Question by Question Specifications Guide
Form 11: Immediate Post-operative Measures
Version 07/01/02 (A)

I. Purpose

Data will be collected on all UITN patients in the immediate post-operative period to gather information about complications of the anti-incontinence surgery that may arise in the post-operative period, to capture all medications prescribed for the patient specific to her recovery from the surgery including pain medications, and to gather data related to post-operative catheter use and removal.

II. Administration

A. Source, Timing and Method of Data Form Completion

The Immediate Post-Operative Measures Data Form should be completed by the UITN-certified surgeon who completed the procedure at the time of the patient's discharge from the hospital. This requirement is meant to ensure that complications are recorded as accurately as possible, thereby providing the highest quality data for the UITN's Data and Safety Monitoring Board's (DSMB) review. At a minimum, the surgeon who completed the surgical procedure should complete Sections A, B & C of the Data Form. A UITN-certified data collector may complete section D.

The medical record (MR) number of the post-operative record considered the source document should be included in the list of MR documents on the patient's Surgical Visit Control Sheet. This record should be readily available for audit at the time of a QA review or site visit. Sites may keep photocopies of clinical records in their research files as long as all patient identifiers are obscured.

Whether the data are recorded at the time of discharge or at some point after discharge, it is preferable that the Data Form be completed by the surgeon who performed the surgery within 24 hours of the patient's discharge. The UITN Study Coordinator should receive this form no later than 24 hours following the patient's discharge.

B. Certification of Surgeons

Surgeons must be certified by and registered with the BCC as UITN Surgeons. The obligations of certification are documented in the QA Plan.

III. Section by Section Review

Section A: General Study Information

A1. **Study ID Number**: Affix the patient ID label in the spaces provided in the A1 field and in the upper right hand corner of each subsequent page of the Data Form. As with all other Data Forms, avoid handwriting ID numbers.

A2. **Visit Number**: The visit number is pre-coded for Form 11, which will always be Visit **SURG**.

A3. **Date Form Completed**: Enter the date that the form was completed. All dates must be in the format of mm/dd/yyyy. If more than one day is required to fill-out the form, enter the date on which the form is completed.

A4. **Initials of person completing this form**: Enter the initials of the person completing the form. The protocol requires Form 11 to be completed by the UITN certified surgeon of record for the procedure in question. Enter your first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If you do not have a middle initial, place a dash in the second space. If your last name is hyphenated or if you have 2 last names, enter the initial of the first last name in the third space. Section D of Form 11 may be completed by a UITN certified data collector. His/her signature and initials will be captured at the end of Section D.

Section B: Complications in the Immediate Post-Operative Period

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 identified in the post-operative period. 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 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.

Organ Injuries

B2. **Organ injuries**: Indicate whether or not there were any organ injuries newly identified in the post-operative period. 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.

Acute Renal Failure

B3. **Acute renal failure**: Indicate whether or not the patient experienced acute renal failure during the post-operative period. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form.

B3a. **Treatments for acute renal failure**: Indicate whether or not there were any treatments for acute renal failure during the post-operative period. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form.

B3b. **Describe any treatments for acute renal failure:** Describe any treatments that were administered/delivered for acute renal failure experienced in the post-operative period.

ACUTE RENAL FAILURE IS A REPORTABLE ADVERSE EVENT. REVIEW THE QXQ FOR FORM 91 AND COMPLETE ADVERSE EVENT FORMS AS REQUIRED.

Cardiovascular Complications

B4. **Cardiovascular complications**: Indicate whether or not there were 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.

B4a-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.

B4e. **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.

B4f. **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.

Febrile Morbidities

B5. **Febrile morbidities**: Indicate whether or not there were 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.

B5a-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.

B5g. **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.

B5h. **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.

Pulmonary Complications

B6. **Pulmonary complications**: Indicate whether or not there were 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.

B6a-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.

B6h. **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.

B6i. **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.

Any Other Complications

B7. **Any other complications**: Indicate whether or not there were any other complications of any kind 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.

B7a. **Describe any other complications**: If any other complications were newly identified in the post-operative period, describe them in this field.

B7b. **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.

B7c. **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.

Blood Transfusions

B8. **Blood transfusion during the post-operative period**: Indicate whether or not the patient received a red blood transfusion during the post-operative period. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form.

B8a. **Number of autologous units**: Indicate the number of autologous units transfused. If no autologous units were transfused, record 00.

B8b. **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.

ICU Admissions

B9. **Surgical complications requiring admission to an ICU**: Indicate whether or not the patient experienced any surgical complications that required admission to an ICU. Circle yes (code 1) or no (code 2).

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

Death

B10. **Patient expiration**: Indicate whether or not the patient expired. Circle yes (code 1) or no (code 2).

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

Section C: Surgeon's Signature

Upon completion of Sections A and B of the Data Form, the surgeon of record for the procedure in question must sign and date the form.

Section D: Other Information in the Immediate Post-Operative Period

D1. **Date of hospital admission**: Document the date that the patient was admitted to the hospital for surgery.

D2. **Date of discharge**: Document the date that the patient was discharged from the hospital.

D3. **Discharge medications for recovery from UITN surgery**: Indicate whether or not the patient was discharged with medications specific to her recovery from her UITN anti-incontinence surgery. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form.

D3a. **Medication names:** Document each medication by name. Please make every effort to record these names legibly and accurately. If a reference is necessary to confirm a medication, please use a universal tool such as the Physician's Desk Reference (PDR).

D4. **Voiding prior to discharge**: Indicate whether or not the patient had voided prior to discharge. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form.

D5. **Measured PVR**: Document the measured post-void residual volume in milliliters.

D5a. **How was PVR determined?:** Indicate the method used to obtain the PVR recorded in D5.

D6. **Voiding management at discharge**: Specify the type of voiding management at discharge. Code type as urethral catheter (code 1), supra pubic catheter (code 2), clean intermittent self-catheterization (code 3), or self-voiding (code 4).

D7. **Any other UITN staff signatures**: If any other UITN certified data collector completes Section D of Form 11, s/he should record her/his initials and sign and date the form in the spaces provided. If the surgeon completes Section D, record -3 in the initials field and the remaining fields can be left blank.