CHAPTER 10. QUALITY OF LIFE

Patient Reported Outcomes in BID: Instructions for Study Coordinators

10.1 Introduction

Health-related Quality of Life (HRQOL) will be assessed using the self-administered MOS SF-36 version 2 (SF-36v2). The assessment of HRQOL is one of the secondary outcomes for the BID study. HRQOL is defined as the subjects’ perception of their physical, functional, emotional and mental well-being. The SF-36v2 is one of the most commonly used instruments to measure global HRQOL, and its eight subscales have been tested extensively for reliability, validity against mortality, and responsiveness to interventions in HD patients. The survey is well-accepted by HD patients, taking only 5 to 10 minutes to complete. In addition, norms for the general U.S. population have been reported.

Fatigue will be measured using the FACIT-F version 4 instrument and the time to recovery item. The FACIT-F consists of 13 items and uses a five-point rating scale. It has been shown to have excellent internal consistency, test-retest reliability and responsiveness to interventions such as anemia management in cancer. It has also been shown to be reliable and valid in the ESRD population (Unruh unpublished data). The time to recovery instrument has been used in the London Study and the FHN study. This single item has been shown to be valid in the hemodialysis population.

10.2 Forms to be Used

The BID study participants will complete the SF-36 and Special QOL Questions including FACIT-F questions and the time to recovery item on Forms 220. The SF-36, FACIT-F and time to recovery questions are available in English and Spanish. The participant can chose whichever language they prefer if they speak English or Spanish. Patients who speak only Chinese will complete the SF-36 but not FACIT or time to recovery items.

Depending on the language preferred by the participant, the QOL forms to be completed include:

**English:**
F220E-MOS 36-Item Short Form Survey Instrument (SF-36v2) and Special Questions

**Spanish**
QOL Packet includes:
F220Admin – MOS 36-Item Short Form Survey Instrument (SF-36) Administrative Form
F220S-MOS 36-Item Short Form Survey Instrument (SF-36v2)
F220S-Recovery/FACIT – Special Questions (Recovery and FACIT-F)

**Chinese**
QOL Packet includes:
F220Admin – MOS 36-Item Short Form Survey Instrument (SF-36) Administrative Form
F220C-MOS 36-Item Short Form Survey Instrument (SF-36v2)
The BID Study’s Forms webpage will allow the Spanish and Chinese QOL forms to be printed out as a packet of forms or by clicking on individual documents at: https://clinicalresearch.ccf.org/bid/forms/FormsTableOfContents.htm.

10.3 Timing of Questionnaire Administration

The above forms will be completed during the baseline period (which lasts up to 12 weeks prior to randomization), 6 months (F6) and again at 12 months (F12). The F6 forms can be administered anytime during the F5 or F6 month visit. The F12 forms can be administered anytime during the F11 or F12 month visit.

In case the subject has recently been administered the Dialysis Clinic Inc. (DCI) SF-36 form, then a separate BID Study MOS SF-36v2 form(s) will be administered the following week.

10.4 Mode of Administration

The above forms will be self-administered by the study participant. Self-administered questionnaires may be more difficult to complete for the elderly, minority groups, and those with high comorbidity.\(^{22}\) In these patients, the questionnaire may be administered by the study coordinator. The mode of administration will be noted in the Form 220. It is very important that the same mode of administration be consistent throughout the study. Therefore, the mode of administration that is done at baseline should be carried out at F6 and F12.

If the participant does not answer all of the questions, the Study Coordinator may ask the participant to respond to the questions that were missed. It is very important that the Coordinator does not interpret or rephrase any of the questions for the participant. There is no right or wrong response to the questions on this questionnaire.

The form should be completed during the dialysis session while in the clinic. This information will be recorded on Form 220.

a. For self-administration, patients should be instructed to read the brief directions at the top of the page. After the patient's correct understanding has been confirmed, he/she should be encouraged to complete every item in order without skipping any.

b. During interviewer-administration, the study coordinator will read the questions and answer choices to the participants and mark their answer. The coordinators should not translate or re-interpret the questions for the patients, as these are validated questionnaires and doing so will invalidate the findings. The site coordinators will be trained by the site Principal Investigator to administer the questionnaire so as to elicit non-biased patient responses.

The coordinators should administer the questionnaire in person. Phone interviews are a last resort. Although telephone interview is not preferred, it may be reasonable to do so in
certain circumstances in which it cannot be completed otherwise e.g. if patient transfers his/her dialysis unit, is in a nursing care facility or due to patient’s preference.

10.5 Data Entry and Scoring

The Study Coordinators will key enter the responses for Form 220 into the database. The Forms will then be scored by the Data Coordinating Center.

10.6 References

status measures in outpatient dialysis. Early experiences in developing an outcomes assessment program. Medical Care 30, 1992