# Chapter 26
# Quality of Life Issues in Research and Clinical Practice

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## Contents

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J.A. Radosevich (ed.), *Head & Neck Cancer: Current Perspectives, Advances, and Challenges*, DOI 10.1007/978-94-007-5827-8_26,

**Abstract** This chapter summarizes current knowledge related to quality of life in general and application of this knowledge to the head and neck cancer patient. People diagnosed with head and neck cancer often experience a wide range of symptoms and substantial impairment in basic human functions, such as difficulty eating, speaking, and breathing. These problems may occur as a result of the cancer and/or treatment. While many of these problems are associated with treatment and are time-limited, others may be long-lasting and irreversible. Information related to quality of life is essential for understanding the full impact of head and neck cancer and how people's lives change as a result. How to best assess quality of life in people with head and neck cancer, however, remains controversial given the lack of a gold standard for quality of life assessment. This chapter will address: (1) definitions and conceptual issues associated with quality of life; (2) factors influencing quality of life measurement, such as choosing an appropriate instrument; (3) common quality of life issues in people with head and neck cancer; (4) using quality of life information in research; and (5) using quality of life information in clinical practice.

**Keywords** Quality of life • Symptoms • Functional status • Functional ability

## Abbreviations

| | |
|---|---|
| CARES | Cancer Rehabilitation Evaluation System |
| COH QOL-CA | City of Hope Quality of Life Scale for Cancer |
| EORTC QLQ C30 | European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 |
| EORTC QLQ-H&N35 | European Organization for Research and Treatment of Cancer Quality of Life Questionnaire – Head and Neck |
| FACT-G | Functional Assessment of Cancer Therapy – General |
| FACT-HN | Functional Assessment of Cancer Therapy – Head and Neck |
| FLIC | Functional Living Index |
| HNRQ | Head and Neck Radiotherapy Questionnaire |
| HNQOL | University of Michigan Head and Neck Quality of Life instrument |
| LORQv3 | Liverpool Oral Rehabilitation Questionnaire (version 3) |
| MOS SF-36 | Medical Outcomes Survey-Short Form 36 |

| | |
|---|---|
| QLI | Quality of Life Index |
| SIP | Sickness Impact Profile |
| SLDS | Satisfaction with Life Domain Scale |
| UW-QOL | University of Washington Quality of Life Instruments |
| WHOQOL-100 | World Health Organization Quality of Life Questionnaire – 100 |
| WHOQOL-BREF | World Health Organization Quality of Life Questionnaire – 26 Items brief questionnaire |

## 26.1 Introduction

Head and neck cancer and the resulting treatment frequently results in highly distressing symptoms along with significant impairments in basic functions, such as eating, speaking, and breathing. These devastating changes in physical functioning influence all aspects of a patient's life. It is for this reason that quality of life assessment and evaluation in people with head and neck cancer is so meaningful. Although length of survival and disease free intervals are widely accepted as primary outcomes for head and neck cancer treatment, quality of life information provides patients/families and health care providers with important supplementary information to guide treatment decisions. Furthermore, understanding quality of life issues across the head and neck cancer trajectory from diagnosis and treatment through palliation/end-of-life or long-term survivorship is essential for providing quality cancer care. Quality of life information from people with head and neck cancer informs patients/families, health care providers and society how well one lives, not just how long one lives.

## 26.2 Defining Quality of Life

While everyone agrees that evaluating quality of life in people with head and neck cancer is essential for providing quality cancer care, how to best do this remains a question. Multiple definitions of quality of life have been published in the health care literature, although no one definition is universally accepted. Table 26.1 lists examples of quality of life definitions found in the cancer literature. One of the most frequently cited defines quality of life as "a state of well being that is a composite of two components: (1) the ability to perform everyday activities that reflect physical, psychological, and social well being and (2) patient satisfaction with levels of functioning and the control of disease and/or treatment-related symptoms" [1]. Importantly, this definition reflects two areas of theoretical agreement among quality of life experts [2]. First, the individualistic perspective is a fundamental component. This means that the individual is the most suitable judge of his/her own quality of life. Second, quality of life is a multi-dimensional concept that encompasses all aspects of life.

**Table 26.1** Quality of life definitions found in the cancer literature

| Author | Definitions (direct quotes) |
|---|---|
| Andrykowski et al. [3] | A multidimensional construct, incorporating information regarding individuals' current physical symptoms and general health perceptions as well as information regarding physical, emotional, occupational and interpersonal functioning |
| Belec [4] | The degree of satisfaction with present life circumstances as perceived by the individual |
| Cella and Tulsky [5] | Patient's appraisal of and satisfaction with their current level of functioning as compared to what they perceive to be possible or ideal |
| Ferrans and Powers [6] | An individual's perceptions of well-being that stems from satisfaction or dissatisfaction with dimensions of life that are important to the individual |
| Gaston-Johansson and Foxall [7] | The degree of satisfaction with present life circumstances as perceived by the individual. QOL is influenced by present as well as past and future experiences |
| Gotay et al. [1] | A state of well-being which is a composite of two components: the ability to perform everyday activities which reflect physical, psychological and social well-being, and patient satisfaction with levels of functioning and the control of disease and/or treatment related symptoms |
| Grant et al. [8] | A personal statement of the positivity or negativity of attributes that characterizes one's life |
| Molassiotis et al. [9] | A concept referring to the individual's own perceptions about the degree of satisfaction and ability to perform in life |
| Testa and Simonson [10] | The physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations, and perceptions |
| World Health Organization Quality of Life Group [11] | An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships and their relationships to salient features of the environment |

## 26.3 Conceptualizations of Quality of Life in Health Care

While most quality of life definitions in the cancer literature address the individualistic perspective and multidimensional nature of the concept, the focus or overall conceptualization of quality of life may differ substantially. The importance of understanding the underlying conceptualization of quality of life cannot be overemphasized as evaluating quality of life from different conceptualizations may lead to dissimilar and even conflicting results. For example, people with head and neck cancer may experience substantial negative changes in functional ability, and yet, report little to no change in overall life satisfaction. These conflicting results often lead to confusion; however, they may be explained by the different conceptualizations of quality of life found in the cancer literature. Understanding the different conceptualizations is vital when considering quality of life issues and outcomes in people with head and neck cancer. Ferrans identified five of the most common conceptualizations of quality of life found in the health care literature: (1) the ability to lead a normal life; (2) the ability to lead a socially useful life; (3) the ability to fulfill personal goals; (4) feeling happy about one's life; and, (5) feeling satisfied with one's life [12]. These five conceptualizations are summarized in Table 26.2. Each conceptualization will be briefly discussed along with implications for head and neck cancer.

### *26.3.1 The Ability to Lead a Normal Life*

The first conceptualization refers to the person's ability to lead a normal life. The closer one gets to the standard of normal, the better the QOL. One of the difficulties associated with normal life conceptualizations of quality of life is deciding upon a standard of normal. In caring for people with cancer, one standard of normal is perfect health. The closer one gets to perfect health, the better the quality of life. Another approach is to compare individuals to a reference group of healthy individuals or a typical individual of a comparable age and/or disease. Quality of life is better when one can function at a level similar to a healthy individual or a typical individual of a comparable age and/or disease. Using the individual as their own standard of normalcy is a third approach. This approach delineates changes in health status before, during, and after an illness in terms of symptoms, level of functioning, ability to return to work, etc. In this context, quality of life is better when comparisons among various time points, such as before, during, and/or after an illness, reveal few, if any, differences.

Assessing quality of life from a normal life conceptualization is a very useful approach for characterizing quality of life changes in the head and neck cancer population. Understanding deviations from perfect health are helpful when trying to determine the impact of health and neck cancer and its treatment on various aspects of life. One problem with making comparisons to perfect health is that perfect health as a standard is rarely attained by anyone, let alone someone with head and neck cancer. This makes the comparisons unrealistic as the goal of perfect health may be impossible to achieve, particularly for someone with advanced disease. More commonly, comparisons to a typical individual of a comparable age or a reference group with the same disease are considered the standard of normal. This type of comparison provides a more realistic picture of the impact on head and neck cancer on quality of life. One disadvantage to this approach is that the reference group may or may not view health in the same way. Using the head and neck cancer patient as their own standard of normal alleviates the difficulties associated with using a reference group and, at the same time, provides the needed information regarding the impact of head and neck cancer treatment on quality of life. Determining "pre-illness" criteria or expecting the patient to remember "pre-illness" health may prove difficult at least for some patients. This is particularly problematic when treatment extends over time, and the individual adapts to a new "normal." This adaptation is called "response shift."

