MEDICATION INVENTORY

1. Background and Rationale

A complete and accurate list of current medication use is essential for several reasons: Some medications affect body composition and bone mass; medication use increases with increasing disability; and a number of ancillary studies require complete medication lists.

We are specifically interested in how individual medications have been actually <u>taken</u> (during the preceeding two weeks) rather than how they were prescribed or intended to be taken.

2. Equipment and Supplies

- Pen
- Container or sack for medications
- Medication Inventory Form (MIF) and MIF Supplement
- Abbreviation list (see page 4)
- Codes for prescription and non prescription formulations (see page 8)

3. Detailed Measurement Procedures

- The participant will have been instructed to bring all prescription and non-prescription medications used in the preceding two weeks with them to the visit.

- The clinic staff person will review all medications and transcribe the name and current dose from the container to the Health ABC Medication Inventory Form (MIF).

- The participant will then be asked how often the medication is taken. Changes in current medication use will be updated at future clinic visits.

3.1 Drug Definition Guidelines

For the purposes of the Health ABC trial, use the following definition guidelines:

1) **Current use:** All medication taken within the two week period (14 days) prior to the baseline clinic visit. Do <u>not</u> include immunizations or medications received during an overnight hospitalization.

2) **Prescription medications:** A medication for which a prescription was written by a physician, dispensed by a pharmacist or physician, and taken by the participant during the two weeks prior to the visit. Prescription medication may include eye drops, pills or tablets, solutions, creams/salves, dermal patches, and injections.

3) **Non-prescription medications:** A medication, vitamin, or dietary supplement that may be purchased without a physician's prescription. This category should include herbal medications and food additives.

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, calcium supplements, and bulk laxatives.

3.2 Medication Reception

Collect all of the medications the participant has brought with them and put these in a container or sack.

Using the script found in **Section A** of the MIF, fill in the appropriate box.

- "Yes" box, if all medication brought in to clinic. Count the total number of medications brought in and record on the MIF. Proceed to **Section B**.

- "No" box, if one or more medications were not brought in. **When a participant forgets to bring in one or more medications that they have taken in the last 2 weeks, each site is responsible for developing a mechanism to gather the information via telephone or return visit.** Missing medications should be sought regardless of study eligibility. It is recommended that the woman be called 1-2 days after the visit to obtain the missing information.

- Took no medication. Self explanatory but ask:

Script: "Are you sure you took no prescription or non prescription medications over the last two weeks?"

3.3 Recording Prescription Medications

B Prescription medications (Section B of MIF)

In this section record the use of prescription medications only.

B1 Medication name

Record only medications used in the two weeks (14 days) prior to the visit. Medications administered in the previous 2 weeks given during surgery or hospitalization will not be recorded on the MIF unless they are continued after discharge. Medications which were prescribed but not taken, or those taken greater than two weeks ago, are not recorded.

Copy the name directly from the medication container using capital letters onto the MIF. Write clearly! Record the complete drug name exactly as written on the container. It is not necessary to record the name of the store or pharmacy where the medicaton was obtained.

Some combination medications contain two or more drugs in a single pill or tablet, and the trade name should be recorded (for example, Dyazide is a combination of hydrochlorothiazide and triamterene).

If a single trade name is not present, record the components separated by a slash (for example, hydrochlorothiazide/triamterene). Combination medications with more than two or three components should be listed by the generic name, as there are only 30 character spaces available to record the medication name.

If a medication is not taken orally, include the route of administration or include the word "cream" or "ointment" in the name.   Some common examples where the route of administration should be listed include:

- suppositories (e.g. "compazine suppository")
- eye drops (e.g. "saline eye drops")
- injections (e.g. "vitamin B12 injection" or "allergy injections")
- inhalers (e.g. "proventil inhaler")
- topical preparations (e.g. "hydrocortisone ointment" or "premarin vaginal cream")
- patches (e.g. "testosterone patch")

Medications which are given with a tapering dose (that is, given in a maximal dose for one or more days, and then taken in successively smaller amounts over several weeks)

should include the word "taper" in the name. For example, if a participant reports the use of a steroid taper, "prednisone taper" would be recorded under "Name."

If additional space is needed to record more than 12 medications, mark the box at the end of **Section B**, and use the supplemental MIF form to record the remaining medications.

