Question by Question Specifications Guide
Form 263: Follow up Medication Audit
Version 04/14/05 (B)

I. Purpose

Due to the nature of the BE-DRI trial, documentation of all medication use is important. 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.

II. Administration

Ideally, the Follow-up 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 randomization and follow-up visits, 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. Medical records can also be used to gather information about medications, but all information must be confirmed with the patient.

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 since the last medication audit, and that we will record all prescribed medications, even if she has stopped taking them of 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 combinative antihypertensive which contains a diuretic, or anticholinergic medication that the patient reports should be documented in its own section i.e., B3, as for these classes of drug, dose is a required data point.

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.

Before meeting with the patient, it is important to print out a copy of the patient's Medication Audit report from the DMS. This report can be found by logging into the ADEPT Production Site, clicking on BE-DRI study → BE-DRI reports → BE-DRI part/event reports → BE-DRI Medication Report. Click on BE-DRI Medication Report, enter the patient's ID number, and select the visit for which the patient is scheduled.

III. Section A

A1. **Study ID Number**: Study ID Number will be automatically printed on F263 Medication Report form when it is printed from the DMS.

A2. **Visit Code**: Circle the correct visit provided on the data form. This form is completed at Randomization and VS05-VS11.

A3. **Date Audit Completed**: Enter the date that the Follow-up 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. **Interview Type:** 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. **Since we last completed this medication audit, have you taken any medication prescribed by a medical doctor, nurse practitioner or physician's assistant?** Code Yes (1) if the patient has taken any medication since the last audit, (including medications the patient is currently taking, continued medications since the last audit, medications prescribed since the last audit even if they have since been stopped, and medications that were never filled). Code No (2) if the patient has not taken any medication prescribed to her since the last audit.

B2. **Are there any additions, discontinuations, or changes in frequency in prescription medications since the last audit?** Based on the patient's answer to B1, the Data Collector should answer B2. If the patient was previously taking medication but answered "No" to B1, then confirm all stop dates with the patient. If the patient answered "Yes" to B1, confirm that all medications are the same and none have been discontinued and then resumed since the last audit. Also, probe to determine if the patient has started a new medication since the last audit was completed. If there are any additions, discontinuations or changes in frequency of prescription medications since the last audit, code Yes (1) If there are no additions, discontinuations or changes in frequency since the last audit, code No (2) and skip to B3.

B2aa. **Addition or Discontinuation?** If the patient has added any medications since the previous medication audit and you are going to add these medication to this F263, code Addition (1) in the first available blank space. If the patient has discontinued a medication from her previous medication audit and you are going to record the stop date, code Discontinuation (2). If the patient has stopped a medication and then restarted it since the last audit, code the preprinted medication as a "Discontinuation" and provide the stop date; then add the same medication in the first available blank space as an "Addition" with the new start date.

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B2ab. **Med ID Number:** The Med ID Number is a random number generated by the DMS and is preprinted on F263. This number is used only for data entry purposes. "Additions" do not require a Med ID number.

B2a. **Medication Name:** Medications that were being taken by the patient at the time of the last audit are pre-printed on F263. 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 (aa-e).

B2b. **Frequency:** For each "Addition" recorded, ask the patient how often she uses the medication. Use the frequency codes written below:

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)

Frequency codes for medications that were being taken at the time of the last audit are pre-printed on F263.

B2c. **Start Date:** For all "Additions," 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. Start dates for medications that were being taken at the time of the last audit are pre-printed on F263.

B2d. **Stop Date:** For all "Discontinuations," or "Additions" that have since been stopped, ask the patient when she stopped taking the medication and record the date in month/year or month/day/year format. If the patient reports that she is still taking the medication at this time, code 01/01/0101.

B2e. **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.
The source code is preprinted for medications that were being taken at the time of the last audit.

B3. **All diuretics (blood pressure pills, water pills) and anticholinergic medications. Are there any additions, discontinuations, or changes in frequency in diuretic and anticholinergic medications since the last audit?** Based on the patient's answer to B1, the Data Collector should answer B3. If the patient was previously taking medication but answered "No" to B1, then confirm all stop dates with the patient. If the patient answered "Yes" to B1, confirm that all medications are the same and none have been discontinued and then resumed since the last audit. Also, probe to determine if the patient has started a new medication since the last audit was completed. If there are any additions, discontinuations or changes in frequency of prescription medications since the last audit, code Yes (1) If there are no additions, discontinuations or changes in frequency since the last audit, code No (2) and skip to B4.

B3aa. **Addition or Discontinuation?** If the patient has added any medications since the previous medication audit and you are going to add these medications to this F263, code Addition (1) in the first available blank space. If the patient has discontinued a medication from her previous medication audit and you are going to record the stop date, code Discontinuation (2). If the patient has stopped a medication and then restarted it since the last audit, code the preprinted medication as a "Discontinuation" and provide the stop date; then add the same medication in the first available blank space as an "Addition" with the new start date.

B3ab. **Med ID Number:** The Med ID Number is a random number generated by the DMS and preprinted on F263. This number is used only for data entry purposes. "Additions" do not require a Med ID number.

B3a. **Medication Name:** Medications that were being taken by the patient at the time of the last audit are pre-printed on F263. 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 (aa-e).

B3b. **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. Dosage for medications that were being taken at the time of the last audit are preprinted on F263.

B3c. **Frequency:** For each "Addition" recorded, ask the patient how often she uses the medication. Use the frequency codes written below:

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)

Frequency codes for medications that were being taken at the time of the last audit are pre-printed on F263.

B3d. **Start Date:** For all "Additions," 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. Start dates for medications that were being taken at the time of the last audit are pre-printed on F263.

