Question by Question Specifications Guide
Form 21: 6 Week Follow-Up Assessment, Part I
Version 07/01/02 (A)

I. Purpose

Data will be collected on all UITN patients 6 weeks following their UITN surgery to gather information related to the patient's post-operative recovery including complications that may arise secondary to the anti-incontinence surgery. Data Form 21 is used specifically for the collection of data that can be gathered through self-report interview (Section B) and/or minimal medical record abstraction (Sections C and D). Any physician visits/ER visits/hospital admissions, adverse events or complications that occur between the time of discharge and up to the 6 Week Visit must be documented appropriately on the 6 Week Follow-Up Data Forms.

II. Administration

A. Window for the 6 Week Follow-up Visit

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 study's follow-up visit events.

The **primary milestone** for creation of the follow-up visit windows is the date of randomization, which in all cases should be equal to the date of the patient's UITN surgery. The **target date** for the 6 week follow-up visit is programmed to be exactly 42 days (6 weeks x 7 days) following the date of randomization. The **visit window** for the 6 week visit is defined as the target date ± 1 week. Therefore, the **6 week follow-up visit window** is between 5 and 7 weeks following the date of randomization; or between 35 days and 49 days following the date of randomization. The patient's 6 week target date and the 6-week visit window will be printed on the patient's 6 week Visit Control Sheet (VCS) for easy reference. This visit window should be considered the target window within which Study Coordinators should aim to start and end follow-up visit measurements.

B. Source of Data

1. Section B: The Interview: The patient is considered the source for data collected in Section B. All elements in Section B must be collected directly from the patient by formal research interview by a certified UITN Interviewer. Data are recorded simultaneous to the conduct of the research interview.

2. Sections C and D: Data gathered in Section C and D may be gathered by interview and medical record review. Regardless of the source, all data must be gathered by UITN research staff certified and registered with the BCC. When medical records are used for data elements in Sections C and D, 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 by 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 6 Week Visit Control Sheet (VCS)
- Form 21 with ID labels attached
- Patient's medical record(s) required to complete Sections C and D

III. Section by Section Review for Form 21

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**: The visit number for Form 21 is pre-coded as Visit = F/U 6 weeks, the 6-week post-operative visit.

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: Patient Interview

Changes in Patterns of Urination

B1. **Increased Frequency**: Ask the question as written and follow the skip pattern on the Data Form.

B2a-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 the listed accommodations to urinate. Code "yes" or "no" for every accommodation listed.

B2h. If the patient reports that she currently makes any accommodation not included on the list, code "yes" for B2g and describe the accommodation in the text field provided.

B3. **Bothered by changes**: Ask the question as written, and code accordingly.

B4a-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.

B4g. If the patient uses any other descriptive not included on the list, code "yes" for B4f and write the descriptive in the text field provided.

B5. **Time it takes to urinate**: Ask the question as written and code accordingly.

B6. **Incomplete bladder emptying:** Ask the question as written and code accordingly.

Symptoms of Bowel Incontinence

B7. **Use of stool softeners**: Ask the question as written and code accordingly.

B8. **Straining**: Ask the question as written and follow the skip pattern on the Data Form.

B8a. **Frequency of straining**: For patients who report "yes" to straining in QB8, ascertain frequency information using the pre-coded responses provided.

B9. **Leaking Gas**: Ask the question as written and follow the skip pattern on the Data Form.

B9a. **Frequency of leaking gas**: For patients who report "yes" to QB9, ascertain frequency information using the pre-coded responses provided.

B10. **Leaking liquid stool**: Ask the question as written and follow the skip pattern on the Data Form.

B10a. **Frequency of leaking liquid stool**: For patients who report "yes" to QB10, ascertain frequency information using the pre-coded responses provided.

B11. **Leaking solid stool**: Ask the question as written and follow the skip pattern on the Data Form.

B11a. **Frequency of Leaking Solid Stool**: For patients who report "yes" to QB11, ascertain frequency information using the pre-coded responses provided.

Status of Post-Operative Pain

B12. **Any pain medications?** Ask the question as written, and code the patient's response to the stem question. Follow the skip pattern on the Data Form. A prompt is provided for your use. If the patient was prescribed a pain medication at the time of discharge for her UITN surgery, the name of the medication will be printed on the 6 week Visit Control Sheet. Be sure to ask the patient if she is still taking that medication. Code the patient's answer to the primary stem question accordingly.

