Intervention Research in Psychosis: Issues Related to the Assessment of Quality of Life

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Abstract

Quality of life has emerged as the ideal of modern medicine viewed from a biopsychosocial perspective. The concept has been increasingly used as an important attribute in patient care and clinical studies as well as the basis in many health economic evaluations. Although the concept has been extensively applied in a number of other medical fields such as oncology, cardiovascular, and arthritis, it is only recently that quality of life has received serious attention in the study of severe psychiatric disorders. For the concept to be meaningfully applied in the study of these disorders, several basic and methodological issues have to be adequately resolved. Five such issues are identified: definition of quality of life, the subjective/objective dichotomy, significant determinants of quality of life, how quality of life is measured, and the role of quality of life in clinical management and health economics. Unless these issues are adequately clarified and resolved, the recent heightened interest in the concept of quality of life may fade away, and that would be a missed opportunity in the mental health field.


Over the past 20 years, the concept of quality of life has come to represent the new image of modern medicine as viewed from biopsychosocial perspectives (Awad et al. 1997a). No one is sure how the general concept originated except that it had its beginning in the post-World War II period. Post-war economic prosperity and enhanced standards of living led to various life expectations such as satisfaction, well-being, and psychological fulfilment. These broad notions were picked up by social scientists, who advanced population-based quality of life research that contributed significantly to social indicators. As frequently happens, such social science concepts gain more significant currency as they get used in the political arena. In 1964, President Johnson introduced the term “quality of life” in his address on “the Great Society.” As a broad, general concept, quality of life has always included several domains related to health, but the concept also originally included many other non-health-related issues such as work, family, prosperity, spirituality, and environment. Such broad domains clearly complicate the usefulness of quality of life as a health outcome.

Over the past 40 years, medicine has been going through major changes as a result of scientific and technological advances. With enhanced life expectancy, the medical focus has shifted from merely prolonging life to improving the quality of life. This has led to a narrower concept of quality of life specifically related to health. This narrower concept was quickly embraced for use in particular medical illnesses such as cancer and arthritis. Although interest in the concept of quality of life of the chronically mentally ill has its roots in the early 1960s, as an extension of the increasing concerns about the unsatisfactory life conditions of chronic psychiatric patients in the community, these interests were unfortunately not adequately sustained over the next two decades, except for some serious contributions by a few researchers (Malm et al. 1981; Lehman et al. 1982; Lehman 1983).

Several reasons have contributed to the lack of interest in quality of life research in psychiatry. In a previous review, we examined several such factors, which include lack of agreement on a definition or what constitutes quality of life in schizophrenia, concerns and doubts about the credibility of chronic psychiatric patients’ self-reports, lack of adequate appropriate conceptual models for the particular population as well as the phase of the illness.
and subsequently, adequate methodology for measurement (Awad et al. 1997a). Fortunately, over the last few years, there has been significant renewed interest in quality of life assessment in psychiatry. Although many might have difficulty in articulating what quality of life is, the concept in its popular usage in society has proved simple for everyone to understand. The concept also appropriately captures what physicians, patients, and their families aspire to accomplish in the treatment of any significant chronic long-term illness. In other words, the concept has come to represent the ultimate outcome of the interaction between the patient and the illness, its treatment, its psychological impact, as well as social contributions and consequences. Other factors have also contributed to the recent increased popularity of the concept. With economic constraints and efforts to contain health care costs, more attention has focused on quality of life as an outcome measure for comparison of therapies and programs as well as for resource allocation. The recent rise in consumerism has increased pressure on clinicians for patients and their families not only to participate in the clinical decision-making process but also to expect better therapies. Recent accelerated developments in neuroscience, both in its research and its technological aspects, have led to the introduction of several new and expensive medical procedures and therapies. In addition, the high acquisition costs of new psychiatric medications have led drug regulatory agencies as well as formulary and drug benefit plans to require data about quality of life and pharmacoeconomics. The pharmaceutical industry, while promoting new products, has emphasized quality of life as a significant marketing tool to highlight differences between individual medications and to project a favorable health economic status.

