Question by Question Specifications Guide
Form 51: Follow-Up Patient Interview
Version 12/11/02 (A)

I. Purpose

Data will be collected on all UITN patients following their UITN surgery to gather information related to the patient's post-operative recovery including untoward outcomes that may arise secondary to the anti-incontinence surgery. Data Form 51 is used specifically for the collection of data that can be gathered through self-report interview (Sections B, C and D) and/or minimal medical record abstraction (Section E). Any adverse events or untoward outcomes that occur between the time of the last visit and the visit for which Form 51 is being completed must be documented appropriately on the Follow-Up Data Forms.

II. Administration

A. Windows for Follow-up Visits

The visit window is defined as the period of time in which measures for a specific study event should be completed. In the best of circumstances, measures completed for a study visit are collected in a single session, but this is not always practical for UITN patients. With this in mind, we have established visit windows for each of the studies' follow-up visit events. Review the "Visit Windows" document published in the Data Management Manual and on the web for information about how target windows are established.

B. Source of Data

1. Sections B, C and D: The Interview: The patient is considered the source for data collected in Sections B, C and D. All elements in these sections must be collected directly from the patient in the format of a formal research interview conducted by a certified UITN Interviewer/Data Collector. Data are recorded simultaneous to the conduct of the research interview.

2. Section E: Data gathered in Section E may be gathered by interview and medical record review. Regardless of the source, all data must be gathered by a certified UITN Interviewer/Data Collector. When medical records are used for data elements in Section E, the source documentation must be readily available for a data audit as required. Sites may use the patient's Visit Control Sheet to maintain a master log of all source documents used for UITN Data Forms.

C. Certification of UITN Interviewers and Data Collectors

Interviewers and Data Collectors must be certified by and registered with the BCC as a UITN Interviewer/Data Collector. The obligations of certification are documented in the QC Plan. Data gathered by non-certified persons may not be entered into the UITN DMS.

D. Materials needed:

- Patient's Visit Control Sheet (VCS) for the appropriate visit
- Form 51 with ID labels attached;
- Patient's medical record(s), depending upon answers to questions in Section E

III. Section by Section Review for Form 51

Section A. General Information

A1. **Study ID Number**: Affix the patient ID label in the spaces provided in the A1 field and at the top of subsequent pages in the Data Form. Avoid handwriting ID numbers. Check carefully to be sure the ID number matches the ID number on the patient's Visit Control Sheet.

A2. **Visit Number**: Circle the correct visit code for the event. If this Data Form is being completed as part of a scheduled UITN study visit, circle the correct visit code. If it is being completed solely because of a treatment failure, circle FAIL.

A3. **Date Interview Completed**: Record the date you complete the interview. Use the mm/dd/yyyy format.

A4. **Interviewer's Initials**: The person completing the interview should record his/her initials in this data field. All Interviewers/Data Collectors must be certified by and registered with the BCC. Data submitted by non-certified individuals should not be data entered into the UITN DMS. Enter first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If you don't have a middle initial, strike a dash in the second space. If your last name is hyphenated or if you have 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 type. The data may be gathered in-person or on the telephone.

A6. **Which version of this form was used?** Record which language version of the form was used to complete the Interview.

Section B: The MESA Interview

Administration: The MESA is a critical measure for the UITN Trial. It is first used to ascertain if a patient has predominant stress urinary incontinence, an essential eligibility criterion. The MESA is also used to determine treatment success or failure following the UITN surgery. Therefore, this instrument will always be administered by a certified UITN interviewer.

Instructions: Read the introduction provided in the data form exactly as written. The response scale for the MESA questions is a four-point scale where '*Never'* is coded as 0; '*Rarely'* is coded as 1, '*Sometimes'* is coded as 2 and '*Often'* is coded as 3. There is no scoring for the follow-up MESA.

MESA Part I: Stress Incontinence:

Read the introduction and the questions to the patient precisely.