**Table 26.2** Conceptualizations of quality of life in the health care literature

| Conceptualization |
|---|
| The ability to lead a normal life |
| Refers to the person's ability to lead a "normal" life |
| Primarily addresses deviations from normal functioning |
| Closer one gets to the standard of normal, the better the quality of life |
| Underlying conceptualization of many quality of life instruments used in the head and neck cancer population |
| Standard of normal varies and/or not explicitly stated (e.g., perfect health, comparable health to a defined reference group, pre-illness health) |
| The ability to lead a socially useful life |
| Refer to the patient's ability to lead a socially useful life |
| Focuses on the ability of the person to make contributions to society through gainful employment or fulfillment of commonly defined social such as worker, mother, teacher, etc. |
| Quality of life is better when the individual is able to fulfill socially useful roles |
| Conceptualization most often used by policy makers |
| Objective measures of quality of life typically fall in this category (e.g. return to work, economic impact, etc.) |
| The ability to fulfill personal goals |
| Focus is on achievement of personal goals. Relates to the congruence between desired and achieved goals |
| The person feels satisfied or happy when personal goals which are important to him/her are achieved |
| May not be culturally relevant for all groups |
| Goals may change over time resulting in ability to accurately assess achievement |
| Feeling happy about one's life |
| Focus is on the range of affective states from depression to euphoria |
| Relates to the balance between positive and negative feeling states |
| Those who are happier have a better quality of life than those who are unhappy |
| Affective states are frequently transitory and quick to fluctuate |
| Feeling satisfied about one's life |
| Refers to a cognitive assessment of life's experiences based on comparisons between desired and actual conditions of life |
| Those who have a better QOL are the ones who are most satisfied with their lives |
| Considered the most appropriate conceptualization of quality of life |
| Comprehensive approach to quality of life assessment in head and neck cancer patients would be measure quality of life that reflects the life satisfaction and ability to lead a normal life |
| Life satisfaction not likely to change as a result of life's minor inconveniences |
| Areas of life that are most important to individual may change over time and/or as a result of life-limiting or life-threatening illness |

### *26.3.2 The Ability to Lead a Socially Useful Life*

The ability to lead a socially useful life is another conceptualization of quality of life. This conceptualization refers to the patient's ability to lead a socially useful life. It most commonly focuses on the ability of the person to make contributions to society through gainful employment or fulfillment of commonly defined social roles such as worker, mother, teacher, etc. Under this conceptualization, quality of life is better when the individual is able to fulfill socially useful roles. This conceptualization is more frequently used by policy makers because of their propensity to consider economic conditions of the populace. Objective measures of quality of life, such as employment status, hours worked per week, patients' perception of their ability to work, financial status, and dependence on state financial aid, are frequently used to reflect the social utility conceptualization.

There are advantages and disadvantages to using the social utility conceptualization in the head and neck cancer population. For policy makers, the ability to contribute to society during or following head and neck cancer treatment may be of particular interest. Depending on the stage of disease, people undergoing treatment for head and neck cancer may be out of work for an extended period or permanently. In addition, treating head and neck cancer can be a very costly endeavor, particularly if multimodal therapy is required. As health care dollars become scarce, policy makers may rely on information related to socially useful functions, such as potential for future employment, when considering quality of life outcomes to inform decisions regarding health care resource allocation.

There are a number of difficulties associated with using social utility definitions of quality of life in the head and neck cancer population, particularly if this is being used for allocation of health care resources. As in the normal life conceptualization, there are a wide range of meanings in terms of socially useful behavior. The difficulty is determining whose criteria of social usefulness to use; society's, the family's, the clinician's, or the head and neck cancer patient's. Moreover, social utility measurements of quality of life do not take into account the patient's perspective, violating one of the central tenets of quality of life assessment. Assessment of returning to work used alone will not adequately capture quality of life in the head and neck cancer population as the desire or ability to return to work may be influenced by a number of other variables, such as the need for frequent follow-up care with medical professionals. Being able to return to work does not necessarily result in good quality of life. Likewise, not being able to return to work does not necessarily result in poor quality of life.

### *26.3.3 The Ability to Fulfill Personal Goals*

The third conceptualization of quality of life focuses on achievement of personal goals. It relates to the congruence between desired and achieved goals. An individual feels satisfied or happy when personal goals which are important to him/her are achieved. The person feels dissatisfaction or unhappiness when he/she fails to achieve desired goals. Fulfillment of personal goals is consistent with an individualist perspective in that it requires input from the individual. Terms like "be all that you can be" reflect its fit with American ideals of individual achievement and advancement. A major strength of this conceptualization when used with head and neck cancer patients is that it requires a personal evaluation of the life's experience in terms of goal achievement. The head and neck cancer patient is asked to rate the degree to which he/she is able to accomplish their goals. Those who are better able to accomplish goals have a better quality of life. In terms of reliability and validity, however, it is often difficult to develop instruments that adequately measure concepts, such as quality of life, which require self-reported, subjective indicators. For some, these are considered “soft” outcomes because of the relative lack of precise measurement when compared to other objective measures typically included in cancer clinical trials, such as tumor response. Furthermore, goal achievement may not be meaningful to all individuals undergoing treatment for head and neck cancer. This inability to capture quality of life in all people from an achievement of personal goals perspective is considered a weakness of this conceptualization.

### *26.3.4 Feeling Happy About One’s Life*

Feelings of happiness represent the fourth conceptualization of quality of life. This conceptualization focuses on the range of affective states from depression to euphoria and represents the balance between positive and negative feeling states. Those who are happier have a better quality of life than those who are unhappy. Like achievement of personal goals, measurement of quality of life from a happiness perspective requires input from the individual. In Western culture, however, happiness implies a more transitory feeling; happy one moment and sad the next. As a result, quality of life from a happiness perspective may be unduly influenced by episodic events that occur throughout the course of a typical day, such as missing a scheduled appointment. Exposure to this type of event may make a head and neck cancer patient feel unhappy but it generally will not change one’s overall evaluation of the quality of their life. While the benefits of happiness for head and neck cancer patients cannot be downplayed, evaluating quality of life from a happiness perspective is more likely to capture fleeting, affective states than overall quality of life.

### *26.3.5 Feeling Satisfied About One’s Life*

Satisfaction, the final conceptualization of quality of life, is closely related to happiness although they are not synonymous. While happiness implies a short-term affective state, satisfaction with life implies a long-term cognitive evaluation. Ferrans advanced the notion that quality of life is the most appropriate conceptualization for quality of life as life satisfaction requires a long-term, personal, cognitive evaluation regarding life’s conditions. When viewed from this perspective, life satisfaction is conceptualized as an assessment of life’s experiences based on comparisons between desired and actual conditions of life. Those who have a better quality of life are the ones who are most satisfied with their lives. An example of the differences between the happiness and life satisfaction conceptualization may be best illustrated with an example. If a head and neck cancer patient is asked, how happy are you with …? He or she most likely will respond with information related to how they are currently feeling? They may have had a particularly trying day and they may be very "unhappy" about it. From this data, knowledge regarding an individual's current affective state is obtained. On the other hand, if a head and neck cancer patient is asked, how satisfied are you with …? They are more likely to make a cognitive judgment going beyond the here and now to consider their total life experience when answering this question. Coupling life satisfaction with relative importance of various aspects of life further enhances measurement of quality of life. Ferrans added the notion of relative importance to her definition of quality of life so that the person's sense of well-being stems from satisfaction or dissatisfaction with the areas of life that are important to him/her [6].

There are similar strengths and weaknesses in terms of using the happiness and satisfaction conceptualizations for assessment and evaluation of quality of life in people with head and neck cancer. Measurement of happiness and satisfaction requires input from the individual, thus, both are consistent with an individualist perspective. While this is a recognized strength, it may also represent a weakness as reliance on self-reported quality of life information makes it more difficult to establish reliability and validity compared to using data obtained from objective measures. Even so, appreciation for the full impact of head and neck cancer on the individual's quality of life can only be obtained with direct input from the individual necessitating the use of self-report measures.

### *26.3.6 Summary of Quality of Life Conceptualizations*

Choosing the appropriate conceptualization for use in use in the head and neck cancer population is dependent upon the reason for the evaluation. In general, all of the conceptualizations provide very useful although different, quality of life information. The life satisfaction conceptualization, however, is the most appropriate to use when evaluating quality of life with head and neck patients as it captures the individual's cognitive evaluation of life's experience. Measurement of quality of life from a life satisfaction perspective promotes the recognition of uniqueness and diversity among individuals (regardless of culture) in terms of perception of quality of life. The satisfaction conceptualization recognizes that quality of life is a dynamic rather than a static concept. Because life's goals are frequently altered following the diagnosis and treatment for head and neck cancer, assessing and evaluating quality of life from a satisfaction conceptualization allows one to capture the patient's changing values. In many situations, however, there is a strong need to determine life satisfaction as well as deviations from normal functioning. In these cases, assessing quality of life from the life satisfaction and ability to lead a normal life conceptualizations provide the most comprehensive approach.

## 26.4 Conceptual Frameworks

As the concept of quality of life has evolved over the past 40 years, the need for theoretical frameworks to guide the assessment and evaluation of quality of life in research and clinical practice has become increasingly important. Two frequently used models to guide quality of life research and clinical practice in people with cancer include Ferrell and colleagues City of Hope Model [13] and Ferrans and Powers Quality of Life Model [14]. These models define the domains of quality of life that are important for all individuals, including people with cancer, and address specific areas of life that should be addressed when collecting information regarding quality of life. The models are remarkably similar. Both view quality of life from an individualistic perspective and as a multidimensional construct. The Ferrans Model consists of four domains; health and functioning, socioeconomic, psychological/spiritual, and family domain. The Ferrell Model consists of physical well-being and symptoms, psychological well-being, social well-being and spiritual well-being. The aspects of life that are addressed by each model are listed in Table 26.3. The fact that these models were developed simultaneously and independently of one another provides substantial support for the theoretical underpinnings of both models.

When reviewing the literature for guidance on quality of life assessment and evaluation, it becomes readily apparent that a wide range of variables have been used to represent quality of life, particularly in individuals diagnosed with a life-changing disease like cancer. The range of variables includes symptoms, changes in functional status, life satisfaction, etc. For the novice clinician and researcher, this lack of a gold standard for assessing quality of life can be confusing and overwhelming. The Revised Wilson and Cleary Conceptual Model of Patient Outcomes provides a conceptual framework for approaching quality of life assessment [15, 16]. This model is particularly useful for clarifying various health outcomes that have been used to measure quality of life, including those associated with head and neck cancer. This model examines the relationship between constructs, such as symptoms, functional status, and quality of life, and provides conceptual clarity for assessing and evaluating a range of variables that are commonly included under the umbrella term, quality of life.

The Wilson and Cleary Model proposes the dominant, causal relationships between traditional, biological and physiological variables to health-related quality of life [15, 16]. The five types of health outcomes include (a) biological function; (b) symptoms; (c) functional status; (d) general health perceptions; and e) quality of life. While an extensive review of all patient health outcomes associated with head and neck cancer is beyond the scope of this chapter, providing examples within each of the Wilson and Cleary categories is desirable to further illustrate the usefulness of the model. Clarity about how each aspect of the model relates to quality of life in the head and neck cancer population is needed to advance science.

