



BE-DRI

Question by Question Specifications Guide

Form 222: Intervention Visit 2

Version 07/19/05 (B)

I. Purpose

The purpose of the Intervention Visit 2 Data Form (F222) is to capture selected information about intervention activities completed at the 2nd intervention visit.

II. Administration

A. Materials Needed

- Completed Visit 2 Encounter Form
- Any Interim Visit Encounter Forms completed between Visit 1 and Visit 2
- Intervention Visit 2 Data Form (F222) with ID labels attached

B. Window for Visit 2

The target date for Intervention Visit 2 is 14 days following Visit 1 with a visit window ± 7 days, i.e. the visit should be completed between 7 and 21 days following visit 1. If unforeseen circumstances prevent the patient from completing Visit 2 prior to the close of the window, Intervention Visit 2 activities will still be completed during her 2nd in-person visit with the BE-DRI Interventionist. These activities will be documented on the Visit 2 Encounter Form and abstracted onto F222.

C. Source, Timing and Method of Data Form Completion

The Visit 2 Encounter Form is considered the primary source document for BE-DRI intervention activities completed at the second intervention visit. Interim Visit Encounter Forms may also be used as source documents if the Interventionist is in contact with the patient between visits. These source documents will be used to complete the BE-DRI Visit 2 Data Form, i.e. F222. F222 should be completed by the Interventionist immediately after the visit or very soon thereafter, i.e. within 24 hours.

D. Maintaining Blinding for Evaluation Staff

Data recorded on F222 identify the patient's treatment assignment. Local procedures must be implemented to maintain blinding of Study Evaluation staff who may complete the post-intervention measurements including interviews, exams, Bladder Diary abstractions, or distribution and/or collection of the self-administered surveys.

III. Section by Section Review for Form 222

Section A. General Information

- A1. **Study ID Number:** Affix the patient ID label in the space provided in the A1 field and at the top of each subsequent page of the Data Form. Avoid handwriting ID numbers. Check carefully to be sure the ID number matches that recorded on the patient's Visit Control Sheet.
- A2. **Visit Number:** The visit number for Form 222 is pre-coded as Visit = INT2.
- A3. **Date Intervention Visit Completed:** Record the date the visit was completed using the mm/dd/yyyy format.

- A4. **Interventionist's Initials:** The certified Interventionist who completes the visit should record her initials in this data field. Enter 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 to record, strike a dash 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. **Date Form Completed:** Enter the date that the form was completed. The Interventionist should complete F222 immediately after Intervention Visit 2 is completed. An unblinded Evaluation staff member, e.g. Study Coordinator, Data Manager, etc s should receive the completed F222 within 24 hours after completion of the visit.

Section B: Summary of Key Elements of the Drug Intervention

Description: Questions in Section B pertain to all patients regardless of their treatment assignment.

'Need To Know' Medications

- B1. **Does the patient report taking any 'Need To Know' drugs since her last visit?** If the patient has taken any 'Need to Know' medications, circle code 1 (Yes) and list them in B1a. If the patient denies taking any 'Need to Know' medications, circle code 2 (No) and skip to B2.
- B1a. **'Need to Know' medications listed by name:** If the patient reports she has taken any 'Need to Know' medications, write them in this text field. Write or print legibly. Illegible entries will be returned to you for clarification in the form of an edit report.

Prescription of or recommendation to use a 'Need To Know' medication as well as the actual use of any 'Need To Know' medications must be reported to the MD Investigator immediately.

Drug Adherence

Description: Questions B2 and B3 aims to capture all drug adherence data.

Detrol LA 4mg capsules

- B2. **Detrol LA 4mg capsules**
Record the number of 4 mg capsules taken since Visit 1. Code this value based on your interview with the patient and your actual pill count. If the patient report does not agree with your actual pill count, probe carefully to resolve the discrepancy.

If the patient forgot to bring her medication bottle to the visit, B2 will be based on patient reports alone. NOTE: B2c will be coded '*missing*' to indicate the pill count was not completed at this visit.

