Incorporating quality of life and patient satisfaction measures into a transplant outcomes assessment program: technical and practical considerations

Objective—To present an overview of methods for incorporating the measurement of health-related quality of life and patient satisfaction into a comprehensive outcomes assessment program in the organ transplantation setting. An introduction to basic psychometric concepts as they relate to survey instrument selection is presented, and the complementary nature of health status instruments and preference-based utility measures is discussed. The role of these concepts and measures in a transplant outcomes assessment and research program and the psychometric evidence for selected instruments are described.
Data Sources—Descriptions of specific survey instruments were abstracted from published reports or manuals. Data describing the Vanderbilt Transplant Center Patient Satisfaction Inventory were derived from a single institution transplant outcomes research database.
Study Selection and Data Extraction—Previously reported research was selected from the literature to provide brief examples of basic concepts, which are not intended to be a comprehensive review of these topics. Illustrative data from the Vanderbilt program were extracted from a longitudinal database.
Data Synthesis—Data and published reports were synthesized for descriptive and illustrative purposes.
Conclusions—This review describes various types of health-related quality of life and patient satisfaction outcomes assessment tools and measurement methods; introduces considerations relevant to survey instrument selection and development; and outlines the evolution of and psychometric support for a transplant center-wide outcomes assessment and research program. (*Progress in Transplantation.* 2007;17:121-128)

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Health-related quality of life (HRQOL) and patient satisfaction are widely recognized as integral components of a comprehensive outcomes assessment program, with these measures having moved beyond the domain of "research" to being accepted and expected indices of clinical and program effectiveness. The purpose of this article is to provide an overview of methods for incorporating the measurement of HRQOL and patient satisfaction into a comprehensive transplant outcomes assessment program. We present an introduction to basic terminology and psychometric concepts relevant to survey evaluation and selection. Also, we discuss the distinction between and complementary nature of health status instruments and preference-based utility measures. We describe the evolution and current structure of the HRQOL outcomes assessment program at the Vanderbilt Transplant Center, including an overview of the development and use of a transplant setting-specific patient satisfaction inventory.

Psychometrics and Other Measurement Considerations

Psychometrics refers to conceptually and statistically defined measurement characteristics of tests, scales, and surveys. A survey battery (collection of survey instruments or "tools") is best identified after closely considering these qualities, which are typically reported in scoring manuals or other published reports of an instrument's validation and application.

Reliability

Reliability refers to the extent to which a score is free of measurement error and is directly related to whether scores are reproducible under consistent circumstances.

Interrater reliability is the degree to which 2 or more observers arrive at the same score when evaluating (in the current application) the same individual. Kappa statistics, reliability coefficients, and intraclass correlation coefficients are statistical measures of interrater reliability or, under specific circumstances, the reliability of a single observer.

Equivalent or alternate forms reliability refers to the agreement between scores on instruments that are intended to measure identical concepts. Statistical measures include Pearson correlation coefficients or (substituting multiple forms for multiple raters) kappa statistics, and intraclass correlation coefficients.

Test-retest reliability is the agreement between scores after repeated administration of an instrument to the same individual under consistent circumstances. Because this type of reliability is affected both by measurement error and the degree to which any actual change has occurred, the potential for real change must be taken into consideration.

Internal consistency reliability is the degree to which the items or questions on a scale correlate strongly with each other and with the total score on the scale they comprise. Objective identification of items that comprise a scale may be conducted using item analysis methods such as principal components or factor analysis. The internal consistency of a scale can be expressed as Cronbach α, with values $\geq .7$ considered adequate.

Validity

Validity refers to the degree to which an instrument is actually measuring the concept that it is intended to measure. A survey cannot be valid without first having demonstrated reliability.

Content validity is the somewhat subjective assessment of the degree to which an instrument's items are relevant to and representative of the intended concept (and is sometimes referred to as "face validity"). This requires that there be an accepted understanding of the target concept(s). Then, systematic consideration of the breadth of items in relation to the target concepts and the context in which the instrument will be used become key developmental steps to ensure content validity.