With all these factors converging to make the concept of quality of life most popular in the psychiatric field, such popularity and high expectations have also brought in several concerns that can undermine the usefulness of the concept. Clinicians, as well as the majority of researchers, have become preoccupied with measurement of quality of life without any clear understanding of what they are measuring or what the factors are that contribute to the concept itself. Much less research has been devoted on how to integrate quality of life measurements into clinical psychiatric care. Based on our experience, over the past 15 years, and the identified gaps in the literature, the following represent some major issues that require concerted research attention:

1. How should quality of life be defined?
2. Whose measurement of quality of life is relevant?
3. What are the significant determinants of quality of life?
4. How should quality of life be measured?

5. What role does quality of life have in clinical management and health economics?

What Is Quality of Life?

A construct such as quality of life cannot be verified, appropriately measured, and subjected to serious study unless it is well-defined. More than three decades ago, Campbell et al. (1976) anticipated the controversy that continues until the present time about the lack of agreement on a definition of quality of life: “Quality of Life is a vague and ethereal entity, something that many people talk about but which nobody clearly knows what to do about.” Over the last 30 years, several definitions of quality of life were introduced; these definitions depended mostly on theoretical orientation and ranged in scope to focus on psychological issues such as feelings of well-being and satisfaction to issues related to standards of living such as housing, finances, and employment.

Several other definitions emerged reflecting the different theoretical frameworks of their authors. In an attempt to circumvent the unresolved issue of absence of a gold standard against which quality of life can be measured, Calman (1984) defined quality of life as the gap between the patients’ expectations and achievements. Wood-Dauphinee and Williams (1987) introduced the concept of “reintegration to normal living” as equivalent to quality of life. A broader definition by Ware (1984) conceptualized quality of life as hierarchical concentric circles, with the center representing the impact of the illness and the outer circles progressing from personal functioning, feelings of well-being, and psychological distress, to overall general health perceptions, and ultimately to social and role functioning. Such a definition broadens the concept of quality of life from a personal individual perspective to a broader social and societal concept. Clearly, there is no agreement on definitions, and it may be that many definitions are needed depending on the population under study, the stage of the illness and its treatment, as well as societal expectations at a particular point of time. With the state of the art as such, it is incumbent on researchers to define what they mean by quality of life in their publications and communications. In a 1994 report examining the quality of quality of life research, using standardized criteria, Gill and Feinstein reported that quality of life was defined in only 15 percent of the reports they reviewed. In our studies in schizophrenia, we adopted a somewhat narrower and more specific definition reflecting our belief that quality of life in schizophrenia represents the functional effect of the illness itself and its treatment upon a patient as perceived by the patient.
The Subjective/Objective Debate: Whose Measurement of Quality of Life Is Relevant?

By definition, quality of life is a subjective construct that needs to include patients' self-reports and their subjective judgement. As such, it requires a degree of cognitive ability. Traditionally, clinicians have been suspicious of subjective assessment by patients of treatment outcomes. As patients with schizophrenia frequently experience disturbed thinking and communication, as well as a range of neurocognitive deficits, their reports about their feelings, values, and levels of satisfaction are frequently uncritically dismissed as unreliable. Paradoxically, clinicians do not feel reluctant to base diagnostic formulations of their patients on unobservable or non-objectively verifiable self-reports about their unique psychotic experiences such as hallucinations and delusions, without questioning the reliability of such information. Over the past few years, a growing body of research has supported the notion that subjective self-reports can be both measured and reliably quantified (Van Putten and May 1978; Hogan et al. 1983; Hogan and Awad 1992; Naber et al. 1994; Awad et al. 1995; Voruganti et al. 1998). In a recent report of the reliability of quality of life self-reports (Voruganti et al. 1998), we confirmed that the reliability coefficient of patients' self-reports measured weekly over a 4-week period were statistically significant ($r = 0.80-0.87$, $p > 0.0001$). In addition, we also reported significant concordance between patients' subjective self-reports and objective measures conducted by clinicians. Repeated ANOVA analysis of variance failed to detect any group by week interaction effects for the severity of symptoms, side effects, neurocognitive deficits, antipsychotic drug doses, or attitudes toward medications (Voruganti et al. 1998). The lack of such interactions confirms that subjective self-reported scores remained consistent for all the subgroups over time (figure 1). Our data were obtained from clinically stable but moderately symptomatic patients with schizophrenia attending a medication clinic.