If you cannot complete an actual pill count, be sure to probe carefully. Review /discuss every day since Visit 1. Use a calendar as a prop to improve the patient's recall. To determine if her report of drug adherence (or non-adherence) is credible, ask the patient what strategies she employs to remember to take her medication. Were there any days that she forgot to take her capsule? Did she take her capsule yet today (day of Visit 2)?

- B2a. **Start Date:** Record the date the patient started taking Detrol LA **4mg**. For most patients this date will match the date Visit 1 was completed. A date recorded in B2a that does not match the Visit 1 date will be considered an ‘out of range’ value. A rationale should be provided in the source document (Visit 2 or Interim Visit Encounter Form) for these dates. Record the date using the mm/dd/yyyy format.
- B2b. **Stop Date:** Record the date the patient stopped taking Detrol LA **4mg**. Most patients will still be taking Detrol LA **4mg** at Visit 2. For these patients, record 01/01/0101 in this date field. If the patient stopped taking Detrol LA **4mg** between Visit 1 and 2, record the date of the last day she took Detrol in B2b. Record the date using the mm/dd/yyyy format.
- B2c. **Number of Detrol LA 4mg capsules remaining:** Complete an actual count of the **4mg** capsules remaining in the medication bottle and record the actual number of Detrol LA **4mg** capsules remaining. If the patient forgot to bring in her medication bottle write the word ‘*missing*’ in this data field. Do not complete this data field based on patient report. You must complete an actual count of the **4mg** capsules remaining in the medication bottle to code a numerical value here.
- B2d. **Number of Detrol LA 4mg capsules recovered:** If the patient stopped taking Detrol LA **4mg**, you must recover all unused **4mg** capsules. Record the number of **4mg** capsules recovered. This value is based on your actual count of the capsules recovered. If the patient stopped taking Detrol **4mg** but forgot to bring her medication bottle to the visit, write ‘*missing*’ in this data field. But the capsules must be recovered at a subsequent visit. Remind the patient to bring the unused **4mg** capsules to her next visit. These ‘recovered’ capsules will be recorded on subsequent Intervention Visit data forms when they are actually recovered.
- B2e. **Number of Detrol LA 4mg capsules dispensed:** Record the number of Detrol LA **4mg** capsules dispensed at Visit 2. Detrol LA **4mg** has been provided by Pfizer in bottles of 30 capsules, hence, if more drug is dispensed at Visit 2, the number dispensed is most likely to be ‘30 capsules’.

Detrol LA 2mg capsules

- B3. **Detrol LA 2mg capsules**
Record the number of 2 mg capsules taken since Visit 1. Most patients will still be taking Detrol LA **4mg**. at Visit 2. For these patients write 00 in this data field and skip to B4.

If the patient changed from a 4mg capsule to a 2mg capsule between Visit 1 and Visit 2, source documentation for this change in dose must be recorded on an Encounter form. Record the number of Detrol LA **2mg** capsules taken since Visit 1. Code this value based on your Interim Visit activities, today’s interview with the patient and your actual pill count completed at an Interim Visit and/or at Visit 2. Record the number of **2mg** capsules the patient actually took since Visit 1. If the patient report does not jibe with your actual pill count, probe carefully to resolve the discrepancy.

If the patient forgot to bring her medication bottle to the visit, the value recorded in B3 will be based solely on your Interim Visit activities and today’s interview with the patient since an actual pill count cannot be completed. NOTE: B3c will be coded ‘*missing*’ to indicate the pill count was not completed at this visit.

If you cannot complete an actual pill count, probe carefully. Review /discuss every day since you dispensed Detrol LA **2mg**. Use a calendar as a prop to improve the patient’s recall. To

determine if her report of drug adherence (or non-adherence) is credible, ask the patient what strategies she employs to remember to take her medication. Were there any days that she forgot to take her capsule? Did she take her capsule yet today (day of Visit 2)?

If you are dispensing Detrol LA 2mg on the day of this visit, code -1 (Dispensed Today) and continue to B3e.

