

A SUPPLEMENT TO

PROGRESS IN TRANSPLANTATION

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JUNE 2003

PATIENT OUTCOMES REGISTRY FOR
TRANSPLANT EFFECTS ON LIFE

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Patient Outcomes Registry for Transplant Effects on Life

Guest Editor: Donna Hathaway, RN, PhD

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Assessing quality-of-life outcomes in organ transplant recipients: progress and priorities

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Notice to CE enrollees:

A closed-book, multiple-choice examination following this article tests your ability to accomplish the following objectives:

1. Identify the purpose and goals of the Patient Outcomes Registry for Transplant Effects on Life
2. Explain the differences that were found in quality-of-life outcomes for organ transplant recipients
3. Discuss the clinical implications of the findings of the Patient Outcomes Registry for Transplant Effects on Life

In 1947, the World Health Organization defined health as “a state of complete physical, mental and social well-being, and not merely the absence of disease and infirmity.”¹ During the same period, the first recognized effort to examine quality of life (QOL) was being developed by Karnofsky et al²—a checklist designed for physicians to document the degree of functional impairment using a single 8-point scale. This early work subsequently led to the development of a number of conceptual frameworks, studies, and instruments related to QOL. Even though work related to QOL has progressed over the last half century, a common definition for this concept has yet to emerge. Despite the lack of a precise definition, QOL is broadly accepted to be a multidimensional construct that represents an individual’s perception of his or her health, happiness, and general well-being at any given period of time. Common dimensions include physical function, psychoemotional function, social function, and role function.

The goal of healthcare today is to improve the QOL of patients, in addition to curing physical illness. Subjective well-being and positive emotions and experiences (eg, happiness, life satisfaction) are critically important to measure in patients because of their adaptive significance. Research has repeatedly shown that people, including those with chronic physical health problems, who are happy and who report an inner experience of contentment, adapt more successfully to changes in health status, have more satisfying interpersonal relationships, maintain perseverance in the face of adversity, and consume fewer healthcare resources.³⁻⁵ Therefore, developing interventions to enhance QOL are crucial for patients confronting significant health changes (ie, chronic illness and transplantation).

As healthcare has become more successful in treating illness, concerns of providers, as well as patients, have gradually shifted to diminishing the side effects of treatment and enhancing QOL. In the field of organ transplantation, although patient and graft survival is remarkably high, opportunities to improve transplant outcomes exist particularly as they relate to patient self-reported indicators of QOL. In the field of kidney transplantation, for example, researchers have found that over the last decade, QOL scores before kidney transplantation have been improving steadily, whereas posttransplant QOL scores have remained stagnant or may even be worsening.⁶ The trend toward improved QOL in kidney transplant candidates may be related to proactive measures being taken in dialysis units to assess QOL and design interventions accordingly, the earlier referral of patients for transplantation,

and an increase in the number of preemptive transplants. The failure to see similar gains in the post-transplant kidney population may be related to (1) the failure to address QOL issues explicitly during the posttransplant period; (2) more aggressive immunosuppression in recent years; and (3) an increased survival rate, which has resulted in more patients with comorbidities retaining functioning grafts. Although observations such as these are limited to the kidney transplant population and may not be directly applicable to recipients of other organ types, we believe that optimal levels of posttransplant QOL are not being achieved within the transplant population as a whole. Therefore, it is important to monitor QOL trends in transplant recipients in order to improve their QOL outcomes.

Use of QOL Findings in Practice

One way to gauge the state of a science and its relevance to practice is by the attention given it in the literature, particularly in the form of review articles. Generally, review articles are prepared only when there is a sufficient body of literature for synthesis and the generation of recommendations for theory, practice, or research. During the 1970s, 4 review articles were indexed in PubMed related to QOL in kidney disease. By the 1980s, interest in QOL grew, producing 38 review articles. By the 1990s, a clear place of prominence was established for QOL as a key outcome in transplantation with the publication of 246 review articles.⁷ Given the information generated over the last several decades, some important questions remain: What are we doing with what we know? Are we systematically assessing and documenting QOL? How are we addressing QOL concerns that have been identified? Is QOL being considered from a sociopolitical perspective?

Despite the accumulation of QOL information related to transplantation, studies are for the most part

descriptive in nature. Ongoing systematic assessment and documentation of QOL needs to replace time-limited, center-specific studies, and build on efforts to incorporate QOL as an outcome in clinical trials. QOL needs to be integrated into our practice and become a goal for transplant recipients. To accomplish this, QOL must be measured systematically and benchmarked as an independent outcome so that strategies may be developed to improve clinical practice.

The Patient Outcomes Registry for Transplant Effects on Life (PORTEL) is a step in that direction. It provides a mechanism for the systematic assessment of QOL outcomes and ultimately serves as a resource for data that can be used for benchmarking purposes. Armed with this information, strategies can be designed hopefully to help transplant recipients dramatically improve their QOL. In this supplement, we present the first annual report of the PORTEL registry and challenge transplant centers across the country to consider how they are addressing their patients' QOL goals.

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The PORTEL registry: overview and selected findings

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A nationwide registry, the Patient Outcomes Registry for Transplant Effects on Life (PORTEL), was established to evaluate the impact of organ transplantation on patients' lives, determine the effects of immunosuppressive regimens on posttransplant outcomes, and identify predictors of posttransplant quality of life (QOL). The QOL framework (Figure 1) that forms the foundation for the PORTEL registry is composed of 5 interrelated domains: (1) health factors, (2) social factors, (3) major health events, (4) major life events, and (5) QOL and related factors. Health factors include conditions that transplant recipients experience related to their health status. These factors are for the most part ongoing in nature, and include examples such as the persistent need to manage chronic health conditions like diabetes or the side effects of therapy such as osteoporosis. Often, an overriding factor for transplant recipients is the adequacy of their organ function. Overall, these health factors are influenced by, and also influence, the occurrence of major health events. Major health events are more episodic in nature and are often related to the occurrence of a rejection episode or a severe adverse event such as a bone fracture due to osteoporosis.

An individual's health status is also linked to social factors and the major life events that he or she encounters. Much like health factors and major health events, social factors are conditions and events that generally characterize the individual's social environment, whereas major life events are more episodic and disruptive to the individual's usual routine. Social factors can include socioeconomic status, available social

support, and employment status. Major life events may include the death of a family member, an unexpected change in living arrangements, or the loss of a job.

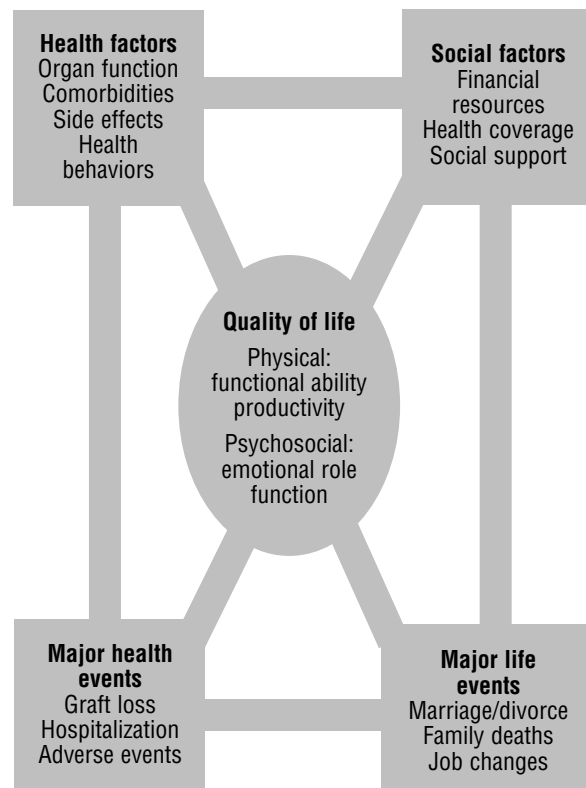


Figure 1 The quality-of-life framework.