*Outcomes measures of biological function* is a term that refers to the assessment of cell function, organ function, and organ system function. Examples of biological

**Table 26.3** Comparison of Ferrell and Colleagues City of Hope Model [13] and Ferrans and Powers Quality of Life Model [14]

| Ferrell model (Multiple adaptations available) | Ferrans model |
|---|---|
| Physical well-being and associated symptom | Health and functioning domain |
| Functional ability | Health |
| Strength/fatigue | Health care |
| Sleep and rest | Pain |
| Nausea | Energy (fatigue) |
| Appetite | Ability to take care of yourself without help |
| Constipation | Control over life |
| | Chances for living as long as you would like |
| | Sex life |
| | Ability to take care of family responsibilities |
| | Usefulness to others |
| | Worries |
| | Things for fun |
| | Chances for a happy future |
| Psychological well-being | Psychological/spiritual subscale |
| Anxiety | Peace of mind |
| Depression | Faith in God |
| Enjoyment/leisure | Achievement of personal goals |
| Pain distress | Happiness in general |
| Happiness | Life satisfaction in general |
| Fear | Personal appearance |
| Cognition/attention | Self |
| Social concerns | Social and economic subscale |
| Roles and relationships | Friends |
| Affection/sexual function | Emotional support from people other than your family |
| Appearance | Neighborhood |
| | Home |
| | Job/Not having a job |
| | Education |
| | Financial needs |
| Spiritual well-being | Family subscale |
| Suffering | Family health |
| Meaning of pain | Children |
| Religiosity | Family happiness |
| | Spouse, lover, or partner |
| | Emotional support from family |

function that may be assessed in people with head and neck cancer include blood pressure, heart rate, and liver function tests. *Outcome measures of symptoms* refers to the subjective experience and cognitive evaluation of the individual as a whole to changes in biological function. Fatigue, pain, and dysphagia are examples of symptoms commonly assessed to evaluate the impact of head and neck cancer and associated treatment. *Outcome measures of functional status* assess the individual's ability to objectively perform functional tasks. One primary goal of head and neck cancer therapy is to preserve as much function as possible of nearby nerves, organs, and tissues; therefore, including tests to assess functional status is of prime importance. Examples of functional outcomes include the ability to speak or swallow. *General health perceptions* refer to the individual's evaluation of functional ability or health status. Examples that may be associated with head and neck cancer include perceived ability to eat, swallow and speak clearly. *Overall quality of life outcomes* refers to the individual's cognitive judgment of well being and life satisfaction. Life satisfaction or satisfaction with health and functioning are examples of overall quality of life outcomes that can be measured in conjunction with an exercise program.

These patient health outcomes range along a continuum of increasing biological, social, and psychological complexity. The biological and physiological outcomes anchor one end of the continuum with the more complex and integrated measures of patient outcomes, such as quality of life, at the other end. As one moves along the continuum, there are an increasing number of individual and environmental contributory influences on patient outcomes that may not be under the control of the health care provider. This model is particularly useful for researchers and clinicians working with head and cancer patients as it provides guidance for examining and predicting relationships among symptoms, functional status and quality of life. Identifying predictors may help patients and providers with health care decisions. If the ultimate outcome of quality cancer care is improvement in quality of life, then understanding these relationships is essential for developing effective interventions.

## 26.5 Qualify of Life: Relationships Between Symptoms, Functioning, and Life Satisfaction

The relationships among symptomatology, functioning, health status perceptions, and life satisfaction are complex, with individual and environmental factors influencing expectations. People with head and neck cancer are told by their health care providers to expect changes in their health status as a result of the disease itself or treatment of the disease. A timeframe to expect anticipated side effects is generally provided. For example, patients receiving treatment for head and neck cancer are typically informed to expect difficulty with swallowing when receiving radiation to the oropharyngeal area. Problems with quality of life, however, may arise when reality and expectations differ substantially. Consider the hypothetical case of a head and neck cancer patient with dysphasia. During the course of radiation and immediately following treatment, this patient expects to have difficulty swallowing, thus, quality of life (in terms of life satisfaction) may not be impacted as this is an expected side effect. If the patient recovers faster than he or she expected, improvements in life satisfaction may follow. If slower, then the patient may report declines in life satisfaction. Thus, a lag time may exist between experiencing actual changes in health status and assimilating these changes into an appraisal of one's quality of life. Recent literature in other cancer populations support this notion and the same may be true for people with head and neck cancer [17].

## 26.6 Quality of Life Measurement

### *26.6.1 Unidimensional Versus Multidimensional*

Ideally, the measurement of quality of life should reflect the underlying conceptualization. Early attempts to measure quality of life, however, were often atheoretical and frequently consisted of instruments that measured only one aspect or domain of quality of life. These are referred to as unidimensional quality of life instruments. Examples of unidimensional quality of life instruments used to assess quality of life in head and neck cancer include the Karnofsky's Performance Index and the Kubrod Performance Scale. These two instruments primarily measure functional status or ability to perform activities of daily living. Over the past three to four decades, however, significant progress in QOL research has been made. Quality of life experts now agree that quality of life is a multidimensional concept consisting of at least the physical, psychological, and social domains. Thus, in order to ensure comprehensive assessment of quality of life, the physical, psychological, and social domains must be measured. Sole reliance on a unidimensional instrument to measure quality of life is considered unacceptable. Furthermore, studies that exclusively rely on a unidimensional instrument to measure QOL are deemed inadequate as the instrument may fail to detect QOL changes in other domains that are of central importance to the individual's quality of life appraisal.

The multidimensional nature of quality of life is well supported in the head and neck cancer literature. The most frequently identified domains include the physical/functional, psychological/emotional, social, economical, and family domains. Measuring the multiple domains associated with quality of life allows the clinicians and researchers to pinpoint problematic areas as well as identify areas of strength for the patient. Researcher and clinicians may use a battery of instruments to measure the various quality of life domains or a single instrument that assesses various domains. More commonly, studies use single quality of life instruments that contain items reflecting the various domains or aspects of life. Examples of single, multidimensional instruments frequently used in the head and neck cancer literature include the FACT [18], EORTC-QLQ C-30 [19], and the SF 36 [20]. A listing of single instruments and the domains that are measured are included in Table 26.4. It should be noted, however, that these instruments reflect different conceptualizations of QOL, thereby producing different results even when used in the same group of patients in the same study.

One troublesome area in quality of life research relates to determining the relative importance of specific domains to the overall quality of life appraisal. Are all domains equally important when appraising QOL? It appears, at least, for some people that the importance of each domain will vary from individual to individual. Furthermore, the domains may vary in importance in one individual at different points in time. How to rectify weighting of the domains is a recognized problem in quality of life research. One approach to resolve this issue is to have the individual weight the importance of the various domains or individual aspects of life. Although

**Table 26.4** Examples of quality of life instruments

| Instrument | Domains measured | Mode of administration |
|---|---|---|
| Generic measures | | |
| Cantril's Self-Anchoring Scale [21] (1 item) | Global uni-dimensional | Self-administered |
| Karnosky Performance Scale [22] (1 item) | Functional status | Observer rated |
| MOS SF-36 [20] | Physical functioning<br>Role functioning<br>Bodily pain<br>General health<br>Vitality<br>Social functioning<br>Role emotional<br>Mental health | Computer-administered<br>Electronic version<br>IVR-version<br>Interviewer-administered<br>Self-administered<br>Telephone-administered |
| SLDS [23] (18 items) | 18 items related to relationships, health, appearance, leisure time, ability to eat, physical strength, and BMT | Self-administered |
| SIP [24] (136 items) | Physical dimension<br>Psychosocial dimension<br>Sleep and rest<br>Taking nutrition<br>Usual daily work<br>Household management<br>Leisure<br>Recreation | Interviewer-administered<br>Self-administered |
| WHOQOL-100 [25] (100 items) | Physical health<br>Psychological health<br>Level of independence<br>Social relations<br>Environment<br>Spirituality/religion/personal beliefs | Self-administered |
| WHOQOL-BREF [26] (26 items) | Physical health<br>Psychological<br>Social relationships<br>Environment | |
| Zubrod Performance Scale [27] (1 item) | Functional status | Observer rated |
| Cancer-specific measures | | |
| CARES [28] (91–132 items) | Global HQOL scale<br>Five summary scales<br>Physical<br>Psychosocial<br>Marital<br>Medical interaction | Self-administered |

(continued)

**Table 26.4** (continued)

| Instrument | Domains measured | Mode of administration |
|---|---|---|
| | Sexual<br>31 Subscales measuring everyday functioning | |
| COH, QOL-CA [29] (28–30 items; different versions) | Physical well-being and symptoms<br>Psychological well-being<br>Social well-being<br>Spiritual well-being<br>Single item global measure of QOL | Self-administered |
| EORTC QLQ C-30 [19] (30 items) | Five functional scales<br>Physical functioning<br>Role functioning<br>Emotional functioning<br>Cognitive functioning<br>Social functioning<br>Multi-item symptom scales<br>Fatigue<br>Pain<br>Nausea and vomiting<br>Global quality of life/health status scale<br>Six single item questions | Self-administered<br>Telephone interview |
| FACT-G [18] (28 items) | Physical well-being<br>Function well-being<br>Social/Family well-being<br>Emotional well-being<br>Satisfaction with doctor/patient relationship | Interviewer-administered<br>Self-administered |
| FLIC [30] (22 items) | Current health<br>Role<br>Sociability<br>Emotional<br>Pain<br>Nausea<br>Hardship due to cancer | Self-administered |
| QLI [6] (35 items related to satisfaction) (35 corresponding items related to importance) | Health and functioning<br>Psychological/spiritual<br>Social and economic<br>Family | Self-administered |
| Head and neck cancer-specific | | |
| EORTC QLQ-H&N35 [31] (35 items) | Pain<br>Swallowing<br>Senses problems<br>Speech problems | Self-administered |

(continued)

**Table 26.4** (continued)

| Instrument | Domains measured | Mode of administration |
|---|---|---|
| | Trouble with social eating<br>Trouble with social contact<br>Less sexuality<br>10 single item questions | |
| FACT-HN [32] (11 items) | Head and neck specific module that can used alone (FHNSI) or in conjunction with FACT-G | Interviewer-administered<br>Self-administered |
| UW-QOL [33] (15 items) | 12 items specific to head and neck<br>3 general questions | Self-administered |
| HNQOQL [34] (20 items) | Pain<br>Communication<br>Eating<br>Emotion | Self-administered |
| HNRQ [35] (22 items) | Oral cavity<br>Throat<br>Skin<br>Digestive function<br>Energy<br>Psychosocial function | Self-administered |
| LORQv3 [36] (25 items) | Oral function<br>Dentation | Self-administered |

this would appear to solve the problem, weighting the importance of the various domains is a cognitively difficult task. In our work, many individuals find this difficult to do and weight most if not all items equally (unpublished data).