B3e. **Stop Date:** For all "Discontinuations," or "Additions" that have since been stopped, ask the patient when she stopped taking the medication and record the date in month/year or month/day/year format. If the patient reports that she is still taking the medication at this time, code 01/01/0101.

B3f. **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.
The source code is preprinted for medications that were being taken at the time of the last audit.

B4. **Does the patient report or is there evidence of a use of diuretic or combination antihypertensive medication that contains a diuretic (i.e.: water pills, blood pressure pills)?** If the patient does report any evidence of the use of a diuretic/combination antihypertensive medication including any taken since the last audit, code Yes (1) and proceed to B4a. If she does not report any evidence of the use of a diuretic/combination antihypertensive medication, code No (2) and skip to B5.

B4a. **If yes, does the patient report or is there evidence of any change in the dose of this/these diuretic/combination antihypertensive medications, including the start of a new diuretic/combination antihypertensive medication, within the last 3 months?** If the patient does report a dosage change in her diuretic/combination antihypertensive medication(s); code Yes (1). If the patient does not report a dosage

change in her diuretic/combination antihypertensive medication(s); code No (2). If the patient answers yes to this question at Randomization, she is ineligible.

B5. **If Randomization, does the patient report or is there evidence of use of or request for a non-study related anticholinergic medication within the last 4 weeks, such as Detrol, Ditropan, Oxytrol Patch, Bentyl, Levsin? If Follow-Up, does the patient report or is there evidence of use of or request for a non-study related anticholinergic medication since the last audit, such as Detrol, Ditropan, Oxytrol Patch, Bentyl, Levsin?** If the patient has made a request for, or there is evidence of use of, or request for an anticholinergic medication; code Yes (1). If the patient has not made a request, nor is there evidence of use of or a request for an anticholinergic medication; code No (2). If the patient answers yes to this question at Randomization, she is ineligible.

B6. **Does the patient report or is there evidence of use of or request for a cholinergic agonist since the last audit?** If the patient has made a request for or there is evidence of use of or request for a cholinergic agonist; code Yes (1). If the patient has not made a request for, nor is there evidence of use of a cholinergic agonist medication; code No (2). If the patient answers yes to this question at Randomization, she is ineligible.

B7. **If Randomization, does the patient report or is there evidence of use of or request for a tricyclic antidepressant in the last 4 weeks such as Elavil, Pamelor, Norpramin? If Follow-Up, does the patient report or is there evidence of use of or request for a tricyclic antidepressant since the last audit such as Elavil, Pamelor, Norpramin?**If the patient has made a request for or there is evidence of use of or request for a tricyclic antidepressant; code Yes (1). If the patient has not made a request for, nor is there evidence of use of a tricyclic antidepressant medication; code No (2). If the patient answers yes to this question at Randomization, she is ineligible. If the patient answers yes to this question during follow up, the request for or use of this tricyclic antidepressant must be documented on F261.

B8. **If Randomization, does the patient report or is there evidence of use of or request for Duloxetine in the last 4 weeks? If Follow-Up, does the patient report or is there evidence of use of or request for Duloxetine since the last audit?** If there is evidence of use of or request for Duloxetine since the last audit; code Yes (1). If there is no evidence of use of or request for Duloxetine; code No (2). If the patient answers yes to this question at Randomization, she is ineligible. If the patient answers yes to this question during follow up, the request for or use of Duloxetine must be documented on F261.

B9. **Since we last completed this medication audit, have you taken any medications supplements or vitamins not prescribed by a physician, NP, PA?** If you have taken any over-the-counter medications, supplements or vitamins since the last audit; code Yes (1). Proceed to B10. If you have not taken any over-the-counter medications, supplements or vitamins since the last audit; code No (2) and skip to the end.

B10. **Are there any additions, discontinuations, or changes in frequency in non-prescription medications since the last audit?** Based on the patient's answer to B9, the Data Collector should answer B10. If the patient was previously taking medication but answered "No" to B9, then confirm all stop dates with the patient. If the patient answered "Yes" to B9, confirm that all medications are the same and none have been discontinued and then resumed since the last audit. Also, probe to determine if the patient has started a new medication since the last audit was completed. If there are any additions, discontinuations or changes in frequency of prescription medications since the last audit, code Yes (1) If there are no additions, discontinuations or changes in frequency since the last audit, code No (2) and skip to the end.

B10aa. **Addition or Discontinuation?** If the patient has added any medications since the previous medication audit and you are going to add these medications to this F263, code Addition (1) in the first available blank space. If the patient has discontinued a medication from her previous medication audit and you are going to record the stop date, code Discontinuation (2). If the patient has stopped a medication and then restarted

it since the last audit, code the preprinted medication as a "Discontinuation" and provide the stop date; then add the same medication in the first available blank space as an "Addition" with the new start date.

B10ab. **Med ID Number:** The Med ID Number is a random number generated by the DMS and preprinted on F263. This number is used only for data entry purposes. "Additions" do not require a Med ID number.

B10a. **Medication Name:** Medications that were being taken by the patient at the time of the last audit are pre-printed on F263. 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 (aa-e).

B10b. **Frequency:** For each "Addition" recorded, ask the patient how often she uses the medication. Use the frequency codes written below:

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)

Frequency codes for medications that were being taken at the time of the last audit are pre-printed on F263.

B10c. **Start Date:** For all "Additions," 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. Start dates for medications that were being taken at the time of the last audit are pre-printed on F263.

B10d. **Stop Date:** For all "Discontinuations," or "Additions" that have since been stopped, ask the patient when she stopped taking the medication and record the date in month/year or month/day/year format. If the patient reports that she is still taking the medication at this time, 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.
The source code is preprinted for medications that were being taken at the time of the last audit.