All 4 of these domains interact with one another, and together influence QOL in terms of both its physical and psychosocial components. The degree to which health and social factors and major health and life events affect QOL can be mediated by a number of variables. For example, compliance with prescribed health regimens and participation in health-related behaviors serve as a buffer, either dampening or enhancing the influence of these factors and events on QOL outcomes.

QOL may be conceptualized in a multitude of ways. Regardless of how QOL is viewed, it is important that any undertaking to study or measure this construct be done within a clear and broad framework that includes physical, emotional, and role function components. The framework created as part of the PORTEL project has successfully aided the development and implementation of the registry.

Methods

Solid-organ transplant recipients were contacted through various mechanisms including national transplant meetings, referrals from transplant centers, community events, support groups, and direct mail. All transplant recipients 16 years of age or older with functioning grafts were eligible to participate. Patients were invited to participate in the registry without restrictions on the type of immunosuppressive regimen that they were on or the amount of time that had elapsed since the date of their transplantation.

Patient confidentiality was assured to all patients, and financial support for the registry (Fujisawa Healthcare, Deerfield, Ill) was disclosed to participating providers and patients. Institutional review board approval and patient informed consents were obtained at participating centers when requested and appropriate. No marketing or educational materials were provided to registry participants along with the survey instruments.

Study Design and Data Collection

The registry was designed as a large observational registry to capture patient-reported outcomes in a real-world environment and to reflect patterns of disease and care. Recruitment occurred through a broad range of settings to ensure a diverse study population. Because this is an observational study with ongoing enrollment, no attempt was made to ensure that patients to date who enrolled from a particular center were a random sample of patients seen at that center. Over time, as enrollment in the registry increases, we will be able to stratify patients based on center-specific and national demographics.

Patients who enrolled in the registry were asked to complete a self-administered 100-item instrument consisting of 5 domains: (1) health factors (organ function, medications, hospitalizations), (2) social factors

(socioeconomic status, social support, and productivity), (3) major health events (rejection episodes, adverse events), (4) major life events (family changes, employment), and (5) QOL and related outcomes (physical appearance, general health, disease specific health). Patients enrolled in the registry were contacted every 6 to 12 months and were asked to complete the same questionnaire. The survey took about 20 minutes to complete.

The survey instrument was organized to collect the following patient variables and outcomes: demographics, clinical outcomes, medications, and side effects.

Demographics. Patients were asked to report demographics including age, gender, race, socioeconomic status, work status, living arrangements, and social support.

Clinical Outcomes. Patients were asked to rate transplanted organ function (on a scale from 0, not at all, to 5, perfectly) and to report comorbidities, hospitalizations, and the number of treatments for rejection, infection, and overimmunosuppression.

Medications. Patients reported antirejection medications and doses taken in the last 6 months. Patients also reported medications taken for a variety of common comorbidities including diabetes and hypertension.

Side Effects. The frequency and severity of known immunosuppressive side effects were assessed using the Memphis Survey. This survey was developed in 1997 independently of the registry to measure the occurrence (frequency) and impact (severity) of side effects of immunosuppressive medications on QOL in transplant recipients.¹ It is the only disease-specific instrument developed using a multistage factor analysis designed to capture items of most relevance to transplant recipients on a variety of immunosuppressive medications including cyclosporine, tacrolimus, mycophenolate mofetil, and rapamycin. The initial questionnaire included more than 100 items representing a wide range of possible problems a patient could face, including headache and hyperglycemia. Following factor analysis, a smaller subset of items emerged as independent factors contributing to QOL.

The Memphis Survey has 4 subscales: emotional burden, life/role responsibilities, mobility, and gastrointestinal distress. A fifth subscale includes miscellaneous side effects (enlarged gums, increased hunger, staying asleep, weight gain, increased hair growth, infections, trembling hands, high blood pressure, easy bruising, loss of interest in sex and sexual performance) found to be more prevalent during the first 2 years after transplantation. Symptom experience consists of 2 dimensions—symptom occurrence (do you

have this problem?) and symptom distress (how troubling is it?). Frequency and severity of each side effect were coded on a scale of 0 to 4, from “no problem” to “always a problem.” Participants obtained subscale scores ranging from 0 to 40, with higher scores representing a worse side effect profile.

Quality of Life. Recent reviews in QOL research have demonstrated the importance of including multiple measures of QOL, including both disease-specific and generic instruments as part of a complete health assessment. According to a report from the Transplant Outcomes and Research Group, a thorough evaluation of health status involves pairing a generic questionnaire with a disease-specific questionnaire.² In keeping with these recommendations, the Memphis Survey was used to provide a disease-specific perspective and the short form-12 (SF-12), a generic QOL instrument, was used to assess overall QOL.³ The SF-12 (Quality-Metric, Boston, Mass) was designed to be a shorter alternative to the SF-36, the gold standard tool in QOL assessment.⁴ The summary measures of the SF-36 comprise an 8-scale health profile, whereas the SF-12 primarily tests patient assessment of physical and mental health, using 2 summary measures: the Mental Component Summary (MCS) and the Physical Component Summary (PCS). Preliminary tests of reliability and validity have found the SF-12 to be highly correlated with the SF-36 making it an appropriate choice for research studies with large sample sizes and constraints on questionnaire length.

Physical Appearance. Due to the known cosmetic side effects of some immunosuppressive medications, questions about physical appearance were designed based on a previously unpublished Physical Appearance Scale developed by Bergner. This scale has been used in prior studies comparing immunosuppressive agents.⁵ The questions were developed prior to the initiation of the registry, and were designed to address the effects of immunosuppressive agents on aspects of physical appearance such as satisfaction with appearance and embarrassment due to increased hair growth or enlarged gums.

Data Analyses

The majority of the data in this report are presented descriptively at the cross-sectional level. Significance testing was conducted only for comparisons of interest, such as the determination of demographic differences between comparative groups. As the registry enrolls more participants, we will be able to conduct additional statistical testing, including longitudinal analysis and predictive modeling.

Descriptive statistics were generated for patient demographics, clinical outcomes, side effects, and QOL.

In addition, data were analyzed by organ type, immunosuppressive regimen, and time since most recent transplantation. Assessments of patient outcomes, side effects, and QOL were conducted across various immunosuppressive agents, although the analyses focused on cyclosporine- and tacrolimus-based regimens. To examine outcomes over time, patients were assigned to clinically relevant discrete groups based on number of years since most recent transplantation: less than 1 year, 1 to 2 years, and 3 to 5 years. All data analyses were performed using SPSS version 10.0.7 statistical software (SPSS Inc, Chicago, Ill).

In the following sections, data collected in each of the 5 domains (health factors, health events, social factors, life events, and QOL outcomes) are presented. In the first section, we describe the characteristics of the registry population. In the second section, we report data on health factors and health events including patient-reported adverse events, side effects and comorbidities. The data are presented by organ type, time since transplantation and immunosuppressive regimen. In the third section, we report social factors and life events including work status and the impact of physical appearance on social activity. The last section examines QOL outcomes across a number of different variables, including demographic, social, and clinical factors.

Selected Findings

Registry Population: Overview

Overall, this report includes 771 patients representing all geographic areas of the United States. The registry population had an average age of 50, consisted of slightly more men than women and although all major racial groups were represented, predominantly included white people (Table 1). Less than 4% of registrants reported an educational level less than 12th grade, nearly 35% reported having at least 1 college degree (Table 2) and nearly one third of patients categorized themselves as having a managerial or professional career (Table 3). In general, the distribution of registrants by organ type was representative of the national transplant population with the majority of patients being kidney transplant recipients (Figure 2). The time since transplantation ranged from less than 1 year to more than 11 years with the majority of patients at 2 years or less posttransplantation (Figure 3). Roughly equal proportions of registry participants reported being on either a cyclosporine- (n=397) or tacrolimus-based (n=311) immunosuppressive regimen. Whether on a tacrolimus- or cyclosporine-based regimen, the majority of patients reported being on triple therapy and the vast majority of registry participants noted the inclusion of prednisone as a part of their immunosuppressive regimen (Figure 4).