B2 Strength (dose)

Record the strength or dose of the medication followed by the unit exactly as it appears on the container. Most preparations will be in milligrams (mg), but all units listed below are acceptable. Fractions of a milligram can be recorded by a decimal fraction (for example two and one-half mg would be 2.5).

When strength is not in milligrams, use the appropriate units as indicated on the container. For example, a potassium supplement may be in milliequivalents and would be recorded as 8 mEq. Use the following abbreviations:

Medication Units	MIF Abbreviation
• milliliter	ml
• milliequivalents	mEq
• milligram per milliliter	mg/ml
• milliequivalent per millilite	mEq/ml
• microgram	mcg
• microgram per milliliter	mcg/ml
• grains	gr
• percent	%
• units or international units	u
• drops	gtts
• puffs	puffs
• teaspoon	tsp
• tablespoon	tbs

Some compound medications are only available in a single dose combination, such as Dyazide, and the strength will not be indicated on the label. In these instances record "NA" in the strength box. Other compound medications are available in several strengths, and if the dose of individual components are listed, the strength of each component should be recorded, separated by a slash, in the same order as the components appear in the name box.

If strength is not available, write "NA" on the form, do not leave blank or use a slash.

For example, Inderide is a combination of propranolol and hydrochlorothiazide, and comes in several strengths. If the bottle lists Inderide 80/25, then 80/25 should be

recorded in the strength box. Follow the same order as listed in the name box, so that a generic combination of 25 mg of hydrochlorothiazide and 50 mg of triamterene would be listed as "hydrochlorothiazide/triamterene" under name, and "25/50" under strength.

Specific instructions are given below for recording the strength of certain medications:

- The strength of solutions are frequently in percent, or mg/ml, and the strength should be recorded with the appropriate units.

- For most inhalers, do not record strength and simply place "NA" in the strength box. Record "puffs" in the unit box.

- Insulin may or may not be labeled with a strength. Most are "U-100"; if the strength is available record it under "strength," otherwise place "NA" in the strength box. Units or "u" will be recorded in the unit box for most types of insulin.

B3 Number taken

Ask the participant how the medication was <u>actually taken</u> over the last two weeks. Record the total number of pills or dose taken for the time period that best describes the participants actual usage. This may differ from the number prescribed.

Circle the appropriate letter to indicate whether the dose recorded was taken per day (D), week (W), or month (M). For example, "I take three pills four times a day" would be coded as 12 with D circled.

When instructions state "take as directed" or include a range (for example, "take 1-2 pills 3-4 times a day"), ask the participant the usual number taken per day, week, or month in the last two weeks.

Since the reference period for medication use is only 2 weeks, number of pills or doses per month should only be used if the medication is taken less than once a week.

Other special circumstances include:

- Complex instructions- Record the average. For example, "I take one pill every other day" would be coded as "0.5" per day, and "I take 1 pill every other day, alternating with 2 pills every other day" would be coded as "1.5" per day.

- Solutions- record the total number of milliliters taken per day, week, or month, and include the units as "ml" in the "Number taken" box. Use the following conversions:

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

For example, two tablespoons of a 10% potassium chloride solution
(KCl) taken twice a day would be coded as "10" under strength, "%"
under units, and "60 ml" per day under "number used."

• Inhalers- Record the total number of sprays or puffs used per day, week, or
  month.

• Creams, lotions- Record the total number of applications used per day, week, or
  month.

• Patches- Record the total number to be applied to the skin per day, week, or
  month.

• Powdered medications- Record the total number of teaspoons or tablespoons
  used per day week or month. For example, if a participant uses 2 tablespoons
  per day of metamucil, it would be coded as "metamucil" under name, "NA"
  under strength, "tbs" under unit, and "2 per day" under number taken. A
  woman who takes "two scoops a day" of Questran, a powdered lipid lowering
  drug, this should be coded as "questran" under name, "NA" under strength,
  "tbs" under unit, and "4 per day" under number taken (as the "scoop" provided
  with the medication is approximately two tablespoons).

• Eye drops- Eye drops may be coded as any other solutions, except that the
  number taken refers to the <u>total number of drops</u> used per day, week, or month.
  For instance if a women uses 4 drops a day in each eye of Timoptic 0.5%, it
  would be coded as "timoptic" under name, "0.5" under strength, "%" under unit,
  and "8 per day" under number taken.