Criterion-related validity is the degree to which a score is associated with another recognized (ie, "gold standard") measure. This association is typically expressed as a correlation coefficient.

Construct validity is the quantifiable assessment of the degree to which scores "behave" as expected in relation to hypothesized relationships with other variables or outcomes.[1,2] For instance, construct validity would be demonstrated if persons awaiting transplantation demonstrated lower HRQOL in comparison to a healthy comparison group.

Responsiveness to Change

Responsiveness to change, which is related to construct validity, is the degree to which an instrument is capable of detecting true differences over time. It can be reported using a variety of statistical indices including a paired *t* test. Authors have suggested that change of half a standard deviation is a useful benchmark of responsiveness for HRQOL instruments,[3] but this rule of thumb is still open to debate.[4]

Response Burden

Response burden, which is the amount of time it takes subjects to complete a survey or collection of surveys, is another practical consideration that should be balanced against the goal of collecting broadly meaningful and applicable data.

Imputation and Missing Data

Imputation and missing data handling rules are documented methods for how missing items are to be addressed when scoring an instrument. These scoring guidelines are generally reported in the instrument's manual.

Normative or Reference Data

Normative or reference data are published standards for interpreting scores in relation to general population and/or condition-specific samples. The availability of relevant norms or reference data is an important consideration when selecting an instrument.

Health Status Instruments

HRQOL may be evaluated using health status instruments, which are generic or condition-specific profiles of patient outcomes. The World Health Organization quality of life group has identified and recommended 5 broad dimensions (physical health, psychological health, social relationship perceptions, function, and well-being) as reflecting generic quality of life.[5] Health status instruments address these dimensions via multiple-item questionnaires that employ quantitative rating scales. Items are then tallied to generate scales, which are sometimes combined to form overall scores.

Generic instruments cover a broad range of dimensions and allow comparisons between different groups of patients. Condition-specific instruments, on the other hand, are designed for a particular condition, disease, patient group, or area of function. Although some generic instruments have condition-specific norms, reference data relevant to transplant patients are often lacking.

The SF-36 Health Survey[6] is one of the most widely employed and extensively validated instruments for the measurement of generic, self-reported HRQOL. It includes 8 health concepts: physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. Aggregate physical and mental component summary scales are derived by adding across the 8 differentially weighted scales, with the weights having been established via principal components analysis. The RAND-36 Health Status Inventory[7] applies an alternative, item-response, theory-based scoring system to the original SF-36 items to the derive scale and component scores.

The Nottingham Health Profile[8] is a generic instrument that was developed for epidemiological studies and consists of 2 independent parts. Part 1 addresses 6 dimensions: pain, physical mobility, emotional reactions, energy, social isolation, and sleep. Part 2 addresses areas of life most affected by health: employment, household activities, social life, home life, sex life, hobbies and interests, and holidays. Weighted scores range from zero (no problems at all) to 100 (presence of all problems within a dimension). Another generic instrument, the McMaster Health Index questionnaire,[9] measures physical, social, and mental health. Each of these generic instruments has been validated, is widely used, and is applicable to a variety of conditions.

Examples of condition-specific instruments for transplant candidates and recipients include the End-Stage Renal Disease Symptom Checklist-Transplant Module,[10] the National Institute of Diabetes and Digestive and Kidney Diseases Liver Transplantation Database instruments,[11] and the Memphis Survey,[12] which has a generic HRQOL core and several condition-specific scales. Condition-specific instruments are designed to enhance sensitivity and specificity, but they have limited utility when comparing between disease groups or to a healthy population. Scores for generic and condition-specific health status instruments are summarized as either a health profile (report of different domain-specific scores) or as a health index (a summary of all domain scores). Health status instruments can accurately describe the health state being investigated, but do not address the value patients place on the health status or the treatment outcome achieved.