B13. **Medications by name/strength/doses taken yesterday**: If the patient reports she is taking any medications for pain, record them here. Record the medication by full name and strength. Record the number of doses taken the day prior to the study visit day. Count a full day for the 24-hour period starting at 12:00 midnight and ending at 12:00 midnight the night prior to the visit. This data field is a repeating segment. You may record as many medications as the patient takes. If there are more than 3 medications to record, document them on the reverse side of this page of the Data Form.

B14. **Is this (are these) medication(s) for pain related to the UITN surgery?** When following the skip patterns properly, this question will only be asked of patients who report that they are taking pain meds.

B15. **Do you have physical pain related to the UITN surgery?** This question will only be asked of patients who report no pain medication use or no pain medication taken for pain related to their UITN surgery.

B16. **Pain rating**: This question will be asked of all patients who report any pain that they feel is directly related to their UITN surgery.

Status of Return to Normal Activities

B17. **Return to full normal activities since surgery**: Ask the question as written, and code the patient's response accordingly. Follow the skip pattern on the Data Form.

B18. **Time it took to return to full normal activities**: Ask the question as written, and record the number of days in the field provided. If the woman is retired or unemployed, code -1 (N/A) in the field.

B19. **Number of paid workdays taken**: Ask the patient how many paid workdays she took off after surgery. If she works but took no paid workdays off, code 00. If she took no paid workdays because she is either unemployed or retired, code -1 (N/A).

Section C: Health Services Utilization

We will gather data related to: visits to a physician (NP or PA), visits to an emergency room, new abdominal or pelvic surgeries, and other hospitalizations that have occurred since the date of discharge from the patient's UITN surgery. Obtain this information through interview with the patient and medical record abstraction. Interviewers should probe to gather accurate information. For example, if a patient reports she visited the doctor 2 times since surgery but only one visit is documented in **your** medical record, you should prompt the patient by saying, "I only find evidence of one visit, but I do see a note from a telephone conversation you had with Dr. Brown. Is that what you are remembering?" In this example, a patient might say, "Oh yes, that's right, I spoke with him first, then a week later I came in to see him." Or, the patient might say, "No, actually I did see Dr. Brown once, but I sprained my ankle just last Monday and I saw an orthopedist for it yesterday." The patient might also mix physician visits and emergency room visits. Probe thoroughly and record the information in the appropriate sections.

C1. **Physician Visits**: 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.

C2. **Dates of and reasons for any MD (NP or PA) Visits**: Record the date (approximate if necessary) and reason for the visit in the text fields provided. A **diagnosis is preferred** over information regarding presenting symptoms at the time of the visit. This data field is a repeating segment. You may record as many physician visits as the patient reports. Record any additional visits on the reverse side of this page of the Data Form.

C2c: **Source codes**: Record the source for the data recorded here. If the only source of information is the patient, record 1 as the source code in the last column of this table. If the only source of information for the data is the medical record, record 2 as the source code. If the source for the data is **both** the patient and the medical record and there is agreement between these sources, record 3 as the source code. If the patient's self-report contradicts information found in the medical record, probe thoroughly to get the most accurate information possible. 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 data are gathered from medical records, use the Visit Control Sheet for the 6-week visit to record any **new** medical record numbers.

C3: **Emergency Room Visits**: These data can be obtained through direct interview with the patient **and** through abstraction of the patient's medical records. Ask the question of the patient as written. Interviewers should probe to gather accurate information. **Note:** It is not necessary to include ER visits that resulted in hospitalization. These will be captured in Item C7. Only include ER visits which did **not** result in hospital admission.

C4: **Dates of and reasons for ER Visits:** Record the date (approximate if necessary) and reason for the visit in the text fields provided. A **diagnosis is preferred** over information regarding presenting symptoms at the time of the visit. This data field is a repeating segment. You may record as many ER visits as the patient reports. Record any additional visits on the reverse side of this page of the Data Form.

