MEDICATION INVENTORY

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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. Because specific medications and doses change with new health states, we plan to document the use of over-the-counter and prescription medications each year. The protocol for collecting medications is similar to that used at baseline with the following exceptions. We will be:

- comparing the current medications with those on the list from Year 5
- asking whether or not these medications have been used continuously.
- asking whether or not these medications have been used intermittently.
- asking about new medications, begun since the last (Year 5) clinic visit during which medications were inventoried.

We are specifically interested in how individual medications have been actually <u>taken</u> (during the preceding 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 6)
- Codes for prescription and non prescription formulations (see page 11)
- Printout of list of medications recorded at the Year 5 clinic visit (Data from Prior Visits report)

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 examiner will review all medications and transcribe the name and strength from the container to the Health ABC Medication Inventory Form (MIF).

- The participant will then be asked how often the medication is taken (number used per <u>D</u>ay, <u>W</u>eek, or <u>M</u>onth).

- The clinic staff person will have a list of the medications that were recorded at the participant's Year 5 clinic visit for reference purposes. However, the name, dosage, and frequency of use <u>must</u> be recorded on the Year 6 Clinic Visit Workbook MIF form for each medication even if it is exactly the same as Year 5. Changes in current medication use will be updated at future clinic visits.

3.1 Drug definition guidelines

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

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

2) **<u>Prescription medications:</u>** 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 medications may include eye drops, pills or tablets, solutions, creams/salves, dermal patches, and injections.

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

   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 **<u>Section A</u>** of the MIF, fill in the appropriate box.

- • "Yes" box, if all medications were brought in to clinic. Count the total number of medications brought in and record on the MIF. Proceed to **<u>Section B</u>**.

- • "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 missing information via telephone or return visit (although occasionally a participant will have brought in an accurate list of the other medications and a follow-up call will not be necessary).** It is recommended that the participant be called 1-2 days after the visit to obtain the missing information. Be sure to fill out the MIF form and indicate that "Yes," the participant was called in order to obtain the missing information. (If the participant was not called because they brought in a complete list of their medications or they were able to recall and convey the information accurately at their clinic visit, mark the "No" response option to answer the question "Did examiner call participant to complete MIF?"

- • Took no medication. Self explanatory, but ask:

  <u>Script:</u> "Are you sure you took no prescription or non-prescription medications over the last two weeks?"

3.3 Recording prescription medications

<u>B Prescription medications (Section B of MIF)</u>

In this section record the use of prescription medications only. The Rx box has been pre-checked next to the Formulation Code box on the form, so it is imperative that only prescription medications be entered in Section B of the MIF.

B1 Medication name

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

Copy the name directly onto the MIF from the medication container, using capital letters. <u>Write clearly!</u> <u>Record the complete drug name exactly as written on the container.</u> It is not necessary to record the name of the store or pharmacy where the medication was obtained. The printout of prescription medications recorded at the Year 5 clinic visit may be helpful, but be sure to take the information directly from the medication container.

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.

<u>If a medication is not taken orally, include the route of administration or include the word "cream" or "ointment" in the name</u>. 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 that 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." See also: "Other special circumstances" instructions on page 8.

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. Be sure to check the Rx box to the right of the Formulation Code on the Supplemental MIF Form.

B2 Strength and Dose

Strength is the amount of medication in one unit of the drug as manufactured; dose is the actual amount taken at a time. For example, ibuprofen is commonly manufactured in 200 mg tablet <u>strength</u>. A person often takes two tablets, a <u>dose</u> of 400 mg.

Record the <u>strength</u> of the medication followed by the units exactly as they appears on the container. Most preparations will be in milligrams (mg), but all units listed below are acceptable. Fractions of a unit can be recorded by a decimal fraction (for example two and one-half mg would be 2.5 mg). **Be careful to make a distinction between milligrams (mg) and micrograms (mcg).** A microgram is only 1/1000th of a milligram!

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 milliliter	mEq/ml
• microgram	mcg
• microgram per milliliter	mcg/ml
• grains	gr
• percent	%
• units or international units	u

Some compound medications, such as Dyazide, are only available in a single strength combination, 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 strengths 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:

- Strength of whole tablets should be reported. If the participant is splitting tablets, refer to "Other special circumstances" below.

