Question by Question Specifications Guide
Form 10: Operative Measures
Version 11/15/02 (A)_revised 101503

I. Purpose

All women participating in the UITN study will undergo one of two randomly assigned surgical procedures: the Burch modified Tanagho procedure or the autologous rectus fascia sling procedure. Elements of both procedures have been standardized, as described in the Surgical Procedures Manual.

II. Administration

A. Source, Timing and Method of Data Form Completion

The Operative Measures Data Form must be available to the UITN-certified surgeon in the operating room and should be completed by the surgeon immediately after surgery or very soon thereafter, i.e. the Study Coordinator should get this form back from the surgeon within 24 hours after the surgery.

The location of the surgical record (considered a source document) should be added to 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 immediately after the surgery or retrospectively, it is preferable that the Data Form be completed by the surgeon who performed the surgery within 24 hours of the procedure.

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. Data from a surgical procedure performed by a non-certified surgeon should not be entered in the UITN DMS.

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 10, which will always be Visit **SURG.**

A3. **Date of Surgery:** Enter the date that the surgery was completed. All dates must be in the format of mm/dd/yyyy.

A4. **Date form completed**: Enter the date that the form was completed. Ideally, the surgeon will complete Form 10 immediately after the surgery. Study Coordinators should receive completed forms no later than 24 hours after the surgery.

A5. **Initials of person completing this form**: Enter the initials of the person completing the form. The protocol requires Form 10 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.

A6. **Which primary surgery was performed**: Circle Sling (code 1) or Burch (code 2) and follow the skip pattern on the Data Form.

Section B: The Sling Procedure

B1. **Length of abdominal incision**: In centimeters, document the length of the incision.

B2. **Orientation of abdominal incision**: Document the orientation of the abdominal incision as vertical (code 1), horizontal (code 2), or other (code 3). If "other" is coded, describe the "other" orientation of the abdominal incision in the specify field.

B3. **Orientation of vaginal incision**: Document the orientation of the vaginal incision as single midline incision (code 1), 2 lateral incisions (code 2), inverted U incision (code 3), or other (code 99). If "other" is coded, describe the "other" orientation of any vaginal incision in the specify field.

B4. **Sling material used**: The protocol requires that autologous rectus fascia be the sling material used. In rare cases when autologous rectus fascia cannot be harvested, the surgeon may use autologous fascia lata for the sling material. Document the material used for the sling and follow the skip pattern on the Data Form.

B4a. **Why was autologous fascia lata used**: Autologous rectus fascia is the sling material required by the protocol. If autologous rectus fascia was not used, indicate the reason in B4a.

B5. **Sutures for closure of harvest site**: Document the type of sutures used to close the site as delayed absorbable (code 1), permanent (code 2) or other (code 99). If "other" is coded, describe the type of suture used in the specify field.

B6. **Size of sling material**: In centimeters, document the dimensions of the sling material used.

B7. **Suture of sling material**: Document the sutures of the sling material as simple one-stitch per side (code1), two stitches per side (code 2), helical x 3 per side (code 3) or other (code 99). If "other" is coded, describe the type of sling material used in the specify field.

B8. **Were the sling ends folded**: Document if the sling ends were folded as yes (code 1) or no (code 2).

B9. **Were the sutures tied over or to the rectus fascia**: Document if the sutures were tied **over** (code 1) or **to** (code 2) the rectus fascia.

B10. **Suture material used**: Use of polypropylene sutures is required by the protocol. Document the suture material used as polypropylene (code 1) or other (code 99). If "other" is coded, identify the suture material used in the specify field.

B10a. **Why**: Use of polypropylene sutures is required by the protocol. If polypropylene sutures were not used, document the reason in B10a.

B11. **Suture gauge**: Use of sutures gauge 0 or 1 is required by the protocol. Document the gauge of the sutures used and follow the skip pattern on the Data Form.