Demographically, the registry participants were similar to the general transplant population in terms of

Table 1 Demographic data of recipients*

Variable	No. of recipients	%
Total respondents	771	
Age, mean, years	50.7	
Race		
White	620	80.4
African American	55	7.1
Asian American	8	1.0
Hispanic	41	5.3
Other	16	2.1
Gender		
Women	361	
Men	407	

*Numbers do not account for missing data.

Table 2 Highest level of education attained*

Education level	No. of recipients	%
8th grade or less	15	1.9
9th to 12th grade	15	1.9
High school graduate	157	20.4
Some college or technical school	302	39.2
4-year college	155	20.1
Graduate school	59	7.7
Postgraduate/professional school	59	7.7

*Numbers do not account for missing data.

Table 3 Occupation before transplantation*

Occupation	No. of recipients	%
Manager/professional	240	31.1
Technical/sales/administrative support	92	11.9
Homemaker	56	7.3
Student	56	7.3
Service occupation	51	6.6
Precision production	42	5.4
Operator/fabricator/laborer	39	5.1
Retired	32	4.2
Other	193	25.9

*Percentage exceeds 100% because of multiple responses.

age, gender, and organ type. However, several differences existed between the registry participants and the general transplant population. The registry participants were much more recent transplant recipients than the general transplant population, with approximately 50% being less than 3 years posttransplantation. In addition, the percentage of African American patients in the registry is lower than the national average. As registry

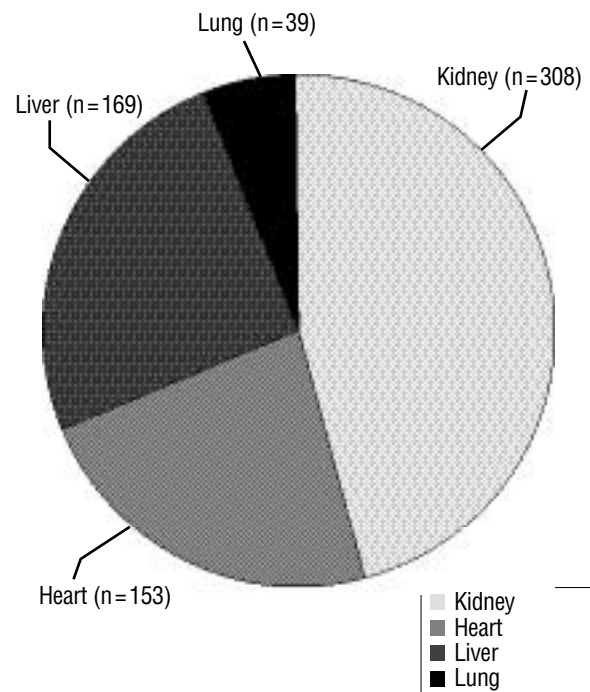


Figure 2 Distribution of single organ transplants.*

*Numbers do not account for 53 repeat transplantations and 33 combined transplantations.

data are reviewed, it is important to do so within the context of these participant characteristics.

Health Factors and Health Events

Health factors and major health events are presented by organ type and because nearly all patients were on either cyclosporine- or tacrolimus-based therapy, data are also presented by primary calcineurin inhibitor. Additionally, because the length of time since transplantation can have a marked influence on QOL outcomes, data are presented by posttransplant time interval.

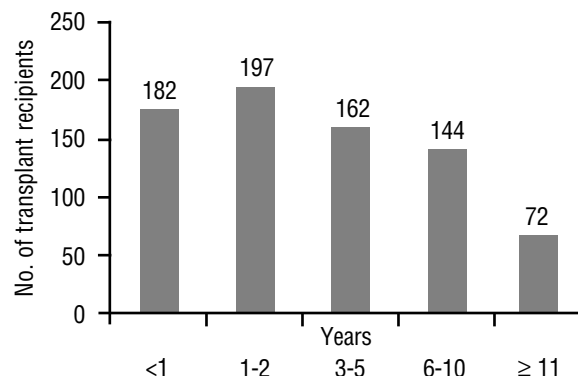


Figure 3 Time since most recent transplantation.

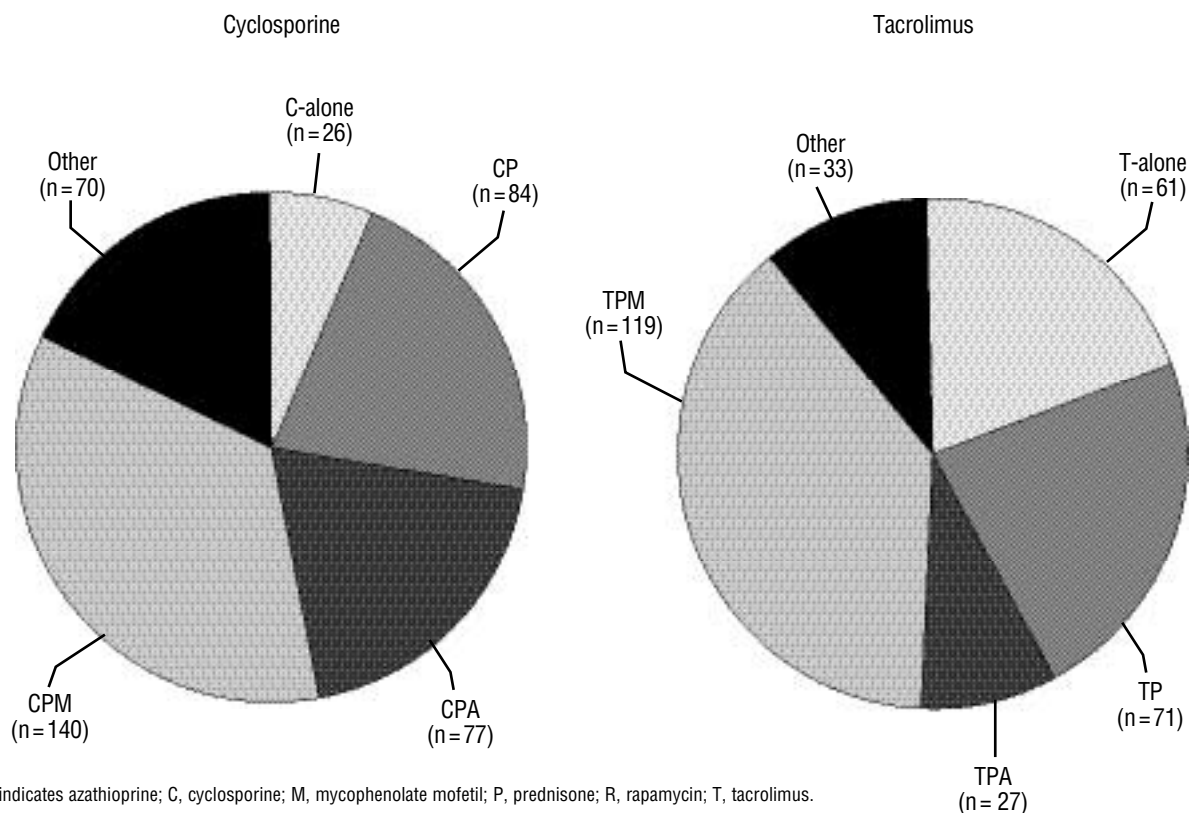


Figure 4 Distribution of immunosuppressive regimens.