- 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 the number of puffs and "puffs" in the Number used box. Provide the strength if one is indicated on the container, but not the size of the container or the dose per actuation (spray). For example: Albuterol aerosol; no strength is required (use NA) since it only comes in one strength. However, Flovent aerosol comes in multiple strengths; record the strength from the container, 44, 110 or 220mcg.

- 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 participant's 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.

  If the complex schedule involves two different strengths of the same medication, record the two different strengths as separate medications and record how each is taken. For example, a participant may take 10 mg and 12.5 mg of Coumadin on alternate days. Coumadin is not available in 12.5 mg strength, so the participant is taking a 10 mg tab every day plus a 2.5 mg tab on alternate days. Record as: Coumadin Tabs, 10 mg, 1 pill per day, and a second entry for Coumadin Tabs, 2.5 mg, 15 pills per month.

• Split doses- If a medication is only available in 50 mg strength and the participant is taking half a pill (25 mg) each day, record as "50" strength, "mg " unit, and "0.5" used per Day.

• Solutions- The examiner should record the medication as it is actually taken, in teaspoons, tablespoons or ounces per day, week, or month and include the units as "TSP," "TBS" or "OZ" in the "Number taken" box.

  For example, two tablespoons of a 10% potassium chloride solution (KCl) taken twice a day would be entered as "10" under strength, "%" under units, and "4 TBS" per day under "number used."

  Another example: Scott-Tussin expectorant comes in 100 mg per 5 ml strength. Therefore, if a participant is taking Scot-Tussin (100 mg), 1 teaspoon per day, convert the strength to 20 mg/ml, and record the following: "20" strength, "mg/ml" units, and "1 TSP" used per Day on the Medication Inventory Form.

  For entry into the data system, the Access system will convert all liquid medications to ml, using the following conversions:

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

- Inhalers- Record the total number of sprays or puffs used per day, week, or month. Put this information in the Number used box (e.g. 2 puffs).

- Creams, lotions (includes any topical medication or shampoo)- 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 and units, and "2 tbs" under number taken. A participant who takes "two scoops a day" of Questran, a powdered lipid-lowering drug, this should be coded as "Questran" under name, "NA" under strength and units, and "4 tbs" per day under number taken (as the "scoop" provided with the medication is approximately two tablespoons). Note that although powders are usually dissolved in water before they are taken, they are not liquid medications, they are powders (formulation code 12, see section B8).

- Eye drops- Eye drops may be coded like any other solutions, except that the number taken refers to the total number of drops used per day, week, or month (not the number per eye). For instance if a participant 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 gtts" 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. **Be sure to record "taper" as part of the name.**

- Occasionally a participant will say that they receive an injection every 3 months. If the participant received an injection within the past 2 weeks and they get this injection every three months, indicate number used as "0.33" per <u>M</u>onth. If they received the injection outside this 2 week period, do not record this medication.

B4 PRN medications (as needed)

Indicate whether the medication is taken on an "as needed" basis by marking yes or no in the PRN box. The strength and number taken should be completed as above for all medications taken "PRN." The strength and number taken refer to the dose 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 from the pharmacy), 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 them to estimate the dates as best as possible. Ask the participant if they have been taking this medication since the last visit. The printout from the Year 5 clinic visit (Data from Prior Visits report) may be helpful, but do not assume just because a medication is not on the previous medication list that it was not being taken at the time of the last visit (they may have forgotten it).

If the medication was not taken at the last visit (i.e. a new medication):
Record the new medication and dosing with the appropriate start date.

 If the medication was taken at the last visit:
Ascertain if the participant continues to take the medication at the same dose and frequency as at the previous visit. If so, the start date should be that recorded on the previous medication list. If the dose or frequency of the medication has changed since the last visit, record the date the current dosing was begun, along with the new dosing information. A new start date should also be entered if there has been a significant interval since the last visit (8 weeks or more) when the medication was not taken.

B8 Formulation code

For each prescription medication, select one of the following formulation 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. The Non Rx box has been pre-checked next to the Formulation Code box on the form, so it is imperative that only over-the-counter medications and supplements be entered in Section C of the MIF.

