University of Alberta

Evaluating the Utility of the Sickness Impact Profile as an Outcome Indicator for Liver Transplant Patients

by

Martha Loadman Joyce 

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of
the requirements for the degree of **Master of Science**

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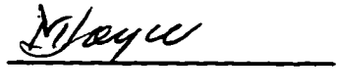

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled **Evaluating the Utility of the Sickness Impact Profile as an Outcome Indicator for Liver Transplant Patients** in partial fulfillment of the requirements for the degree of **Master of Science.**

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Dated: April 14, 1997.

Dedication

To my father and mother, Gordon and Rita, who have given me all that I need for a lifetime, and to my husband, Anthony, who is all that I want for a lifetime.

ABSTRACT

Comprehensive outcome measurement has become an increasingly important requirement in the Canadian health care system. Demonstrating treatment efficacy becomes even more crucial for new and costly procedures such as liver transplants. With the refinement of general health status measures such as the Sickness Impact Profile (SIP), detailed health information to describe and quantify functional capacity of patient populations is now possible. This study evaluates the utility of the SIP as an outcome indicator for liver transplant patients. A one group pretest/posttest design is used to obtain health status information. Health data is collected from a group of liver transplant candidates (n=34) prior to their transplant and the same group of patients are reassessed at two months and six months subsequent to their surgery. The instruments used are the Sickness Impact Profile (SIP), a self-rating of dysfunction scale, a clinician rating of dysfunction scale and the Child-Pugh Classification of Liver Function. The psychometric properties of the SIP that are evaluated include concurrent validity, convergent-discriminant validity and sensitivity. With regard to concurrent validity, SIP scores significantly correlated with patient-rated health scores. The aspect of convergent-discriminant validity was supported by the strength and pattern of intercorrelations. Patient-rated scores correlate more strongly with SIP scores than clinician-rated scores do. The biological variables correlate in expected ways with physical and psychosocial dimension scores. The SIP is also found to be sensitive to changes in health status over time. The SIP appears to detect clinically relevant, disease-specific changes in health such as pre-operative

impairment of sleep and rest patterns and level of alertness. Subsequent to the transplant procedure, the SIP quantifies the marked and generally rapid recovery that many liver transplant recipients make. Statistically significant F values were achieved for comparisons in health status made pre-operatively compared to the post-operative assessment period. Overall, the study provides support for the utility of using the SIP as an outcome indicator for liver transplant patients. Among pre-operative patients with Grade 2 or higher encephalopathy, however, the instrument is not an efficient method for data collection.

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Many thanks to my fellow graduate students, staff at The University of Alberta Hospitals, and friends who have encouraged me. My parents have provided continual love and support and my sister, Amy, reminded me that after self-care and work comes leisure.

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CHAPTER I

INTRODUCTION

Rigorous and comprehensive outcome measurement has become an increasingly important requirement in the Canadian health care system. Outcome measures that encompass the physical, social and emotional aspects of health are used to evaluate treatments or programs. These global health status measures provide important information with regard to overall health and functioning. Demonstrating treatment efficacy is particularly crucial for relatively new and costly procedures such as liver transplants. To date, morbidity and mortality statistics have commonly been used as outcome indicators. Recent reports indicate that Canadian liver transplant patients who underwent surgery between 1991 and 1994 have a three month survival of 90%, and a one year survival that approaches 85% (Canadian Organ Replacement Registry, 1996). The Alberta liver transplant program has reported similar results (see Table 1). For all Canadian patients ever transplanted, one year patient survival approaches 80% and five year survival exceeds 70% (Canadian Organ Replacement Registry, 1996). Given the risk of mortality, information with regard to the overall functioning of surviving patients becomes important for patients, clinician, and health care funders.

The Sickness Impact Profile (SIP) is a global health status measure that enables clinicians to evaluate health from both a functional capacity and psychosocial perspective. "Functional capacity" refers to the ability to engage in meaningful daily activities. "Psychosocial capacity" refers to the qualities necessary for intra- and

interpersonal well-being. The purpose of this study was to evaluate the utility of the SIP as an outcome indicator for a liver transplantation program in a large general hospital in Western Canada. Testing the utility of the SIP as a global health measure for patients in this program, and collecting functional outcome data post-operatively has several important applications. The results will add to data on the validity of the SIP, help program managers to respond to the growing pressure to describe and quantify service outcomes, and provide data that can be used to support the continuation of the liver transplantation program in the face of provincial health care budget reductions.

