



Question by Question Specifications Guide
Form 58: 12 & 24 Month Follow-Up Patient Survey Part II
Version 09/06/02 (A)

I. Purpose

The measures included in Part II of the 12 & 24 Month Follow-Up 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 and as part of the Failure Protocol if the patient is determined to be a treatment failure between the 12 and 24-month follow-up visits.

II. Administration

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 was 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. Materials Needed

The following materials will be required:

- The 12 & 24 Month Follow-Up Patient Survey Part II with ID labels attached
- QxQ Specifications Guides for the 12 & 24 Month Follow-Up Patient Survey 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. As with all other Data Forms, do not handwrite ID numbers.
- A2. **Visit Number:** Circle the correct visit code for the event. If this Data Form is being completed as part of a scheduled UITN study visit, circle the correct visit code. If it is being completed solely because of a treatment failure, circle FAIL.
- 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. **Date Survey completed:** This date should be recorded by the patient on the day she starts to complete the survey.

Section B: Expenses for Supplies, Laundering and Dry Cleaning

Section B: Incontinence Expenses

Description: 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 resulted 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 A7. Ask her to write in the date that she completes the survey here. Then, review Section B with her. 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 multiple-choice questions on vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain to elicit responses about health status during the past week. The UITN will be the first detailed analysis of utilities before and after treatment for women with stress urinary incontinence.

Instructions to the Patient: Show the patient the first page of Section C. Briefly review the instructions with her. Ask the patient to circle **only** one response for each question.

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.

Instructions to the Patient: Show the patient the first page of Section D. Briefly review the instructions with her. Ask the patient to check **only** one box for each question.

D4. Personal Annual Income:

Some patients will be hesitant to answer this question as income is taken to be a highly personal and private matter for most people. In addition, patients may honestly not know their annual income without a careful consideration or consultation with a spouse/partner or other family member. The following standard prompt can be told to the patient if she asks why questions regarding income are being asked.

“Let me assure you that all of your answers are completely confidential, and your responses are never associated with your name in any manner. We ask the same questions of all the women who are participating in this study so that we will be certain we are including women from all walks of life and income levels.”

D5. Household income: This question refers to the total income of her **household** rather than only **her** personal income. This includes the income of any person living in the same household as the patient.