B11a. **Why**: Use of sutures gauge 0 or 1 is required by the protocol. If sutures gauge 0 or 1 were not used, document the reason in B11a.

Section C: The Burch Procedure

C1. **Length of abdominal incision**: Document the length of the incision in centimeters.

C2. **Orientation of incision**: Document the orientation of the abdominal incision as vertical (code 1), horizontal (code 2), or other (code 99). If "other" is coded, document a description of the incision in the specify field.

C3. **Suture material used**: Use of polypropylene sutures is required by the protocol. Document the suture material used as polypropylene (code 1) or other (code 99). If "other" is coded, document a description of the suture material used in the specify field.

C3a. **Why**: Use of polypropylene sutures is required by the protocol. Document the reason why polypropylene sutures were not used.

C4. **Suture gauge**: Use of sutures gauge 0 or 1 is required by the protocol. Document the gauge of the sutures used and follow the skip pattern on the Data Form.

C4a. **Why**: Use of sutures gauge 0 or 1 is required by the protocol. Document the reason why sutures gauge 0 or 1 were not used.

C5. **Number of sutures on each side**: Document the number of sutures used on each side as 2 sutures (code 2), 3 sutures (code 3), or other (code 99). If "other" is coded, document the number of sutures used in the specify field.

C6. **Number of suture passes through Cooper's ligament**: Document the number of passes made through Cooper's ligament as one pass (code 1) or two passes (code 2).

Section D: Other Operative Information

D1. **Any other surgeries:** Indicate whether or not any other surgeries were performed during this procedure. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form.

D1a-p. **Other surgeries**: Circle yes (code 1) or no (code 2) for every surgery listed on the form. Items without a circled code will be treated as missing data. If "other" is coded as yes (code 1), describe the "other" surgery in the specify field.

Medical Staff Present at Surgery

D2: **Surgeon of record**: Enter the initials of the surgeon of record for the procedure in question. S/he must be a surgeon certified for UITN participation.

D2a-b. **Did a resident assist**: Circle yes (code 1) or no (code 2) and specify the post-graduate training year for any assisting resident.

D2c-d. **Did a fellow assist:** Circle yes (code 1) or no (code 2) and specify the postgraduate training year for any fellow assisting.

D3. **Non-study surgeon present**: Indicate whether or not a non-study surgeon was present during the procedure. Circle yes (code 1) or no (code 2). If "no" is coded, follow the skip pattern on the Data Form.

D3a. **Specify**: Specify the specialty of the non-study surgeon present.

D4. **Did any other medical professional assist**: Indicate whether or not any other medical professional assisted in the procedure. Circle yes (code 1) or no (code 2). If "no" is coded, follow the skip pattern on the Data Form.

D4a. **Specify**: Specify the credentials and the role of any other medical professional who assisted.

D5. **Total operative time**: Document the operative times in military time. Document the time the first incision was started and the time that the last wound was closed.

D6-10. **Anesthesia used**: Circle yes (code 1) or no (code 2) for every type of anesthesia listed on the form. Anesthesia types without a circled code will be treated as missing data.

D11. **Prophylactic antibiotics prior to surgery**: Indicate whether or not prophylactic antibiotics were administered prior to surgery. Administration of prophylactic antibiotics is required by the UITN protocol. Document yes (code 1) or no (code 2).

D11a. **Administration time closest to first incision**: Document in military time the time closest to incision at which prophylactic antibiotics were administered.

D12. **Local pain medication administered before incision**: Indicate whether or not a local pain medication was administered before the incision to minimize post-operative pain. Document yes (code 1) or no (code 2).

D12a. **Medication name**: If "yes" to D12, document medication name here.

D13. **Local pain medication administered before closing**: Indicate whether or not a local pain medication was administered **before closing** to minimize post-operative pain. Document yes (code 1) or no (code 2).

D13a. **Medication name**: If "yes" to D13, document the medication name here.

