



Question by Question Specifications Guide
Form 23: 6 Week Patient Survey
Version 07/01/02 (A)

I. Purpose

The only measure included in the 6 Week Patient Survey is the Health Utilities Index, a secondary outcome measure for the UITN. 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). The HUI is completed at the 6 week follow-up visit to evaluate the effects of surgery on utilities.

II. Administration

The Patient Survey can be completed by the patient during the 6 week 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 may 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, every effort should be made to administer it as an interview at subsequent visits to be comparable to baseline measure.

A. Materials Needed

The following materials will be required:

- The 6 Week Patient Survey with ID labels attached
- QxQ Specifications Guide for the 6 Week Patient Survey

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 for Form 23 is pre-coded as visit = F/U 6 weeks, the 6 week post-operative 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 who distributes 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 23. 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:** Instruct the patient to record the date when she starts to complete the survey.

Section B: 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 B. 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.