Obviously, one cannot be sure to what extent these findings can be extended to other subgroups of patients, such as those with severe psychotic disorganization or marked cognitive impairment, who may also be markedly compromised in insight and judgement. A striking finding in our study is that the subgroup of patients with a higher level of symptoms was as reliable in their self-reports as the subgroup of patients with a lower level of symptoms. This suggests that severity of illness in itself does not undermine the ability of patients to report their experiences consistently. Other authors have advanced an opposite point of view. Skantze et al. (1992), in a comparative study of persons with schizophrenia and a matched control of college students, concluded that subjective quality of life measures such as spirituality and feelings of wellbeing of patients with schizophrenia were unrelated to objective measures of their standard of living such as housing or financial and social support. Warner et al. (1998), in their study comparing a sample of patients with schizophrenia in Bologna, Italy, and Boulder, Colorado, reported that objective quality of life variables using a factor analysis sorted separately from subjective satisfaction scores, suggesting that they may be measuring different underlying constructs. Although objective measures of quality of life were rated as more favorable for schizophrenia patients in Bologna, as compared with Boulder, subjective satisfaction ratings were not different in both sites. Interestingly enough, another study reported that subjective quality of life was rated higher in a sample of patients with schizophrenia than in those with affective disorder, although in objective measures, the reverse was true (Atkinson et al. 1997). Such dichotomy was also demonstrated in our recent study of neurocognitive deficits and quality of life in a sample of patients with schizophrenia. We were unable to demonstrate significant correlation between neurocognitive deficits and self-rated quality of life (Heslegrave et al. 1997). Although patients in our sample have demonstrated significant neurocognitive deficits, the correlation to their subjective self-reports of quality of life was weak, at best. On the other hand, in a recent report by Green (1996), a review of data from several studies pointed to strong correlation between aspects of neurocognitive deficits and functional status as measured by objective criteria. The issue of subjective self-reports of quality of life and the quest for objectivity is clearly far from being resolved. Most likely, both approaches are measuring different constructs. Where does this leave researchers?
in the field for future directions? On one hand, one has to accept the subjective nature of quality of life and the importance of including patients' self-reports in any measurement of quality of life. On the other hand, how does one reconcile this with the fact that, at least, a subgroup of the schizophrenia population suffer from severe psychotic symptoms and seriously impaired insight and judgment? To minimize bias in subjective self-reports, our experience has been that using multidimensional approaches rather than a global self-report rating can yield more reliable information. Using a global self-rating approach can be misleading as it has been observed that psychiatric patients, in general, tend to report higher scores as most of the responses tend to gravitate toward the middle. It is likely that patients tend to project themselves as somewhat better. Such bias can be minimized by eliciting self-reports on a number of specific domains and detailed dimensions. Our data question the reliability of information from single global self-rating as this information did not significantly correlate with clinician-rated quality of life (Voruganti et al. 1998; Awad and Voruganti 1999a, 1999c).

What Are the Significant Determinants of Quality of Life?

