Question by Question Specifications Guide
Form 30: 3 Month Post-Operative Voiding Management Summary
Version 03/13/03 (B)

I. Purpose

Data will be collected on all UITN patients 3 months following 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.

UITN Investigators have agreed to comply with standards for the removal of catheters (or cessation of CISC) post-operatively to minimize variability between patients secondary to differences in post-op voiding management strategies employed by UITN surgeons. The Standards for Post-Op Catheter Removal are documented in the UITN Protocol (Section G6) and included here for easy reference.

> **G.6 Standardization of Post-Op Catheter Removal**
>
> Following surgery, a patient might be discharged having resumed spontaneous voiding or she may require one of the following three means of bladder drainage. Removal or discontinuation of a catheter is standardized as follows:
>
> Continuous Foley Drainage: For any patient discharged home with an indwelling urethral catheter, remove catheter by at least post-op day #5 after bladder filled retrograde to the lesser of 300cc or maximum capacity.
> - If the patient is able to void at least 150cc, the catheter should **not** be reinserted;
> - If the patient voids less than 150cc, the catheter may be reinserted; or
> - The patient may be taught CISC.
>
> Voiding capabilities should be re-checked every 3-5 days following the procedures above until she voids at least 150 cc after retrograde filling to the lesser of 300 cc or maximum capacity, or PVR <150cc.
>
> Supra pubic Catheter: For any patient discharged home with a supra pubic catheter, the catheter should be removed once both morning and evening residuals are below 150cc.
>
> Clean Intermittent Self Catheterization (CISC): For any patient discharged home on CISC, she should be directed to stop CISC once both morning and evening residuals are below 150cc.

Data Form 30 is designed to capture the voiding management between 6 weeks and 3 months following the UITN surgery.

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 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 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 of Data

Patients discharged with a supra pubic catheter or completing CISC following the 6 week visit will be asked to keep a PVR log to keep track of their post void residual (PVR) urine volumes after the visit. Data from these patient logs will be used to complete Data Form 30. Other source documents may also be used, including the CTC medical record. In some cases, patients may have a urethral catheter or a supra pubic catheter removed by a home-health nurse. In these cases, special care should be taken to direct the home health RN to follow the UITN standards stated below for catheter removal documented in the UITN protocol:

- **For patients with a urethral catheter**: retrograde filling to the lesser of 300 cc or maximum capacity and measurement of voided volume post catheter removal. If voided volume is less than 150 cc, re-insert urethral catheter or initiate patient teaching for institution of CISC.
- **For patients with S/P tube:** Confirm both morning and evening PVRs < 150cc prior to removal of S/P tube. Record and report last morning and evening PVR prior to the time of S/P tube removal.

Pertinent data from office-based or home-based post-operative catheter care should be recorded in the UITN clinic record, or the HHA medical records should be obtained and data abstracted from the HHA should be recorded on Form 30. Source documentation should be available for a data audit as required when medical records are used to complete the UITN Data Forms. Sites may use the patient's Visit Control Sheet to maintain a master log of all source documents used for completion of UITN Data Forms.

D. Certification of UITN Interviewers and Data Collectors

Interviewers and data collectors must be certified by and registered with the BCC as a UITN Interviewer / Data Collector. The obligations of certification are documented in the QC Plan. Data gathered by non-certified persons may not be entered into the UITN DMS.

E. Materials needed:

- Patient's 3 Month Visit Control Sheet (VCS)
- Form 30 with ID labels attached;
- Patient's PVR Logs
- Medical record(s) required to complete the form

III. Section by Section Review for Form 30

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 30 is pre-coded as Visit = FU03, the 3 month post-operative visit.

A3. **Date form completed**: Record the date you complete the form. Use the mm/dd/yyyy format.

A4. **Initials of person completing the form**: The person completing the form should record his/her initials in this data field. Enter first initial in the first space provided, middle initials 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: Voiding Management History

Date of the 6 Week Study Visit: This date should be taken from the 3 Month Visit Control Sheet and will be used as a reference date throughout Form 30.

B1. **Voiding Management at Completion of the 6 Week Visit:** This information comes from Form 20, but it will be printed on the patient's 3 Month Visit Control Sheet. Circle the correct code, and follow the skip pattern on the form.

B2. **Any alternate voiding management plan subsequent to the 6 Week Visit**: Code this question only for those patients who completed the 6 Week Visit having resumed spontaneous voiding. We will capture additional information for patients who have been subsequently catheterized or started CISC. Circle the appropriate code, and follow the skip patterns on the form.

Section C: Urethral Catheter

Section C will be completed for patients who were sent home from the 6 Week Visit using a urethral catheter.

C1. **Date urethral catheter removed after the 6 Week Visit**: Record the date that the urethral catheter was first removed following the 6 Week Visit. If the catheter was removed but re-inserted, record the date the catheter was first removed.

C2. **PVR at time of first removal**: Record the PVR that was measured at this time (the date recorded in C1).