D14. **Type of urine drain in place**: Specify the type of urine drain in place at the end of the surgical procedure as urethral catheter (code 1), supra pubic catheter (code 2), or none (code 4).

D15. **Type of wound drain in place**: Specify the type of wound drain in place at the end of the surgical procedure as JP (code 1), Penrose (code 2), other (code 3) or none (code 4). If type of drain is coded as "other" (code 3), describe in the specify field.

D16. **Results of cystoscopy**: Document the results of **ALL** cystoscopies here. That means that if ANY cystoscopy was "abnormal," this question should be coded as such (i.e. code 2) and the situation should be thoroughly explained in D16a. If all cystoscopy results were normal, code "1" and follow the skip pattern on the Data Form.

D16a. **Describe**: Describe all abnormal cystoscopy results. Some of this information may need to be documented in Section E (Operative Complications During Surgery).

Section E: Operative Complications During Surgery

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

Intra-Operative Organ Injuries

E1. **Intra-operative organ injuries**: Indicate whether or not any organ injuries were recognized intra-operatively. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form. When coding this item, review the surgical record completely, including the results from the cystoscopy. Evidence of needle passage through the bladder constitutes an organ injury.

E1a-i. **Types of organ injuries**: If there was evidence of any organ injuries recognized intra-operatively, circle yes (code 1) or no (code 2) for every type of injury listed on the form. If "other" is coded as yes (code 1), describe the organ injury in the specify field. Items without a circled code will be treated as missing data.

E1j. **Treatments for organ injuries during surgery**: Indicate whether or not there were any treatments for any organ injuries that occurred during surgery. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form.

E1k. **Describe any treatments for organ injuries during surgery**: Describe any treatments that were administered/delivered for organ injuries that were recognized intra-operatively.

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

Cardiovascular Complications

E2. **Cardiovascular complications**: Indicate whether or not there were any cardiovascular complications recognized intra-operatively. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form.

E2a-c. **Types of cardiovascular complications**: If there were any cardiovascular complications recognized intra-operatively, 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.

E2d. **Treatments for cardiovascular complication during surgery**: Indicate whether or not there were any treatments for any cardiovascular complications that occurred during surgery. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form

E2e. **Describe any treatments for cardiovascular complications during surgery:** Describe any treatments that were administered/delivered for cardiovascular complications recognized intra-operatively.

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

Other Complications

E3. **Any other complications**: Indicate whether or not there were any other complications of any kind recognized intra-operatively. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form.

E3a. **Describe**: If "yes" to E3, describe in this field.

E3b. **Treatments for any other complications during surgery**: Indicate whether or not there were any other treatments for any other complications of any kind that occurred during surgery. Circle yes (code 1) or no (code 2) and follow the skip pattern on the Data Form.

E3c. **Describe any treatments for any other complications:** Describe any treatments that were administered/delivered for any other complications of any kind recognized intra-operatively.

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

Blood Transfusions

E4. **Estimated blood loss**: Document the estimated blood loss in milliliters.

E5. **Blood transfusion during surgery**: Indicate whether or not the patient received a red blood cell transfusion during surgery. Document yes (code 1) or no (code 2) and follow the skip pattern on the Data Form.

E5a. **Number of autologous units**: Indicate the number of autologous units transfused. If no autologous units were transfused, record 00.

E5b. **Number of non-autologous units**: Indicate the number of non-autologous units transfused. If no non-autologous units were transfused, record 00.

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

ICU Admissions

E6. **Anesthetic complication requiring admission to the ICU**: Indicate whether or not the patient experienced an anesthetic complication requiring admission to the ICU. Document yes (code 1) or no (code 2).

AN ANESTHETIC COMPLICATION REQUIRING ADMISSION TO AN ICU IS A REPORTABLE ADVERSE EVENT. REVIEW THE QXQ FOR FORM 91 AND COMPLETE ADVERSE EVENT FORMS AS REQUIRED.

Death

E7. **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 F: Surgeon's Signature

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