To measure quality of life meaningfully, one has to define its major determinants as well as the relative contribution of such factors. Over the years, parallel to the diversity of definitions that have been introduced for quality of life, a number of conceptual constructs were proposed. Safety, employment, financial support, and family and social relations were identified as primary determinants of quality of life (Lehman et al. 1982; Lehman 1983). Another study concluded that social relations and finances are the main determinants of quality of life for chronic psychiatric patients (Sullivan et al. 1991). Another study identified different dimensions such as the number of readmissions in the previous year, frequency of family contacts, and satisfaction with social life as the best predictors of quality of life (Levitt et al. 1990). Most of these conceptual constructs relied to a large extent on exploring patients' living conditions and identifying objective indicators of quality of life. Other constructs focused mostly on subjective psychological dimensions such as satisfaction derived through hedonism, achievement, and conformity but not through obtaining satisfaction with objective needs were proposed as the major determinants of quality of life (Corten et al. 1994). These diverse conceptual approaches have lead to different emphasis on measurement and suggest that the primary dimension of quality of life in schizophrenia differs markedly depending on theoretical constructs as well as whether objective or subjective criteria are used.

Since our research interests, over the years, have been to explore the impact of the illness and its treatment on quality of life in schizophrenia, we realized the need for an integrative model that can reflect the multidimensional aspects of the disorder. Of particular interest for us has been the elucidation of the impact of antipsychotic medications, both positively and negatively, on quality of life in schizophrenia. In our conceptual and integrative model of quality of life in schizophrenia patients on medications, we defined quality of life as the outcome of interaction between three major determinants: psychotic symptoms and their severity, medication side effects, and the level of psychosocial performance (Awad et al. 1997b). We also identified other important second order issues, which can modulate such dynamic interaction and eventually impact on outcome. Such factors include personality characteristics, premorbid adjustment, values and attitudes toward health and illness, and resources and the ability to make use of them. We conceptualized these factors to be integrated in a circular model that emphasizes the multidimensional nature of the concept of quality of life as well as underscores the interrelatedness of the factors. Since these factors are affected to a greater or lesser degree by various interventions, the balance will shift with any change in the patients' regimen. These factors are not simply baseline conceptual factors for judging quality of life; they are also factors that can influence therapeutic outcome. Details of our conceptual model have been published elsewhere (Awad 1992, 1995). Although our conceptual model was clinically intuitive in its development, it allowed us to conduct a series of studies to experimentally test its validity. Based on multiple regression analysis of data from a sample of stable chronic schizophrenia patients attending a medication clinic, psychotic symptoms and their severity as well as subjective distress caused by specific side effects of medication—notably, akathisia and neuroleptic dysphoria—have accounted for nearly half of the variance in quality of life (Awad et al. 1997b) (table 1).

These preliminary results can be interpreted as broadly endorsing the key components of our conceptual model and confirm its multidimensionality. In this approach, we have been able to identify the significant components that contribute to the quality of life profile of patients on antipsychotic medications as well as their relative contribution. The development of such a model has also provided us with a framework for measurement of quality of life in our studies. We are convinced that there have to be different conceptual models appropriate for the population studied, as well as the phase of the illness and the impact of its treatment in a recognized psychosocial context. The field of quality of life in psychiatry urgently requires more research attention to basic fundamental
Table 1. Clinical indices and self-rated global quality of life in schizophrenia, based on multiple regression analysis

<table>
<thead>
<tr>
<th>Predictor variable</th>
<th>Scale</th>
<th>Variance (partial $R^2$)</th>
<th>F test</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychopathology</td>
<td>PANSS</td>
<td>0.24</td>
<td>12.38*</td>
<td>0.001</td>
</tr>
<tr>
<td>Patients' subjective responses and attitudes</td>
<td>DAI</td>
<td>0.11</td>
<td>6.40*</td>
<td>0.01</td>
</tr>
<tr>
<td>Side effects</td>
<td>HAS</td>
<td>0.06</td>
<td>4.03*</td>
<td>0.05</td>
</tr>
<tr>
<td>Psychosocial functioning multidimensionality</td>
<td>SPS</td>
<td>0.01</td>
<td>0.81</td>
<td>0.37</td>
</tr>
<tr>
<td>Psychosocial functioning global</td>
<td>GAF</td>
<td>0.01</td>
<td>0.87</td>
<td>0.35</td>
</tr>
</tbody>
</table>