Organ Type and Time Since Transplantation. The number of pancreas and lung recipients participating in the registry was insufficient for data analysis; therefore, data only from kidney, heart, and liver recipients are included in this annual report. Figure 5 reports the major health events experienced by registry participants. Infection was the predominant problem for all groups of recipients and with the exception of hospitalizations, kidney recipients reported the fewest problems.

Table 4 indicates that heart recipients experience the greatest rate of diabetes, hypercholesterolemia, and osteoporosis whereas kidney recipients have the greatest rate of hypertension. Figure 6 reports the side effect profile using Memphis Survey results for kidney, liver, and heart recipients who are less than 1 year, 1 to 2 years, and 3 to 5 years posttransplantation. At less than 1 year, side effects in the emotional and mobility domains were the most problematic for patients regardless of organ type. Mobility continued to be the most problematic domain at 1 to 2 years and 3 to 5 years for recipients of all organ types. Furthermore, problems with mobility were greatest for all three groups of transplant recipients who were 1 to 2 years posttransplantation. Life role problems were also greater for all groups of recipients who were 1 to 2 years posttransplantation compared with patients who were less than

1 year posttransplantation. Kidney and heart recipients who were 1 to 2 years posttransplantation reported more emotional problems than those who were less than 1

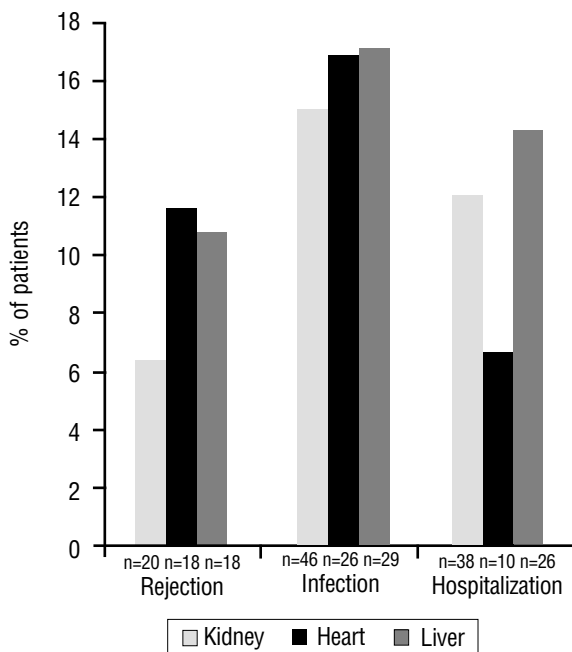


Figure 5 Health events by organ type.

Table 4 Comorbidities by organ type

	Diabetes No. (%)	Cholesterol No. (%)	Hypertension No. (%)	Osteoporosis No. (%)
Kidney	55 (17.9)	123 (39.9)	231 (75.0)	51 (16.6)
Heart	35 (22.9)	78 (51.0)	100 (65.4)	43 (28.1)
Liver	25 (14.8)	17 (10.1)	69 (40.8)	36 (21.3)

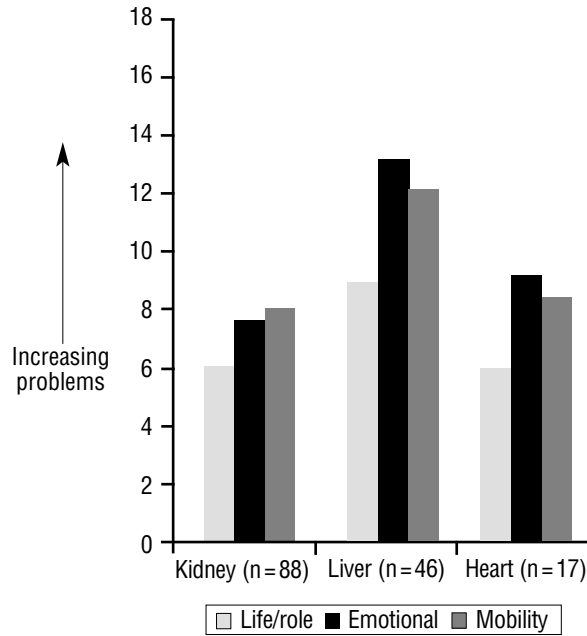


Figure 6A Memphis life/role, emotional, and mobility side effect severity scores at <1 year by organ type.*

*Significance testing was conducted for kidney vs liver recipients. For the life/role subscale, $P < .05$; for the emotional subscale, $P < .001$. Significance testing was not conducted for heart recipients because of small sample size.

year posttransplantation. Liver and heart recipients who were 3 to 5 years posttransplantation did not report a markedly different side effect profile than those who were 1 to 2 years posttransplantation. However, kidney recipients who were 3 to 5 years posttransplantation reported more problems than their counterparts who were 1 to 2 years posttransplantation. These data suggest a stabilization of side effects for liver and heart recipients and increasing problems for kidney recipients over time since transplantation. This interpretation is limited by the cross-sectional nature of the analysis. Additional data that follows a cohort of transplant recipients over time will be required to confirm whether these trends do in fact reflect the common trajectory of side effects encountered after transplantation.

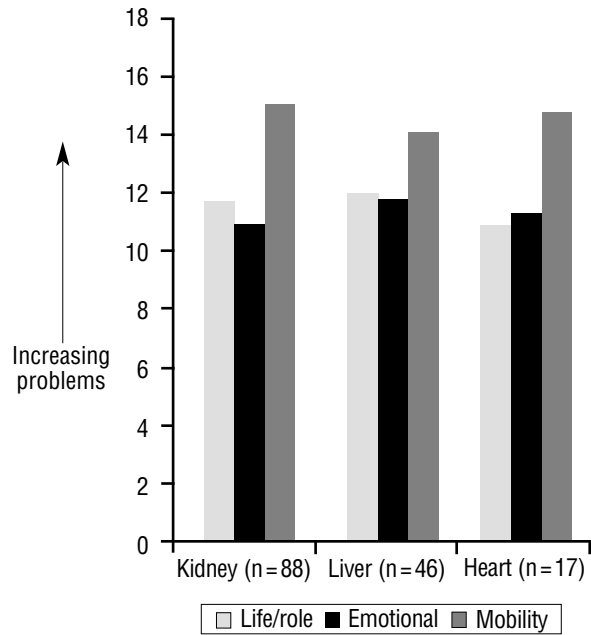


Figure 6B Memphis life/role, emotional, and mobility side effect severity scores at 1 to 2 years by organ type.*

*No comparisons were found to be significantly different for kidney vs liver recipients.

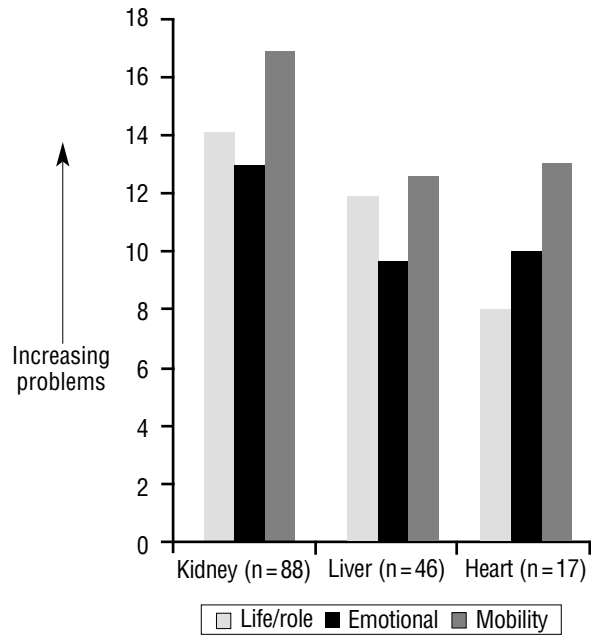


Figure 6C Memphis life/role, emotional, and mobility side effect severity scores at 3 to 5 years by organ type.*

*Significance testing was conducted for kidney vs liver recipients. For the emotional subscale, $P < .05$. The life/role and mobility subscales were not found to be significantly different for kidney vs liver recipients.