To simplify the coding of non-prescription medications, some medications may be coded in the following fashion:

1) If a <u>cold medication</u> is a well-known national brand, such as "Actifed," the trade name may be used and the appropriate strength recorded. For others, enter the name and strengths of the primary ingredients such as "Acetaminophen 500 mg/Psuedoephedrine 30 mg/Chlorpheniramine 4 mg. When multiple ingredients (>3) are included, record as "cold remedy" or antihistamine/decongestant".

2) If an <u>allergy medication</u> is a well-known national brand, such a "Allerest," the trade name may be used and the appropriate strength recorded. For other allergy preparations, enter the name and strength of the primary ingredients such as "Pseudoephedrine 30 mg/Chlorpheniramine 4 mg. Include the strengths in the name box and place "NA" in the strength box. When multiple ingredients (>3) are included, record as "allergy medication" or "antihistamine/ decongestant" and write NA in the strength box.

3) <u>Herbal medications</u> should be coded with the name of the herbal ingredients; avoid brand names or product names like "Herbal Prostate Supplement" or "Herbal Lung Support." Herbal products with unidentifiable ingredients or more than 3 ingredients may be coded as "herbal preparations," "dietary herbal," or "topical herbal."

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." If they also contain vitamin D, they should be coded as Calcium/vitamin D (include strengths of both).

5) Any <u>vitamin preparation</u> with three or more components may be coded as a "multivitamin." 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>. However, for local or regional brand names please provide names and strengths of main ingredients. National brand names may be used; when in doubt, provide the main ingredients and strengths.

If additional space is required, mark the box at the end of **Section C**, and use the **Supplemental MIF Form**. Be sure to check the Non Rx box to the right of the Formulation Code on the Supplemental MIF Form. The printout of non-prescription medications recorded at the Year 5 clinic visit may be helpful, but be sure to take the information directly from the medication container.

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-Cal 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 box.

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 date, ask them to estimate the dates as best as possible. Ask the participant if they have been taking this medication since the last visit. The printout from the Year 5 clinic visit (the previous medication list) may be helpful, but do not assume that just because a medication is not on the previous medication list that it was not being taken at the time of the last visit (they may have forgotten it last time).

<u>If the medication was not taken at the last visit (i.e. a new medication):</u>
Record the new medication and dosing with the appropriate start date.

<u>If the medication was taken at the last visit:</u>
Ascertain if the participant continues to take the medication at the same dose and frequency as at the previous visit. If so, the start date should be that recorded on the previous medication list. If the dose or frequency of the medication has changed since the last visit, record the date the current dosing was begun along with the new dosing information. A new start date should also be entered if there has been a significant interval since the last visit (8 weeks or more) when the medication was not taken.

C8 Formulation code

For each non-prescription medication, select one of the following formulation 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

3.5 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. Most medications listed in the Health ABC MIF will be matched to an existing preparation and strength in the Health ABC medication dictionary, but new or unusual medications

may not be in the dictionary. Medications, formulations, and strengths not found in the Health ABC medication dictionary will be identified and coded by the Coordinating Center. Medication edits for the field centers will be periodically generated for medications that seem incorrect or cannot be coded. This year the Forms Access application has been modified to make data entry of liquids and powders more straightforward. If the medication is a liquid or a powder, you will be sent to a separate screen, where you will enter the Number used exactly as the examiner recorded it. The Access application will take care of the conversion (if needed) and place the information in the correct places in the data system.

4.1 Starting a new session

The information on the form must be hand entered through the Health ABC Forms Access system. It is very important to be sure that these data are entered into the correct visit year. The main menu for the Forms Access system shows five buttons on the left side, one for each visit year in which medication information was collected. Be sure to click the "MIF Data Entry: Year 6" button to enter data from the Year 6 MIF. This will bring you to a screen "Find MIF for ID=_____." If the first participant you have to enter has not yet had any Year 6 medications entered, click "Add New." If the first participant you have to enter already has had one or more medications entered for Year 6, enter the participant's Health ABC Enrollment ID# in the box and click "OK"

4.2 Entering MIF data for a new participant

Although MIFs may have been entered for baseline through Year 5, each participant seen in Year 6 must be added to the Year 6 MIF database. To start entering the MIF information for a new participant, follow the instructions in section 4.1 above (if this is the first participant of your data entry session) or click the smiley face button at the top right of the screen (for all other new participants entered in a session).   Either way, you will be taken to a screen where you can enter the information from the top of the MIF form.

