Question by Question Specifications Guide
Form 22: 6 Week Follow-up Assessment, Part II
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. Any adverse events or complications that occur in the time-period after hospital discharge from the study surgery and through the 6 Week Visit must be appropriately documented on the 6 Week Follow-Up Forms. Even if an Adverse Event was reported via an Adverse Event Form, that information must also be documented on the corresponding follow-up form(s).

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 and Method of Data Form Completion

The 6 Week Follow-Up Assessment Part II should be completed at the time of the patient's 6 week follow-up visit by the UITN-certified surgeon who completed the surgery. This requirement is meant to ensure that complications and Adverse Events are recorded as accurately as possible, thereby providing the highest quality data for the UITN's Data and Safety Monitoring Board's (DSMB) review.

C. Materials needed:

- Patient's 6 Week Visit Control Sheet (VCS)
- Form 22 with ID labels attached

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III. Section by Section Review for Form 22

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 form completed**: Record the date that the form is being completed. Use the mm/dd/yyyy format.

A4. **Initials of person completing this form**: Enter the initials of the person completing the form. This form should be completed by the UITN-certified surgeon who completed the surgery. 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 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.

Section B: Post-Discharge Complications Per Physician's Assessment(s)

PLEASE REFER TO THE ADVERSE EVENT FORM (FORM 91) QXQ SPECIFICATION GUIDE FOR INSTRUCTIONS IN REGARDS TO THE REPORTING OF ADVERSE EVENTS.

Wound Complications

B1. **Wound complications:** Indicate whether or not any wound complications were newly identified since the patient's discharge from her UITN surgery. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B1a-i. **Types of wound complications**: If there was evidence of any wound complications identified in the post-operative period, circle yes (code 1) or no (code 2) for every type of wound complication listed on the form. If "other" is coded as yes (code 1), describe the wound complication in the specify field. Wound complications without a circled code will be treated as missing data.

B1j. **Treatments for wound complications in the post-operative period**: Indicate whether or not there were any treatments for wound complications identified in the post-operative period. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B1k. **Describe any treatments for wound complications**: Describe any treatments that were administered/delivered for wound complications that were identified in the post-operative period.

MOST WOUND COMPLICATIONS ARE CONSIDERED REPORTABLE ADVERSE EVENTS. REVIEW THE QXQ FOR FORM 91 AND COMPLETE ADVERSE EVENT FORMS AS REQUIRED.

ADDITIONALLY, MOST WOUND COMPLICATIONS REQUIRE MD/ER VISITS OR HOSPITAL ADMISSIONS. IF THAT IS THE CASE, BE SURE THE VISIT/ADMISSION IS DOCUMENTED ON FORM 21 IN ADDITION TO PROVIDING INFORMATION ABOUT THE AE/COMPLICATION IN THIS SECTION B.

Organ Injuries

B2. **Organ injuries**: Indicate whether or not there were any organ injuries newly identified since the patient's discharge after surgery. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B2a-i. **Types of organ injuries**: If there was evidence of an organ injury newly identified in the post-operative period, circle yes (code 1) or no (code 2) for every injury type listed on the form. If "nerve injury" is coded as yes (code 1), specify the site of the injury in the specify field. If "other" is coded as yes (code 1), describe the organ complication in the specify field. Items without a circled code will be treated as missing data.

B2j. **Treatments for organ injuries in the post-operative period**: Indicate whether or not there were any treatments for organ injuries that were newly identified in the post-operative period. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B2k. **Describe any treatments for organ injuries:** Describe any treatments that were administered/delivered for organ injuries newly identified in the post-operative period.

MOST ORGAN INJURIES ARE CONSIDERED REPORTABLE ADVERSE EVENTS. REVIEW THE QXQ FOR FORM 91 AND COMPLETE ADVERSE EVENT FORMS AS REQUIRED.

ADDITIONALLY, MOST ORGAN INJURIES REQUIRE MD/ER VISITS OR HOSPITAL ADMISSIONS. IF THAT IS THE CASE, BE SURE THE VISIT/ADMISSION IS DOCUMENTED ON FORM 21 IN ADDITION TO PROVIDING INFORMATION ABOUT THE AE/COMPLICATION IN THIS SECTION B.

Cardiovascular Complications

B3. **Cardiovascular complications**: Indicate whether or not there were any cardiovascular complications newly identified since the patient's discharge after surgery. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B3a-d. **Types of cardiovascular complication**: If there was evidence of any cardiovascular complications newly identified in the post-operative period, circle yes (code 1) or no (code 2) for each type listed on the Data Form. If "other" is coded as yes (code 1), describe the cardiovascular complication in the specify field. Items without a circled code will be treated as missing data.

B3e. **Treatments for cardiovascular complications**: Indicate whether or not there were any treatments for any cardiovascular complications newly identified in the post-operative period. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B3f. **Describe any treatments for cardiovascular complications:** Describe any treatments that were administered/delivered for cardiovascular complications that were recognized in the post-operative period.

MOST CARDIOVASCULAR COMPLICATIONS ARE CONSIDERED REPORTABLE ADVERSE EVENTS. REVIEW THE QXQ FOR FORM 91 AND COMPLETE ADVERSE EVENT FORMS AS REQUIRED.

ADDITIONALLY, MOST CARDIOVASCULAR COMPLICATIONS REQUIRE MD/ER VISITS OR HOSPITAL ADMISSIONS. IF THAT IS THE CASE, BE SURE THE VISIT/ADMISSION IS DOCUMENTED ON FORM 21 IN ADDITION TO PROVIDING INFORMATION ABOUT THE AE/COMPLICATION IN THIS SECTION B.

