

# Quality of Life Measurement in Osteoporosis

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**ABSTRACT.** Quality of life measurement may be helpful in randomized clinical trials in osteoporosis to assess therapeutic tradeoffs and compare effects of different interventions. Quality of life measures include generic measures, disease targeted measures, and performance based measures. Disease targeted measures increase the coverage of domains that are of particular importance to the patient with established osteoporosis. Several disease targeted measures are currently available. These measures show discriminant validity, but data on longitudinal responsiveness and validity in randomized clinical trials are not yet available. (*J Rheumatol* 1997;24:1218-21)

**Key Indexing Terms:**  
OSTEOPOROSIS

QUALITY OF LIFE

Osteoporosis has been defined as a loss of bone mineral density greater than 2.5 standard deviations below young adult peak bone mass or the presence of fracture<sup>1</sup>. Yet this definition does not address the effect on quality of life of osteoporotic fracture<sup>2,3</sup>. Osteoporosis represents more than bone loss. Osteoporosis is a clinical syndrome with functional sequelae<sup>4</sup>. Furthermore, quality of life should be measured in osteoporosis to assess therapeutic tradeoffs, to compare effects of different interventions, to compare the relative burden of different diseases, and to assess the cost utility of different interventions<sup>4</sup>. Vertebral deformities result in chronic back pain and disability<sup>5-7</sup> with resulting psychosocial problems<sup>2,6</sup>.

Quality of life includes both the functioning or performance of individuals in their daily lives and their subjective perception of well being. This perception may depend in part on the gap between the individual's perceived health and functioning and the individual's expected health and functioning. Quality of life is conceived of as being greater than disease or infirmity (World Health Organization definition)<sup>8</sup>. Quality of life is considered to be multidimensional, encompassing physical, mental, and social function as well as well being<sup>8</sup>. Individual aspects of functioning are ascertained by a series of individual questions or items grouped into domains<sup>9</sup>. Groups of similar domains are called dimensions. Individuals may assign a certain degree of importance to each area of functioning, which is called weighting. There are 2 major methods of quality of life assessment: self-report and interviewer based<sup>4</sup>. For large randomized clinical trials, self-assessment may be preferred to avoid the cost of interviewer training and interviewer bias<sup>4</sup>. There are several

types of instruments currently available to assess osteoporosis. These include performance measures, generic measures, and disease targeted measures. Performance based measures assess the degree of disability when carrying out observed activities of physical performance such as functional reach, mobility skills, and 6 minute walk test. These measures were used by Jette and Deniston to create the Functional Status Index<sup>10</sup>. The index was used by Lyles, *et al* to show that patients with vertebral compression fractures have reduced levels of functional performance<sup>11</sup>.

Generic instruments include health profiles and utility measurements<sup>12</sup>. Health profiles measure all important aspects of Health Related Quality of Life Questionnaire<sup>12</sup>. Available generic health profiles include the SF-36<sup>13</sup>, Arthritis Impact Measurement Scale 2 (AIMS2)<sup>14</sup>, Nottingham Health Profile<sup>15</sup>, the Sickness Impact Profile<sup>16</sup>, and modified Health Assessment Questionnaire<sup>17</sup>. Generic health profiles may be of value in osteoporosis since they may be used to compare disease burden and provide an assessment of comorbidity<sup>18</sup>. Generic health status instruments, however, may be unresponsive to change in a specific disease<sup>12</sup>. Generic utility measurements are derived from decision and economic theory<sup>19</sup>. The advantage of utility measures is that they incorporate preference measurements and can be employed in health economic analysis. Utilities can be used to have patients assign one value between 0 and 1 to their overall health (e.g., time tradeoff, standard gamble, feeling thermometer). Similarly, a score from a health status instrument may be converted to a utility score by using preference values that are obtained in a different population (e.g., Quality of Well-Being<sup>20</sup>, Torrance's Health Utility Index<sup>21</sup>, and European Quality of Life<sup>22,23</sup>). Utility instruments are especially important in the area of technology assessment and resource allocation.

Disease targeted instruments are shown in Table 1 and include the Osteoporosis Quality of Life Questionnaire<sup>24</sup>, the Osteoporosis Functional Disability Questionnaire<sup>25</sup>, the Osteoporosis Assessment Questionnaire<sup>26</sup>, and the Quality of Life Questionnaire of the European Foundation for Osteoporosis<sup>27</sup>. These have been developed to increase cov-

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Table 1. Available quality of life instruments in osteoporosis.

Instrument	Author	Type	No. of Questions	Time
OQLQ	Cook, Guyatt	Interviewer	30	20 min
FSI	Lyles	Examiner	45/18	N/A
OFDQ	Helmes	Self-administered	8 - Back pain, general health 20 - Depression 26 - ADL 2 - Finance/social 3 - Program	
OPAQ	Silverman	Self-administered	5 - General health 56 - Functional state 10 - Weighting	30 min
QualEFFO	Lips	Self-administered	54	N/A

OQLQ: Osteoporosis Quality of Life Questionnaire;

FSI: Functional Status Index

OFDQ: Osteoporosis Functional Disability Questionnaire;

OPAQ: Osteoporosis Assessment Questionnaire.