Note.—DAI = Drug Attitude Inventory (Hogan et al. 1983; Awad et al. 1995); GAS = Global Assessment Scale (Endicott et al. 1976); HAS = Hillside Akathisia Scale (Fleishhacker et al. 1989); PANSS = Positive and Negative Syndrome Scale (Kay et al. 1987); SPS = Social Performance Scale (Wykes et al. 1986).

* Statistically significant.

issues such as the key factors that influence and contribute to the concept of quality of life. Such understanding of these issues can make it possible to translate data from quality of life measurement into meaningful clinical management.

How To Measure Quality of Life

As the concept of quality of life in psychiatry has become popular, there has been noticeable proliferation in the development of scales for its measurement, in addition to the well-established ones. A frequent request for us has been, over the past few years, to recommend one of these quality of life scales. As we oblige and try to assist in these situations, we frequently discover that the researcher or the clinician is unclear about why he or she needs to employ a measure of quality of life. Frequently, the decision to include a quality of life measure in clinical trials appears to be an afterthought. Similarly, we realized that certain scales were used without having adequate information about their psychometric properties or without their having been tested and validated for the particular population or the particular clinical condition under study. Similarly, many scales are used without understanding the framework or the theoretical constructs behind them. Our suggestions for choosing an appropriate quality of life scale include the following:

1. The scale has to be appropriate to the population under study, the clinical condition, and the phase of illness. Its psychometrics have to be known and documented.
2. Quality of life is a multidimensional construct, and this has to be reflected in its measurement.
3. Quality of life is a subjective phenomena, and any approach to its measurement has to include patients' self-reports.
4. The scale has to be adapted to the life of psychotic patients. Many scales include extensive numbers of items that frequently tax the already compromised cognitive ability of many patients with schizophrenia and contribute to inadequate collection of information. Using two short scales that tap specific areas is often preferable to using a multipurpose long scale.
5. The scale has to be consistent with the theoretical framework that the researcher uses to understand and define quality of life in the study.
6. The scale has to be sensitive to pick up relatively small changes that are expected, even under optimum conditions of response. Most clinical trials with medications are relatively short term, lasting from 8 weeks to 3–6 months. Under these conditions, the scale needs to be sensitive enough to pick up small differences. The ideal scale for pharmacological clinical trials is one that can also capture differences in pharmacological effects as translated to feelings and behaviors (Awad et al. 1997c). Certain scales are more suited to measure quality of life after long-term interventions, such as in rehabilitation programs, but are not suited or sensitive enough to be used in short-term pharmacological clinical trials.

What Role Does Quality of Life Have in Health Economics and Clinical Management?