### *26.6.2 Global Measures*

Global measures of quality of life have been used in the head and neck cancer literature. Global ratings of quality of life refer to those measures that result in one score representing overall quality of life. An example of a single item, global measure of quality of life is Cantril's Self-Anchoring Scale [21]. This particular scale asks respondents to rate their quality of life based on a 10 point scale with the endpoints anchored by the best and worst quality of life they can imagine. The advantage to using a global measure is that it takes into account the patient's values. The interactive nature of the various quality of life domains is implicitly understood. The disadvantage to using a global measure relates to its specificity. For clinicians and researchers who plan to test interventions to improve quality of life, it will be important to determine which dimensions of quality of life stay the same, improve, or deteriorate over the course of treatment for head and neck cancer. For this reason, a global measure, used alone, may not be the most suitable approach.

### 26.6.3 Generic Measures

Generic measures of quality of life attempt to provide a comprehensive measure of all quality of life domains. These instruments have commonly been developed to measure quality of life in the general population. They have also been used in a variety of illness groups including head and neck cancer patients. The SF-36 is an example of a quality of life instrument developed for use in the general population that has been used in head and neck cancer patients. The advantages to using a generic instrument are that it allows one to make quality of life comparisons with the general population as well as across illness groups. This is particularly helpful when trying to evaluate the impact of a cancer therapy. The disadvantages of using a generic tool relates to its sensitivity. Because such a broad approach to measuring quality of life is required, the instrument may not be sensitive enough to detect specific changes in quality of life that are directly impacted by head and neck cancer or the various treatments.

### 26.6.4 Cancer-Specific Measures

In the head and neck cancer literature, many studies evaluating quality of life rely on cancer-specific quality of life instruments. These instruments generally emphasize quality of life issues that are most pertinent to the diagnosis of cancer, treatment of the malignancy, and potential side effects. Most of these instruments contain items related to the physical, psychological, and social domains, at a minimum. Additional domains, such as the spiritual domain, are tool specific. Because of the focus on cancer, these tools tend to be more sensitive to treatment effects and changes in particular conditions such as fatigue and dysphagia. On the other hand, use of a cancer-specific tool may be so specific that it misses critical aspects of the patient's life, not associated with cancer and/or treatment, that impact quality of life perception. The recommended approach, in terms of choosing a generic versus cancer specific tool in the head and neck cancer population, would depend on the reason for the quality of life assessment, whether for research or clinical practice. In general, the safest approach would be to choose an instrument that is generic enough to cover broad aspects of the patient's life and specific enough to detect changes related to the head and neck cancer and subsequent treatment.

### 26.6.5 Head and Neck Cancer-Specific Measures

Like most cancers, the clinical manifestations of the malignancy and associated treatment side effects depend on the anatomical location of the disease. Likewise, head and neck cancer-specific quality of life instruments target the unique concerns of head and neck cancer patient that are likely to be affected by the cancer and/or treatment. For instance, difficulty with swallowing and chewing, are problems that are more likely to occur in someone with head and neck cancer as opposed to an individual with colon cancer. Head and neck cancer-specific instruments will primarily contain items that are unique to head and neck cancer. A number of well-established head and neck cancer-specific quality of life instruments exist, such as the Functional Assessment of Cancer Therapy – Head and Neck (FACT – H & N), and the University of Michigan Head and Neck Quality of Life Questionnaire. The major advantage to using a site specific instrument is the ability to determine the nature and severity of commonly occurring health issues that are specific to head and neck cancer. These issues are unlikely to be address by a more generic instrument. This disadvantage to only using a head and neck cancer-specific instrument is that comparisons to the general public or even other cancer populations will not be possible. Depending on the reason for the quality of life assessment, one approach to ensure a comprehensive assessment would be to include a generic instrument in order to make comparisons to the general public and a head and neck cancer-specific instrument so that the unique concerns of head and neck cancer patients would be adequately captured.

### *26.6.6 Proxy Measures*

There may be times when the head and neck cancer patient is unable to provide quality of life information, yet, judgments regarding the head and neck cancer patient's quality of life are needed. In these cases, information regarding the head and neck cancer patient's quality of life may be sought from other closely related individuals, such as the spouse, treating physician, etc. These "proxy measures" must be used with extreme caution. When considering the use of proxy measures, the question becomes whose values are important to the quality of life evaluation? Is it the patient's, the physician's, or is it the spouse's values that are important? Different people value different things. What is important to one person may or may not be important to another. As the individual is the only appropriate judge of his/her own quality of life, there may be wide discrepancies when a proxy measure is used. Some studies have documented that observers frequently assign lower scores to the patients' quality of life than the patients did themselves. These finding do not mean that the proxy measures are not important or valid [37, 38]. Rather, they are important because they represent the proxy's point of view in terms of the head and neck cancer patient's quality of life. If it is the head and neck cancer patient's point of view that is important, then it is the individual's perspective which should be sought. Unfortunately, there may be times when this is not possible and a proxy assessment of quality of life is the only option. In a study of 116 recurrence free patients with laryngeal, pharyngeal, and oral cavity cancer following radiotherapy or surgical treatment, an observer rater toxicity scale (DAHANCA toxicity score) effectively assessed objective treatment-induced toxicity but severely underestimated patient complaints [39].

### *26.6.7 Recall or Observation Period*

Another important factor to consider when assessing quality of life is the recall or observation period. The recall or observation period should be driven by the purpose of the quality of life assessment in head and neck cancer patients. Treating healthcare providers interested in determining changes in quality of life following an aggressive chemotherapy protocol may require more frequent assessments with shorter recall periods to capture treatment effects. Conversely, a researcher interested in long-term effects of head and neck cancer treatment may opt for less frequent assessment with longer recall periods. While there is no gold standard for recall or observation periods associated with assessing quality of life in people with head and neck cancer, clinicians and researchers must carefully consider the recall period so that the chances of detecting quality of life changes are enhanced.

Retrospective assessments of quality of life are the norm; yet, there are a number of issues associated with recall bias that should be considered. Recall bias occurs when people are asked to recall events or experiences that have occurred in the past. The memory of the event or experience is distorted due to cognitive restructuring [40]. In the head and neck population, cognitive restructuring potentially impacts the ability to provide accurate quality of life information. Multiple factors influence the reconstruction of memories, such as length of time since the event/experience, whether the event/experience was anticipated, and novelty of the event/experience [41, 42]. For example, a head and neck cancer patient who has been relatively pain-free but experiences one short-lived episode of extreme pain is likely to be more heavily influenced by the acute, short-lived episode of pain rather than the relatively pain-free periods. This is particularly true if the short-lived painful episode occurs immediately prior to completing a self-report questionnaire. Individuals simply do not add up the number of painful episodes, incorporate intensity ratings, and then average them over time to produce a summary of the experiences of the past week.

More recently, greater attention has been paid to collecting real-time assessments of patient reported outcomes, such as symptoms and quality of life, to reduce the problems associated with recall biases. Ecological momentary assessment is a methodological approach for capturing repeated real-time data in a naturalistic environment. Because people respond in real time, the problems with recall biases and summarization processes are minimized [43]. The three components of ecological momentary assessment (real-time data collection) include (1) studying people in their natural environment, (2) collecting information regarding the person's immediate or near immediate state, and (3) sampling the phenomena under study multiple times throughout the course of the day. In recent years, advances have been made in methods for collecting information on patient-reported outcomes, such as quality of life. Several studies have demonstrated the feasibility of using computerized programs for the self-report of symptoms during scheduled clinic visits or at home, providing support for this approach [44–46].

### *26.6.8 Psychometric Properties of Quality of Life Instruments*

As quality of life is self-reported construct, there are a number of factors, specifically related to the instrument itself, that impact the interpretability of the results. These psychometric properties are considered essential elements for determining the quality of an instrument. Reliability and validity are generally considered the most important properties for self-reported data. Reliability refers to whether an instrument consistently measures a construct, such as quality of life, over time, as well as across individuals, groups, and/or situations. Validity refers to whether an instrument measures what it is intended to measure. The vast majority of frequently used quality of life instruments employed with the head and neck cancer population are well-established in terms of reliability and validity. For clinicians and researchers developing a new instrument to collect this data, however, these properties must be determined prior to interpreting the results. The Patient Reported Outcome and Quality of Life Instruments (PROQOLID) contains information regarding 700+ quality of life instruments, including information regarding psychometric properties and available translations [47].