You <u>must</u> complete this screen for all participants who had any type of visit in Year 6, even if the participant took no medications or refused to allow you to complete the Medication Inventory Form. Enter the Health ABC Enrollment ID#, acrostic, date the form was completed, and the examiner's staff ID# on the first line. The introductory question corresponding to the next box is different on the Core Home Visit MIF and the Clinic Visit Workbook. Just click the bubble that most closely corresponds to the response on the form you are working from.

If the participant did not take any medications in the preceding 2 weeks, click "Took no medicines" and type "0" in the "Total Number brought in" box. The "Did examiner call participant to complete MIF?" question should only be completed if the participant responded "No" to the question regarding whether the medications recorded were <u>all</u> of the medications taken during the last 2 weeks. If the participant refused to cooperate with a medication inventory, mark the second line "Refused" and type "0" in the "Total Number brought in" box.

When the first screen is complete, click the "Add" button to save the data. If you have entered an invalid Health ABC Enrollment ID#/Acrostic combination, you will get the error message "Year 6 Clinic Visit not yet entered" and the data will not be saved. You will need to start again using the correct identifiers. If you have already entered some or all of the Year 6 medications for that participant, you will get the error message "This ID has already been entered in MIF file" (see below).

4.3 Adding additional medications for participants already entered

If you have started entering the MIF for a participant in Year 6 and need to add an additional medication, you need to search for the participant first. After clicking the MIF Data Entry: Year 6 button, click the button with the binocular icon. You will be asked to "Please Enter a HABC ID." Enter the participant's Health ABC Enrollment ID# (including the HA or HB prefix) and then click "OK." You will be brought to the first record for that participant. Be sure the medication you intend to enter isn't already in there for that participant. If not, click the button between the smiley face and the binoculars to insert a new record for that participant.

4.4 Completing a medication screen

After either adding a new participant (see section 4.1) or adding a new record for an existing participant (see section 4.2), you will see a screen entitled "Year 6 Medication Inventory Form: Add new medication for participant _____." (The participant's Health ABC Enrollment ID# will be entered in the following box.) <u>If the participant took no medications or you have reached this screen in error</u>, click "Cancel." If you click the "Add" button, a blank medication will be entered and will have to be deleted during editing.

To enter the medication name, pull down the menu under Medication Name (or start typing the medication as written on the MIF). You will usually see more than one entry with a very similar medication name. Each medication in the medication dictionary is a specific strength and formulation, so you must pick the one that exactly matches the medication recorded on the MIF (the few exceptions to this rule are listed below.) If

you do not find a match (be sure to scroll up and down a bit), then simply type in the name as written on the MIF. If the examiner has recorded a medication with multiple ingredients and the strengths for each, type all of this information in the Name box. (The Strength box will not accept multiple strengths.) Do <u>not</u> match to a medication that is close but not an exact match. As noted above, medications, formulations, and strengths not found in the Health ABC medication dictionary will be identified and coded by the Coordinating Center. In particular, if the examiner has written the word "taper" after the medication name, do not match to a dictionary entry without the word "taper," even if the strength and formulation are the same. Instead, if no appropriate entry with the word "taper" exists, type the medication exactly as the examiner recorded it <u>without matching</u>. The Coordinating Center will take care of adding an appropriate taper entry to the dictionary.

After entering the medication name, a dialog box will pop up asking whether the medication is a liquid or a powder. If you click the bubble for either a liquid or a powder, you will be taken to a new sub-screen, where you can enter the information exactly as the examiner recorded it (i.e., no need to convert tsp to mL, etc). Note that you will put the units for the <u>strength</u> (e.g. %, mg/mL, mEq, etc) in the Units (strength) box and the units for the number used (e.g. Tbs, tsp, cc, ounces) in the Units (used) box. The Access application will take care of putting the correct information, with conversion, if appropriate, in the correct places in the data system and then take you back to the regular medication entry screen to complete entry of the medication.