Immunosuppressive Regimen and Time Since Transplantation. Demographically, significant differences were found between patients on cyclosporine-

	Cyclosporine	Tacrolimus	<i>P</i>
No. of recipients (%)	402 (52.1)	313 (40.6)	NA
Age, years	52.9	48.3	<.001
Gender			
Men, No. (%)	233 (58)	150 (47.9)	<.01
Years since last transplantation	5.7	2.6	<.001

NA indicates not available.

versus tacrolimus-based therapy in terms of age, gender, and time since transplantation (Table 5). However, it may be argued that an age difference of 4.6 years and a 10% difference in the number of men between the 2 groups are not clinically important. The difference in time since transplantation is, however, of importance and the fact that patients reporting tacrolimus-based therapy are only 2.6 years posttransplantation should be taken into consideration when examining data by immunosuppressive regimen.

Health factors impinging on QOL in the form of comorbidities were similar for both groups in terms of diabetes and osteoporosis; however, across most time intervals, the tacrolimus-based group reported less hypertension and high cholesterol than the cyclosporine-based group (Figures 7 and 8).

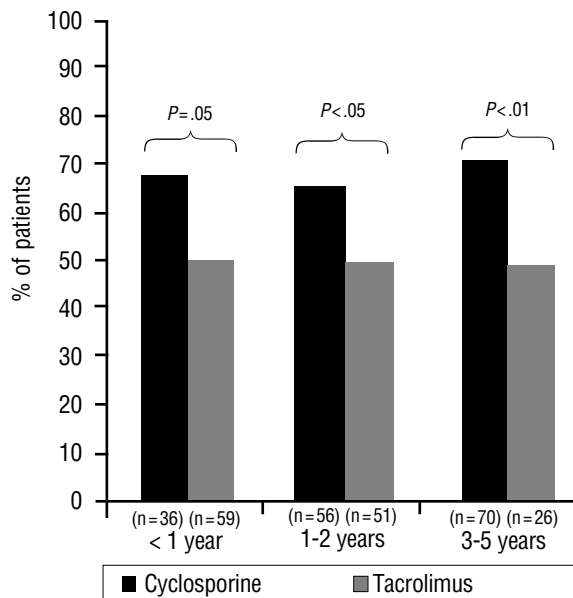


Figure 7 Prevalence of high blood pressure by regimen and time since transplantation.

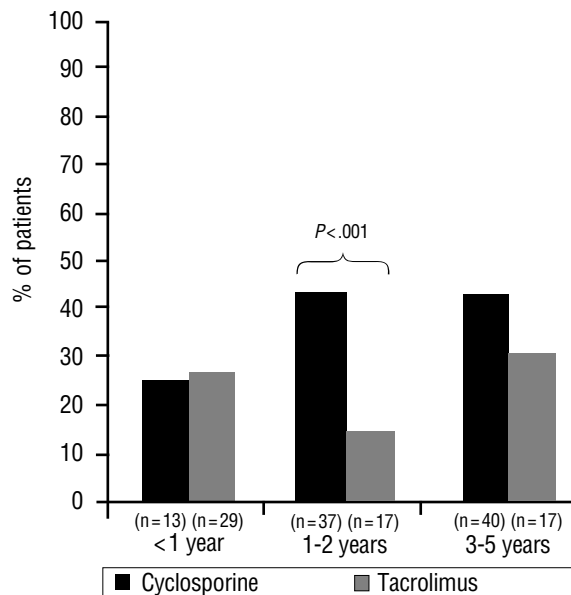


Figure 8 Prevalence of high cholesterol by regimen and time since transplantation.

The Memphis Survey indicated that side effects were present regardless of what immunosuppressive agent formed the basis of therapy, but were not at highly problematic levels. Overall, both groups of patients reported the fewest problems in life role with a stable level over time since transplantation. The mobility subscale indicated that patients who were less than 1 year posttransplantation experienced the fewest problems, whereas problems were greater for patients at 1 to 2 years posttransplantation and 3 to 5 years. The miscellaneous subscale (Figure 9) that

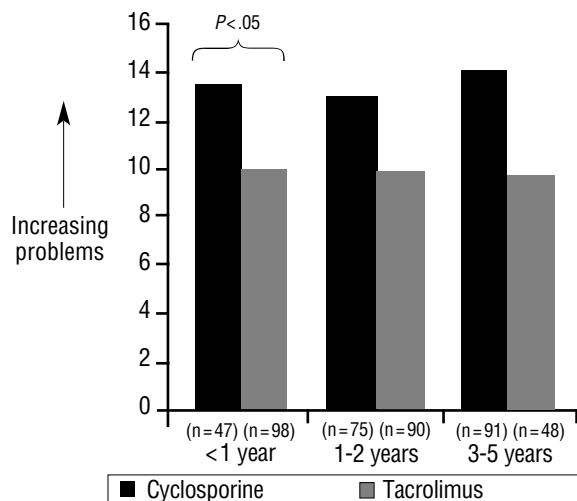


Figure 9 Memphis miscellaneous subscale severity scores by regimen and time since transplantation.

includes items found to be most problematic during the first year after transplantation—high blood pressure, staying asleep, easy bruising, weight gain, loss of interest in sex, increased hair growth, sexual performance, infections, enlarged gums, trembling hands, and increased hunger—did in fact have the highest scores for both groups of patients who were less than 1 year posttransplantation. However, patients who were 1 to 2 years and 3 to 5 years posttransplantation reported a similar level of problems in the miscellaneous domain compared to the mobility domain. Patients on tacrolimus-based regimens reported fewer problems in the mobility, life/role, and miscellaneous domains at all time intervals. It is of interest that lower scores on the miscellaneous subscale are an unexpected finding given that this subscale reflects problems encountered more commonly during the first year posttransplantation, and that the tacrolimus-based therapy group has a shorter mean time from transplantation than the cyclosporine-based group.

Summary. Although all groups of organ recipients experience some degree of health problems following transplantation, the mere existence of these problems should not diminish the importance of the overall benefit of transplantation as a life-changing procedure. The severity of the side effects reported by the participants in this registry indicated that they reached levels described as being only mildly problematic. Similarly, the percentage of major health events experienced by this group of patients was arguably much less than what would have occurred had they not undergone transplantation. Therefore, these data provide evidence that although some health problems accompany transplantation, recipients do not consider these problems to be major limiting factors in their lives.

Social Factors and Life Events

The primary social factors reported by registrants that could affect QOL included work status, social support, and living status. In terms of work status, approximately 38% patients reported working either full-time or part-time during the past 6 months (Figure 10). Patients at 1 to 2 years and 3 to 5 years posttransplantation reported a higher rate of employment than those less than 1 year posttransplantation (Figure 11).

Major life events occur as a result of a significant change in an individual's life situation, such as a marriage or divorce, loss of employment, or something of similar significance. Data in this first annual report are cross-sectional in nature and as such cannot capture change in the registry participants' status from a previous data collection point. Future reports will be able to examine the presence and influence of major life events for transplant recipients.

Perhaps one of the biggest concerns of transplant recipients that affect social role function is body image.