Preference or Utility Measures

In addition to health status measures such as those described above, HRQOL may be expressed as utilities. As summarized by Shaw et al,[13(p203)] "cost-utility analysis (CUA) is one form of cost-effectiveness analysis that compares the cost of health care programs or interventions to the outcomes, which are measured in terms of both quantity and quality of life." The quality-adjusted life year (QALY) is a common metric for this concept[14] that adjusts years of life on the basis of patients' preference-based valuation of various health states.

Instruments that measure traditional HRQOL domains are used to determine health status. The health status measure is then associated with a specific preference for that state, which is then "combined with time to calculate an outcome such as QALYs gained."[13(p203)] Health status instruments measure the impact of a treatment on quality of life but do not incorporate length of life into the metric. Comparisons between treatments for different illnesses as well as within an illness can be made when QALYs are used as the outcome measure in CUAs. CUAs addressing clinical outcomes are limited to comparisons between different treatments within an illness.[15]

Preference-based utilities quantify the strength of preference for a wide variety of health states.[16] Approaches to establishing utilities include rating scales, the standard gamble, or the time trade-off. A common rating scale method is the visual analog scale in which respondents assign a numerical value ranging from, for instance, 0 (worst possible health or death) to 100 (best possible health). The standard gamble technique incorporates risk assessments and gives respondents a choice between (a) living in their current health state with certainty or (b) accepting a treatment that could return them to full health but carries a risk of death. Probabilities are assigned to the 2 possible outcomes (full health or death) for the choice "b" gamble. The utility for the health state is equal to the probability at which the respondent is indifferent. For example, if indifference occurs when the probability of success is 60%, the assessment for that health state is 0.60.

The time trade-off technique asks respondents to choose between living a period in perfect health or a longer period in a well-defined decreased state of health.[14] QALY can be determined after the utilities or valuations have been established for a variety of health states using one of the above methods. They are computed as the number of years at a given health state multiplied by the utility valuation for that health state. For example, 4 years of life in a health state valued at 0.25 is equal to 1 year of perfect health. A QALY of 0.5 is interpreted to mean that a full year of life with a health-related disability is the same value, from the respondent's perspective, as a half year (6 months) of perfect health.

Preference-based measures include the Quality of Well-Being Scale,[17] the Health Utility Index (HUI),[18-20] and the EuroQoL Group's EQ-5D.[21] The Quality of Well-Being Scale is interviewer-administered and measures well-being on the basis of social preferences for functioning (mobility, physical activity, and social activity) and symptomatic complaints that might

inhibit function. A functional level is assigned for each domain and is given a weight based on large population surveys of preferences for the various levels. The HUI, particularly the HUI Mark III, is a widely used index that measures utilities via a questionnaire that assesses 8 HRQOL attributes (vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain). Each attribute has 5 or 6 defined levels, which yield 972 000 possible unique health states. Preference scores for these HUI Mark III health states were derived from and validated in a Canadian general population sample.[20]

The EQ-5D is a 5-dimension questionnaire (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), with each item/dimension having 3 possible response options (no problems, moderate problems, extreme problems). Scores on these 5 dimensions represent health states, each of which can be assigned a preference-based index score or weight. Two hundred forty-three possible health states may range from 11111 (no problems on any dimension) to 33333 (extreme problems on all dimensions). Before 2005, EQ-5D preference weights were derived from non-US populations. However, Shaw and coauthors[13] have published US population-based preference weights for the 243 EQ-5D health states that can be incorporated into computations of QALYs for CUA.

Recently Luo and coauthors[22] assessed the validity and comparability of the HUI Mark II, HUI Mark III, and EQ-5D in the US population. They reported generally strong correlations between similar EQ-5D dimensions and HUI attributes, but that most correlations between dimensions/attributes evaluating different aspects of health were weak. They concluded that the 3 health status classification systems have construct validity but that they are not equivalent or interchangeable because of differences in descriptions of health states, preference elicitation methods, source populations for preference data, and mathematical models employed to generate preference scores.