Febrile Morbidities

B4. **Febrile morbidities**: Indicate whether or not there were any febrile morbidities newly identified since the patient's discharge after surgery. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B4a-f. **Types of febrile morbidities**: If there was evidence of any febrile morbidities identified in the post-operative period, circle yes (code 1) or no (code 2) for each type listed on the form. If "other" is coded as yes (code 1), describe the febrile morbidity in the specify field. Items without a circled code will be treated as missing data.

B4g. **Treatments for febrile morbidities**: Indicate whether or not there were any treatments for any febrile morbidities identified in the post-operative period. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B4h. **Describe any treatments for febrile morbidities:** Describe any treatments that were administered/delivered for febrile morbidities that were identified in the post-operative period.

A FEBRILE MORBIDITY MAY BE CONSIDERED A REPORTABLE ADVERSE EVENT. REVIEW THE QXQ FOR FORM 91 AND COMPLETE ADVERSE EVENT FORMS AS REQUIRED.

ADDITIONALLY, SOME FEBRILE MORBIDITIES REQUIRE MD/ER VISITS OR HOSPITAL ADMISSIONS. IF THAT IS THE CASE, BE SURE THE VISIT/ADMISSION IS DOCUMENTED ON FORM 21 IN ADDITION TO PROVIDING INFORMATION ABOUT THE AE/COMPLICATION IN THIS SECTION B.

Pulmonary Complications

B5. **Pulmonary complications**: Indicate whether or not there were any pulmonary complications newly identified since the patient's discharge after surgery. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B5a-g. **Types of pulmonary complications**: If there was evidence of any pulmonary complications identified in the post-operative period, circle yes (code 1) or no (code 2) for each type listed on the form. If "other" is coded as yes (code 1), describe the pulmonary complication in the specify field. Items without a circled code will be treated as missing data.

B5h. **Treatments for pulmonary complications**: Indicate whether or not there were any treatments for any pulmonary complications identified in the post-operative period. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B5i. **Describe any treatments for pulmonary complications:** Describe any treatments that were administered/delivered for pulmonary complications that were identified in the post-operative period.

MOST PULMONARY COMPLICATIONS ARE CONSIDERED REPORTABLE ADVERSE EVENTS. REVIEW THE QXQ FOR FORM 91 AND COMPLETE ADVERSE EVENT FORMS AS REQUIRED.

ADDITIONALLY, MOST PULMONARY COMPLICATIONS REQUIRE MD/ER VISITS OR HOSPITAL ADMISSIONS. IF THAT IS THE CASE, BE SURE THE VISIT/ADMISSION IS DOCUMENTED ON FORM 21 IN ADDITION TO PROVIDING INFORMATION ABOUT THE AE/COMPLICATION IN THIS SECTION B.

Any Other Complications

B6. **Any other complications**: Indicate whether or not there were any other complications of any kind that were newly identified since the patient's discharge after surgery. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B6a. **Describe any other complications**: If any other complications were newly identified in the post-operative period, describe them in this field.

B6b. **Treatments for any other complications**: Indicate whether or not there were any treatments for any other complications identified in the post-operative period. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B6c. **Describe any treatments for any other complications**: Describe any treatments that were administered/delivered for any other complications that were recognized in the post-operative period.

REVIEW THE QXQ FOR FORM 91 AND COMPLETE ADVERSE EVENT FORMS AS REQUIRED.

ADDITIONALLY, "OTHER" COMPLICATIONS COULD REQUIRE MD/ER VISITS OR HOSPITAL ADMISSIONS. IF THAT IS THE CASE, BE SURE THE VISIT/ADMISSION IS DOCUMENTED ON FORM 21 IN ADDITION TO PROVIDING INFORMATION ABOUT THE COMPLICATION IN THIS SECTION B.

Blood Transfusions

B7. **Blood transfusion since discharge after surgery**: Indicate whether or not the patient has received a blood transfusion since discharge after surgery. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B7a. **Number of autologous units**: Indicate the number of autologous units transfused. If no autologous units were transfused, record 00.

B7b. **Number of non-autologous units**: Indicate the number of non-autologous units transfused. If no non-autologous units were transfused, record 00.

A BLOOD TRANSFUSION IS A REPORTABLE ADVERSE EVENT. REVIEW THE QXQ FOR FORM 91 AND COMPLETE ADVERSE EVENT FORMS AS REQUIRED.

ADDITIONALLY, A BLOOD TRANSFUSION WOULD REQUIRE AN MD/ER VISIT OR A HOSPITAL ADMISSION. BE SURE THE VISIT/ADMISSION IS DOCUMENTED ON FORM 21 IN ADDTION TO PROVIDING INFORMATION ABOUT THE TRANSFUSION IN THIS SECTION B.

Vaginal Prolapse

B8. **Vaginal prolapse development since discharge after surgery**: Indicate whether or not the patient has developed vaginal prolapse since discharge after surgery. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B8a. **Describe vaginal prolapse**: If the patient has developed vaginal prolapse since discharge, indicate the method by which the prolapse was assessed. If the prolapse was determined by POPQ, record the staging of the prolapse in this field. Record any other pertinent information about the newly developed prolapse.

Adverse Events/Complications

B9. **Adverse Events/Complications**: If the patient reports any adverse events or complications, this item should be coded "yes." This event or complication should also be appropriately documented on Form 21. 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.