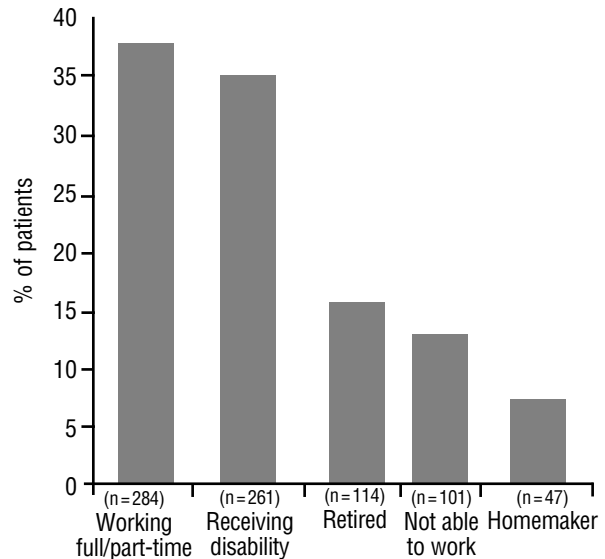


Figure 10 Current work status.

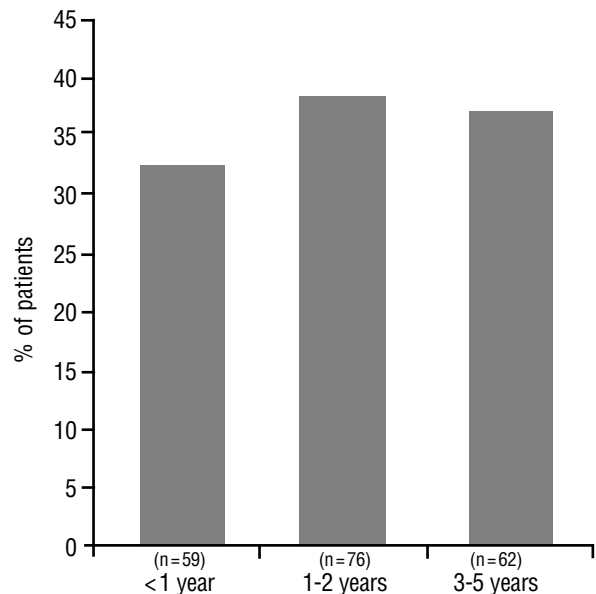


Figure 11 Percentage of patients working full or part-time by time since transplantation.

Self-reported physical appearance improved following transplantation, but continued to cause problems for patients in various social situations and interpersonal relationships such as spending time with family and friends, working outside the home, and sexual relations (Figures 12 and 13). Over 15% of patients reported problems with social functioning with friends and at work while nearly 30% reported problems with sexual functioning as a result of physical appearance. Although these percentages reflect a significant number of patients, physical appearance has not typically been a concern of healthcare providers during the posttransplant course

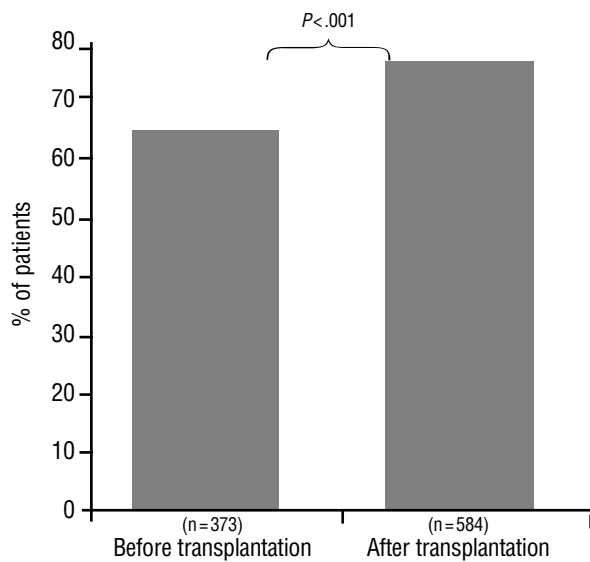


Figure 12 Patients reporting good to excellent physical appearance before and after transplantation.

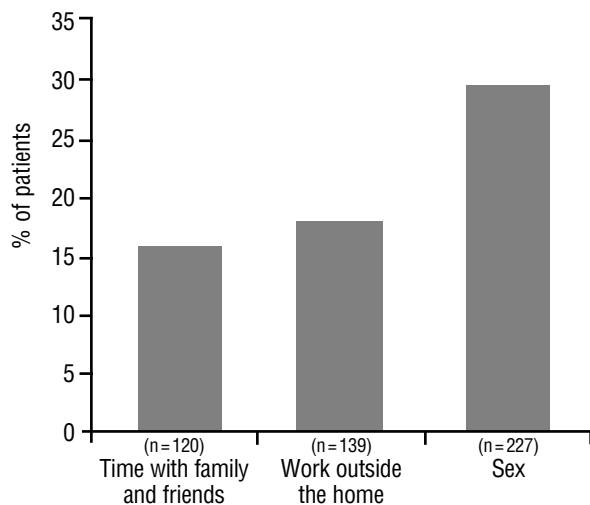


Figure 13 Patients reporting having problems with social functioning because of physical appearance.

of care. These data suggest that the quality of transplant recipients' lives could be further improved if concerns regarding physical appearance are addressed.

QOL Outcomes

Overall, QOL is represented by the PCS and MCS component scores of the SF-12. Scores for the general US population on this instrument range from 13 to 69 for the PCS and 10 to 70 for the MCS. Overall, MCS scores for transplant recipients were comparable to MCS scores for the general US population.; However, PCS scores were lower compared to the general population, indicating impaired physical QOL.

Health Factors and Health Events. Age and gender are demographic factors that can influence health. Although gender differences in QOL were not apparent, a trend appeared related to age (Figure 14). Although physical QOL seems to diminish somewhat for registry participants in older age groups, mental QOL appears to be better for the older age groups.

Type of transplanted organ and time since transplant are key factors associated with transplantation

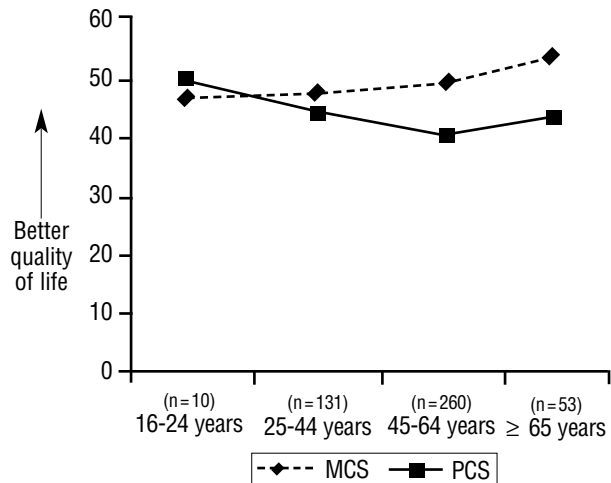


Figure 14 SF-12 scores by age.