Incorporating Patient Satisfaction Into a HRQOL Survey Battery

Patient satisfaction can be considered from 2 perspectives: (1) patients' satisfaction with their health outcome (eg, after transplantation) and (2) patients' satisfaction with the healthcare delivery process. Both measures of satisfaction may be valid and useful and both serve complementary purposes with respect to outcomes assessment and research. The measurement of patient satisfaction has gained increasing attention over the last 20 years and is considered an important HRQOL-related outcome measure. However, the utility and underlying assumptions of many satisfaction surveys are not well understood and are worthy of future research.[23-25] The following summary describes the impetus behind and the development of the Vanderbilt Transplant Center Patient Satisfaction Inventory (VTCPSI) in an effort to incorporate a transplant-specific patient satisfaction measure into a HRQOL assessment program.

The VTCPSI was developed after statistically testing the degree to which the SF-36 physical and mental summary components were associated with the 7 scales of another instrument, the Psychosocial Adjustment to Illness Scale (PAIS).[26] Analyses demonstrated that, with the exception of the healthcare orientation scale, each of the PAIS scales were significantly associated with one or both the SF-36 summary components.[27] Therefore, inclusion of the PAIS in the battery would largely be redundant. However, eliminating the PAIS from the battery would mean that general information about satisfaction with healthcare delivery would not be captured. The VTCPSI was developed to address specific aspects of transplantation healthcare delivery in an effort to capture information about patient satisfaction in this specific context.

The VTCPSI is a collection of 6 parallel forms that query patients' satisfaction with their encounter with the transplantation healthcare system at various time points. Service-related content themes are (1) understanding of clinical processes (eg, risks and benefits, compliance expectations); (2) understanding of and coping with medications and their side effects; (3) courtesy and respect; (4) healthcare professionals meeting needs (3 items); (5) communication among clinical care providers; (6) scheduling and efficiency of clinical care visits (2 items); (7) coordination of billing information; (8) understanding of out-of-pocket financial obligations; (9) quality of medical care; and (10) overall satisfaction. Each time-specific version of the inventory contains 13 core items and a consistent number of items within each content theme. Three miscellaneous time-specific items are also included on each form.

Forms were designed to address the changing aspects of care over the preoperative and postoperative phases of the transplantation process and to complement the concepts captured by other instruments in the HRQOL battery (Table 1). Items are simple declarative sentences that are rated using a 4-point ordinal system (0=strongly disagree, 3=strongly agree). Items were chosen after a developmental process that included input over several iterations by an interdisciplinary group of healthcare providers (physicians, nurses, social workers, psychologists, pharmacists, psychometricians, and outcomes researchers) and patients. Language was targeted to an eighth grade reading level and the forms were piloted via interviews with patients that focused on both content and clarity of presentation.

Initial and confirmatory analyses (in 902 and 2708 surveys, respectively) demonstrated that, given

Table 1 Vanderbilt Transplant Center survey battery and assessment schedule

Instrument	Evaluation	Listed every 6 months	At transplantation	1 month after transplantation	3 months after transplantation	6 months after transplantation	Annually after transplantation
SF-36 Health Survey	X	X		X	X	X	X
Beck Anxiety Inventory	X	X		X	X	X	X
CES-D	X	X		X	X	X	X
Satisfaction (VTCPSI)	X	X		X	X	X	X
Visual analog scale (overall health)	X	X		X	X	X	X
Employment survey	X					X	X
EQ-5D	X	X		X	X	X	X
Karnofsky performance (clinician assessment)	X	X	X	X	X	X	X

Abbreviations: CES-D, Center for Epidemiologic Studies Short Depression Scale; VTCPSI, Vanderbilt Transplant Center Patient Satisfaction Inventory.

X indicates that the survey is administered at the given monitoring point.