• Insulin injections- Record the total number of units given per day, week, or
  month. For instance if a participant took 10 units of regular (U-100) insulin every
  morning and 5 units each night, it would be recorded as "regular insulin" under
  name, "U-100" under strength, "u" under units, and "15 per day" under
  "number taken."

• Tapered medications. Record the maximal dose taken during the taper, even if
  the participant is currently taking a smaller dose. For example, if a participant
  had been given a steroid taper 3 weeks prior to the visit with a starting dose of 60
  mg of prednisone per day, and was currently taking 10 mg per day, "60 mg per
  day" would be recorded.

B4 PRN medications (as needed)

Indicate whether the medication is taken on an "as needed" basis by marking yes or no in the PRN column. The strength and number taken should be completed as above for all medications taken "PRN." The strength and number taken refer to the dose used when the medication is actually used, not the average usage over some period of time. For example, a sleeping pill such as halcion, 0.25 mg taken at bedtime about twice a week should be recorded as "halcion" under name, "0.25 under strength, "mg" under units, and "1 per day" under number used. Please note that "As needed" is not the same as "As directed." PRN is generally used for allergy, pain, or sleep medications.

B5 Container seen

For each medication recorded, indicate if the container was actually seen by Health ABC staff.

B6 Reason for use

Each current medication listed on the Health ABC MIF must have a primary reason for use to identify the indication and to facilitate coding. Limit the reason for use to the primary indication, and use the best medical indication offered by the participant. For example, if told that a medication was taken for "high blood pressure" record "high blood pressure" or "hypertension" after "reason for use."

For vitamins, minerals, and herbal supplements, use "supplement" as the reason for use unless a more specific indication is volunteered by the participant. For example, most multiple vitamins are taken as nutritional supplements, and "supplement" will usually be the reason for use. A multiple vitamin with iron, however, might be taken because of iron deficiency anemia, and the appropriate reason for use in this instance would be "anemia" or "iron deficiency anemia."

B7 Start date

The start date is the approximate month and year the medication was first taken on a regular basis (not the date prescribed or obtained), or the date a new dose or frequency of use began. If the participant is unable to recall the exact start or stop date, ask her to estimate the dates as best as possible.

B8 Formulation code

For each prescription medication, select one of the following drug codes.

> 0=unidentifiable
> 1=oral tablet
> 2=oral capsule
> 3=oral liquid
> 4=topical cream, lotion, or ointment
> 5=other liquid
> 6=ophthalmic
> 7=missing
> 8=rectal or vaginal
> 9=inhaled or nasal
> 10=injected
> 11=transdermal patch
> 12=powder
> 99=other

3.4 Recording Non-Prescription Medications

C Non-prescription medications (Section C of MIF)

This section uses the same format as the section on prescription medications. To simplify the coding of non-prescription medications, some medications may be coded in the following fashion:

1)   If a cold medication is a well known national brand, such as "Actifed," the trade name may be used and the appropriate strength recorded. Other cold preparations, such as "Walgreen's Cold Medication," may be coded as "cold remedy" or "antihistamine/decongestant."

2)   If an allergy medication is a well known national brand, such a "Allerest," the trade name may be used and the appropriate strength recorded. Other allergy preparations, may be coded as "allergy medication" or "antihistamine/decongestant." Place "NA" the strength box if "allergy medication" or "antihistamine/decongestant" codes are used.

3) All herbal medications, such as garlic capsules, brewer's yeast, root extract, wheat germ, and pectins may be coded as "herbal preparations"

4) All <u>calcium preparations</u>, regardless of the brand or type of calcium, may be coded as "calcium". As with other non-prescription (over the counter) medications, avoid using the brand name where possible. For example, Walgreen's calcium carbonate, oyster shell calcium, and calcium citrate could all be coded as "calcium."

5) Any <u>vitamin preparation</u> with three or more components may be coded as a "multivitamins". Those multivitamins with a single extra component, such as extra calcium or iron, should be coded as "multivitamins/calcium" or "multivitamins/iron." Preparations with just two components (for example, one vitamin and one mineral, or two different vitamins) should be coded as combination medications, including strength.

