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

I. Purpose

The Baseline Patient Survey includes measures of secondary outcomes. Because it is possible that the cure rates of the two surgeries will not be significantly different from one another, it is in these measures that differences between the two surgeries might be shown.

The Quality of Life and Sexual Function measures will be included in the Baseline Patient Survey and most all of the subsequent follow-up visits. Expectations of Surgery, included in the Baseline Survey, will be replaced by the Satisfaction with Surgical Results measure at subsequent visits. Resumption of Normal Activities is included n the Baseline survey at the 3 and 6-month follow-up visits. Data gathered at baseline 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 Survey Packet in accordance with local IRB requirements. The Patient Survey Packet 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. Ideally, these measures will always be administered as self-administered measures but remember, if you administer the survey as an interview at the baseline visit, you must administer the survey as an interview at all subsequent visits.

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 must 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 Packet with ID labels attached
- QxQ Specifications Guide for the Patient Measurements

III. Section by Section Review

Section A:

A1. **Study ID Number:** Affix the patient ID label in the spaces provided in the A1 field. 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 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.

A6. **Which version of this form was used?:** Record which language version of the packet was used by the patient to complete the Survey.

A7. **Is this a repeat Survey?** If more than 6 months transpires between completion of the Baseline Patient Survey and the planned date of surgery, the entire Baseline Patient Survey should be repeated. Circle code yes or no and continue with form completion.

Section B: Expectations of Surgery

Description: With the increasing concern regarding patient satisfaction with medical care and the documented association between satisfaction and treatment adherence, patient satisfaction has been included as a secondary outcome of interest in this trial. Because it has been established that treatment satisfaction is affected by the patient's pre-treatment expectations of the outcome, a measure of treatment expectations will be administered at baseline, prior to surgery. The 10-item self-administered questionnaire measures expectations of improvement in UI symptoms, improvement in activities limited by UI, and improvement in emotions associated with UI. The accompanying measure of satisfaction with treatment will be administered in all postoperative follow-up surveys. Both measures of treatment expectations and satisfaction with treatment have been developed for this study.

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 each of the items in this section is actually a 2-part question. Show her that the first question asks her to tell us if she experiences the symptom, limitation or emotion listed. Then, for each YES symptom, we ask her to tell us what she expects will happen regarding that symptom after her recovery from surgery.

B4 and B8: For these items, explain to the patient that she may experience a symptom or limitation that isn't listed. If so, she should write it in, in the specify field, circle yes and tell us about her expectation.

B10: For this item, we want her to tell us, of all the symptoms or limitations that she experiences, which one she expects to improve the most after recovery from surgery. The symptoms or limitations are not limited to those asked about in this questionnaire.

Section C: Quality of Life

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 which encompasses well-being that is related to health and is distinguished from measures of health and functional status. A condition-specific measure 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 is like Section B in that items 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 – C20), 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 07. 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: Normal Activities

Description: The Normal Activities questionnaire is from the SF-36 short form of the Medical Outcomes Study Questionnaire. 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. For the Baseline Patient Survey, the Normal Activities questionnaire is used to establish a baseline of normal activities for the patient. These will be compared to the post-surgical activities of the patient to determine how long it takes for her to resume her normal level of activities.

Instructions to the Patient: Show the patient the first page of Section D. Briefly review the instructions with her. This instrument is frequently used as a self-administered measure in population-based surveys and should be self-explanatory. If questions do arise, the point to emphasize is that items D1-D10 ask the patient to tell us if her health now limits her in the performance of the activity. So she might say, "Well, I never do that." But we want to know if she doesn't do it because of her health. If she decides that her health **does** limit her in the activity, we want to parse out if she judges the limitation to be "*a little*" or "*a lot*".

Sections E, F and G: Sexual Activities

Description: Little is known about the sexual functioning of women with UI. As with measurement of QOL, a condition-specific measure of sexual function will be used in this trial. The short form of the Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) developed by Rogers et al (2001) is a 12-item self-administered questionnaire. Baseline results will provide important information about the impact of incontinence on sexual function. Postoperative results will indicate if surgery results in improvements in sexual function.

Instructions to the Patient: Tell the patient this is the last part of the Survey. Show her Section E. Briefly review the instructions with her. Emphasize that E1 tells her which part of this measure she should complete, either Section F or Section G. Tell her that, for a variety of reasons, some patients report that while they **do** engage in sexual activity, they do not engage in sexual intercourse. This may be by personal preference, perhaps she does not engage in sex with a male partner, or for some other reason. If this is true for her, point out that a few of the questions may seem like they don't pertain to her, but that we would still like her to provide an answer. In these cases, the appropriate answer would be "never".
If a woman asks "what is meant by sexual intercourse?" the answer is "whatever it means to you." Many women have different definitions of what constitutes sexual intercourse.