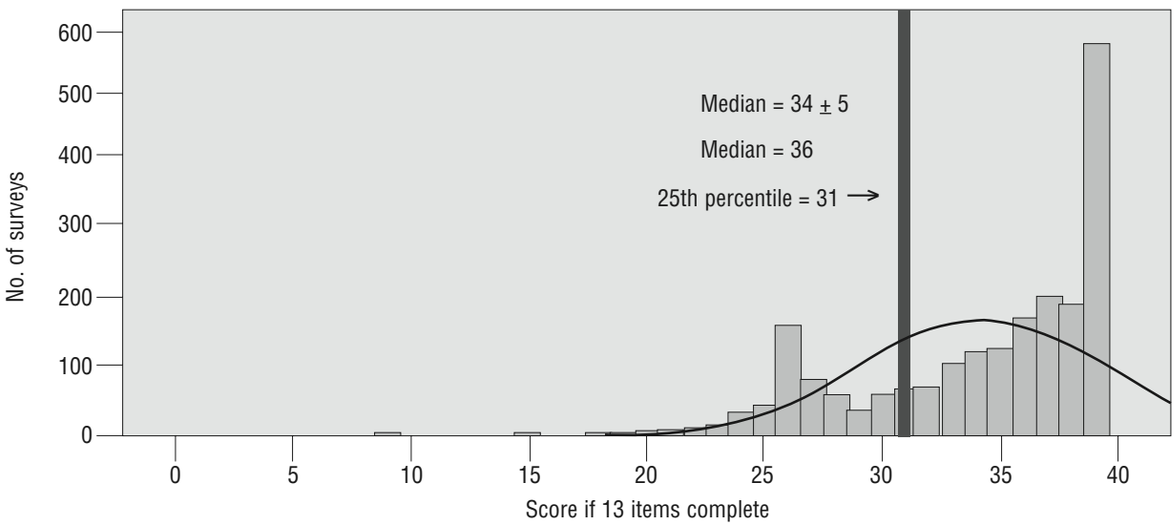

Figure 1 A frequency distribution of Vanderbilt Transplant Center Patient Satisfaction Inventory scores for all respondents and monitoring periods. Survey scores are negatively skewed (ie, tend to have a preponderance of responses at the higher end of the scale—more satisfied). The 25th percentile score of 31 provides a useful benchmark for identifying areas for improvement.

responses on each core item, the 13 core items of the VTCPSI should be summed to form a total score that may range from 0 to 39, with higher scores representing greater satisfaction with transplantation healthcare delivery.[28,29] This single scale was consistent across all 6 monitoring point-specific forms and has strong internal consistency reliability, with coefficient $\alpha > .90$. Short-term test-retest reliability was good ($r = 0.77$). The overall score distribution is negatively skewed, with the majority of scores being at the upper end of the scale (Figure 1). Construct validity was demonstrated on the basis of a divergent pattern of correlation coefficients among the VTCPSI, patient report of overall health, and the physical and mental component scores of the SF-36. The 25th percentile score of 31 provides a useful criterion for identifying areas for improvement by targeting specific concerns of patients whose total scores fall below that threshold (Figure 2).[28,29]

Current Survey Battery

The survey battery was approved by the institutional review board and was revised in 2006 to include the EQ-5D (Tables 1 and 2). Surveys are produced in scannable format and no personally identifying information appears on the forms. Data linking individuals and completion dates to random survey identifiers are stored in a separate secured database. A rolling enrollment process ensures that patients may participate at

Table 2 Vanderbilt Transplant Center survey battery: reported psychometric characteristics

Instrument	No. of items (response burden)	Health status and/or preference-based utility measure	Generic or condition-specific measure
SF-36 Health Survey	36	HS	G
Beck Anxiety Inventory	21	HS	CS
CES-D	20	HS	CS
Satisfaction (VTCPSI)	16	HS	CS
Visual analog scale	1	HS	G
Employment survey	20 before, 17 after	NA	CS
EQ-5D	5	HS and PBU	G
Karnofsky performance	1	HS	G

Abbreviations: α, coefficient α; AF, alternate/parallel forms; CES-D, Center for Epidemiologic Studies Short Depression Scale; CS, condition specific; CR, criterion-related; G, generic; GP, general population; HS, health status; IC, internal consistency; IR, interrater; NA, not applicable; PBU, preference-based utility; TR, test-retest; VTCPSI, Vanderbilt Transplant Center Patient Satisfaction Inventory.

