

CHAPTER 32. QUALITY OF LIFE

Participant Reported Outcomes in PVDOMICS: Instructions for Study Coordinators

32.1 Introduction

Health-related Quality of Life (HRQOL) will be assessed using three different instruments:

- self-administered MOS SF-36 version 2 (SF-36v2)
- self-administered Minnesota Living With Heart Failure (MLHF)
- self-administered emPHasis-10

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 HRQOL¹, and its eight subscales have been tested extensively for reliability, validity against mortality, and responsiveness to interventions in HD participants.¹ The survey is well-accepted by participants, taking only 5 to 10 minutes to complete. In addition, norms for the general U.S. population have been reported.¹ A licensing agreement is required and is on file at the DCC.

The 21-question Minnesota Living with Heart Failure (MLHF) instrument was designed as a self-administered measure of the effects of heart failure and treatments for heart failure on participants' quality of life. The content of the questionnaire was selected to be representative of the ways heart failure can affect important physical, emotional, social and mental dimensions of a participant's life without being too long to administer during clinical trials or practice. A licensing agreement is required and is on file at the DCC.

Emphasis-10 is designed to determine how pulmonary hypertension (PH) affects a participant's life. The instrument was jointly developed by The Pulmonary Hypertension Association UK ("PHA") and The University of Manchester ("Manchester") as an output of a PHA funded study (2011-2013). The English and Spanish versions are a copyrighted quality of life instrument used by the PVDOMICS study with full permission of Dr. Janelle York of University of Manchester and The Christie NHS Foundation Trust.

32.2 Forms to be Used

The PVDOMICS study participants will complete the SF-36v2, MLHF, and emphasis-10. The participant can choose whichever language they prefer if they speak English or Spanish. Depending on the language preferred by the participant, the QOL forms to be completed include:

English:

- F170 36-Item Short Form Survey Instrument (SF-36v2)
- F171 Minnesota Living with Heart Failure
- F172 EmPHasis-10

Spanish

QOL Packet includes:

F170 Admin – MOS 36-Item Short Form Survey Instrument (SF-36) Administrative Form
F170S-MOS 36-Item Short Form Survey Instrument (SF-36v2)

F171 Admin – Minnesota Living with Heart Failure Administrative Form
F171S- Minnesota Living with Heart Failure

F172 Admin – EmPHasis-10 Administrative Form
F172S- EmPHasis-10

The PVDOMICS Study's Forms webpage will allow the Spanish QOL forms to be printed out as a packet of forms or by clicking on individual documents at:

http://qhsapps.ccf.org/pvdomics/open_web/FORMS/Forms_TOC.htm

32.3 Timing of Questionnaire Administration

The three QOL instruments can be administered anytime during the PVDOMICS visits. It is recommended that the instruments be completed during the clinic visit to minimize the chance a participant will forget to bring them back if taken home to complete.

32.4 Mode of Administration

The primary mode of completion for 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. In these participants, the questionnaire may be administered by the study coordinator. The mode of administration will be noted in Forms 170-172.

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 forms should be completed during a study visit in the clinic. This information will be recorded on Forms 170-172. Follow institution's guidelines for illiterate or visually-impaired participants.

- a. For self-administration, participants should be instructed to read the brief directions at the top of the page. After the participant'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 Coordinator should not

translate or re-interpret the questions for the participants, as these are validated questionnaires and doing so will invalidate the findings. The Coordinators will be trained to administer the questionnaires so as to elicit non-biased participant responses.

The Coordinator should administer the questionnaires in person at a clinic visit. However, exceptions can be made (e.g., phone interview) in certain circumstances in which the questionnaires cannot be completed otherwise.

32.5 Data Entry and Scoring

Study Coordinators will enter the responses for Forms 170, 171, and 172 into the database. The forms will then be scored by the Data Coordinating Center.

32.6 References

Maruish ME. (Ed.). 2011. *User's manual for the SF-36v2 Health Survey* (3rd ed.). Lincoln, RI: QualityMetric Incorporated.

Rector TS, Kubo SH, Cohn JN. 1987. Patients' Self-Assessment of Their Congestive Heart Failure: Content, Reliability and Validity of a New Measure, the Minnesota Living With Heart Failure Questionnaire. *Heart Failure* 3: 198-209.

Yorke J, Corris P, Gaine S, Gibbs JS, Kiely DG, Harries C, Pollock V, Armstrong I. 2014. emPHasis-10: development of a health-related quality of life measure in pulmonary hypertension. *Eur Respir J* 43: 1106-1113.