



**Question by Question Specifications Guide**  
**Form 08: Baseline Patient Survey Part II**  
**Version 07/01/02 (A)**

**I. Purpose**

The measures included in Part II of the Baseline Patient Survey are all secondary outcome measures for the UITN, i.e. the Health Utilities Index, Summary of Incontinence Expenses, and Willingness to Pay Survey. Urinary incontinence is both a common and costly condition, yet little is known about costs that women pay out-of-pocket or the cost-effectiveness of treatment. Therefore, measures of costs associated with incontinence and the impact of treatment outcomes on costs are being included in the UITN Patient Surveys as a secondary outcome of interest in this trial. We will evaluate patient's out-of-pocket expenses and willingness-to-pay for improvement in incontinence. Since incontinence is one of the chronic health conditions that most adversely affect patient's preference for a specific health state (called utilities), we will assess utilities with the Health Utility Index (HUI). These data will be collected at baseline and will be compared with data gathered at the 12 and 24-month follow-up visits to answer the study research questions. The HUI will also be completed at the 6-week follow-up visit to evaluate the effects of surgery on utilities.

**II. Administration**

All consent procedures must be completed prior to the completion of the Baseline Patient Survey in accordance with local IRB requirements. The Patient Surveys can be completed by the patient during a study visit, or at home and returned by mail. All of the items in this Survey were designed to be self-administered (completed by the patient). Study staff can give minimal help or assistance to a patient who is completing this questionnaire (see details below). If a woman is unable to complete the questionnaire on her own, it should be administered as an interview. Ideally, these measures will always be administered as self-administered measures but if the Survey is administered as an interview at the baseline visit, it should be administered as an interview at all subsequent visits to be comparable to baseline measure.

**A. Window for Re-Screening of Patients:**

The results of these measures expire 6 months following their completion; therefore, if more than 6 months transpires between the date the survey is completed and the date of the planned UITN surgery, the Survey should be repeated to ensure collection of 'current' baseline values that would be subject to change over a 6-month period.

**B. Materials Needed**

The following materials will be required:

- The Patient Baseline Survey Part II with ID labels attached
- QxQ Specifications Guides for the Patient Measurements, Part II

**III. Section by Section Review**

**Section A:**

- 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. At all costs, avoid handwriting ID numbers. Transcription errors are very common when transcribing long numbers and errors in an eight digit ID usually cannot be corrected. Furthermore, handwritten numbers are often illegible. Most research studies will not accept handwritten IDs, making the data gathered on such data forms unusable.

- A2. **Visit Number:** The visit number is pre-coded for Form 08 which will always be Visit **BASE**. This form is completed at the baseline visit.
- A3. **Date Form Distributed:** Enter the date that you give the Survey to the patient. All dates must be in the format of mm/dd/yyyy.
- A4. **Study Staff Initials:** Enter the initials of the person completing the form. 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 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 your first last name in the third space
- A5. **Mode:** Circle the code for the mode of completion of Form 08. This Survey is designed to be completed by the patient with only minimal assistance provided by study staff. In the case of extreme circumstances when the patient is unable to complete the form without assistance, it may be administered as an interview.
- A6. **Which version of this form was used?:** Record which language version of the Survey was used by the patient.
- A7. **Is this a repeat Survey?** If more than 6 months transpires between completion of the Baseline Patient Survey Part II and the planned date of surgery, the Baseline Patient Survey Part II should be repeated. Circle code yes or no and continue with form completion.
- A8. **Date Survey completed:** This date should be completed by the patient when she starts to complete the survey.

## Section B: Expenses for Supplies, Laundering and Dry Cleaning

### Section B: Incontinence Expenses

**Description:** A majority of the costs for incontinence are paid out-of-pocket by patients for supplies used specifically for urinary incontinence like pads, diapers, laundry, dry cleaning and other products. However, there is little information quantifying these costs for individual women or the effect of treating incontinence on costs. The impact of treatment outcome on the patient's incontinence expenses is an important secondary outcome of interest in this trial. The most accurate method to estimate costs is to quantify how many resources a patient uses and apply a cost for each resource. This self-administered Survey will measure the number of products a patient uses for incontinence (pads, diapers, supplies, laundry, dry cleaning) and estimate limits on employment or volunteer work due to incontinence. Baseline results will provide important information about the cost of incontinence, and postoperative results collected at the 12 and 24-month follow-up visits will indicate if the surgery results in a reduction in these costs. For the data analysis, a national average price will be used to calculate total expenses.

**Instructions to the Patient:** Begin by showing the patient item A8. Ask her to write in the date that she completes the survey here. Then, review Section B. Section B contains questions about costs the patient might have incurred purchasing supplies or doing extra laundry or dry-cleaning because of her incontinence. Ask the patient to check **only** one box for each question.

**Section C: Matters of Health: The Health Utilities Index (HUI)**

**Description:** We will assess patient preferences (aka utilities for states of health) associated with incontinence using a well-tested patient preference measure, the Health Utilities Index (HUI). The HUI is a generic health status and health-related quality of life measure used in both clinical and population health studies. The HUI has fifteen multiple choice questions on vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain to elicit responses about health status during the past week. However, incontinence is one of the three chronic health conditions that most adversely affect utility scores (the others are Alzheimer's disease and stroke). The UITN will be the first detailed analysis of utilities before and after treatment for women with stress incontinence. The HUI will be completed at Baseline and at the 6-week, 12 month and 24 month follow-up visits.

**Instructions to the Patient:** Show the patient the first page of Section C. Briefly review the following instructions with her.

*This questionnaire contains a set of questions which ask about various aspects of your health. When answering these questions please think about your health and your ability to do things on a day-to-day basis, during the past week. To define the past week period, please think about the date this time 7 days ago and recall the major events that you have experienced during this period. Please focus your answers on your overall abilities, disabilities and how you felt during the past week.*

*You may feel that some of these questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar; please excuse the apparent overlap and answer each question independently.*

*Please read each question and consider your answers carefully. For each question, please select one answer that best describes your level of ability or disability during the past week. Please indicate the selected answer by circling the number (1, 2, 3,...) beside the answer.*

*All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities and feelings.*

**Section D: Matters of Money: Willingness to Pay**

**Description:** Little is known about women's willingness to pay for improvement in incontinence, which is another method to estimate the burden of incontinence. Willingness to pay for improvement in incontinence severity reflects the value an individual places on a specific health state by estimating the maximum dollar amount she would pay for health-improving interventions. In this section, we are asking women to quantify how much money they would be willing to pay to have an improvement in their incontinent episodes of 25%, 50% and 100% (cure). We will also quantify willingness to pay as a proportion of yearly income. This will be the first detailed analysis with data before and after treatment of willingness to pay for women with stress incontinence. Data will be collected at Baseline and at the 12 and 24-month follow-up visits.

**Instructions to the Patient:** Show the patient the first page of Section D. Briefly review the instructions with her.