- B3a. **Start Date:** Record the date the patient started taking Detrol LA **2mg**. This date should match the date you dispensed Detrol LA **2mg**. Confirm with the patient she started taking the **2mg** capsules on the date dispensed.
- B3b. **Stop Date:** If the patient stopped taking Detrol LA **2mg**, record the date the patient stopped taking it here. If a patient is still taking Detrol LA **2mg** at the time of Visit 2, record 01/01/0101 in this date field.
- B3c. **Number of Detrol LA 2mg capsules remaining:** Complete an actual count of the **2mg** capsules remaining in the medication bottle and record the actual number of Detrol LA **2mg** capsules remaining. If the patient forgot to bring in her medication bottle write the word '*missing*' in this data field. Do not complete this data field based on patient report. You must complete an actual count of the **2mg** capsules remaining in the medication bottle to code a numerical value here.
- B3d. **Number of Detrol LA 2mg capsules recovered:** If the patient stops taking Detrol LA **2mg**, you must recover all unused/remaining **2mg** capsule (# in B3c). Record the number of capsules recovered. This value is based on your actual count of the **2mg** capsules. If the patient stopped taking Detrol **2mg** but forgot to bring her medication bottle to the visit, write '*missing*' in this data field. But the capsule must be recovered at a subsequent visit. Remind the patient to bring the unused capsules to her next visit. These 'recovered' capsules will be recorded on subsequent Intervention visit data forms.
- B3e. **Number of Detrol LA 2mg capsules dispensed:** Record the number of Detrol LA **2mg** capsules dispensed at Visit 2. Pfizer also supplies Detrol LA **2mg** in bottles containing 30 capsules, so if more Detrol LA **2mg** capsules are dispensed at Visit 2, the number of capsules dispensed is likely to be 30 capsules.
- B4. **Did the patient take Detrol at the same time most days?** Code this item 'yes' or 'no' by circling the corresponding value. This information is gathered via patient self-report.
- B5. **Were any interventions initiated for bothersome 'yes' symptoms recorded on the Symptoms Checklist (F205)?** Code this item 'yes' or 'no' by circling the corresponding value. Source documentation must be available on the Visit 2 or Interim Visit Encounter Form. If you initiate an intervention for any of the symptoms on the Checklist (F205) circle code 1 (yes) and complete B6.
- Do not write in symptoms if they are not included on the Checklist, even if an intervention is provided.
 - Do not document 'yes' symptoms in B6 if interventions were not initiated for them but if the patient complains of pain and burning with urination, you should rule out the presence of a urinary tract infection (UTI) in accordance with your customary clinical practice and document your assessment in a source document. You should also circle code 1 (yes) to B5

and write the symptom and the intervention and/or assessment in B6. Likewise, if you complete an **assessment** to rule out a reportable adverse event, even if you do not initiate a clinical intervention, for the purposes of this study, you should treat such an assessment as an intervention, i.e. document your actions in a source document, code yes to B5 and write the symptom and the intervention/assessment in B6.

- The following actions alone would not necessitate recording a symptom in B6, “discussed (symptom) with the patient”; “will monitor at future visits”; “patient taking Rx from primary”.

B6. Record the symptom(s) and code(s) and the intervention(s) and code(s) for each bothersome ‘yes’ symptom from the Symptoms Checklist:

- Symptom Name:** Write the ‘yes’ symptom name in this text field. Write or print legibly. Illegible entries will be returned to you for clarification in the form of an edit report.
- Symptom code:** Write in the code number of the ‘yes’ symptom written in the preceding text field. Use the codes from the Symptom and Intervention Codes Attachment provided on the back of F222 and attached here.
- Intervention:** Write or describe the intervention or treatment provided in this text field. Write or print legibly. Illegible entries will be returned to you for clarification in the form of an edit report.
- Intervention code:** Write in the code number of the intervention initiated for the ‘yes’ symptom recorded in the preceding text field. Use the codes from the Symptom and Intervention Codes Attachment provided on the back of F222 and attached here.

