Review of the concept of Quality of Life assessment and discussion of the present trend in clinical research

Giovanni Apolone and Paola Mosconi

Laboratorio di Epidemiologia della Assistenza Sanitaria, Istituto di Ricerche Farmacologiche Mario Negri, Milano, Italy

Background

In the medical field health status measurement, Quality of life (QoL) and Health-Related Quality of Life (HRQoL) assessment are interchangeably adopted to describe an evaluative process in which the instruments only concern about the effects that a disease, treatment or a more complex intervention may have on a person’s physical or emotional performance in everyday activities. But the concept of quality of life is indeed distinct from health, though related to it. Outside the medical community the term QoL has a different meaning. Here it is intended, rather than a mere description of patients health status, as a way patients perceive and react to many health- and non-health-related aspects of their lives in which family life, finances, housing, job, and others aspects of human experience that are beyond the action of health care system play a major role.

Thus, HRQoL, or the subset of the overall concept of quality of life that relates specifically to a person’s health, refers to the measure of the patients’ functioning, well-being and general health perception in each of three domains: physical, psychological and social (Figures 1 and 2).

QoL assessment in medical literature

Although the use of standardized instruments to assess patients’ point of view about life and health can be traced back over 300 years, our capability to transform patients’ subjective opinions, ratings, and reports in standardized pieces of information are mainly based on the results of the efforts made in the last decade.

In order to have a qualitative description of the role of QoL assessment in the biomedical literature, we carried out a Medline search, listing articles indexed with the following keywords: quality of life, health-related quality of life, health outcome assessment, health status measurement for the period 1985–1994. Figure 3 shows the published articles per year containing the keywords adopted. An impressive ‘explosive’ trend is shown: the proportion of ‘quality of life’ articles was 0.21% of all the published articles in 1985 and 0.76% in 1994. A more qualitative review of the nature of the articles identified shows that during last 10 years three different phases can be identified:

![Health and Quality of Life](image1)

Fig. 1. The role of HRQoL in the conceptualization of QoL.

![A matrix to measure HRQoL concepts](image2)

Fig. 2. A matrix to measure HRQoL concepts.

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First phase: most of the articles traced contain the selected keywords, but no formal assessment is identified; when some assessments are reported, they can be classified as physicians’ judgment of the patients’ health; in the remaining articles simple physical performance or disability batteries are used.

Second phase: the centrality of the patients’ points of view becomes more apparent, and long and cumbersome tools from the psycho-social fields are applied; although multidimensional, most of the time the tools yield synthetic global measures.

Third phase: in this phase, short, simple and multi-dimensional questionnaires are adopted, frequently containing both negative and positive aspects of health that is multi-dimensionally conceptualized. Although interchangeably used, QoL, HRQoL and health status begin having different meanings. A lot of attention is paid to produce data about validity and robustness, across different subgroups and settings.

QoL assessment in end stage renal disease (ESRD) literature

The Medline search was repeated by focusing the analysis in ESRD papers to assess the role and nature of QoL assessment in this field. In addition to the keywords adopted to identify QoL, the following keywords were adopted to identify the area of interest: end stage renal disease, dialysis, chronic renal failure. A total of 339 articles were identified. Findings are displayed in Figure 4 where ESRD data are tabulated according to the year of publication. In order to give an idea of the phenomenon, the results of a similar search in oncology is also shown. Although the contribution of ESRD is low in terms of absolute values (it is well documented that cancers occupies 22% of the total QoL literature), the proportion of papers that contain QoL keywords is higher in ESRD than in oncology in each year considered, ranging from 0.76 to 2.73%. Although, as elsewhere documented (Mingardi et al., personal communication), the presence of a given keyword in the title, abstract and text does not mean that a formal QoL was actually carried out, these findings at least support the idea that QoL issues were always considered relevant in this field, and are increasingly addressed, with, on average, 3% of all published papers containing at least one keyword related to QoL.

Present trends

Outcome measures have evolved from simple binary variables such as survival or occurrence of relevant clinical events to complex patient-oriented measures, ranging from functional disability scales to spiritual quality of life and economic measures.

At present, a distinction between QoL and HRQoL is more clearly stated and operationalized. HRQoL measures pertain to the outcome research field: in the present era information about people functioning and well being are considered essential not only to compare costs and benefits of individual interventions but, also to monitor the impact of new ways of organizing and

![Fig. 3. Published articles per year containing ‘QoL’ keywords.](image)
The concept of quality of life assessment

financing health care services on the whole population or on specific sub-groups (Table 1).