QualEFFO: Quality of Life Questionnaire of the European Foundation for Osteoporosis.

erage of domains of particular importance to the symptomatic patient with established osteoporosis, including fear of falling, independence, back pain and discomfort, self image, etc.<sup>24-26,28</sup>. In both the Osteoporosis Quality of Life Questionnaire and Osteoporosis Assessment Questionnaire, patients with established osteoporosis participated in the design of the instrument by weighting the importance of various items<sup>24,26</sup>. In the development of the Osteoporosis Quality of Life Questionnaire all patients were required to have a diagnosis of chronic back pain<sup>24</sup>, while in that of the Osteoporosis Assessment Questionnaire patients were required to have established osteoporosis with greater than 2 fractures (> 25%)<sup>26</sup>. Disease targeted instruments may be more responsive to change than generic instruments. The term disease targeted rather than disease specific is preferred for these measures since none of them have proven to have domains unique to osteoporosis and may detect problems seen in other musculoskeletal conditions such as lumbar osteoarthritis.

The Osteoporosis Quality of Life Questionnaire<sup>24</sup>, an interviewer based questionnaire, was developed by Cook and Guyatt from a longer questionnaire, the Health Related Quality of Life Questionnaire<sup>28</sup>. The Osteoporosis Functional Disability Questionnaire was developed by Helmes<sup>25</sup> and is a self-report instrument. The Osteoporosis Assessment Questionnaire was developed by Silverman and Mason<sup>26</sup> and is a self-report questionnaire that uses an AIMS2 core. A newer self-report questionnaire is the Quality of Life Questionnaire of the European Foundation for Osteoporosis developed by Lips<sup>27</sup>. When tested, all the instruments have been shown to be reliable by 2 week test-retest and have internal consistency by Cronbach's alpha. The Quality of Life Questionnaire of the European Foundation for Osteoporosis is undergoing reliability and validity testing at this time. All these measures were devel-

oped using the paradigm of the established patient with osteoporosis. For studying quality of life in protocols that involve prevention in the early postmenopausal patient, quality of life measures that are targeted to cover domains related to menopausal symptoms such as the Women's Health Questionnaire<sup>29</sup> may be more appropriate. The Women's Health Questionnaire is reliable, has excellent internal consistency, correlates with estrogen levels and other quality of life scales<sup>29</sup>, and is sensitive to changes with treatment<sup>29</sup>.

Quality of life measures have 2 major properties: discriminant and longitudinal. The discriminant property of an instrument is its ability to differentiate 2 different populations at a given point in time. The evaluative property of an instrument is its ability to detect changes in a population or individual over time. The discriminant property is evaluated by examining the correlation to clinical state and to other quality of life instruments at a given point in time. The evaluative property of an instrument is evaluated by longitudinal correlation to other measures and responsiveness to change.

The discriminative properties of available instruments are shown in Table 2. The Osteoporosis Assessment Questionnaire and Osteoporosis Functional Disability Questionnaire showed significant correlation to clinical severity, while the Osteoporosis Quality of Life Questionnaire did not. The Osteoporosis Quality of Life Questionnaire and Osteoporosis Functional Disability Questionnaire have correlation to existing generic measures. There is little data on the evaluative properties of existing instruments as shown in Table 3. Both the Osteoporosis Assessment Questionnaire and Osteoporosis Functional Disability Questionnaire have been validated in a nonrandomized clinical trial. However, no disease targeted instrument has been validated in a randomized clinical trial. The Osteoporosis Assessment Questionnaire is currently being studied in an

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Table 2. Discriminative properties of available quality of life instruments in osteoporosis.

Instrument	Reliability	Other Measures	Correlations to Clinical
OFDQ	Yes	Yes	Yes
OPAQ	Yes	N/A	Yes
QualEFFO	N/A	N/A	N/A
OQLQ	Yes	Yes	N/A
FSI	Yes	N/A	Yes

OFDQ: Osteoporosis Functional Disability Questionnaire;  
 OPAQ: Osteoporosis Assessment Questionnaire;  
 QualEFFO: Quality of Life Questionnaire of the European Foundation for Osteoporosis;  
 OQLQ: Osteoporosis Quality of Life Questionnaire;  
 FSI: Functional Status Index.

Table 3. Evaluative properties of quality of life instruments in osteoporosis.

Instrument	Responsiveness	Longitudinal Correlation
OFDQ	Nonrandom exercise trial	N/A
OPAQ	Nonrandom fluoride trial	N/A
QualEFFO	N/A	N/A
OQLQ	Detected patients with global change	Poor
FSI	N/A	N/A

OFDQ: Osteoporosis Functional Disability Questionnaire;  
 OPAQ: Osteoporosis Assessment Questionnaire;  
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international multicenter bisphosphonate trial and in an international multicenter estrogen agonist trial. The Osteoporosis Assessment Questionnaire is also under study in the Dubbo study, a longterm epidemiology study in Australia.

There is considerable information on the reliability and discriminative properties of generic instruments in other diseases. However, there is little information on the discriminative properties of generic instruments in osteoporosis. An unpublished study by Armour Pharmaceuticals using the Sickness Impact Profile showed a hierarchy of decreasing functional state from one compression fracture to multiple compression fractures to hip fracture. This hierarchy persisted when the physical dimension alone was analyzed; however, analysis of the psychosocial dimension alone suggested that the effect of multiple vertebral compression fractures was not too dissimilar from that of hip fracture. There is no information on the responsiveness of generic instruments in a randomized clinical trial in osteoporosis. Furthermore, the Sickness Impact Profile does not assess pain and is lengthy to complete.

In summary, quality of life measurement is important in a randomized clinical trial to assess therapeutic tradeoffs and to allow comparison between different interventions. Quality of life is an important endpoint. Both generic and

disease targeted instruments may be helpful in measuring quality of life. While osteoporosis disease targeted instruments are useful in trials of patients with established osteoporosis, they may not be useful in prevention trials. Existing quality of life measures are reliable but their responsiveness in a randomized clinical trial is as yet unknown.

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