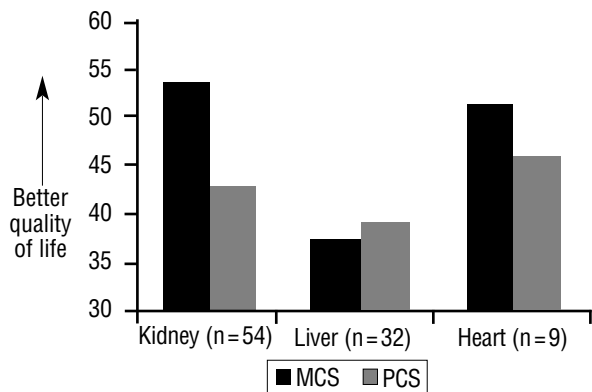


Figure 15A SF-12 scores by organ type at < 1 year since transplantation.*

*No comparisons were found to be significantly different for kidney vs liver recipients. Heart recipients were not compared because of small sample size.

that can influence QOL outcomes. Figure 15A suggests that for patients less than 1 year from transplantation, kidney and heart patients fared somewhat better than liver recipients in terms of QOL. Interestingly, liver recipients who were 1 to 2 years posttransplantation reported better QOL than their fellow liver recipients who were less than 1 year posttransplantation (Figures 15 A and B). In contrast, kidney recipients 1 to 2 years

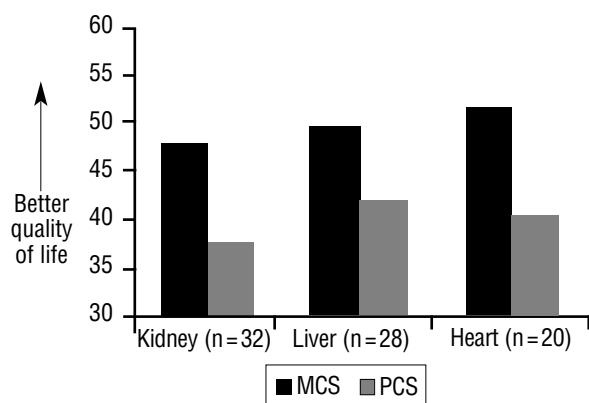


Figure 15B SF-12 scores by organ type at 1 to 2 years since transplantation.*

*No comparisons were found to be significantly different for kidney vs liver recipients. Heart recipients were not compared because of small sample size.

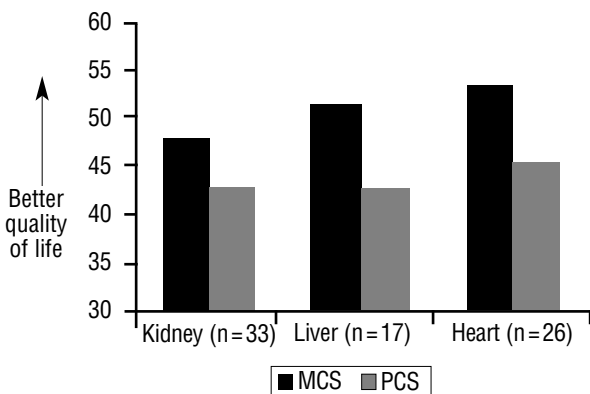


Figure 15C SF-12 scores by organ type at 3 to 5 years since transplantation.*

*No comparisons were found to be significantly different for kidney vs liver recipients. Heart recipients were not compared because of small sample size.

posttransplantation reported poorer QOL than did those less than 1 year, and heart recipients at the 2 time points were quite similar (Figures 15A and B). The net result of these shifts is that little difference appears to exist in SF-12 scores for patients who were 1 to 2 years posttransplantation regardless of transplant type. The observation remains essentially unchanged when SF-12 scores are examined for patients who were 3 to 5 years posttransplantation (Figure 15C).

Social Factors and Major Life Events. Employment and social support are key social factors that have the potential to influence QOL significantly. Registry participants who were employed reported better MCS and PCS scores than participants who were not employed (Figure 16). Available data do not permit determination of whether physical status prohibited employment, employment enhanced physical

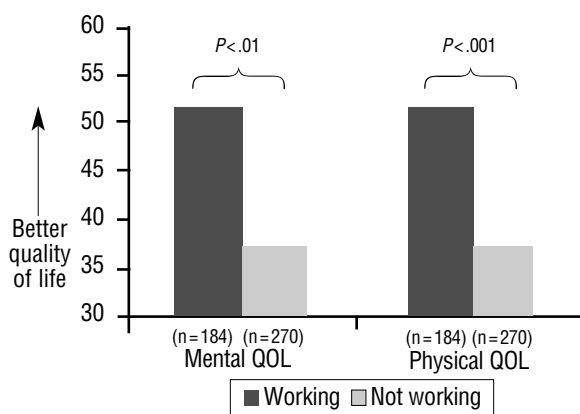


Figure 16 SF-12 scores by work status.

status, or both situations were present. Regardless, it should be a goal for transplant recipients to return to a productive life whether it be employment for pay, volunteer work, or an active life as a homemaker.

Whether an individual lives alone or with other people is one indicator of social support. For our registry participants, the presence of another person in the household was associated with a higher mental, but lower physical component score (Figure 17). These data suggest that having another person physically close to share your day-to-day experiences enhances emotional well-being. In terms of physical well-being, the presence of another person could be viewed much like employment. Is another person present because the transplant recipient needs the assistance, or does living alone enhance independent physical activity? Examination of social support data regarding the number of people available to provide support suggests an answer to this question (Figure 18). These data show that as the number of individuals available for support increased, so did both the mental and physical component scores, suggesting that the support of more people is associated with better physical well-being.

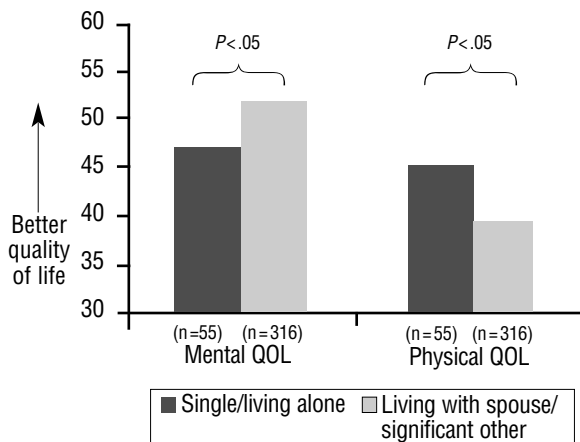


Figure 17 SF-12 scores by living status.

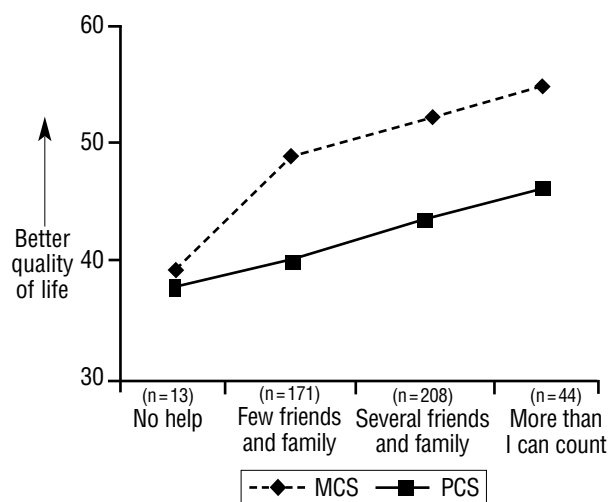


Figure 18 SF-12 scores by social support.

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Future directions in quality-of-life research and intervention

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The future will continue to bring an increasing emphasis on quality-of-life (QOL) outcomes in healthcare. As we make more strides in our ability to conquer disease and illness, the consequences of therapies on people's lives will be of major importance, not only as factors in determining which of several alternative therapies should be chosen, but if a therapy should be chosen at all. A key consideration of patients has always been how therapies influence their lives. Increasing consumer knowledge and empowerment will result in greater participation of patients in managing their illness and making key therapeutic decisions. The growing interest of third-party payers in QOL outcomes will further contribute to the increasing significance placed on QOL. As payers examine the cost-effectiveness of various therapeutic interventions, more questions will arise concerning the QOL they provide.

The continued emphasis on QOL will have direct implications for research and practice. Most of our QOL research in transplantation has been descriptive in nature. Studies are emerging that focus on the prediction of outcomes and on interventions that may enhance QOL. For example, researchers have begun to examine whether specific psychological interventions have QOL benefits for transplant recipients. One such clinical trial is currently underway at the University of Florida. Funded by the American Lung Association of Florida, researchers are randomizing adult lung transplant candidates on the waiting list to receive either traditional supportive psychotherapy or QOL therapy. In the latter group, patients receive weekly sessions targeting 16 areas of life that appear to be most relevant to overall life satisfaction or QOL. These include health, self-esteem, goals and values (or philosophy of life), standard of living, work, recreation, learning, creativity, helping others, love relationship, friendships, relation-

ships with children, relationships with relatives, home, neighborhood, and community. Researchers are monitoring changes in perceived QOL, psychological functioning, relationship satisfaction, physical health, and health service utilization patterns.

