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Question by Question Specifications Guide
Form 47: 6 Month Patient Survey
Version 09/06/02 (A)

I. Purpose

The 6-Month 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 Satisfaction with the Results of Surgery, Quality of Life, Resumption of Normal Activities, and Sexual Function surveys will be asked at the 6 Month follow-up visit. Data gathered at baseline will be compared with data gathered at each follow-up time point to answer the study research questions.

II. Administration

The 6 Month Patient Survey can be completed by the patient during the 6 Month study visit, or at home during the visit window 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 the baseline measure.

A. Materials Needed

The following materials will be required:

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

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 47 which will always be Visit **FU06**. This form is completed at the 6 Month follow-up 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 <u>first</u> last name in the third space.

A5. **Mode:** Circle the code for the mode of completion of Form 47. 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 form was used by the patient to complete the Survey.

Section B: Satisfaction with the Results 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. The 9-item self-administered questionnaire measures satisfaction with improvement in UI symptoms, activities limited by UI and emotions associated with UI as a result of surgery.

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.

B1-B7: For these items, the patient should record how satisfied she is with the result of her surgery regarding the symptom, limitation or emotion listed.

B8: For this item, the patient should record if, knowing what she knows now about the results of her bladder surgery, she would still go back and have the surgery?

B9: For this item, the patient should record whether or not she would recommend the surgery she received to a family member or friend.

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 items C1 – C20 are all 2-part questions. Show her that, for these items, the first question asks her to record whether or not she currently experiences the symptom listed. Then, for each "YES" symptom, she should record how bothersome the symptom currently is for her.

C21 & C21a: These items ask the patient to record any symptom she might have that was not previously listed.

C22: This item asks the patient to record, of all the symptoms in the first part of Section C (C1 – C21), which one symptom bothers her the most. After the patient returns the completed Data Form 33, study staff should be sure that the documented response clearly corresponds to one of the symptoms listed in C1-C20. If the response is unclear, study staff should confirm with the patient which symptom she was referring to. Study staff should then record in small box at the right of the text, the question number corresponding to the written answer of item C22.

C23- C52: These items are all one-part questions. No extra explanations are 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 record whether or not her health now limits her in the performance of the activity. For example, the patient might say, "Well, I never do that." But we want to know if she doesn't do it because of her health. If the patient decides that her health **does** limit her in the activity, she should record 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 that 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.