All the accredited HRQoL instruments are now based on a conceptualization of health that is multi-dimensional, in which the source of information is the patient. Available tools are classifiable as generic (assessing health concepts that represent basic human values and are relevant to everyone’s health status and well-being are not specific for age, disease or treatment group) or specific (assessing health concepts that are tailored to a given disease or intervention), yielding separate scores for each domain/area, or overall index summarizing all the health aspects considered.

### Empirical examples: the SF-36 and the GIVIO Questionnaires

In Italy there are a few generic HRQoL measures available at present that were fully validated in Italian language and only one kidney disease oriented instrument (the Kidney Disease Short Form Quality of Life Questionnaire) that is now under extensive evaluation after being translated by an international Working Group on 1995.

Available generic questionnaires are the Nottingham Health Profiles, the Sickness Impact Profile, the SF-36 Health Survey and the GIVIO Questionnaire. The last

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Types</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>Clinical events</td>
<td>Myocardial infarctions, cerebrovascular accidents</td>
</tr>
<tr>
<td></td>
<td>Physiologic and metabolic measures</td>
<td>Blood pressure, measurement of cholesterol levels</td>
</tr>
<tr>
<td></td>
<td>Mortality</td>
<td>Death-specific cause (such as cardiovascular) or all causes (total)</td>
</tr>
<tr>
<td>Humanistic</td>
<td>Symptoms</td>
<td>Rotterdam symptom check list</td>
</tr>
<tr>
<td></td>
<td>HR Quality of life</td>
<td>SF-36 Health Survey, Nottingham Health Profile, Sickness Impact Profile</td>
</tr>
<tr>
<td></td>
<td>Functional status</td>
<td>Katz Activities of Daily Living scale, Karnofsky index, other I-ADL scales</td>
</tr>
<tr>
<td></td>
<td>Patient satisfaction</td>
<td>Group Health Association of American survey</td>
</tr>
<tr>
<td>Economic</td>
<td>Direct medical</td>
<td>Hospitalizations, outpatient visits, emergency department visits</td>
</tr>
<tr>
<td></td>
<td>Indirect medical</td>
<td>Work loss, restricted activity days</td>
</tr>
</tbody>
</table>

From Epstein RS et al., 1996 (adapted).
two were also adopted in a large prospective observational study where more than 500 ESRD patients were enrolled. The SF-36 is the only one questionnaire for which data from a representative sample of Italians are available. Table 2 summarizes the concepts and the number of items that are in the SF-36 form and in its shorter version. The GIVIO questionnaire, developed initially for cancer patients and eventually adapted for the ESRD setting, is a multidimensional questionnaire that contains a core section with 27 items describing six HRQoL concepts and a 13-item symptoms check list. Three other modules dedicated to health care utilization (three items), patient satisfaction and opinion (10 items) and impact on working status (eight items) are also available. Because of the availability of data on the performance of SF-36 and GIVIO questionnaire in ESRD patients, in the case a formal HRQoL assessment is needed in research projects, the use of these two instruments is suggested, together with short disease targeted modules.

Table 2. Number of SF-36 and SF-12 items per concept

<table>
<thead>
<tr>
<th>Concept</th>
<th>SF-12</th>
<th>SF-36</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Role—physical</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>General health</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Energy/lattitude</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Social functioning</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Role—emotional</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Mental health</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Change in health</td>
<td>–</td>
<td>1</td>
</tr>
</tbody>
</table>

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Discussion

The introduction of the patients’ point-of-view in quality and effectiveness studies can be considered a further step towards a more comprehensive humanistic approach to the patient who is seen, as a ‘complex individual’ member of a dynamic community and not a ‘complex machine’ assembled with separate organ systems. While researchers, physicians and policy makers usually discuss the pros and cons of adopting such instruments in specific settings by challenging their validity, reliability and robustness across different and relevant sub-groups, seldom it is understood that these tools are only a complementary way of assessing the impact of medical interventions on the population. The available tools were indeed developed in a time of traditional medical outcomes, it is unrealistic to hope that patients’ self-reported measures might capture differences in health that are not measurable by other more traditional medical approaches. The potential negative results might be attributed to two main reasons: first, the instruments are valid and appropriate but the effect of size of the phenomenon under study is too small to be detected, second available instruments are not sensitive enough to identify and quantify the phenomenon under study because they are not targeted on it.

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**QoL and HRQoL**


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### Questionnaires for HRQoL assessment