We need more of these studies if our research is ultimately to direct practice. Data from these efforts need to be assembled and published to further our body of knowledge, help to identify patients who are most at risk for compromised QOL and to determine the types of interventions that will be most helpful to them.

As we apply our findings to patient care, we must carefully consider how to make the transition from existing practices to new ones. Most QOL instruments have been research-driven; we now need to consider their utility in the clinical practice setting. Specifically, we must determine if the currently available tools are measuring what we want to know in a clinically relevant manner. We must also examine the social services offered to patients by transplant centers. Many transplant programs offer some type of supportive therapy, usually in a group format, for their transplant recipients. Most of these groups are organized to provide some elements of peer discussion and information pertinent to the transplant process. Despite their widespread use and hypothesized benefits, further research must be conducted systematically to validate their effectiveness in either improving QOL or ameliorating psychological distress.

Another trend is the emphasis on multidisciplinary practice and research. Multidisciplinary teams are being utilized more frequently in the exploration of QOL with research scientists representing the fields of nursing, medicine, psychology, sociology, and statistics. Because of the limited availability and competition for research dollars, as well as the fresh perspective brought by other disciplines, the emphasis on multidisciplinary work will

continue. Finally, it will be important to keep in mind that QOL is value-laden and is an individual's self-perception. The subjective nature of QOL must be considered as we determine what dimensions of QOL should be assessed and how we use this information.

The PORTEL (Patient Outcomes Registry for Transplant Effects on Life) project provides a mechanism by which we can begin to address some of the important QOL issues facing transplantation. The framework upon which the registry is built provides an essential multidisciplinary view of QOL and main-

tains the necessary patient perspective of this construct. As a nationwide registry, PORTEL will generate multisite data that are longitudinal in nature and provide an opportunity for us to move beyond mere description of posttransplant QOL outcomes. Ultimately, registry data may be used for benchmarking purposes and to design and monitor interventions to enhance posttransplant QOL. We know organ transplantation improves QOL. Through a systematic assessment of posttransplant QOL we will be able to help transplant recipients attain the highest level of QOL possible.

PROGRESS IN TRANSPLANTATION

CE

CE Test Instructions

To receive continuing education credit for this test (ID 4000-J31S), mark your answers on the form below, complete the enrollment information, and submit it with the \$13 processing fee (payable in US funds) to the American Association of Critical-Care Nurses (AACN). Answer forms must be postmarked by June 1, 2005. Within 3 to 4 weeks of receipt of your test form and determination of your passing score, AACN will send you a CE certificate. Your certificate will be accepted by ABTC and AACN for continuing education credit.

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CE Test Form

Test ID: 4000-J31S
Form expires: June 1, 2005
Contact hours: 2.5
Passing score: 11 correct (73%)
Test writer: Ruth Kleinpell-Nowell, RN, PhD, CS, CCNS
AACN Category: A
ABTC Category: I
Test fee: \$13

Patient Outcomes Registry for Transplant Effects on Life

Objectives

1. Identify the purpose and goals of the Patient Outcomes Registry for Transplant Effects on Life
2. Explain the differences that were found in quality-of-life outcomes for organ transplant recipients
3. Discuss the clinical implications of the findings of the Patient Outcomes Registry for Transplant Effects on Life

Mark your answers clearly in the appropriate box. There is only one correct answer. You may photocopy this form.

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Program evaluation

	Agree	Neutral	Disagree
Objective 1 was met	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 2 was met	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Objective 3 was met	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The content was appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
My expectations were met	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This method of CE is effective for this content	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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CE Test Questions

Patient Outcomes Registry for Transplant Effects on Life

1. What instrument is considered the gold standard tool in quality-of-life (QOL) assessment?
 - a. Karnofsky Performance Measure
 - b. Quality of Life Index
 - c. SF-12
 - d. SF-36
2. Which one of the following is not a domain of the QOL framework for the Patient Outcomes Registry for Transplant Effects on Life (PORTEL)?
 - a. Major life events
 - b. Health factors
 - c. Employment status
 - d. Social factors
3. The PORTEL registry represents survey results from how many patients?
 - a. 125
 - b. 322
 - c. 771
 - d. 950
4. Transplant recipients of which organ have the greatest rate of hypertension?
 - a. Kidney
 - b. Heart
 - c. Liver
 - d. Pancreas
5. Transplant recipients of which organ experience the greatest rate of diabetes, hypercholesterolemia, and osteoporosis?
 - a. Kidney
 - b. Heart
 - c. Liver
 - d. Pancreas
6. Miscellaneous side effects of immunosuppressive therapy, such as enlarged gums, weight gain, and increased hunger, are found to be more prevalent during what time frame after transplantation?
 - a. 2 years
 - b. 4 years
 - c. 5 years
 - d. 6 years
7. What QOL domains were the most problematic for transplant recipients at less than 1 year, regardless of the organ type?
 - a. Health and physical status
 - b. Activities of daily living and work
 - c. Emotional and mobility
 - d. Psychological and physical status
8. Transplant recipients of which organ experienced the highest incidence of rejection?
 - a. Kidney
 - b. Liver
 - c. Pancreas
 - d. Heart
9. Which QOL domain was the most problematic at 3 to 5 years for recipients of all organ types?
 - a. Return to work
 - b. Health status
 - c. Social
 - d. Mobility
10. What period after transplantation demonstrated the fewest problems in the mobility subscale?
 - a. Less than 1 year
 - b. 1 to 2 years
 - c. 2 to 4 years
 - d. 5 to 7 years
11. Patients receiving what type of immunosuppressive regimen reported fewer problems in mobility life/role, and miscellaneous domains at all time intervals?
 - a. Tacrolimus-based regimen
 - b. Cyclosporine-based regimen
 - c. Mofetil-based regimen
 - d. Prednisone-based regimen
12. What percentage of patients in the PORTEL registry reported working either full- or part-time?
 - a. 25%
 - b. 38%
 - c. 58%
 - d. 72%
13. What percentage of patients reported problems with social functioning with friends and at work?
 - a. 5%
 - b. 10%
 - c. 15%
 - d. 25%
14. What social factor was associated with increased physical and mental component scores for registry participants?
 - a. Marriage
 - b. Having children
 - c. Employment
 - d. Retirement
15. What is one of the biggest concerns of transplant recipients that affect social role function?
 - a. Employment
 - b. Marital status
 - c. Body image
 - d. Mobility

Shaping the future of transplant health



PORTEL (Patient Outcomes Registry for Transplant Effects on Life) is a survey-based study that focuses on the quality of life of transplant recipients. The goals of this research are to understand the impact of organ transplantation on people's lives and to provide the basis for educational tools to be developed to improve the quality of life of transplant recipients.

Data collected will help create a long-term profile of quality of life following transplantation. Participating centers may request specific reports for benchmarking purposes. Registry findings are also presented at national conferences and events in the transplant community.

Every 6 to 12 months, we send a questionnaire to transplant recipients, asking them about their transplant and how it's affecting their lives. The easy to understand questionnaire takes less than 20 minutes to complete, and asks participants about various issues of concern to them, including:

- Health status
- Medication side effects
- Ability to perform everyday functions
- Family and social support

To find out more about PORTEL or if you would like to start enrolling patients, contact us via phone toll free at (866) 344-7626 or via email at transplantregistry@yahoo.com

PORTEL

Patient Outcomes Registry for Transplant Effects on Life