DYSMENORRHEA	62530
ECZEMA	69200
EDEMA	78230
EMPHYSEMA	49200
ENDOCRINE DISORDER	25990
EPILIPSY	34590
ERECTILE DYSFUNCTION	30272
ESOPHAGUS (Barrets)	53085
EYE DISEASE (Macular Degeneration)	36250
FATIGUE (Tiredness)	78079

FEVER		78060
FIBROMYALGIA		72910
FLU/COLDS		46590
FUNGAL INFECTION (skin)		11190
GAS		78730
GERD (reflux)		53081
GINGIVITIS (Gum Disease)		
	Acute	52300
	Chronic	52310
GLAUCOMA		36590
GOUT		27400
GRAVES		24200
GUM DISEASE (Gingivitis)		
	Acute	52300
	Chronic	52310
HAIR LOSS		70400
HEADACHE		78400
HEART ATTACK		41090
HEART HEALTH		41090
HEARTBURN		53081
HEART FAILURE		42800
HEART PROBLEMS		42990
HEMORRHOIDS		45560
HERPES SIMPLEX		05409
HERPES ZOSTER		05309
HIATAL HERNIA		55330
HIV		04200
HIGH CHOLESTEROL		27200

HIVES	70890
HORMONE REPLACEMENT (Menopause)	62720
HUNTINGTON'S DISEASE	33340
HYPERTENSION/HTN (Blood pressure)	40100
HYPOGLYCEMIA	25080
HYPO-KALEMIA (low potassium)	27680
HYPER-THYROID (High Thyroid)	24280
HYPO-THYROID (Low Thyroid)	24490
IBS (Irritable bowel)	56410
INCONTINENCE (urine)	78830
(bowel)	78760
INDIGESTION	53081
INFECTION	04190
INFLAMMATION (due to Arthritis)	71600
INSOMNIA	78052
IRREGULAR MENSTRUAL CYCLE	62640
ITCHING	69890
JOINT PAIN	71940
KIDNEY STONES	59200
KIDNEY PROBLEMS	59200
LACTOSE INTOLERENCE	27130
LEG CRAMPS	72982
LICHEN PLANUS (SKIN	

DISEASE)	69700
LIMB PAIN	72950
LOW BLOOD COUNT (Anemia)	28590
LUPUS	69540
MACULAR DEGENERATION (Eye disease)	36250
MEMORY LOSS	79700
MENIERE'S DISEASE	38600
MENAPAUSE	62720
MENSTRUAL CRAMPS	62530
METHADONE MAINTENANCE	30400
MIGRAINE	34690
MITRAL VALVE PROBLEMS	42400
MOTION SICKNESS	99460
MOOD SWINGS	29699
MULTIPLE SCLEROSIS	34000
MUSCLE PAIN	72910
MUSCLE SPASM	72885
NARCOLOPSY	00347
NAUSEA	78702
NEURALGIA/NERVE DAMAGE	72920
NEUROGENIC BLADDER	59564
NEUROPATHY	72920
NIGHT SWEATS	78080
NUMBNESS	78200
OCD	30030

OVERWEIGHT	78360
OSTEOPENIA	73390
OSTEOPOROSIS	73300
OTITIS MEDIA	38200
PAIN	71940
PANIC ATTACK	30001
PARANOID/SCHIZOPHRENIA	29530
PARKINSONS DISEASE	33200
PERIPHERAL NEUROPATHY	35600
PERNICIOUS ANEMIA	28100
PHLEBITIS	45190
POLYMYALGIA RHEUMATICA	72500
POTASSIUM DEPLETION	27680
PREMENSTRUAL SYNDROME	62540
PROSTATE CANCER	18500
PROSTATE PROBLEMS/ PROSTATE HEALTH	60190
PSORIASIS	69610
PSYCHOSIS	29590
RASH	69200
RECTAL PAIN	56942
RESTLESS LEGS	33399
RESPIRATORY INFECTION GENERAL	47890
RHEUMATOID ARTHRITIS	71400
RHINITIS (chronic)	47200
RICKETS	26800

ROSACEA	69530
SCHIZOPHRENIA/PARANOID	29530
SEIZURES	34590
SHINGLES	05309
SHORTNESS OF BREATH	78605
SCIATICA	72210
SINUSITIS	47300
SKIN CANCER	17390
SLEEP/SLEEP AID (Insomnia)	78052
SORE THROAT	46400
SPASTIC COLON (IBS)	56410
STOMACH CRAMPS	78900
STOMACH PARASITES	53630
STRESS	30990
STROKE	45390
SYNCOPE	78020
TENDONITIS	72690
THROMBOSIS (blood clot)	45390
THRUSH	11200
TIA (trans ischemic attack)	43590
TIC (Muscle Spasm) – e.g. eye tic	30720
TINNITIS	38830
TIREDNESS (Fatigue)	78079
TOBACCO USE	30510
TOOTH ABCESS	52360

TREMOR	33310
ULCER	53190
ULCERATIVE COLITIS	55690
UNKNOWN	99997
UPPER RESP. INFECTION	46590
URTICARIA	70890
URINARY TRACT INFECTION	59900
URINARY FREQUENCY	78841
URINE RETENTION	78820
VARICOSE VEINS	45400
VERTIGO	43885
VITAMIN D DEFICIENCY	26890
WARTS	07819
WEGENER'S DISEASE	44640
WEIGHT LOSS	78360
WHEEZING	78607
YEAST INFECTION	11289