B1–B9. **Stress Symptoms**: The Interviewer should read the questions precisely as written on the Data Form. The response choices must be read aloud for **every question** to be certain the patient selects from all of the available responses. An example of this follows:

Interviewer "*Does coughing gently cause you to lose urine? Would you say never, rarely, sometimes or often?"*

Interviewer "*Does coughing hard cause you to lose urine? Would you say never, rarely, sometimes or often?"*

Interviewer "*Does sneezing cause you to lose urine? .... Never, rarely, sometimes or often?"*

Interviewer "*Does lifting things cause you to lose urine? ... Never, rarely, sometimes or often?"*

It is very common for women to respond to the MESA questions using terms not among the standard choices given in this measure. For example, a woman may respond, "*Oh that happens to me all the time*." Or "*That happens frequently*." In all cases, the Interviewer should repeat the standardized choice categories from the measure, i.e. "*So, would you say never, rarely, sometimes or often?*" Furthermore, **the Interviewer should not code a "*no*" response as "*never*" *(code 0*)**. The Interviewer should repeat the response choices and ask the patient to select from among **all** the choices. In such instances, it is not uncommon for a woman to make a final choice of "*rarely"* when asked to select from the full range of choices.

B7. **Walking briskly**: If a patient reports she never walks briskly or jogs, you should prompt her by saying, "*Does walking or moving at a pace that is faster than your usual pace cause you to lose urine?"*
In Spanish, ask: *"¿Al caminar o moverse más rápido de lo usual tiene escapes de orina?"*

B8. **Straining**: If a patient reports she is never constipated you should prompt her by saying, "*Do other types of straining, such as opening a tightly closed food container or jar cause you to lose urine?*"
In Spanish, ask: " *¿Tiene escapes de orina cuando se esfuerza de otras formas, tales como cuando abre la tapa de un frasco o envase que esta dura?"*

B10. **Any response of "Sometimes" or "Often" to B1-B9:** Record whether or not the patient responded with "Sometimes" or "Often" to any of the MESA Stress symptoms in B1-B9. A response of "Sometimes" or "Often" to any of the MESA Stress symptoms constitutes a Treatment Failure and the Failure protocol should be completed at this time. This includes the completion of Data Form 51, Data Form 94, and all of the other Data Forms required at this visit.

MESA Part II: Urge Incontinence:

Be sure to read the introduction and the questions to the patient precisely as they are written.

B11-B16. **Urge Symptoms**: The Interviewer should read the questions precisely as written in the Data Form. The response choices should also be read aloud for **every question** to be certain the patient selects from all of the available responses.

As a reminder, it is very common for a woman to respond to the MESA questions using terms not among the standard choices given in this measures. For example, a woman may respond, "*Oh that happens to me all the time*." Or "*That happens frequently*." In all cases, Interviewers should repeat the standardized choice categories from the measure, i.e. "*So, would you say never, rarely, sometimes or often?*" Furthermore, **the Interviewer should not code a "*no*" response as "*never*" *(code* 0)**. The Interviewer should repeat the response choices and ask the patient to select from among **all** the choices. In such instances, it is not uncommon for a woman to make a final choice of "*rarely"* when asked to select from the full range of choices.

B14. **Washing Hands**: A patient may report even the sound of running water may cause her to lose urine. This can be taken as the equivalent to the washing hands stimulus.

B15. **Cold Weather**: Dr. Diokno, co-developer of the MESA scale and PI of the UITN Beaumont Hospital CTC, reports that some women who live in warmer climates have asked for clarification for this item. If a woman responds, "*I never experience cold weather*." You can probe, "*Have you ever lost urine when you entered the freezer section of the grocery store, or when you entered a very cold, air conditioned building?"*
In Spanish, ask: *"¿Ha tenido escapes de orina al entrar a la sección de congelados del supermercado, o cuando entra a un edificio con aire acondicionado muy frio?"*

Assessment of Other Physical Symptoms

C1. **Increased frequency**: Ask the question as written and code the answer accordingly.

C2. **Increased urgency:** Ask the question as written and code the answer accordingly.

C3. **Catheter use:** Ask the question as written and code the answer accordingly. Follow the skip pattern on the form. If the patient responds, "Yes" and has been diagnosed with Retention or Obstruction, a Data Form 93 should be completed to further document this treatment information.