### *26.6.9 Determining the Appropriate Mode of Administration for Assessing Quality of Life*

The explosion in technology has broadened the approaches used to assess, collect, and report quality of life outcomes. These advances, such as smart phones, personal digital assistants (PDAs), interactive voice response (IVR) systems, computers and the Internet, have made it possible to collect data from head and neck cancer patients that previously may not have been accessible. Platforms for collecting QOL data now include (1) paper and pencil based instruments; (2) telephone-based; (3) computer-based; or, (4) web/Internet-based platforms [48]. The vast majority of quality of life instruments are paper and pencil based although more and more of these are being converted so that they can be administered via other platforms. Telephone-based technology uses computer applications to gather quality of life information through land-lines or cellular phones. Interactive Voice Response systems are one example of telephone-based technology that can be used to collect quality of life information. Computer-based technology collects quality of life data through computerized applications installed on stand-alone computer devices allowing the individual of interest to directly input their own quality of life information. This can occur in a variety of locations, such as the health care providers' office or a clinic examination room. Web/Internet-based technology collects QOL information directly from the person of interest through a web-based program accessed on an Internet-ready computerized device. This approach offers even wider accessibility as patients are able to input quality of life data from any location that has internet availability, such as the patient's own home or even via a smart telephone.

The various modes of administration (paper and pencil, telephone-based, computer-based, and web/internet-based) share several parallel benefits, such as the ability to choose a language and formatting options for the delivery of questions. The technology-based approaches offer some additional benefits that may be particularly attractive for use in people with head and neck cancer. For example, all of the technology-based approaches have the ability to send medical alerts to the health care providers if programmed to do so. This is particularly helpful if quality of life information is being collected for clinical purposes. A predetermined threshold for notification may be set by the health care providers. Head and neck cancer patients who cross the threshold are able to immediately notify the provider of adverse events and potentially initiate treatment for the problem earlier. For instance, the head and neck cancer patient may be experiencing severe pain. Notifying health care providers in real-time potentially accelerates access to treatment as opposed to waiting for a clinic visit. In addition, each technology-based category has several distinct advantages that are particularly helpful for assessing and evaluating quality of life information in head and neck cancer patients. Telephone services (either land-lines or cellular) have widespread availability making telephone-based technologies highly accessible to almost all people. For those head and neck cancer patients that have difficulty speaking, using the keypad to enter quality of life information further improves accessibility. Computerized devices are manufactured in a variety of shapes and sizes, making this category highly flexible for meeting the needs of broad categories of people. Quality of life outcomes in head and neck patients may be collected and stored on smart phones, tablets, PDA’s, or even wrist actigraph devices with subjective event markers. Accessibility of these computerized applications to collect quality of life data is further enhanced when applied to web/internet based approaches. Web/Internet based technology has the capacity to reach diverse populations in a variety of geographic locations. This is particularly helpful for collecting quality of life information from head and neck cancer patients who are engaged in research studies. In addition, computer- and internet-based technologies allow for audio as well as visual cues when collecting quality of life information which may be particularly helpful for head and neck cancer patients who experience functional deficits that impact their ability to hear or see. While these various modes of collecting quality of life information improve the ability to access this data, choosing the appropriate mode of administration primarily depends on the reason for collecting this information in the first place.

## 26.7 Common Quality of Life Issues in People with Head and Neck Cancer

Head and neck cancer is a relatively uncommon malignancy, yet, attracts a substantial amount of quality of life research interest due to the myriad of structural, functional, and cosmetic sequelae associated with the disease and/or treatment [49]. A recent search of PubMed using the search terms, “quality of life” and "head and neck cancer" revealed over 3,500 research articles. While significant progress related to understanding quality of life in head and neck cancer patients has been made, a number of issues impede progress and impair our understanding. Small sample sizes, including patients with diverse stages of head and neck cancer as well as disease sites in the same study, cross-sectional as opposed to prospective, longitudinal assessments of quality of life, and lack of a gold standard to measure quality of life hinder interpretation of quality of life findings in head and neck cancer. Even so, general statements regarding changes in quality of life following the diagnosis and treatment of head and neck cancer are possible although these may not be applicable to all patients, across all disease sites and stages. Specific information related to the effects of a particular type of head and neck cancer on quality of life requires an in-depth analysis of the current research findings. More importantly, the impact of head and neck cancer on quality of life is more closely associated with the stage and site of the disease [50]. For example, the effects of a stage 1 laryngeal cancer on quality of life may be substantially different than the effects of a stage 4 anterior floor of mouth cancer. The time immediately following diagnosis can be very stressful as people with head and neck cancer and their families speculate about the potential changes that the diagnosis will make on their lives. Providing specific information regarding expected changes in symptoms and functional status may reduce anxiety and ultimately improve patient satisfaction and overall quality of life [51].

### *26.7.1 Overall Quality of Life*

Like other cancers, a general trajectory of changes in quality of life can be expected following the diagnosis and treatment for head and neck cancer. Overall, quality of life can be expected to decline immediately following the initiation of cancer treatment, whether the treatment includes surgery, radiation therapy, or chemotherapy [49]. This decline is associated with increased symptoms and decreased functional status [52, 53]. Following completion of treatment, however, many symptoms associated with treatment should start to resolve, although not all symptoms will completely disappear and some may become worse [54]. For example, problems with teeth, dry mouth, and sticky saliva became worse over time, between diagnosis and 5 years after diagnosis, in one longitudinal study of people with pharyngeal cancer [55]. While patients with head and neck cancer should expect some improvements in functional status following completion of therapy as a result in improvements in symptoms, many patients face long-term functional problems [56]. Improvements in functional status will primarily depend on the cause of the problem, whether the problem is reversible or irreversible, and availability and implementation of rehabilitative interventions. Even with the expected increase in symptoms and decreases in functional status in the first year following diagnosis, many patients report improvements in quality of life as compared to baseline level 12 months following treatment [57–59]. Again, a word of caution is necessary as people with head and neck cancer may have been experiencing problems at the time of diagnosis so a return to baseline as measured at the time of diagnosis may not truly reflect a return to normal functioning [60]. Long-term, people with head and neck cancer may continue to experience problems for years following treatment, although this too will depend on the disease site and stage, treatment, and co-morbid conditions [61, 62].

### *26.7.2 Physical Domain*

Changes in health status and physical functioning in patients with head and neck cancer may result from the underlying cancer or from the subsequent treatment with surgery, radiation, chemotherapy and/or the multimodal therapy. The major complications and side effects associated with each therapy are detailed in the respective chapters of this textbook. From a quality of life perspective, the complications and problems that are likely to impact the physical domain include problems with eating, swallowing, speech and communication, taste, breathing particularly if a tracheotomy or laryngectomy is required, skin and mucous membrane integrity, changes in the consistency and amount of saliva and mucous, as well as changes in physical appearance. The relative impact on quality of life is generally associated with severity of symptoms although other factors, such as intrinsic coping mechanism may play a role [63]. In addition to these site specific changes, patients may experience a range of systematic issues, such as fatigue, that further diminish quality of life [64]. While this is not a comprehensive list, items related to these problems will typically be included on a head and neck specific quality of life instrument. The impact that symptoms and other associated problems have on physical functioning has important consequences for quality of life outcomes in head and neck cancer patients. In cross-sectional study of head and neck cancer patients who had received definitive or post-operative radiotherapy +/− chemotherapy for head and neck cancer, treatment modality significantly impacted physical and cognitive functioning, while disease stage significantly affected global quality of life [65]. In addition, pretreatment functioning may be predictive of post treatment physical morbidity as seen in one prospective study of head and neck cancer patient with a variety of disease sites [66]. In this study, pretreatment performance status predicted post treatment morbidity. The ability to accurately predict those at risk for developing adverse outcomes prior to the start of treatment may have important therapeutic implications particularly if rehabilitative efforts are employed early to mitigate some of these effects.

### *26.7.3 Psychological Domain*

There is substantial interest in the psychological impact of head and neck cancer and subsequent treatment. Numerous studies have detailed the prevalence and severity of psychosocial effects. Psychological issues range from anxiety and depression to changes in body image. It is likely that these psychological factors are inter-related in a wide variety of situations and depend on the disease site and stage as well as the amount of disfigurement associated with the disease and treatment. To illustrate, anticipation of disfiguring facial surgery has been associated with extremely high levels of anxiety [67]. Likewise, successful reintegration of body image following disfiguring surgery is a crucial component of bolstering quality of life. A number of factors, such as gender, may influence the role that psychosocial functioning has on quality of life. Males and females may respond differently to disfiguring surgery. While both men and women with greater levels of disfigurement experience more depression, social support appears to buffer the impact of greater levels of disfigurement on well-being for women but not for men [68]. A thorough review of the psychological impact of head and neck cancer is found in the respective chapter of this textbook.

### *26.7.4 Social Domain*

There are a wide range of potential social implications of head and neck cancer. Issues related to the social domain include role functioning, employment, social functioning, belong to groups, etc. A number of factors associated with head and neck cancer impede social functioning, like the inability to speak or speak clearly. Following treatment, head and neck cancer patients often report impaired social functioning [69]. For example, head and neck cancer or the treatment of cancer may negatively impact employment status. In one study, over 35% of those patients who were employed changed jobs primarily due to the discomfort caused by the head and neck cancer treatment [70]. Others may not be able to return to their line of work due to changes in functional abilities. An individual who relies on verbal communication as a requirement for their job may no longer be able to perform the job duties if their ability to speak has been significantly altered. As people are living and working longer, rehabilitative efforts directed toward employability following head and neck cancer treatment are needed especially for those who are no longer able to continue in their current profession but are cured of the underlying disease. Like the physical and psychological domain, disease site and stage as well as treatment received impact the head and neck cancer patient's social function [61]. People with head and neck cancer often rely on sources of social support during the treatment phase to cope with activities of daily living. At least some patients, however, report that perceived social support decreased from pre to post treatment even though it seems likely that this is the time when the support is most needed [71]. Head and neck cancer can be associated with a high caregiving burden particularly for those that are elderly and/or have more advanced disease. The high caregiving burden may result in high unmet supportive care needs, particularly if sources of social support were strained prior to diagnosis [72].

