Question by Question Specifications Guide
Form 32: 3 Month Follow-up Assessment, Part II
Version 07/01/02 (A)

I. Purpose

Data will be collected on all UITN patients 3 months 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. Any adverse events or untoward outcomes that occur in the time-period after the 6 Week Visit and through the 3 Month Visit must be appropriately documented on the 3 Month 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 3 Month 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 studies' 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 3 month follow-up visit is programmed to be exactly 91 days (13 weeks x 7 days) following the date of randomization. The **visit window** for the 3 month visit is defined as the target date ±2 weeks. Therefore, the **3 month follow-up visit window** is between 11 and 15 weeks following the date of randomization; or between 77 days and 105 days following the date of randomization. The patient's 3 month target date and the 3 month visit window will be printed on the patient's 3 month 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 3 Month Follow-Up Assessment Part II should be completed at the time of the patient's 3 Month 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 Safety and Monitoring Board.

C. Materials needed:

- Patient's 3 Month Visit Control Sheet (VCS)
- Form 32 with ID labels attached
- Medical record(s), depending on data reported in Data Form 31

III. Section by Section Review for Form 32

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 32 is pre-coded as Visit = F/U 3 months, the 3 Month 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

PLEASE REFER TO THE ADVERSE EVENT FORM (FORM 91) QXQ SPECIFICATION GUIDE FOR INSTRUCTION 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 6 week follow-up visit. 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 since the patient's 6 week follow-up visit, circle yes (code 1) or no (code 2) for every 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 since the patient's 6 week follow-up visit. 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 since the patient's 6 week follow-up visit.

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 31 IN ADDITION TO PROVIDING INFORMATION ABOUT THE AE/UNTOWARD OUTCOME IN SECTION B.

Organ Injuries

B2. **Organ injuries**: Indicate whether or not there were any organ injuries newly identified since the patient's 6 week follow-up visit. 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 since the patient's 6 week follow-up visit, 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 since the patient's 6 week follow-up visit. 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 since the patient's 6 week follow-up visit.

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 31 IN ADDITION TO PROVIDING INFORMATION ABOUT THE AE/UNTOWARD OUTCOME IN THIS SECTION B.

Cardiovascular Events

B3. **Cardiovascular Events**: Indicate whether or not there were any cardiovascular events newly identified since the patient's 6 week follow-up visit. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B3a-d. **Types of cardiovascular events**: If there was evidence of any cardiovascular events newly identified since the patient's 6 week follow-up visit, 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 event in the specify field. Items without a circled code will be treated as missing data.

B3e. **Treatments for cardiovascular events**: Indicate whether or not there were any treatments for any cardiovascular events newly identified since the patient's 6 week follow-up visit. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B3f. **Describe any treatments for cardiovascular events:** Describe any treatments that were administered/delivered for cardiovascular events that were recognized since the patient's 6 week follow-up visit.

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

ADDITIONALLY, MOST CARDIOVASCULAR EVENTS REQUIRE MD/ER VISITS OR HOSPITAL ADMISSIONS. IF THAT IS THE CASE, BE SURE THE VISIT/ADMISSION IS DOCUMENTED ON FORM 31 IN ADDITION TO PROVIDING INFORMATION ABOUT THE AE/UNTOWARD OUTCOME IN THIS SECTION B.

Febrile Morbidities

B4. **Febrile morbidities**: Indicate whether or not there were any febrile morbidities newly identified since the patient's 6 week follow-up visit. 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 since the patient's 6 week follow-up visit, 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 since the patient's 6 week follow-up visit. 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 since the patient's 6 week follow-up visit.

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 31 IN ADDITION TO PROVIDING INFORMATION ABOUT THE AE/COMPLICATION IN THIS SECTION B.

Pulmonary Events

B5. **Pulmonary events**: Indicate whether or not there were any pulmonary events newly identified since the patient's 6 week follow-up visit. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B5a-g. **Types of pulmonary events**: If there was evidence of any pulmonary events identified since the patient's 6 week follow-up visit, 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 event in the specify field. Items without a circled code will be treated as missing data.

B5h. **Treatments for pulmonary events**: Indicate whether or not there were any treatments for any pulmonary events identified since the patient's 6 week follow-up visit. Circle yes (code 1) or no (code 2), and follow the skip pattern on the Data Form.

B5i. **Describe any treatments for pulmonary events:** Describe any treatments that were administered/delivered for pulmonary events that were identified since the patient's 6 week follow-up visit.

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

ADDITIONALLY, MOST PULMONARY EVENTS REQUIRE MD/ER VISITS OR HOSPITAL ADMISSIONS. IF THAT IS THE CASE, BE SURE THE VISIT/ADMISSION IS DOCUMENTED ON FORM 31 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 surgery of any kind that were newly identified since the patient's 6 week follow-up visit. 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 of surgery were newly identified since the patient's 6 week follow-up visit, describe them in this field.

B6b. **Treatments for any other complications**: Indicate whether or not there were any treatments for any other complications of surgery identified since the patient's 6 week follow-up visit. 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 of surgery that were recognized since the patient's 6 week follow-up visit.

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 31 IN ADDITION TO PROVIDING INFORMATION ABOUT THE COMPLICATION IN THIS SECTION B.

Blood Transfusions

B7. **Blood transfusion since 6 Week Visit**: Indicate whether or not the patient has received a blood transfusion since the 6 week follow-up visit. 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 31 IN ADDTION TO PROVIDING INFORMATION ABOUT THE TRANSFUSION IN THIS SECTION B.

Vaginal Prolapse

B8. **Vaginal prolapse development since the 6 week visit**: Indicate whether or not the patient has developed vaginal prolapse since the 6 week follow-up visit. 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 the 6 week visit, 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.

Summary of Adverse Events/Untoward Outcomes

C1. **Summary of Adverse Events/Untoward Outcomes:** If the patient reports any adverse events or untoward outcomes that have occurred since the 6 Week Visit, this item should be coded "yes." This AE/Outcome should also be appropriately documented on Form 31. If the AE/Outcome qualifies as a "reportable" AE (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.