C3a. **Frequency of catheter use**: This question captures the frequency with which the patient uses a catheter. Ask the question as written and code accordingly.

C4a-g. **Physical accommodations for urination**: This question is meant to capture physical accommodations that the patient might make to facilitate complete bladder emptying. Ask the patient if she **currently** has to make any of the listed accommodations to urinate. Code "yes" or "no" for every accommodation listed.

C4h. If the patient reports she currently makes any accommodation not included on the list, code "yes" for C2g and describe the accommodation in the text field provided.

C5a-f. **Urine stream:** This question is meant to capture the character of the patient's urine stream since surgery. Get the patient to describe her **current** urine stream by asking her to respond "yes" or "no" for each of the urine stream descriptives listed. Code "yes" or "no" for every descriptive listed.

C5g. If the patient uses any other descriptive not included on the list, code "yes" for C4f and write the descriptive in the text field provided.

C6. **Time it takes to urinate**: Ask the question as written and code accordingly.

C7. **Bothered by changes**: Ask the question as written, and code accordingly.

C8. **Vaginal bulging or protrusion**: This question is meant to capture any symptoms of prolapse that the patient might be experiencing since her surgery.

Symptoms of Bowel Incontinence

C9. **Use of stool softeners**: Ask the question as written and code accordingly.

C10. **Straining**: Ask the question as written. Follow the skip pattern on the Data Form.

C10a. **Frequency of straining**: For patients who report "yes" to straining in C10, ascertain frequency information using the pre-coded responses provided.

C11. **Leaking Gas**: Ask the question as written and follow the skip pattern on the Data Form.

C11a. **Frequency of leaking gas**: For patients who report "yes" to C11, ascertain frequency information using the pre-coded responses provided.

C12. **Leaking liquid stool**: Ask the question as written and follow the skip pattern on the Data Form.

C12a. **Frequency of leaking liquid stool**: For patients who report "yes" to C12, ascertain frequency information using the pre-coded responses provided.

C13. **Leaking solid stool**: Ask the question as written and follow the skip pattern on the Data Form.

C13a. **Frequency of Leaking Solid Stool**: For patients who report "yes" to C13, ascertain frequency information using the pre-coded responses provided.

Status of Pain and Pain Management

D1. **Any medication(s) for pain related to UITN surgery?** Ask the patient if she is taking any medication for pain related to her UITN surgery. Code the answer accordingly and follow the skip pattern on the Data Form. If the patient reports "yes", the current pain medication should be recorded on the Medication Audit for this visit.

D2. **Do you have physical pain related to UITN surgery?** This question will only be asked of patients who report that pain medication is not being taken for pain related to their UITN surgery.

D3. **Pain rating**: This question will be asked of all patients who report any pain that they feel is directly related to their UITN surgery.

Section E: Other Treatments/Health Services Utilization

We will gather data related to visits to a physician (NP or PA), the emergency room, or any hospital admissions for urinary symptoms or the UITN surgery, and new abdominal or pelvic surgeries since the patient's last visit. Obtain this information through interview with the patient and medical record abstraction. Interviewers should probe to gather accurate information from the patient. If any discrepancies are found between what the patient reports and what is documented in the medical record, please confirm with the patient what the correct information is.

E1. **Physician visits, emergency room visits, hospital admissions or other pelvic surgeries that may be related to the incontinence surgery**: These data can be obtained through direct interview with the patient **and** through abstraction of information from the patient's medical records. Ask the question of the patient as written. Interviewers should probe to gather accurate information. Follow the skip pattern on the Data Form.

E1a. **Specify:** If the patient reports that she saw a physician, she went to the emergency room, she was admitted to the hospital, and/or she had pelvic surgery for a reason that might be related to her incontinence surgery since her last study visit, please specify the reason(s) on the lines provided.

E2. **Treatments for any problems reported in E1 since the last study visit**: Record whether the patient has received any treatments for any problems recorded in E1a. These data can be obtained through direct interview with the patient **and** through abstraction of information from the patient's medical records. Ask the question of the patient as written. Interviewers should probe to gather accurate information. If the patient or the medical record report any treatment(s) for any problems, code this item as Yes (1) and document the treatment(s) on Data Form 52.