## 26.8 Using Quality of Life Information

### *26.8.1 Using Quality of Life Information in Research*

While conducting quality of life assessments for clinical practice is becoming more commonplace, most formal assessments are conducted for research purposes. For this reason, most quality of life information published in the head and neck cancer literature has been gathered from research studies. These studies are significant because they focus on real world concerns of head and neck cancer patients and build knowledge in terms of providing a better understanding of the problems experienced by patients as well as identifying patients who may be at greater risk for problems. In order for society to benefit from knowledge related to quality of life in head and neck cancer patients, the assessments must be conducted in a research setting in order for the knowledge to be generalizable to other like patients.

Quality of life studies in head and neck cancer fall into three broad categories; to describe and/or predict quality of life, compare quality of life outcomes in treatment trials, and/or to test the effectiveness of supportive care interventions. Specifically, information discovered from quality of life studies may be used to (1) compare quality of life outcomes in clinical trials that examine the effectiveness of a new treatment to a standard treatment; (2) compare quality of life outcomes when both treatments are equivalent in terms of survival, and quality of life outcomes may influence decision making; (3) to determine the short- and long-term impact of head and neck cancer and/or specific treatments on quality of life; (4) identify factors that predict quality of life outcomes; (5) to identify quality of life outcomes that predict survival; (6) identify, prioritize, and develop interventions for problems that significantly impact the head and neck cancer patient's ability to comply with planned treatment; and (7) test interventions that enhance supportive care throughout the head and neck cancer care continuum.

Researchers must consider a number of factors when designing a quality of life study for people with head and neck cancer. The first and most important issue is to clearly determine the purpose of the study. All other research design decisions flow directly from the purpose of the study. The second issue to consider is the selection of an instrument to measure quality of life. Table 26.5 lists examples of questions that researchers may consider prior to selecting an instrument. Most importantly, the quality of life instrument must be reliable, valid and able to provide the information that the investigator needs to address the research question. No single quality of life instrument can adequately address all research questions across all head and neck cancer populations. For instance, a instrument that is appropriate for use when studying the long-term consequences of head and neck cancer treatment may not be appropriate for use when examining the short term consequences of head and neck surgery. On the other hand, it may be helpful and even necessary to use the same instrument across all assessment points when conducting a longitudinal study to describe QOL trends post transplant.

**Table 26.5** Selecting a quality of life instrument to use in the research setting

| Examples of questions to consider when selecting a quality of life instrument for head and neck cancer patients |
|---|
| Research |
| Should a generic or a cancer-specific, or head and neck cancer-specific instrument be used? |
| What aspects of life does the instrument address? Head and neck specific issues? Treatment issues? |
| Does the instrument provide the information needed to address the research questions? |
| Is there consistency between the research question and underlying conceptualization of the instrument? Is there agreement between the conceptual and operational definitions? |
| Does the instrument have established psychometric properties? Reliability? Validity? |
| What type of scores does the instrument provide? Overall quality of life? Domain or subscales scores? Both? |
| How many items are included in the instrument? |
| How long does it take to complete the instrument? |
| How will the instrument be administered? Paper and pencil? Telephone administration? Computer administration? Internet administration? |
| Given the head and neck cancer patient's expected health status, is it likely that the patient will be able to complete the instrument in a timely manner? |
| How often will the instrument be administered? |
| Is the instrument responsive to changes in the head and neck cancer patient's condition? |
| Is the instrument sensitive enough to reflect true changes in the head and neck cancer patient's condition? |
| Can clinicians easily interpret the research findings obtained from the instrument? |

As illustrated earlier in the chapter, choosing a quality of life instrument has multiple implications related to the interpretability and generalizability of research findings. While designing a perfect study to examine quality of life in head and neck cancer is nearly impossible, researchers must attempt to minimize the limitations. Several research design decisions specifically related to quality of life deserve special mention. There must be a clear link between the research purpose and design. A longitudinal design adds strength to a quality of life study in that it allows changes in the physical, psychological, and social domains to be examined at various important time points, such as the prior to treatment, completion of treatment, 1 year post diagnosis, and so on. In additional, a longitudinal approach as opposed to a cross-sectional design adds power to the study as subjects serve as their own control while controlling for extraneous variables. The primary disadvantage to using a longitudinal approach is that these designs are costly, lengthy, and patient attrition may be a problem. Importantly, subject burden must be minimized to ensure continued participation in the study. Head and neck cancer patients frequently experience a wide range of stressors, particularly during the treatment phase when quality of life outcomes are particularly salient for determining the impact of treatment. Making a conscious effort to collect enough information to address the quality of life research question needs to be balanced against overburdening the subject with unnecessary questionnaires. Finally, careful attention must be paid to sample selection. Because head and neck cancer is relatively rare, there may be a tendency to group patients together in one quality of study regardless of disease site and/or stage. This is particularly true for single site studies when large numbers of head and neck cancer patients are not available as potential subjects. Given the heterogeneity of potential complications associated with the various head and neck disease sites, the ability to find statistical significant findings may be hampered with a heterogeneous group of head and neck cancer patients. Every attempt should be made to limit the sample to comparable head and neck cancers and/or stages of disease to recruit a more homogeneous sample, thus, improving the likelihood of finding statistical significance.

### *26.8.2 Using Quality of Life Information in Clinical Practice*

Quality of life questionnaires can be used in clinical practice to facilitate communication and identify problems in people with head and neck cancer that otherwise might go undetected. Unfortunately, the criteria to select a quality of life instrument that is appropriate for clinical practice are not as clear. No one quality of life instrument will satisfactorily capture all the necessary information to address all clinical practice needs. Different situations may call for different QOL tools. Clinicians require instruments that can be readily administered, scored, and interpreted. Many instruments, however, may be burdensome, particularly if it contains a large number of items. An alternate approach would be to administer a single-item global rating of quality of life. Unfortunately, this type of assessment would not provide adequate information to identify specific needs of the head and neck.

Table 26.6 lists several examples of questions that may be helpful in the selection process. As in the research setting, the instrument must be able to provide the head and neck health care practitioner with adequate information to assess the patient's quality of life. The clinician must also determine when changes in quality of life ratings reflect clinically meaning changes in quality of life perception that would justify altering treatment. The lack of clarity related to the interpretation of quality of life findings for individual patients in a clinic setting is one of the major barriers to implementing quality of life assessment in clinical practice.

### *26.8.3 Statistical Significance Versus Clinical Significance*

One of the underlying principles for assessing quality of life in people with head and neck cancer is to recognize change, both negative and positive, and then determine whether the change is meaningful enough to have clinical ramifications for patient care. In order to better recognize and interpret quality of life changes in people with head and neck cancer, the significance should be evaluated on two levels, statistical and clinical [73]. Determining the clinical significance of quality of life changes helps bridge the gap between research and clinical practice, thereby,

**Table 26.6** Selecting a quality of life instrument to use in the clinical setting

| Examples of questions to consider when selecting a quality of life instrument for head and neck cancer patients |
|---|
| Clinical |
| What purpose does assessment of quality of life serve in the clinical setting? |
| Who will be responsible for reviewing the findings? |
| Will the tool be able to provide adequate information to assess the impact of head and neck cancer on quality of life? |
| What specific aspects of quality of life does the instrument address? Functional status? Symptoms? Global quality of life? Satisfaction? |
| Is the instrument sensitive enough to detect changed in the head and neck cancer patient's quality of life? |
| Does the instrument have established psychometric properties? Reliability? Validity? |
| Can the instrument be easily administered in a clinical setting? |
| How will the instrument be administered? Paper and pencil? Telephone administration? Computer administration? Internet administration? |
| How many items are included in the instrument? |
| How long does it take to complete the instrument? |
| How frequently will the instrument be administered? Daily? Weekly? At preset times? At each office visit? |
| Where will the instrument be completed? In the clinic? In the home? |
| How will information be transmitted from the head and neck cancer patient to the health care provider? |
| Given the head and neck cancer patient's expected health status, is it likely that the patient will be able to complete the instrument in a timely manner? |
| Are there guidelines available for determining clinically meaningful changes in quality of life in cancer patients in general or head and neck cancer patients, specifically? |
| How will the instrument be scored? Who will score it? |
| Are the findings obtained from the instrument easily interpreted? |

improving patient care. Researchers use inferential statistics to test hypotheses, such as comparing quality of life outcomes among head and neck cancer patients who are receiving different types of treatments for their disease. Quality of life outcomes are considered statistically significant if the probability of obtaining the observed outcomes is considered unlikely by chance alone (usually less than 1 in 20 or 5%). Statistically significant changes in quality of life may or may not translate into differences in quality of life that the patient can actually perceive. Likewise, the change may be too small to warrant changes in care. For a change to be clinically significant, it must be large or important enough to have clinical ramifications for patient care. For instance, a small numerical change in quality of life scores may be large enough to be deemed statistically significant, but the change is too small to be considered clinically meaningful or even detectable to individual head and neck cancer patients [74]. In this example, the evidence for incorporating the quality of life research findings into patient care may not be warranted.

Determining the clinical significance of various quality of life instruments is a major focus of quality of life research. This helps those who care for head and neck cancer patients interpret the findings. Different methods for determining the clinical significance of quality of life scores are available [75–77]. One commonly used method is the anchor-based approach, which uses other clinically relevant indicators as “anchors” for interpretation of the quality of life scores. For instance, mean score changes for the multi-item subscales of the EORTC QLQ-C30 were found to correspond with patients’ ratings of change in their perceived health status [78, 79]. As a result, guidelines for interpreting the clinical significance of scores for the EORTC QLQ-C30 are available. Mean score changes of 5–10 points are considered small clinically significant differences; mean score changes of 10–20 points are considered moderate differences; and changes over 20 points indicate large clinically significant differences. Thus, a 21 point difference between two sets of scores on the physical functioning subscale of the EORTC QLQ-C30 would be interpreted as a large, clinically significant change.