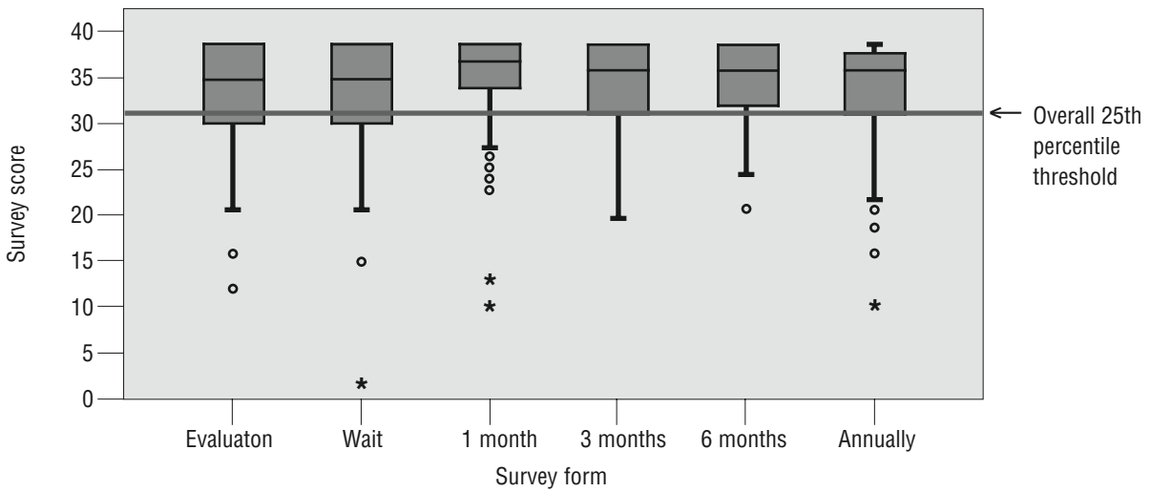

Figure 2 A box and whisker plot depicting satisfaction survey scores by monitoring period. This approach permits a program to monitor patient satisfaction scores and identify period-specific targets for improvement. The bottom of each box represents the 25th percentile and the top represents the 75th percentile (ie, the lower and upper quartiles). The midline represents the 50th percentile (median). Whiskers represent the "adjacent values" (ie, extreme values that are not more than 1.5 times the height of the box from a quartile). Other marks (circles and asterisks) represent cases having more extreme values. The goal would be to have the overwhelming majority of cases (eg, the entire box) at or above the reference score of 31.

any point in the transplant evaluation and follow-up process without regard for whether they completed surveys at a previous time point. Thus far more than 2000 liver, heart, kidney, lung, or stem cell transplant recipients have participated in the program, with data being used for both clinical effectiveness and outcomes research purposes.

Summary

Optimal HRQOL outcomes assessment batteries can be identified through attention to (1) technical details such as psychometric qualities of published instruments and missing data handling; (2) use of both generic and condition-specific instruments; (3) breadth of construct representation; (4) inclusion of preference-based utility measures; (5) response burden; and (6) the availability of appropriate published norms (Table 2). There are a variety of validated published instruments appropriate for the pretransplant and posttransplant settings. Because a substantial time commitment and large samples are necessary for the validation of new surveys, close review of the literature is recommended before developing and administering a user-developed survey.

Reliability	Validity	Responsive to change	General population and/or condition-specific reference data	Missing data imputation rules
TR, AF, IC, α	Content, CR, Construct	Yes	GP and CS	Yes
TR, IC, α	Content , CR, Construct	Yes	GP and CS	No
TR, IC, α	Content , CR, Construct	Yes	GP and CS	No
TR, AF, IC, α	Content , Construct	NA	CS	Pending
TR	Content , CR, Construct	Yes	GP and CS	NA
TR	Content , Construct	Yes	NA	NA
TR	Content , CR, Construct	Yes	GP and CS	No
IR	Content , CR, Construct	Yes	NA	NA

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