C1 Medication name

Record only non-prescription medications used in the two weeks (14 days) prior to the visit. <u>Write clearly!</u> <u>Record the complete drug name exactly as written on the container</u>. If additional space is required, mark the box at the end of **Section C**, and use the **Supplemental MIF Form**.

C2 Strength

Record strength as indicated on the label of all non-prescription medications.

Please do record a strength for all calcium supplements, but in general it is not necessary to record the strength of calcium contained within a multiple vitamin. In addition, if the preparation contains extra amounts of calcium it should be recorded. For example, "extra strength TUMs" would be coded as "TUMS EX" or "calcium " or "calcium carbonate" under name, and "750" under strength. "Os-call 500+D" would be recorded as "calcium/vitamin D" under name, and "500/250" under strength.

C3 Number taken

Follow instructions as given for prescription medications.

C4 PRN medications

Indicate whether the non-prescription medication is usually taken on an "as needed" basis by marking the "yes" or "no" box in the PRN column.

C5 Container seen

For each medication recorded, indicate if the container was actually seen by Health ABC staff.

C6 Reason for use

Each current medication listed on the Health ABC MIF must have a primary reason for use to identify the indication and to facilitate coding. Limit the reason for use to the primary indication, and use the best medical indication offered by the participant.

For vitamins, minerals, and herbal supplements, use "supplement" as the reason for use unless a more specific indication is volunteered by the participant. For example, most multiple vitamins are taken as nutritional supplements, and "supplement" will usually be the reason for use. A multiple vitamin with iron, however, might be taken because of iron deficiency anemia, and the appropriate reason for use in this instance would be "anemia" or "iron deficiency anemia."

C7 Start date

The start date is the approximate month and year the medication was first taken on a regular basis (not the date prescribed or obtained), or the date a new dose or frequency of use began. If the participant is unable to recall the exact start or stop date, ask her to estimate the dates as best as possible.

C8 Formulation code

For each non-prescription medication, select one of the following drug codes.

        0=unidentifiable
        1=oral tablet
        2=oral capsule
        3=oral liquid
        4=topical cream, lotion, or ointment
        5=other liquid
        6=ophthalmic
        7=missing
        8=rectal or vaginal
        9=inhaled or nasal
        10=injected
        11=transderm patch
        12=powder
        99=other

3.5 Returning Medications

After double checking that all medications have been added to the list, return the medications to the participant and thank them.

4. Instructions for Data Entry

The Health ABC MIF must be entered by hand into the Health ABC Database (see Data Users Manual for details). Most medications listed in the Health ABC MIF will be matched to an existing preparation and dose in the Health ABC medication dictionary, but new or unusual medications may be in the dictionary. Medication, formulations, and doses not found in the Health ABC medication dictionary will be identified and coded by the Coordinating Unit. Medication edits for the clinical site will be periodically generated for medications that seem incorrect or cannot be coded.

5. Procedures for Performing the Measurement at Home

The same procedures described above may be performed at home.

6. Quality Assurance

6.1 Training Requirements

The technician requires no special qualifications for performing this assessment. The training should include:

- review of medication procedures and codes
- review data manual for Health ABC Medication Inventory
- observation of medication recording by experienced examiner

6.2 Certification Requirements

- successful completion of mock MIF form with sample medications.
- demonstrate how medications are entered into the data system
- observation of performance by QC officer using QC checklist
- copies of completed mock MIF and certification form sent to the CU

6.3 Quality Assurance Checklist

Ñ   Participant asked if they brought in all prescription and non prescription medications used in the past 2 weeks

Ñ   Participant asked how often medication is taken

Ñ   If no medications taken, participant asked "Are you sure you took no prescription or non prescription medications over the last two weeks?"

Ñ   Records only medications used in the past 2 weeks

Ñ   Indicates if container was seen by Health ABC staff

Ñ   Properly categorizes medications (prescription and non prescription)

Ñ   Properly records name of medication

Ñ   Properly records route of administration of medication, if route is not oral

Ñ   Properly records strength of medication

Ñ   Properly records medication amount taken (number of pills, milliliters of liquid, puffs, applications, patches, drops, units of injection, tapered dosages)

Ñ   Records reason for use of medication

Ñ   Records start date of use of medication

Ñ   Uses correct abbreviations for dosage units

Ñ   Uses correct formulation code for each medication

7. Form