Other numeric changes in quality of life scores to determine clinical significance have been established for a variety of quality of life instruments. A difference of two points or more in mean scores is recognized as clinically significant For the Quality of Life Index [80–82]. For the FACT-General and Fact-Head and Neck, a change of 5–10% corresponds to clinically significant differences in quality of life in patients with laryngeal cancer [83].

Another method for determining the clinical significance of quality of life changes in head and neck patients is the distribution-based approach. The ½ standard deviation method [84] and the empirical rule effect size [85] are two of the primary methods used in clinical research. The ½ standard deviation method simply uses a ½ standard deviation to estimate differences in quality of life that are likely to be clinically significant. Quality of life scores that deviate from baseline scores by more than ½ standard deviation are considered to be clinically significant. The empirical rule effect size builds upon the ½ standard deviation method by incorporating effect sizes into the determination of clinical significance. While both of these methods are helpful for determining the clinical significance of quality of life changes in head and neck patients, these ½ standard deviation and the empirical rule effect size were developed primarily for use with group level data and may or may be correspond to clinically significant changes in individual patients. These methods, therefore, must be used with caution when applied to the care of individual head and neck patients.

Finally, determining whether a change in quality of life scores is considered clinically significant is also influenced by the user and the reason for the quality of life assessment. In the head and neck cancer population, there are three primary users of quality of life information; the patients, clinicians and society [86, 87]. The values and standards of each group varies, and the different values and standards influence whether a quality of life outcome is interpreted as clinically significant. A clinical significant change in quality of life for the patient may or may not be interpreted as clinically significant by the health care provider. For example, a head and neck cancer patient may perceive a 10 point increase in oral cavity pain to be clinically significant and question whether it is worth continuing therapy. The head and neck clinician, on the other hand, must weigh the benefits of treatment against increased symptomatology to determine if a change in clinical practice is warranted. A 10 point increase in pain, while concerning for the clinician, may not justify changing a treatment strategy that has a high cure rate. Obviously, the primary intent of the oncology professional would be to relieve symptoms as best as possible. There are times, however, when complete alleviation of symptoms is not possible. In a case such as this, a clinically significant change in quality of life as perceived by an individual patient may or may not be acted upon by clinicians, depending on the magnitude to change. The important message being that goals of therapy should be thoroughly discussed and agreed upon by patients and clinicians so that there is a clear understanding of the goals of therapy. For further information related to the clinical significance of quality of life, the reader is referred to a series of six articles published by a consensus group of quality of life QOL experts [88–93].

## References

1. Gotay CC, Korn EL, McCabe MS, Moore TD, Cheson BD (1992) Quality-of-life assessment in cancer treatment protocols: research issues in protocol development. J Natl Cancer Inst 84(8):575–579
2. Donovan K, Sanson-Fisher RW, Redman S (1989) Measuring quality of life in cancer patients. J Clin Oncol 7(7):959–968
3. Andrykowski MA, Greiner CB, Altmaier EM et al (1995) Quality of life following bone marrow transplantation: findings from a multicentre study. Br J Cancer 71(6):1322–1329
4. Belec RH (1992) Quality of life: perceptions of long-term survivors of bone marrow transplantation. Oncol Nurs Forum 19(1):31–37
5. Cella DF, Tulsky DS (1990) Measuring quality of life today: methodological aspects. Oncology (Williston Park) 4(5):29–38, Discussion 69
6. Ferrans CE, Powers MJ (1985) Quality of life index: development and psychometric properties. ANS Adv Nurs Sci 8(1):15–24
7. Gaston-Johansson F, Foxall M (1996) Psychological correlates of quality of life across the autologous bone marrow transplant experience. Cancer Nurs 19(3):170–176
8. Grant M, Padilla GV, Ferrell BR, Rhiner M (1990) Assessment of quality of life with a single instrument. Semin Oncol Nurs 6(4):260–270
9. Molassiotis A, Boughton BJ, Burgoyne T, van den Akker OB (1995) Comparison of the overall quality of life in 50 long-term survivors of autologous and allogeneic bone marrow transplantation. J Adv Nurs 22(3):509–516
10. Testa MA, Simonson DC (1996) Assessment of quality-of-life outcomes. N Engl J Med 334(13):835–840
11. The WHOQOL Group (1996) What quality of life? World Health Organization quality of life assessment. World Health Forum 17(4):354–356
12. Ferrans CE (1990) Quality of life: conceptual issues. Semin Oncol Nurs 6(4):248–254
13. Ferrell B, Grant M, Padilla G, Vemuri S, Rhiner M (1991) The experience of pain and perceptions of quality of life: validation of a conceptual model. Hosp J 7(3):9–24
14. Ferrans CE (1996) Development of a conceptual model of quality of life. Sch Inq Nurs Pract 10(3):293–304
15. Wilson IB, Cleary PD (1995) Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. JAMA 273(1):59–65
16. Ferrans CE, Zerwic JJ, Wilbur JE, Larson JL (2005) Conceptual model of health-related quality of life. J Nurs Scholarsh 37(4):336–342
17. Hacker ED, Ferrans CE (2003) Quality of life immediately after peripheral blood stem cell transplantation. Cancer Nurs 26(4):312–322
18. Cella DF, Tulsky DS, Gray G et al (1993) The functional assessment of cancer therapy scale: development and validation of the general measure. J Clin Oncol 11(3):570–579

19. Aaronson NK, Ahmedzai S, Bergman B et al (1993) The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst 85(5):365–376
20. Ware JE Jr, Sherbourne CD (1992) The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 30(6):473–483
21. Cantril H (1965) The patterns of human concern. Rutgers University Press, New Brunswick
22. Karnofsky DA, Abelmann WH, Craver LF, Burchenal JH (1948) The use of nitrogen mustards in the palliative treatment of cancer. Cancer 1(4):634–656
23. Baker F, Curbow B, Wingard JR (1992) Development of the satisfaction with life domains scale for cancer. J Psychosoc Oncol 10(3):75–90
24. Bergner M, Bobbitt RA, Pollard WE, Martin DP, Gilson BS (1976) The sickness impact profile: validation of a health status measure. Med Care 14(1):57–67
25. The World Health Organization Quality of Life Assessment (WHOQOL) (1998) Development and general psychometric properties. Soc Sci Med 46(12):1569–1585
26. The WHOQOL Group (1998) Development of the World Health Organization WHOQOL-BREF quality of life assessment. Psychol Med 28(3):551–558
27. Oken MM, Creech RH, Tormey DC et al (1982) Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol 5(6):649–655
28. Schag CA, Heinrich RL, Aadland RL, Ganz PA (1990) Assessing problems of cancer patients: psychometric properties of the cancer inventory of problem situations. Health Psychol 9(1):83–102
29. Padilla GV, Presant C, Grant MM, Metter G, Lipsett J, Heide F (1983) Quality of life index for patients with cancer. Res Nurs Health 6(3):117–126
30. Schipper H, Clinch J, McMurray A, Levitt M (1984) Measuring the quality of life of cancer patients: the functional living index-cancer: development and validation. J Clin Oncol 2(5):472–483
31. Bjordal K, Hammerlid E, Ahlner-Elmqvist M et al (1999) Quality of life in head and neck cancer patients: validation of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-H&N35. J Clin Oncol 17(3):1008–1019
32. D'Antonio LL, Zimmerman GJ, Cella DF, Long SA (1996) Quality of life and functional status measures in patients with head and neck cancer. Arch Otolaryngol Head Neck Surg 122(5):482–487
33. Hassan SJ, Weymuller EA Jr (1993) Assessment of quality of life in head and neck cancer patients. Head Neck 15(6):485–496
34. Terrell JE (1999) Quality of life assessment in head and neck cancer patients. Hematol Oncol Clin North Am 13(4):849–865
35. Browman GP, Levine MN, Hodson DI et al (1993) The Head and Neck Radiotherapy Questionnaire: a morbidity/quality-of-life instrument for clinical trials of radiation therapy in locally advanced head and neck cancer. J Clin Oncol 11(5):863–872
36. Pace-Balzan A, Cawood JI, Howell R, Lowe D, Rogers SN (2004) The Liverpool Oral Rehabilitation Questionnaire: a pilot study. J Oral Rehabil 31(6):609–617
37. Sneeuw KC, Aaronson NK, Osoba D et al (1997) The use of significant others as proxy raters of the quality of life of patients with brain cancer. Med Care 35(5):490–506
38. Sneeuw KC, Aaronson NK, Sprangers MA, Detmar SB, Wever LD, Schornagel JH (1998) Comparison of patient and proxy EORTC QLQ-C30 ratings in assessing the quality of life of cancer patients. J Clin Epidemiol 51(7):617–631
39. Jensen K, Bonde Jensen A, Grau C (2006) The relationship between observer-based toxicity scoring and patient assessed symptom severity after treatment for head and neck cancer. A correlative cross sectional study of the DAHANCA toxicity scoring system and the EORTC quality of life questionnaires. Radiother Oncol 78(3):298–305
40. Bradburn NM, Rips LJ, Shevell SK (1987) Answering autobiographical questions: the impact of memory and inference on surveys. Science 236(4798):157–161
41. Gendreau M, Hufford MR, Stone AA (2003) Measuring clinical pain in chronic widespread pain: selected methodological issues. Best Pract Res Clin Rheumatol 17(4):575–592
42. Stone AA, Broderick JE (2007) Real-time data collection for pain: appraisal and current status. Pain Med 8(Suppl 3):S85–S93

