**BE-DRI**
**Question by Question Specifications Guide**
**Form 203: Baseline Medication Audit**
**Version 03/04/05 (B)**

## I. Purpose

Due to the nature of the BE-DRI trial, medication use at baseline is important for eligibility determination. Investigators are interested in all medications. Medications of special interest include diuretics or combination antihypertensive medications (water or blood pressure pills), anticholinergic medications, tricyclic antidepressants, cholinergic agonists and duloxetine. Dose and changes in dose for some of these medications may affect BE-DRI eligibility and must be captured accurately. Prescription medications taken or stopped in the past 4 weeks must also be captured in addition to current medication use. All of this information will be used post-intervention to ensure that the patient has achieved treatment success as defined by the BE-DRI protocol.

## II. Administration

Ideally, the Baseline Medication Audit can be conducted as the Interviewer looks at the patient's prescription and medicine bottles. If the patient can bring all of her medicines with her when she comes in for the screening visit, this should be arranged. Remind the patient that we are interested in both prescribed and over-the-counter medications or self-prescribed remedies that the patient takes on her own.

At the start of the Audit, the Interviewer should tell the patient that we are interested in all current medications including those that she has stopped taking in the past 4 weeks, and that we will record all prescribed medications, even if she has stopped taking them on her own accord. We will also include any over-the-counter medications that a patient says the doctor has told her to take, e.g. Motrin or ibuprofen for arthritis. These prescribed, over-the-counter medications should be recorded in the PRESCRIBED medication section of the Audit. If the patient is using an over-the-counter medication on her own, record this medication in the SELF-PRESCRIBED section of the Audit.

Any diuretic or anticholinergic medication that the patient reports should be documented in its own section i.e., B3. For these medications, dose must also be documented.

Ideally the information can be extracted directly from the labels on the patient's pill bottles. Research staff may also use a medical record to gather information about medications, but the drug use must be confirmed with the patient.

MEDICATIONS RECORDED ON THE DATA FORM MUST BE WRITTEN LEGIBLY AND CORRECTLY. CHECK THE SPELLING TWICE, as the spelling of generic drug names can be difficult. When in doubt, check for the correct spelling of the medication against the AHFS or other recognized drug reference texts.

**Window for Re-Screening of Patients:**

The results of this interview expire 3 months following its completion; therefore, if more than 3 months transpires between the date the Audit is completed and the date of the planned BE-DRI Intervention, the patient must be assigned a new ID and <u>all screening measures</u> must be repeated to ensure collection of current baseline data.

## III. Section A

A1. **Study ID Number**: Affix the patient ID label in the spaces provided in the A1 field and on each subsequent page of the Data Form in the upper right-hand corner of the page. As always, avoid handwriting ID numbers.

A2. **Visit Code**: The visit code is precoded as SCRN (BE-DRI Baseline Event).

A3. **Date Audit Completed**: Enter the date that the Baseline Medication Audit is completed. All dates must be in the format of mm/dd/yyyy.

A4. **Interviewer's Initials**: Enter the initials of the BE-DRI Interviewer/Data Collector completing the Audit. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If there is not a middle initial, strike a mark in the second space. If the last name is hyphenated or if there are 2 last names, enter the initials of the first last name in the third space.

A5. **Mode:** Circle the code that describes the interview mode used to complete the Audit. (NOTE: The Audit should be completed in person at all required in-person visits.)

## IV. Section B. The Medication Audit

B1. **Prescribed Medications, Current or in Past 4 Weeks?**: Ask the patient the question as written. Code Yes (1) or No (2) and follow the skip pattern on the form.

B2a. **Record Each Prescribed Medication By Name (All prescribed medications <u>other than</u> diuretics and anticholinergic medications)**: Probe thoroughly to get a complete list of current or recently prescribed medications. A scripted probe is provided for your use. Any segment of the probe may be used to prompt the patient in her response. If the number of prescribed medications outnumbers the lines provided on the form, please continue the audit on the backside of the form, being sure to fill out the information for each column (a-e).

