



BE-DRI

Question by Question Specifications Guide

Form 207: Baseline Patient Survey

Version 06/01/04 (A)

I. Purpose

The measures included in the Baseline Patient Survey are all secondary outcome measures for the UITN, i.e. Quality of Life, the Health Utilities Index, Summary of Incontinence Expenses, and Willingness to Pay Survey. These data will be collected at baseline and will be compared with data gathered at each follow-up time point to answer the study research questions.

II. Administration

All consent procedures must be completed prior to the completion of the Baseline Patient Survey in accordance with local IRB requirements. The Baseline Patient Survey can be completed by the patient during a study visit, or at home and returned by mail or at the next study visit.

All of the questionnaires in this packet are 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, but then all follow-up survey packets must be administered in interview format to be comparable to baseline measure.

A. Window for Re-Screening of Patients:

The results of these measures expire 3 months following their completion; therefore, if more than 3 months transpires between the date the Survey is completed and the date of randomization, all baseline measures including the Survey must be repeated to ensure collection of 'current' baseline values that would be subject to change over a 3-month period.

B. Materials Needed

The following materials will be required:

- The Baseline Patient Survey with ID labels attached, and
- QxQ Specifications Guide for the Baseline 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 subsequent 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 Form 207 which will always be Visit **SCRN**. This form is completed at the baseline visit.
- A3. **Date Form Distributed:** Enter the date that you give the form 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 07. This form 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 interviewer-administered.

Section B: Quality of Life, Part I

Description: The impact of treatment outcome on the patient's quality of life (QOL) is an important secondary outcome. Health-related QOL is a multidimensional concept that encompasses well-being that is related to health and is distinguished from measures of health and functional status. For this study, the 12-item version of the SF-36 of the Medical Outcomes Study Questionnaire is being used. This questionnaire was designed as a generic indicator of health status for use in population surveys and evaluative studies of health policy and can also be used in conjunction with disease-specific measures as an outcome measure in clinical practice and research, which is how it is used for the UITN.

Instructions to the Patient: Start out by showing the patient item A7 and ask her to write in the date that she completes the survey here. Then, show the patient the first page of Section B. Briefly review the instructions with her; emphasize to her that the response choices for each of the items in this section vary. Some are a choice of yes or no (B4-B7). Most require her to select an answer that best represents the frequency B9-B12) or the degree to which she experiences something B2-B3, B8). Show her the differences in response choices. Emphasize that she should answer these questions based on her current health and activities. Also emphasize that there is no right or wrong answer to these questions.

Section C: Quality of Life, Part II

Description: A condition-specific measure of quality of life will be used in this trial so as to be sensitive enough to detect change, i.e. the Incontinence Impact Questionnaire (IIQ) and the Urogenital Distress Inventory (UDI) developed by Shumaker et al (1994). The former measure assesses the impact of UI on various activities, roles, and emotional states, whereas the latter measure assesses the degree to which UI symptoms are troubling to women.

Instructions to the Patient: Show the patient the first page of Section C. Briefly review the instructions with her; emphasize to her that the first part of this section (C1-C20) are all 2-part questions. Show her that, for these items, the first question asks her to tell us if she experiences the symptom, listed. Then, for each YES symptom, we ask her to tell us how bothersome the symptom is for her currently.

C21 and C21a: Gives her a chance to tell us about any symptom she might have that we haven't listed.

C22: C22 asks her to tell us, of all the symptoms in the first part of Section C (C1 – C21), which one symptom bothers her the most. The small box at the right of the text should be filled in by study staff after the woman returns the completed Form 207. Study staff should fill in the question number to which the text answer of item C22 refers.

C23- C52: All are one-part questions. No extra explanations should be necessary.

Section D: 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 follow-up results collected at all follow-up visits will indicate if the treatment 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: Review Section D. Section D contains questions about the number of incontinence aid supplies used in a typical week.

- D1-D8. **Supplies Used in a Typical Week:** Ask the patient to record the number of each type of supply used specifically for urine leakage in a typical week. If the woman uses a supply not included in D1-D7, tell her to record it in item D8. If she does not use a supply, instruct her to record zero for that item.
- D9-D14. **Laundry and Dry Cleaning:** These items ask how about how many loads of laundry are done or items of clothing are dry cleaned during a typical week because of urine leakage. Instruct the patient to check **only** one box for each question.
- D15. **Loss of Employment and Volunteer Work:** This question asks if the woman's urinary incontinence limited her employment or volunteer work. If yes, she should also answer D15a and D15b.

Section E: 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 all follow-up visits.

Instructions to the Patient: Show the patient the first page of Section E. 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.

E1-E16. Instruct the patient to circle only one response for each question.

E17. Instruct the patient to record if she completed the questionnaire by herself or with someone's help. If she had help, she should record who helped her in item E17a.

Section F: 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. Data will be collected at Baseline and at all follow-up visits.

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