Question by Question Specifications Guide
Form 05: Baseline Urodynamic Studies
Version 07/25/03 (C)

I. Purpose

Urodynamic Studies (UDS) are the focus of one of the secondary aims of this study. More specifically, UDS data will be used to determine the prognostic value of urodynamic studies and to identify urodynamic parameters that predict treatment success in each surgical procedure.

All women participating in the UITN study will undergo UDS performed and interpreted in a standardized manner. Testing and Interpretation requirements are documented in the UDS Testing Procedures Manual and the UDS Reviewers' Interpretive Guidelines.

II. Administration

A. Order of Administration

The order of UDS administration is described in the UDS Procedures Manual.

B. Source and Method of Data Form Completion

There must be source documentation for all data points recorded on the UDS Data Form. Data points not found on the UDS signals, e.g. size of the catheter, prolapse staging, must be recorded in the medical record and records must be available for audit at the time of a QA Site Visit.

Review the UDS Reviewers' Interpretive Guidelines for a complete description of the interpretive standards adopted by the UITN Steering Committee for this measurement.

C. Certification of Testers and Reviewers

A UITN certified UDS Tester must perform UDS following the UITN UDS Testing Procedures.

Testers and Reviewers must be certified by and registered with the BCC. The obligations of certification for Testers and Surgeons are documented in the SISTEr QA Plan. Results of UDS performed and/or interpreted by non-certified staff cannot be entered in the UDS database. Studies performed by a non-certified Tester will need to be repeated by a certified Tester. Only a UITN certified surgeon may interpret the UDS and complete the UITN UDS Data Form.

D. Missing and Invalid Data Points

Reviewers should review the UDS signals and the medical record / source documents and record the UDS data points on the UDS Data Form. Do not leave data fields blank on the UDS Data Form as Data Managers will be unable to determine if the value was reviewed or inadvertently overlooked.

- If the values do not meet the criteria described in the Guidelines, write the word "***invalid***" in the data field and describe why the data should not be used.
- Write the word "***missing***" in the data field if the data are missing for any other reason and describe why the data are missing.

Be sure to note any invalid or missing data along with a reason in the space provided for missing data at the end of each section of the Data Form.

III. Section by Section Review

Section A: General Study Information

A1. **Study ID number:** Affix the patient ID label in the space provided in the A1 field and in the upper right hand corner of each page of the Data Form. Do not handwrite ID numbers as transcription errors are common and handwritten numbers are often illegible.

A2. **Visit number:** The visit number is pre-coded for FM05 which will always be Visit **BASE**.

Section B: Non-Instrumented Uroflowmetry (NIF)

B1. **Maximum flow rate:** Record the rate to the tenth of a milliliter per second. Patients with POP-Q Stage 0 or I are ineligible if both the NIF and PFS maximum flow rate is <12 ml/sec.

B2. **Mean flow rate:** Record the rate to the tenth of a milliliter per second.

B3. **Classify the flow pattern of the urine stream:** Note and code the character of the urine stream as normal (code 1) or abnormal (code 2).

B4. **Time to maximum flow:** Record the time it took to achieve the maximum flow rate to the tenth of a second.

B5. **Voided volume:** Record the total voided volume in milliliters. If the voided volume during NIF is <150 ml, NIF should be repeated with a full bladder at another time. If two NIF studies are done, record the NIF data points from the study with the larger bladder volume.

B5a. **From a spontaneous or a mechanical fill?:** Record whether or not the NIF (recorded in B1-B5) was completed with a bladder volume that was achieved via spontaneous fill (code 1) or mechanical fill (code 2). This information must be documented in the medical record and the record must be available at the time of a Site Visit.

B6. **Post void residual:** Record the PVR in milliliters. Record the PVR from an NIF with a voided volume >150. If this is not available, you may record the measured PVR from an NIF with a voided volume <150 ml. A calculated PVR should not be recorded in B6. If there is no data point for PVR other than a calculated PVR, write "missing" in B6; code B7 as Yes (code 1), and record the calculated PVR volume in B7a along with an explanation of why this was the only PVR obtained. Patients with POP-Q Stage 0 or I are ineligible if both the Stress Test PVR and UDS PVR are >150 ml.

B7. **Are any NIF data points invalid or missing?:** Record yes (code 1) or no (code 2) to indicate whether or not any NIF data points are missing or determined to be invalid and follow the skip pattern on the Data Form.

B7a. **Describe:** Describe the reason why any NIF data points are missing in the text field provided.

B8. **Date exam completed:** Record the date the NIF was completed. The date recorded on the Data Form must match the date on the NIF signal sent to the UDS repository at the BCC. All dates must be in the format of mm/dd/yyyy.

B9. **NIF Tester's Initials:** Enter the initials of the Tester who performed the NIF.

B10. **Date Review Completed:** Record the date you complete your interpretation. All dates must be in the format of mm/dd/yyyy.