C4c: **Source codes**: Record the source for the data recorded here. If the only source of information is the patient, record 1 as the source code in the last column of this table. If the only source of information for the data is the medical record, record 2 as the source code. If the source for the data is **both** the patient and the medical record and there is agreement between these sources, record 3 as the source code. If the patient's self-report contradicts information found in the medical record, probe thoroughly to get the most accurate information possible. 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 data are gathered from medical records, use the Visit Control Sheet for the 6-week visit to record any **new** medical record numbers.

C5: **New abdominal or pelvic surgeries since UITN 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.

C6: **Dates and description of new abdominal or pelvic surgeries since UITN surgery:** Record the date (approximate if necessary) and description of the new abdominal or pelvic surgeries in the text fields provided. This data field is a repeating segment. You may record as many new abdominal or pelvic surgeries as the patient reports. Record any additional surgeries on the reverse side of this page of the Data Form.

C6c: **Source codes**: Record the source for the data recorded here. If the only source of information is the patient, record 1 as the source code in the last column of this table. If the only source of information for the data is the medical record, record 2 as the source code. If the source for the data is **both** the patient and the medical record and there is agreement between these sources, record 3 as the source code. If the patient's self-report contradicts information found in the medical record, probe thoroughly to get the most accurate information possible. 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 data are gathered from medical records, use the Visit Control Sheet for the 6-week visit to record any **new** medical record numbers.

C7: **Any other hospitalizations**: 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. Note: It is not necessary to include any hospitalizations that have been captured in previous items. For example, if a woman reported a new pelvic surgery since her UITN surgery in Item C6, do not record the hospitalization for that item here.

C8: **Dates of and reasons for any other hospitalizations**: Record the date (approximate if necessary) and reason for the hospitalization in the text fields provided. A **diagnosis is preferred** over information regarding presenting symptoms at the time of the hospitalization. This data field is a repeating segment.

You may record as many hospitalizations as the patient reports. Record any additional hospitalizations on the reverse side of this page of the Data Form.

C8c: **Source codes**: Record the source for the data recorded here. If the only source of information is the patient, record 1 as the source code in the last column of this table. If the only source of information for the data is the medical record, record 2 as the source code. If the source for the data is **both** the patient and the medical record and there is agreement between these sources, record 3 as the source code. If the patient's self-report contradicts information found in the medical record, probe thoroughly to get the most accurate information possible. 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 data are gathered from medical records, use the Visit Control Sheet for the 6-week visit to record any **new** medical record numbers.

Use of Antibiotics

C9. **Antibiotic use since 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. The patient's discharge medications are listed on her 6 week VCS. If she was prescribed an antibiotic at the time of discharge, ask the patient about it specifically. **Only include antibiotics prescribed at discharge <u>if the prescription was renewed or represcribed since then</u>.** Code the item and follow the skip pattern on the Data Form.

C10. **Antibiotics by name including/strength per Rx'd dose/days taken/current use**: If the patient reports she has taken or is currently taking any antibiotics, record them here. Record the medication by full name, including strength and unit dose and the total number of days taken. Record if the patient is still taking the antibiotic and document the reason why this medication was prescribed. This data field is a repeating segment. You may record as many antibiotics as the patient has taken since surgery. If there are more than 3 medications to record, document them on the reverse side of this page of the Data Form.

C10d. **Source codes**: Record the source for the data recorded here. If the only source of information is the patient, record 1 as the source code in the last column of this table. If the only source of information for the data is the medical record, record 2 as the source code. If the source for the data is **both** the patient and the medical record and there is agreement between these sources, record 3 as the source code. If the patient's self-report contradicts information found in the medical record, probe thoroughly to get the most accurate information possible. 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 data are gathered from medical records, use the Visit Control Sheet for the 6-week visit to record any **new** medical record numbers.

Summary of Adverse Events/Complications

D1. **Summary of Adverse Events/Complications:** If the patient reports physician visits, hospitalizations, ER visits, surgeries or any adverse event or complication, this item should be coded "yes" and this event or complication should be appropriately documented on Form 22. If the event or complication also qualifies as a "reportable" Adverse Event (as described in the protocol and the QxQ for Data Form 91), be sure to complete and submit an Adverse Event Form according to the procedures outlined in the QxQ for Data Form 91.