B2b. **Frequency of Use**: For each medication recorded, ask the patient how often she uses the medication. Use the frequency codes written on the form.

| Code | Description |
|---|---|
| Circle code 1: | for medications taken regularly |
| Circle code 2: | for medications taken only as needed (prn) |
| Circle code 3: | for medications prescribed but not taken |
| Circle code 4: | for medications just prescribed today (e.g., prescribed at this visit but not started) |

B2c. **Start Date**: Ask the patient when she began taking the medication. Record her response in mm/dd/yyyy. A start date will not be required for medications that were just prescribed today.

B2d. **Stop Date:** Ask the patient when she stopped taking the medication. This date should be no greater than 4 weeks ago today. If the patient reports that she is still taking the medication at this time, code 01/01/0101.

B2d. **Source Code**: Record the source code in the last column. If the only source of information is from the patient, record 1 as the source code in the last column of this table. If the source for the data is both the patient and the medical record, record 3 as the source code. If there is evidence in the medical record that a medication is prescribed but the patient reports that she does not take the medication, record the frequency code (B2b) as code 3, prescribed, not used and record the source code as 3. If the source of information for the data is the patient and a medical record has been sent for, record 5 as the source code. This code will prompt a pending edit that must be resolved when the medical record arrives, when it should then be changed to 3; or if the medical record proves to be unattainable, when it should be changed to 1.
If medical record(s) are used for any of these items, the medical records must be readily available for a data audit as required.

B3a. **Record Each Prescribed Medication By Name (All diuretics and anticholinergic medication; see Attachment B)**: Probe thoroughly to get a complete list of current or recently prescribed diuretics or anticholinergic medications. A scripted probe is provided for your use. Any segment of the probe may be used to prompt the patient in her response. If the number of prescribed medications outnumbers the lines provided on the form, please continue the audit on the backside of the form, being sure to fill out the information for each column (a-e).

B3ai. **Dose:** Obtain the dose information for each diuretic and anticholinergic taken by the patient. This information is integral to future inquiries about changes in dose for these medications.

B3b. **Frequency of Use**: For each medication recorded, ask the patient how often she uses the medication. Use the frequency codes written on the form.

| **Code** | **Description** |
|---|---|
| Circle code 1: | for medications taken regularly |
| Circle code 2: | for medications taken only as needed (prn) |
| Circle code 3: | for medications prescribed but not taken |
| Circle code 4: | for medications just prescribed today (e.g., prescribed at this visit but not started) |

B3c. **Start Date**: Ask the patient when she began taking the medication. Record her response in mm/dd/yyyy. A start date will not be required for medications that were just prescribed today.

B3d. **Stop Date:** Ask the patient when she stopped taking the medication. This date should be no greater than 4 weeks ago today. If the patient reports that she is still taking the medication, code 01/01/0101.

B3d. **Source Code**: Record the source code in the last column. If the only source of information is from the patient, record 1 as the source code in the last column of this table. If the source for the data is both the patient and the medical record, record 3 as the source code. If there is evidence in the medical record that a medication is prescribed but the patient reports that she does not take the medication, record the frequency code (B2b) as code 3, prescribed, not used and record the source code as 3. If the source of information for the data is the patient and a medical record has been sent for, record 5 as the source code. This code will prompt a pending edit that must be resolved when the medical record arrives, when it should then be changed to 3; or if the medical record proves to be unattainable, when it should be changed to 1.
If medical record(s) are used for any of these items, the medical records must be readily available for a data audit as required.

B4. **Use of Diuretic or Combination Antihypertensive Medication That Contains a Diuretic:** Record whether the patient reports taking a diuretic or antihypertensive medication that contains a diuretic in B3. Then, code Yes (1) or No (2) accordingly to this question and follow the skip pattern on the form.

B4a. **Change in Dose within Last Three Months:** If B4 is coded "Yes," ask the patient B4a as written. Code Yes (1) or No (2). If the patient reports a dose change within the past 3 months, she is ineligible for BE-DRI. The patient may be eligible at a later date once her dose has remained stable for 3 months or more. The remainder of the Baseline Medication Audit should be completed regardless of the outcome of this question.