B11. **UITN MD Reviewer's Initials:** Enter your initials here. If you performed the UDS, you may record "–3" for this item.

B12. **Equipment BCC Registration ID#:** Record the 5-digit BCC Registration ID# assigned to the equipment used to complete the NIF.

Section C: Cystometrogram (CMG) and Leak Point Pressure (LPP)

C1. **Patient's position:** Record the patient's position, circle freestanding, weight bearing (code 1), leaning (code 2), supine (code 3), sitting upright (code 4), or sitting at 45˚ angle (code 5). This information must be documented in the medical record and the record must be available for review at the time of a Site Visit.

C1a. **Why not freestanding?:** If the test was not conducted with the patient in the required position, record the reason in the open-text field in C1a. This information must be documented in the medical record and the record must be available for review at the time of a Site Visit.

C2. **Catheter diameter:** Record the diameter of the catheter used for the CMG and LPP measurements. This information must be documented in the medical record and the record must be available at the time of a Site Visit.

C2a: **Specify catheter diameter:** If an alternate catheter diameter was used, specify what size was used.

C2b: **Specify reason alternate catheter was necessary:** Specify why an alternate catheter size was used in the open-text field in C2b.

C3. **Baseline Pves:** Record the baseline Pves as centimeters of water pressure.

C4. **Baseline Pabd:** Record the baseline Pabd as centimeters of water pressure.

C5. **Bladder volume at first desire to void:** Record the bladder volume of first desire to void in milliliters.

C6. **Bladder volume at strong desire to void:** Record the volume of strong desire to void in milliliters.

C7. **Prolapse status:** Record whether or not there is a Stage III or IV anterior prolapse. If yes, skip to C10. This information must be documented in the medical record and the record must be available for review at the time of a Site Visit.

C8-9. **LPP measures for a woman without anterior prolapse Stage III or IV:** Complete these items if the patient does not have an anterior prolapse Stage III or IV. Record the answers to questions C8-C9 and follow the skip patterns on the Data Form.

C8. **Did leakage occur with Valsalva:** To code this item yes, leakage must occur with Valsalva at least twice at the same volume level. If no leakage was observed, skip to C15.

C9. **At what volume?:** Record in milliliters at what volume leakage occurred at least twice at the same volume with Valsalva.

C9a-c. **LPP measurements:** Record the VLPPs as centimeters of water pressure. If there are only 2 VLPPs, record the first in C9a and the second in C9b, record "***N/A***" for C9c. Follow the skip pattern on the Data Form.

C10-14. **LPP measures for a woman with a Stage III or IV anterior prolapse:** Complete these items if the patient has an anterior prolapse Stage III or IV. Record the answers to questions C10-C14 and follow the skip patterns on the Data Form.

C10. **Did leakage occur with Valsalva without reduction?:** To code this item yes, leakage must occur with Valsalva without reduction at least twice at the same volume level. If no leakage was observed, skip to C12.

C11. **At what volume?:** Record in milliliters the volume at which leakage occurred at least twice at the same volume with Valsalva maneuvers without prolapse reduction.

C11a-c. **LPP measurements:** Record the VLPPs that produced leakage without prolapse reduction as centimeters of water pressure. If there are only 2 VLPPs, record the first in C11a and the second in C11b, and record "***N/A***" for C11c. Follow the skip pattern on the Data Form.

C12. **How was prolapse reduced?:** Record how the patient's Stage III or IV prolapse was reduced. Circle gauze vaginal packing (code 1), sponge stick (code 2), pessary (code 3), speculum (code 4), or other (code 99) and follow the skip pattern on the Data Form. If other, specify the method by which the prolapse was reduced. This information must be documented in the medical record and the record must be available for review at the time of a Site Visit.

C12a. **Specify pessary size:** Record the pessary size used to reduce the prolapse.

C12b. **Specify pessary type:** Record the type of pessary used to reduce the prolapse.

C12c. **Why wasn't gauze vaginal packing or sponge stick?:** Record the reason why the patient was reduced by a method other than gauze vaginal packing or sponge stick.

C13. **Did leakage occur with Valsalva with reduction?:** Record whether or not leakage was observed with Valsalva and with prolapse reduction. To code this item yes, leakage must occur with Valsalva with reduction at least twice at the same volume level. If no leakage was observed, skip to C15.

C14. **At what volume?:** Record in milliliters at what volume leakage occurred at least twice, at the same volume, with Valsalva maneuvers, and prolapse reduction.

C14a-c. **LPP measurements:** Record the VLPPs that produced the leakages **with** prolapse reduction as centimeters of water pressure. If there are only 2 VLPPs, record the first in C14a and the second in C14b, record "***N/A***" for C14c. Follow the skip pattern on the Data Form.

C15. **Why were VLPPs not obtained?:** If VLPPs were not obtained, record the reason why not in C15.