43. Shiffman S, Stone AA, Hufford MR (2008) Ecological momentary assessment. Annu Rev Clin Psychol 4:1–32
44. Basch E, Artz D, Iasonos A et al (2007) Evaluation of an online platform for cancer patient self-reporting of chemotherapy toxicities. J Am Med Inform Assoc 14(3):264–268
45. Wilkie DJ, Judge MK, Berry DL, Dell J, Zong S, Gilespie R (2003) Usability of a computerized PAINReportIt in the general public with pain and people with cancer pain. J Pain Sympt Manag 25(3):213–224
46. Karras BT, Wolpin S, Lober WB, Bush N, Fann JR, Berry DL (2006) Electronic Self-report Assessment–Cancer (ESRA-C): working towards an integrated survey system. Stud Health Technol Inform 122:514–518
47. Al-Majid S, Waters H (2008) The biological mechanisms of cancer-related skeletal muscle wasting: the role of progressive resistance exercise. Biol Res Nurs 10(1):7–20
48. Hacker ED (2010) Technology and quality of life outcomes. Semin Oncol Nurs 26(1):47–58
49. Murphy BA, Ridner S, Wells N, Dietrich M (2007) Quality of life research in head and neck cancer: a review of the current state of the science. Crit Rev Oncol Hematol 62(3):251–267
50. Chaukar DA, Walvekar RR, Das AK et al (2009) Quality of life in head and neck cancer survivors: a cross-sectional survey. Am J Otolaryngol 30(3). doi:176
51. Ziegler L, Newell R, Stafford N, Lewin R (2004) A literature review of head and neck cancer patients information needs, experiences and views regarding decision-making. Eur J Cancer Care (Engl) 13(2):119–126
52. Abdel-Wahab M, Abitbol A, Lewin A, Troner M, Hamilton K, Markoe A (2005) Quality-of-life assessment after hyperfractionated radiation therapy and 5-fluorouracil, cisplatin, and paclitaxel (Taxol) in inoperable and/or unresectable head and neck squamous cell carcinoma. Am J Clin Oncol 28(4):359–366
53. Fang FM, Tsai WL, Chien CY et al (2005) Changing quality of life in patients with advanced head and neck cancer after primary radiotherapy or chemoradiation. Oncology 68(4–6):405–413
54. Bansal M, Mohanti BK, Shah N, Chaudhry R, Bahadur S, Shukla NK (2004) Radiation related morbidities and their impact on quality of life in head and neck cancer patients receiving radical radiotherapy. Qual Life Res 13(2):481–488
55. Jellema AP, Slotman BJ, Doornaert P, Leemans CR, Langendijk JA (2007) Impact of radiation-induced xerostomia on quality of life after primary radiotherapy among patients with head and neck cancer. Int J Radiat Oncol Biol Phys 69(3):751–760
56. Dwivedi RC, Kazi RA, Agrawal N et al (2009) Evaluation of speech outcomes following treatment of oral and oropharyngeal cancers. Cancer Treat Rev 35(5):417–424
57. Weymuller EA, Yueh B, Deleyiannis FW, Kuntz AL, Alsarraf R, Coltrera MD (2000) Quality of life in patients with head and neck cancer: lessons learned from 549 prospectively evaluated patients. Arch Otolaryngol Head Neck Surg 126(3):329–335, Discussion 335–326
58. Rogers SN, Laher SH, Overend L, Lowe D (2002) Importance-rating using the University of Washington quality of life questionnaire in patients treated by primary surgery for oral and oro-pharyngeal cancer. J Craniomaxillofac Surg 30(2):125–132
59. Hammerlid E, Silander E, Hornestam L, Sullivan M (2001) Health-related quality of life three years after diagnosis of head and neck cancer–a longitudinal study. Head Neck 23(2):113–125
60. Infante-Cossio P, Torres-Carranza E, Cayuela A, Gutierrez-Perez JL, Gili-Miner M (2009) Quality of life in patients with oral and oropharyngeal cancer. Int J Oral Maxillofac Surg 38(3):250–255
61. Boscolo-Rizzo P, Maronato F, Marchiori C, Gava A, Da Mosto MC (2008) Long-term quality of life after total laryngectomy and postoperative radiotherapy versus concurrent chemoradiotherapy for laryngeal preservation. Laryngoscope 118(2):300–306
62. Boscolo-Rizzo P, Stellin M, Fuson R, Marchiori C, Gava A, Da Mosto MC (2009) Long-term quality of life after treatment for locally advanced oropharyngeal carcinoma: surgery and postoperative radiotherapy versus concurrent chemoradiation. Oral Oncol 45(11):953–957

63. Ohrn KE, Sjoden PO, Wahlin YB, Elf M (2001) Oral health and quality of life among patients with head and neck cancer or haematological malignancies. Support Care Cancer 9(7):528–538
64. Butt Z, Rosenbloom SK, Abernethy AP et al (2008) Fatigue is the most important symptom for advanced cancer patients who have had chemotherapy. J Natl Compr Canc Netw 6(5):448–455
65. Alicikus ZA, Akman F, Ataman OU et al (2009) Importance of patient, tumour and treatment related factors on quality of life in head and neck cancer patients after definitive treatment. Eur Arch Otorhinolaryngol 266(9):1461–1468
66. de Graeff A, de Leeuw JR, Ros WJ, Hordijk GJ, Blijham GH, Winnubst JA (2000) Pretreatment factors predicting quality of life after treatment for head and neck cancer. Head Neck 22(4):398–407
67. Dropkin MJ (1999) Body image and quality of life after head and neck cancer surgery. Cancer Pract 7(6):309–313
68. Katz MR, Irish JC, Devins GM, Rodin GM, Gullane PJ (2003) Psychosocial adjustment in head and neck cancer: the impact of disfigurement, gender and social support. Head Neck 25(2):103–112
69. Bozec A, Poissonnet G, Chamorey E et al (2009) Quality of life after oral and oropharyngeal reconstruction with a radial forearm free flap: prospective study. J Otolaryngol Head Neck Surg 38(3):401–408
70. Liu HE (2008) Changes of satisfaction with appearance and working status for head and neck tumour patients. J Clin Nurs 17(14):1930–1938
71. Penedo FJ, Traeger L, Benedict C et al (2012) Perceived social support as a predictor of disease-specific quality of life in head-and-neck cancer patients. J Support Oncol 10(3):119–123
72. Chen SC, Tsai MC, Liu CL, Yu WP, Liao CT, Chang JT (2009) Support needs of patients with oral cancer and burden to their family caregivers. Cancer Nurs 32(6):473–481
73. Sloan JA, Cella D, Frost M, Guyatt GH, Sprangers M, Symonds T (2002) Assessing clinical significance in measuring oncology patient quality of life: introduction to the symposium, content overview, and definition of terms. Mayo Clin Proc 77(4):367–370
74. Osoba D (1999) What has been learned from measuring health-related quality of life in clinical oncology. Eur J Cancer 35(11):1565–1570
75. Sloan JA, Frost MH, Berzon R et al (2006) The clinical significance of quality of life assessments in oncology: a summary for clinicians. Support Care Cancer 14(10):988–998
76. Wyrwich KW, Bullinger M, Aaronson N, Hays RD, Patrick DL, Symonds T (2005) Estimating clinically significant differences in quality of life outcomes. Qual Life Res 14(2):285–295
77. Guyatt GH, Osoba D, Wu AW, Wyrwich KW, Norman GR (2002) Methods to explain the clinical significance of health status measures. Mayo Clin Proc 77(4):371–383
78. King MT (1996) The interpretation of scores from the EORTC quality of life questionnaire QLQ-C30. Qual Life Res 5:555–567
79. Osoba D, Rodrigues G, Myles J, Zee B, Pater J (1998) Interpreting the significance of changes in health-related quality-of-life scores. J Clin Oncol 16(1):139–144
80. Bliley AV, Ferrans C (1993) Quality of life after angioplasty. Heart Lung 22(3):193–199
81. Hathaway D, Hartwig M, Milstead J et al (1994) A prospective study of changes in quality of life reported by diabetic recipients of kidney-only and pancreas-kidney allografts. J Transpl Coord 4:12–17
82. Johnson C, Wicks M, Milstead J et al (1998) Racial and gender differences in quality of life following kidney transplantation. Image J Nurs Sch 30:125–130
83. Ringash J, O’Sullivan B, Bezjak A, Redelmeier DA (2007) Interpreting clinically significant changes in patient-reported outcomes. Cancer 110(1):196–202
84. Norman GR, Sloan JA, Wyrwich KW (2003) Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. Med Care 41(5):582–592
85. Sloan J, Symonds T, Vargas-Chanes D, Fridley B (2003) Practical guidelines for assessing the clinical significance of health-related quality of life changes within clinical trials. Drug Inf J 37:23–31

86. Symonds T, Berzon R, Marquis P, Rummans TA (2002) The clinical significance of quality-of-life results: practical considerations for specific audiences. Mayo Clin Proc 77(6):572–583
87. Frost MH, Bonomi AE, Ferrans CE, Wong GY, Hays RD (2002) Patient, clinician, and population perspectives on determining the clinical significance of quality-of-life scores. Mayo Clin Proc 77(5):488–494
88. Guyatt GH, Osoba D, Wu AW, Wyrwich KW, Norman GR, Group CSCM (2002) Methods to explain the clinical significance of health status measures. Mayo Clin Proc 77(4):371–383
89. Sloan JA, Cella D, Frost M et al (2002) Assessing clinical significance in measuring oncology patient quality of life: Introduction to the symposium, content overview, and definition of terms. Mayo Clin Proc 77(4):367–370
90. Sprangers M, Moinpour C, Moynihan T, Patrick D, Revicki D, Group CSCM (2002) Assessing meaningful change over time in quality of life: a user's guide for clinicians. Mayo Clin Proc 77(4):561–571
91. Symonds T, Berzon R, Marquis P, Rummans TA, Group CSCM (2002) The clinical significance of quality-of-life results: practical considerations for specific audiences. Mayo Clin Proc 77(4):572–583
92. Cella D, Bullinger M, Scott C, Barofsky I, Group CSCM (2002) Group vs individual approaches to understanding the clinical significance of differences or changes in quality of life. Mayo Clin Proc 77(4):384–392
93. Frost M, Bonomi A, Ferrans C, Wong G, Hays R, Group CSCM (2002) Patient, clinician, and population perspectives on determining the clinical significance of quality of life scores. Mayo Clin Proc 77:488–494