Schizophrenia, as a long-term illness without any known cure, is costly both in terms of direct and indirect costs (Davies and Drummond 1990). Over the past 50 years, biomedical and technological advances have significantly reduced to society the risk of life-threatening illnesses, but this risk has been replaced by the risk of chronic long-term conditions. With the rising cost of management of such
chronic illnesses, emphasis has shifted from merely prolonging life, to enhancing quality of life. In such a context, quality of life measurement has become not only a new paradigm for enhancing the life of chronic patients but also a tool for comparing programs and various interventions, and subsequently, for allocating resources. Pharmacoeconomic studies have received major impetus, in recent years, by the introduction of second generation antipsychotic medications. New antipsychotic medications are generally better tolerated, with fewer side effects, yet their acquisition cost is much higher compared with the old conventional antipsychotics (Awad and Voruganti 1999a; Voruganti et al., in press). Although the cost of medications represents less than 5 percent of the total direct costs of management of schizophrenia, historically low psychiatric budgets have become stretched, which has led to increased interest in demonstrating whether the increased benefits of such new antipsychotics can justify their high acquisition costs. Although health economics, and particularly pharmacoeconomics in schizophrenia, is in its early infancy, several important contributions have already been published (Rivicki and Luce 1995; Hargreaves and Shumway 1996; Awad and Voruganti 1999b). It is clear that the present state of the art in methodology requires a good deal of refinement and adaptation to the unique clinical picture of the illness. Generally, quality of life measurements have been used in two approaches: a direct health profile approach or as part of cost utility evaluation. The central issue of any health economic evaluation is to compare the dollar costs and consequences of different interventions or health care programs. Although there have been several attempts to estimate the costs of schizophrenia, the issue still continues to be, largely, unresolved. It is difficult to analyze costs of management for schizophrenia because there are many cost factors and several different perspectives on cost. The major expense in direct costs generally relate to hospitalizations, but even comparing hospitalizations can be challenging, because of differences in procedures and efficiencies from one hospital to another. A more recent and innovative approach is cost utility analysis. This approach is grounded on well-defined economic and decision theory and elicits patients’ preferences for a particular health state based on quality of life. The measurement of scores for the utility of health states is performed using a number of techniques such as Standard Gamble or Time Trade-Off. In the Standard Gamble approach, the individual is offered a choice between two alternative health states: living in the present health state with a degree of certainty or taking a gamble on the proposed treatment choice with uncertain outcome. In the Time Trade-Off paradigm, the patient is offered living for several years in perfect health or fewer or longer years in some alternative health state that is less desirable. Although the cost utility approach is interesting and has proved useful in a number of other medical conditions, its usefulness in psychiatric illness, particularly schizophrenia, has not yet been adequately demonstrated. In a recent study, we reported that the cost utility approach in schizophrenia, although feasible, requires further research to resolve several methodological difficulties (Awad and Voruganti 1999b). In clinical management, quality of life measurements can serve a variety of important purposes. They can serve as a needs assessment, and they can yield valuable information for the clinician about gaps in management, which can lead to development of corrective measures. As an outcome, quality of life can demonstrate the effectiveness of the various management approaches, and conceptually, can change the focus of management from just symptoms improvement to broader outcomes that include function, satisfaction, and possibly the return to a somewhat productive role. It is clear that raising the quality of life for patients with schizophrenia may at first lead to higher costs in the provision of psychiatric care related to the cost of new medications, rehabilitation, social assistance, and support groups. However, one expects that the higher the level of quality of life obtained by treatment, the more likely the patient may, again, become a somewhat productive member of society and not simply a source of large medical expenditures and a recipient of social assistance. It is our contention that the most cost-effective treatment is the one that brings about the highest quality of life through rehabilitation, even if it is more expensive in the short term. Although interest in measurement of quality of life, both in research and clinical management, has phenomenally increased over the past few years, unfortunately there is no indication that such enhanced interest in measurement has been integrated in clinical management or translated into better outcomes. A significant recent contribution has been the recommendations from the Schizophrenia Patient Outcomes Research Team, which provided an approach on how to translate research into practice (Lehman et al. 1998).

Concluding Remarks

The concept of quality of life has emerged over the past two decades as a popular concept in health sciences. It has been used increasingly as an outcome of treatment in clinical management, as an outcome variable in clinical trials, as well as a basis for various pharmacoeconomic evaluations of new antipsychotic medications. However, such recent enhanced interests in quality of life measurement have not been equally matched by more research interests in exploring a number of basic issues related to the concept itself, such as its boundaries and determinants as well as its meaningful application in clinical management and health economics. Unless several methodological issues are adequately
resolved, interest in the quality of life concept may fade away. If that is allowed to happen, it would constitute a missed opportunity since the concept of quality of life has provided a common language that seems to be relevant and easily understood by clinicians, patients and their families, health economists, health administrators, and policy makers.

References


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