C16. **Did leaking occur with cough at MCC?:** Record yes (code 1) or no (code 2) to indicate whether or not leaking occurred with cough at MCC. This maneuver is not required if the patient leaked at lower volumes.

C17. **Bladder volume at MCC:** Record the patient's bladder volume at MCC in milliliters. The patient is ineligible if the MCC is < 200 ml.

C18. **Pves at MCC:** Record the Pves at MCC. Record the pressure in centimeters of water pressure.

C19. **Pabd at MCC:** Record Pabd at MCC. Record the pressure in centimeters of water pressure.

C20. **Detrusor Overactivity:** Record yes (code 1) or no (code 2) if there was detrusor overactivity during the performance of the CMG/VLPP measurements. If no, skip to C21.

C20a-c. **Volume at each occurrence:** If detrusor overactivity was present, record the volume at every occurrence of detrusor overactivity in milliliters and indicate if leakage occurred for each occurrence. If there were fewer than 3 occurrences of detrusor overactivity, record "***N/A***" in the first line for which no detrusor overactivity was demonstrated.

C21. **Are any CMG data points invalid or missing, or are any required annotations missing?:** Record yes (code 1) or no (code 2) to indicate whether or not any CMG data points are invalid or missing, or if any required annotations are missing, and follow the skip pattern on the Data Form.

C21a. **Describe:** Describe the reason why any CMG data points or annotations are missing in the text field provided.

Section D: Pressure Flow Study

D1. **Did the patient cough before voiding?:** Record yes (code 1) or no (code 2) to indicate whether or not the patient coughed before voiding.

D2. **Maximum flow rate:** Record the maximum flow rate to the tenth of a milliliter per second. Patients with POP-Q Stage 0 or I are ineligible if both the NIF and PFS maximum flow rate is <12 ml/sec.

D2a. **Pves at maximum flow:** Record Pves at maximum flow as centimeters of water pressure.

D2b. **Pabd at maximum flow:** Record Pabd at maximum flow as centimeters of water pressure.

D2c. **Pdet at maximum flow:** Record the Pdet at maximum flow as centimeters of water pressure. Patients with POP-Q Stage 0 or I may be ineligible if Pdet at maximum flow is >50cm H_2O.

D3. **Time to maximum flow:** Record the time it took to achieve the maximum flow rate to the tenth of a second.

D4. **Voided Volume:** Record the volume of urine voided in milliliters.

D5. **Urethral sphincter relaxation during voiding:** Only perineal surface EMG electrodes should be used to document sphincter relaxation. Record yes (code 1) or no (code 2) to indicate whether or not the urethral sphincter relaxed during voiding. If EMG surface electrodes were not used, record cannot determine (code 3). If EMG surface electrodes were used but were not functioning or results were not conclusive, record cannot determine (code 4).

D6. **Voiding Mechanism:** Record the voiding mechanism. Circle detrusor (code 1), abdominal (code 2), mixed (code 3), other (code 4) or uinterpretable (code 5).

D7. **Cough at the end to the PFS?:** Circle yes (code 1) or no (code 2) to indicate whether or not the patient coughed at the end of the PFS.

D8. **Are any PFS data points invalid or missing, or are any required annotations missing?:** Record yes (code 1) or no (code 2) to indicate whether or not any PFS data points are invalid or missing, or if any required annotations are missing and follow the skip pattern on the Data Form.

D8a. **Describe:** Describe the reason why the PFS data points are missing in the text field provided.

D9. **Date CMG Completed:** Record the date the CMG was completed. The date recorded on the Data Form must match the date on the CMG signal sent to the UDS repository at the BCC. Dates must be in the format of mm/dd/yyyy.

D10. **CMG Tester's Initials:** Enter the initials of the Tester who performed the CMG.

D11. **Date PFS Completed:** Record the date the PFS was completed. The date recorded on the Data Form must match the date on the PFS signal sent to the UDS repository at the BCC Dates must be in the format of mm/dd/yyyy.

D12. **PFS Tester's Initials:** Enter the initials of the Tester who performed the PFS.

D13. **Date Review Completed**: Record the date you completed your interpretation. All dates must be in the format of mm/dd/yyyy.

D14. **UITN MD Reviewer's Initials:** Enter your initials here. If you also performed the UDS, you may record "–3" for this item..

D15. **Equipment BCC Registration ID#:** Record the 5-digit BCC Registration ID# assigned to the equipment used to complete the CMG and PFS.

Section E: Eligibility Summary

E1. **Is the patient still eligible?:** Review the completed Data Form, specifically items B1, B6, C17, D2, and D2c to determine if the patient meets all UDS eligibility criteria. Circle yes (code 1) or no (code 2). If the answer is no, the patient is ineligible.

E2. **Date Eligibility Summary Completed:** Record the date on which the eligibility summary was completed. All dates must be in the format of mm/dd/yyyy.

E3. **Data Collector's Initials:** Enter the initials of the person who coded F1.