C2a. **How was PVR determined?:** Indicate the method used to obtain the PVR recorded in C2.

C3. **Specify voiding management plan after this test**: Circle the appropriate code to indicate the voiding management plan instituted post measurement of the PVR (in C2). Then follow the skip pattern on the form.

C4. **Does the patient still have a urethral catheter?:** This item applies only if the patient's urethral catheter was re-inserted. Code yes (1) or no (2), and follow the skip pattern on the form. .

C5. **Date urethral catheter last removed:** Record the date that the urethral catheter was last removed. If the catheter was re-inserted and removed on more than one occasion, record the date the catheter was last removed.

C6. **PVR at time of last removal**: Record the PVR that was measured at this time (the date recorded in C5).

C6a. **How was PVR determined?:** Indicate the method used to obtain the PVR recorded in C6.

C7. **Specify voiding management plan after this test**: Circle the appropriate code to indicate the voiding management plan instituted post measurement of the PVR (in C6). Then follow the skip pattern on the form.

C8. **Describe other:** Describe any other voiding management plan not listed in items C3 or C7. Follow the skip pattern on the form.

Section D: Supra Pubic Catheter

Section D will be completed for patients who were sent home from the 6 Week Visit using a supra pubic catheter.

D1. **Does the patient still have an S/P tube?**: Circle the appropriate code, and follow the skip pattern on the form.

D2. **Date S/P tube removed**: Record the date that the S/P tube was removed. Use the mm/dd/yyyy format.

D3. **Last PVR recorded**: Document the last PVR recorded.

D4. **Source codes**: Record the source for the data recorded in D2 and D3 here. If the only source of information is the patient, record 1 as the source code in the field provided on the data form. If the only source of information for the data is a medical record, record 2 as the source code. If the source for the data is **both** the patient and medical record(s), record 3 as the source code. If the source is the patient's PVR log(s), record 5 as the source code.

D5. **How was PVR determined?:** Indicate the method used to obtain the PVR recorded in D3. Follow the skip pattern on the form.

D6. **Specify voiding management plan after this test**: Circle the appropriate code to indicate the voiding management plan instituted post measurement of the PVR (in D2). Then follow the skip pattern on the form.

D7. **Does the patient still have a urethral catheter?:** This item applies only if a urethral catheter was inserted following removal of the S/P tube. Code yes (1) or no (2), and follow the skip pattern on the form.

D8. **Date urethral catheter last removed:** Record the date that the urethral catheter was last removed. If the catheter was re-inserted and removed on more than one occasion, record the date the catheter was last removed.

D9. **PVR at time of last removal**: Record the PVR that was measured at this time (the date recorded in D8).

D9a. **How was PVR determined?:** Indicate the method used to obtain the PVR recorded in D9.

D10. **Specify voiding management plan after this test**: Circle the appropriate code to indicate the voiding management plan instituted post measurement of the PVR (in D9). Then follow the skip pattern on the form.

D11. **Describe other:** Describe any other voiding management plan not listed in items D6 or D10. Follow the skip pattern on the form.

Section E: Clean Intermittent Self Catheterization (CISC)

Section E will be completed for patients who were who were sent home from the 6 Week Visit conducting clean intermittent self-catheterization (CISC) and for patients who began CISC post- 6 Weeks, after the removal of a urethral catheter.

E1. **Is the patient still practicing CISC?:** Circle the appropriate code, and follow the skip pattern on the form.

E1a. **At what frequency?:** Indicate the frequency at which the patient is still practicing CISC by circling the appropriate code. If the patient is experiencing no spontaneous voiding and must always use CISC to empty her bladder, code 1. If the patient is experiencing minimal spontaneous voiding and must use CISC more than once per day to empty her bladder, code 2. If the patient needs only use CISC once per day to empty her bladder, code 3. If the patient needs use CISC less than daily to empty her bladder, code 4.

E2. **Date CISC stopped**: Record the date that the patient stopped CISC. Use the mm/dd/yyyy format.

E3. **Last PVR recorded**: Document the last PVR recorded.

E4. **Source codes**: Record the source for the data recorded here. If the only source of information is the patient, record 1 as the source code in the field provided on the data form. If the only source of information for the data is a medical record, record 2 as the source code. If the source for the data is **both** the patient and medical record(s), record 3 as the source code. If the source is the patient's PVR logs, record 5 as the source code.

E5. **How was PVR determined?:** Indicate the method used to obtain the PVR recorded in E3.

Section F: Summary of Current Voiding Management Status

F1. **Describe any unusual voiding management pathways or problems not otherwise captured by this Data Form:** If the patient followed a voiding management pathway or experienced any voiding problems that are not otherwise captured by this Data Form, record this detailed information here. If there were no unusual pathways or problems, write "N/A" or code "-1."

F2. **Current Voiding Management Status**: Circle the code that corresponds to the patient's current voiding management status at the end of the 3 Month follow-up visit.