B5. **Use of Anticholinergic Medication:** Record whether the patient reports taking an anticholinergic medication within the last 4 weeks in B3. Then, code Yes (1) or No (2) accordingly to this question. If the patient reports use of an anticholinergic medication within the last 4 weeks, she is ineligible for BE-DRI. The patient may be eligible at a later date once she has been off of anticholinergics for at least 4 weeks. The remainder of the Baseline Medication Audit should be completed regardless of the outcome of this question.

B6. **Current Use of a Cholinergic Agonist (see Attachment C):** Record whether the patient reports that she is currently taking a cholinergic agonist in B2. Then, code Yes (1) or No (2) accordingly to this question. If the patient reports current use of a cholinergic agonist, she is ineligible for BE-DRI. The patient may be eligible at a later date once she has stopped taking a cholinergic agonist. The remainder of the Baseline Medication Audit should be completed regardless of the outcome of this question.

B7. **Use of Tricyclic Antidepressant (see Attachment C):** Record whether the patient reports taking a tricyclic antidepressant within the last 4 weeks in B2. Then, code Yes (1) or No (2) accordingly to this question. If the patient reports use of a tricyclic antidepressant within the last 4 weeks, she is ineligible for BE-DRI. The patient may be eligible at a later date once she has been off of a tricyclic antidepressant for at least 4 weeks. The remainder of the Baseline Medication Audit should be completed regardless of the outcome of this question.

B8. **Use of Duloxetine:** Record whether the patient reports taking duloxetine within the last 4 weeks in B2. Then, code Yes (1) or No (2) accordingly to this question. If the patient reports use of duloxetine within the last 4 weeks, she is ineligible for BE-DRI. The patient may be eligible at a later date once she has been off of duloxetine for at least 4 weeks. The remainder of the Baseline Medication Audit should be completed regardless of the outcome of this question.

B9. **Over-The-Counter and/or Self-Prescribed Medications**: Ask the patient the question as written. Code Yes (1) or No (2) and follow the skip pattern on the form.

B10a. **Record Each Self-Prescribed Medication By Name**: Probe thoroughly to get a complete list of self-prescribed medications, including over-the-counter medications that the patient takes on her own including medications, supplements and vitamins. A scripted probe is provided for your use. Any segment of the probe may be used to prompt the patient in her response. If the number of self-prescribed medications outnumbers the lines provided on the form, please continue the audit on the backside of the form, being sure to fill out the information for each column (a-e).

B10b. **Frequency of Use**: For each medication recorded, ask the patient how often she uses the medication. Code frequency as taken regularly (code 1) or only as needed (code 2).

B10c. **Start Date**: Ask the patient when she began taking the medication. Record her response in mm/dd/yyyy. A start date will not be required for medications that were just prescribed today.

B10d. **Stop Date:** Ask the patient when she stopped taking the medication. If the patient reports that she is still taking the medication, code 01/01/0101.

B10e. **Source Code**: Record the source code in the last column. If the only source of information is from the patient, record 1 as the source code in the last column of this table. If the source for the data is both the patient and the medical record, record 3 as the source code. If there is evidence in the medical record that a medication is prescribed but the patient reports that she does not take the medication, record the frequency code (B2b) as code 3, prescribed, not used and record the source code as 3. If the source of information for the data is the patient and a medical record has been sent for, record 5 as the source code. This code will prompt a pending edit that must be resolved when the medical record arrives, when it should then be changed to 3; or if the medical record proves to be unattainable, when it should be changed to 1.
If medical record(s) are used for any of these items, the medical records must be readily available for a data audit as required.

B11. **Summary of Eligibility Status:** Review codes to items B4a, B5, B6, B7 and B8 to ascertain if the patient is still eligible to continue with the screening measures, and then code yes or no. If the patient meets all eligibility criteria in this Data Form, continue with the screening measures. If not, no further measurements should be completed at this time.