Question by Question Specifications Guide
Form 93: Reintervention or Treatment
Version 04/08/03 (B)

I. Purpose

The purpose of the Reintervention or Treatment Form is to document any treatment for de novo or persistent urge incontinence, retention beyond 6-weeks post-op, vaginal prolapse, or retreatment for stress urinary incontinence (SUI) occurring after the index procedure. If retreatment for SUI is being reported, be sure that all required elements of the Failure Protocol are completed (including a FM94).

II. Administration

A. When to Use This Data Form

The UITN-certified surgeon who completed the index surgery is required to complete this Data Form. This form should be completed any time a new treatment for de novo or persistent urge incontinence, retention, vaginal prolapse, or SUI is initiated post randomization. Additionally, the certified surgeon is also required to complete this Data Form at any time a previously documented treatment(s) is reported as "continuing" at the 6-month visit or at any Follow-Up visit. Multiple treatments can be documented on the same Data Form if reported on the same visit day. If multiple treatments are reported on different dates, multiple Data Forms should be completed in order to document the initiation and/or continuation of all new treatments for any of the previously mentioned diagnoses. The "date of first treatment" field is a unique field that will be used to link multiple Data Forms completed for the same diagnosis. For example, if a patient reports that she started using a pessary for the treatment of vaginal prolapse on 11/11/2002, the date of first treatment would be recorded as such. If at a later date, the same patient receives surgical treatment for the previously diagnosed vaginal prolapse, a second Data Form 93 should be completed to document the additional treatment with the "date of first treatment" field being recorded as 11/11/2002 to link the two Data Forms. Likewise, if both treatments were reported on the same day, only one Data Form 93 should be completed. Both treatments should be circled, and the "date of first treatment" recorded should be the date that the first treatment was received.

B. Source

The source of this information will be the patient and the medical record.

III. Section by Section Review

Section A: General Study Information

A1. **Study ID Number:** Affix the patient ID label in the space provided in the A1 field. As with all other Data Forms, do not handwrite ID numbers.

A2. **Visit Number:** The visit number is pre-coded for Form 93 which will always be Visit **RETR.**

A3. **Date Form Completed:** Enter the date the form was completed in the format of mm/dd/yyyy.

A4. **Initials of Person Completing this Form:** The surgeon completing this Data Form should enter his/her initials. 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 the surgeon does not have a middle initial, strike a dash in the second space. If the surgeon's last name is hyphenated or if s/he has two last names, enter the initial of the first last name in the third space.

Section B: Reintervention/Treatment

B1. **Did the patient require treatment for urge incontinence?** Record whether or not the patient received treatment for urge incontinence. Circle "1" (YES) or "2" (NO), and follow the skip pattern on the Data Form.

B1a. **Type of treatments for urge incontinence:** If the patient received treatment for urge incontinence, circle "1" (YES) or "2" (NO) for each type of treatment listed. If "other" is coded as "1" (YES), describe the type of treatment in the specify field (i.e. B1.a.iii.a). Items without a circled code will be treated as missing data.

B1b. **Classify the type of urge incontinence**: If the patient was treated for de novo urge incontinence, circle "1." If the patient was treated for persistent urge incontinence, circle "2" and skip to B1d.

B1c. **Date of first treatment for de novo urge incontinence?** Record the date that the patient received her first treatment for de novo urge incontinence in the format of mm/dd/yyyy, then skip to B2.

B1d. **Did the patient receive treatment for persistent urge incontinence prior to her UITN surgery?** Record whether or not the patient received treatment for persistent urge incontinence prior to her UITN surgery. Circle "1" (YES) or "2" (NO).

B1e. **Date of first treatment for persistent urge incontinence following UITN surgery?** Record the date that the patient received her first treatment for persistent urge incontinence following her UITN surgery in the format of mm/dd/yyyy.

B2. **Did the patient require treatment for retention?** Record whether or not the patient received treatment for retention. Circle "1" (YES) or "2" (NO), and follow the skip pattern on the Data Form.

B2a. **Types of treatments for retention:** If the patient received treatment for retention, circle "1" (YES) or "2" (NO) for each type of treatment listed. If "other" is coded as "1" (YES), describe the type of treatment in the specify field (i.e. B2a.iv.a.). Items without a circled code will be treated as missing data.

B2b. **Date of first treatment for retention:** Record the date that the patient received her first treatment for retention in the format of mm/dd/yyyy. For a patient who started catheter use during her initial hospitalization for her index surgery and is continuing to use the catheter beyond 6 weeks post-op, the date of discharge from her hospital stay should be documented as the date of first treatment for retention. Otherwise, for patients who start catheter use after being discharged from the hospital, the first day that she starts using a catheter should be recorded.

B3. **Did the patient require treatment for vaginal prolapse?** Record whether or not the patient received treatment for vaginal prolapse. Circle "1" (YES) or "2" (NO), and follow the skip pattern on the Data Form.

B3a. **Types of treatments for vaginal prolapse:** If the patient received treatment for vaginal prolapse, circle "1" (YES) or "2" (NO) for each type of treatment listed. If "other" is coded as "1" (YES), describe the type of treatment in the specify field (i.e. B3a.vi.a.). Items without a circled code will be treated as missing data.

B3b. **Date of first treatment for vaginal prolapse:** Record the date that the patient received her first treatment for vaginal prolapse in the format of mm/dd/yyyy.

B4. **Did the patient require treatment for recurrent SUI?** Record whether or not the patient received treatment for SUI. Circle "1" (YES) or "2" (NO), and follow the prompts on the Data Form.

B4a. **Types of treatments for recurrent SUI:** If the patient received treatment for SUI, circle "1" (YES) or "2" (NO) for each type of treatment listed. If "other" is coded as "1" (YES), describe the type of treatment in the specify field (i.e. B4a.xii.a.). Items without a circled code will be treated as missing data.

B4b. **Date of first treatment for recurrent SUI?** Record the date that the patient received her first treatment for recurrent SUI in the format of mm/dd/yyyy.