For example, if the participant is taking Walgreen's Gingko Liquid Elixer, 10 mg/mL, 1 tsp per Day, you will type in "Walgreens Gingko Liquid Elixer" under the medication name (no match possible), then click the Yes button in response to the question "Is this medication a liquid or a powder?" On the next screen you would click the Oral liquid button, then enter 10 in the Strength box, mg/mL in the Units (strength) box, 1 in the Number Used box, and tsp in the Units (number) box. Then click OK. This will take you back to the usual medication screen, where you will see a 10 in the Strength box, mg/mL in the Units box and 5 (1 tsp converted to 5 mL) in the Number used box. Another example, if the participant is taking 1 Tbs of Metamucil a day, you would match to Metamucil, click the Yes button, click the Powder button, then enter NA for Strength, NA for Units (strength), 2 for Number used, and tbs for Units (used). Then click OK. This will take you back to the usual medication screen, where you will see nothing in the Strength box, tbs in the Units box, and 2 in the Number Used box.

After matching the medication to one in the medication dictionary, the "strength" box may automatically be filled in. Although this strength may look peculiar, the system will not allow you to alter this number. Do not worry. This is how the matching system is intended to work. You only need to complete the strength box if the

dictionary does not supply it or you are unable to match the medication to anything in the dictionary. Be sure to enter the Units (e.g., mg, mcg, etc) as entered on the MIF.

Continue completing the medication by the number used per Day, Week, or Month (click the appropriate button), whether the medication is taken as needed (PRN), whether the container was seen by the examiner, the reason for use, and the formulation code. All of these fields should have been completed by the examiner. If any field is blank, an edit will be generated. Please note that for each medication, the Rx or Non Rx button must be checked. These boxes are pre-checked on the MIF as a reminder to the examiner enter this data in the appropriate section of the MIF.

When all fields are completed, click the "Add" button. If you wish to add additional medications for the <u>same</u> participant, click the "Yes" button in the dialog box "Enter Another?" Otherwise, click "No." If you find an error after entering the medication, this will have to be corrected using the web-based data editing system (see Section 4.4).

4.5 Correcting medications already entered

Either as a result of an automated edit generated by the editing system, or because you have been sent an edit on paper by the Coordinating Center, it may become necessary to change a medication entry after it has been entered. <u>Please note that a new match cannot be made through the editing system</u>. If the medication has been mis-matched, or no match was entered but a match is now possible, the old medication entry will have to be deleted and the medication re-entered through Forms Access.

To delete a medication, go to that medication record in the Post Queries portion of the web-based data editing system: enter the participant's ID and pull down the Specific Form menu to the appropriate year's MIF, then click "Submit." All the medications entered for that participant for that year will be shown, with the medication name (as matched or as typed in) in the "Visit/Other ID" column. Click the View button. Create a query for the "Reason for Use" field (e.g., type "need to delete") and click the "Post Query" button. This will take you directly to your newly created query. Type the single word "DELETE" in the highlighted "Reason for Use" field (<u>no other field will work</u>) and save your change. The next time the data are updated (usually overnight), that medication will be automatically deleted.

Other, minor, changes <u>can</u> be made through the web-based data entry system. If an edit does not already exist for the medication, simply create a query for the field in question and make the correction in the usual way. <u>Note</u> that it is not necessary to create a query for every field that needs correction if a medication entry needs more than one correction (e.g., in response to the edit "Incomplete medication record.") Just click the

"Fix" button for the one edit or query created for that medication and make all the changes needed.

5. Procedures for performing the measurement at home

The same procedures described above may be performed at home. If a participant is given a phone visit in lieu of a clinic visit or home visit, the participant should be asked to gather all the medications they took in the last 2 weeks and help you complete the inventory over the phone. For proxy interviews, ask the proxy to provide this information. In other words, medications should be collected for all participants who do not have a Missed Visit Form.

6. Quality assurance

6.1 Training requirements

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

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

6.2 Certification requirements

- successful completion of mock MIF form with sample medications.
- understand 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 Coordinating Center

6.3 Quality assurance checklist

☐   Examiner consults Data from Prior Visits Report for list of medications from the Year 5 clinic visit

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

☐   Participant asked how often medication is taken

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

☐   Records only medications used in the past 2 weeks

☐   Indicates if container was seen by Health ABC staff

☐   Properly categorizes medications (prescription and non-prescription)

☐   Properly records name of medication

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

☐   Properly records strength of medication

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

☐   Records reason for use of medication

☐   Records start date of use of medication

☐   Uses correct abbreviations for dosage units

☐   Uses correct formulation code for each medication