

### c. Crohn's Disease

When the SF-36 form was used with patients suffering from Crohn's disease, Cadahia et al. (10) found that the study drug (infliximab) resulted in improvements in the physical role (PR) scale, but no change in the physical function (PF) scale. The PR scale of SF-36 is determined by questions about time required to complete tasks, difficulties in completing tasks, and ability to accomplish things. In contrast, the PF scale reflects questions on bending, walking, climbing, and lifting.

### d. Chronic Obstructive Pulmonary Disease

When the SF-36 form was used by subjects in a clinical trial on chronic obstructive pulmonary disease (COPD), Eaton et al. (11) found that administering oxygen gas resulted in an improvement in HRQoL, for example, in reduction of anxiety. In this study, the experimental group received oxygen from a tank of compressed gas, while the placebo group received air from a tank of compressed gas. The authors were careful to point out that the requirement of both groups of subjects to carry a heavy tank of compressed gas might have reduced quality of life. The authors concluded that their study was one of the first to provide justification to the widespread belief that COPD patients can benefit from oxygen.

### e. Multiple Sclerosis

HRQoL questionnaires are used for clinical studies, as well as in ordinary medical practice, for patients diagnosed with multiple sclerosis. These questionnaires are used for a number of reasons. Multiple sclerosis produces a deterioration in HRQoL. Thus, use of the HRQoL instruments can be used to measure drug efficacy in clinical trials on multiple sclerosis (12). Additionally, some of the factors measured by HRQoL forms, such as fatigue, pain, bladder or bowel control, and physical functioning, cannot be readily measured by laboratory tests (13). Moreover, according to Mowry et al. (14), data from HRQoL questionnaires may be used as a surrogate for clinical outcomes.

## III. HRQoL INSTRUMENTS SPECIFIC FOR MULTIPLE SCLEROSIS

The SF-36 form is a generic form, suitable for use with many disorders, including multiple sclerosis. Depending on needs and resources, an investigator may wish to use an HRQoL instrument that is specific for multiple sclerosis. These specific instruments include the Multiple Sclerosis Quality of Life Inventory (MSQLI), and others. MSQLI includes the questions found on SF-36 plus

<sup>10</sup>Cadahia V, García-Carbonero A, Vivas S, et al. Infliximab improves quality of life in the short-term in patients with fistulizing Crohn's disease in clinical practice. *Rev. Esp. Enferm. Dig.* 2004;96:369–74.

<sup>11</sup>Eaton T, Garrett JE, Young P, et al. Ambulatory oxygen improves quality of life of COPD patients: a randomised controlled study. *Eur. Respir. J.* 2002;20:306–12.

<sup>12</sup>Rudick RA, Miller D, Hass S, et al. Health-related quality of life in multiple sclerosis: effects of natalizumab. *Ann. Neurol.* 2007;62:335–46.

<sup>13</sup>Robinson Jr D, Zhao N, Gathany T, Kim LL, Cella D, Revicki D. Health perceptions and clinical characteristics of relapsing-remitting multiple sclerosis patients: baseline data from an international clinical trial. *Curr. Med. Res. Opin.* 2009;25:1121–30.

<sup>14</sup>Mowry EM, Beheshtian A, Waubant E, et al. Quality of life in multiple sclerosis is associated with lesion burden and brain volume measures. *Neurology* 2009;72:1760–5.