Documentation for all symptom complaints and interventions provided at a study visit must be included on an Encounter Form or other source document for reference during a QA Site Visit.

Section C: Abstraction of Key Elements from the Bladder Diary

Description: Questions in Section C pertain to all patients regardless of their treatment assignment. Use all the Blue Intervention Diaries completed by the patient since Visit 1.

- C1. Average number of leaks per week:** Include all accidents from all valid days in your calculation. **Do not count leaks from invalid days.**
- First, determine the grand total of leaks from all valid days;
 - Next, divide this number by the total # of valid days to get the average # of leaks per day;
 - Finally, multiply this number by 7 to get the average number of leaks per week.

Record the average # of leaks per week as a whole numbers. Follow common rounding rules as the last step in your calculation, i.e. round up to the next whole value for fractions equal to or greater than .5.

- C2. Average # of voids per day (24 hour period):** Include all voids from all valid days in your calculation. **Do not count voids from invalid days.**
- First, determine the grand total of voids from all valid days,
 - Next, divide this number by the total # of valid days to get the average # of voids per day.

Record the average # of voids per days as a whole numbers. Follow common rounding rules at the very end of your calculations, i.e. round up to the next whole value for fractions equal to or greater than .5.

- C3. **What is the patient's treatment group assignment?** Circle the patient's treatment group assignment. If the patient is in the drug-only treatment arm, circle code 1 and skip to item D5.

Section D: Summary of Key Elements of the Behavioral Intervention (Combination Patients Only)

Description: Questions D1-D4 pertain only to patients receiving the combination treatment. D5 and D6 should be answered for patients in both treatment arms.

- D1. **Did she perform 5 consecutive pelvic floor muscle contractions?** Based on your evaluation completed during the intervention, code this item 'yes' or 'no' by circling the corresponding value.
- D2. **Was she able to minimize Valsalva and accessory muscle contractions?** Based on your evaluation completed during the intervention, code this item 'yes' or 'no' by circling the corresponding value.
- D3. **Was Bladder Training initiated?** Code this item 'yes' or 'not indicated' by circling the corresponding value. If C2 is >8 voids/day at either Visit 1 or 2, Bladder Training is indicated and should be initiated, so this item should be coded yes.
- D4. **Was Stress Training initiated?** Code this item 'yes' or 'not indicated' by circling the corresponding value. Stress Training is indicated and should be initiated if there is evidence of one or more stress accidents on the patient's Diary.
- D5. **How long did the visit last?** Record the actual number of minutes spent with the patient completing the intervention. In addition, count the time the patient spent completing the Symptoms Checklist and Exercise Adherence Questionnaire. Do not count any other waiting room wait time.
- D6. **Record the number of minutes spent with the patient between visits.** Count all time spent with the patient in phone contact or in-person between study visits. Each contact should be recorded on a separate Interim Visit Encounter Form. Do not count minutes spent making or rescheduling appointments.

SYMPTOM AND INTERVENTION CODES ATTACHMENT

| SYMPTOM CODES | |
|---------------|--|
| 01 | pain or burning with urination |
| 02 | blood in your urine |
| 03 | difficulty emptying your bladder |
| 04 | difficulty starting your urine stream |
| 05 | skin rash |
| 06 | nausea |
| 07 | heartburn |
| 08 | dizziness |
| 09 | confusion or difficulty thinking clearly |
| 10 | sore throat |
| 11 | dry mouth |
| 12 | blurred vision |
| 13 | abdominal pain |
| 14 | constipation |
| 15 | diarrhea |
| 16 | pelvic muscle soreness |
| 17 | insomnia |
| 18 | fever |
| 19 | drowsiness |
| 20 | headache |

| INTERVENTION | |
|--------------|----------------------------------|
| 120 | Dry mouth handout |
| 121 | Constipation handout |
| 122 | Decrease study drug dose to 2 mg |
| 123 | Stopped study drug |
| 999 | Other |