CHAPTER II

RELATED LITERATURE

An overview of the development of general health status indicators and the psychometric properties of the Sickness Impact Profile (SIP) is presented in this chapter. Studies where the SIP was used as an outcome measure are reviewed to identify the inventory's strengths and weaknesses when applied to various patient groups. The results of outcome studies that have applied various health status indicators to the liver transplantation population to evaluate outcome will be summarized.

Measurement of General Health Status

Long-standing measurement issues as well as recent developments in the areas of health and medicine have been cited as the forces which prompted the development of general health status measures. Leighton Read (1987) indicates that maintaining overall health is the primary objective of health care. Meaningful, summary measures are being developed because few disease or health care interventions have a single clinical effect. Spitzer (1987) dates functional status measurement back to Karnofsky (1949) who developed one of the first "performance status" indices for use with cancer patients. Katz (1970) produced one of the earliest "Activities of Daily Living" indices and measured patients' capacity to carry out personal care tasks independently. The focus of both of these measures is purely "functional", not etiological or physiological. Results simply indicate the extent to which disease or illness impacts

upon a person's performance of everyday activities. The American Rheumatism Association (ARA) functional classification for arthritis (Steinbrocker, Traeger & Batterman, 1949) and the New York Heart Association Functional Classification (The Criteria Committee of the New York Heart Association, 1964) are additional examples of long-standing functional capacity health indices that have been used extensively for several decades.

The World Health Organization (1947), another significant contributor to the history of health measurement, promoted the idea that health is not only the absence of disease but also a state of physical, mental and social well-being. The WHO views health as multi-dimensional and general health status measures attempt to quantify these dimensions.

Recent trends in health care have prompted continued use of indices that assess global health domains. The growing number of palliative rather than curative treatments have forced medicine to recognize the impact a therapy may have on aspects of a patient's life that are not strictly medical. Interventions may have a substantial effect on everyday functioning as well as on a patient's subjective well-being. Both of these outcomes become important to document and monitor in evaluating palliative interventions (Leighton Read, 1987).

Fava (1990) discussed the relevance of health measurement with regard to chronic disease where the goal of therapy is not "cure", but improvement of function as a result of decreased symptoms or severity of illness, or limitation of disease progression. Fava (1990) advocates that evaluation of new therapies for chronic

diseases should not be limited to biomedical measures. The impact of therapy on the lifestyle of the individual should also be assessed. Because chronic conditions such as cardiovascular and respiratory disease are a major public health problem in terms of both the prevalence of the disease and the proportion of health care resources directed towards them, an interest in measuring quality of life and functional status has evolved to meet the need for more comprehensive measurements of treatment outcome.

Deyo and Patrick (1989) suggest that health status information can be used to identify unexpected functional and emotional problems, monitor disease progression or response to therapy, and enhance physician-patient communication about functional impairments. Indeed, for both patients and their communities, maintenance of functional ability is often the most important outcome of medical care. Although physiological measures have diagnostic and monitoring importance for physicians, biological indicators have little inherent social value except as they influence symptoms, functioning and prognosis.

The psychometric properties of newer health measures with regard to improved reproducibility and validity have also offered substantial advantages over traditional measures and have given users more confidence in the results obtained. A good example of the psychometric rigor of these newer measures has been demonstrated by one index's capacity to predict the mortality of patients with lung cancer (Deyo & Carter 1992).

Feinstein (1992) views the newer, psychometrically sound and multi-dimensional

health status measures as offering scientific, humanistic, and economic benefits to modern clinical medicine. Scientifically, the appraisal of health status provides reproducible data regarding the clinical "material" under investigation. Diagnoses alone does not distinguish between important differences in the clinical condition and the functional capacity of patients. Humanistically, assessments of health status are important because improvements in symptoms, clinical problems and functional capacity are usually the main goals of patients who seek medical care. Economically, health status information identifies benefits that are often inadequately specified or unsuitably quantified in the "risk/benefit" or "cost/benefit" assessments being conducted to provide clinical-economic data. Specific to end-stage liver disease patients, the risk of mortality is ever present. Survival and survival data remain critical outcome indicators. Collecting functional data from those patients who survive the process of waiting for and receiving organ transplantation remains an important aspect of outcome measurement.

Drummond (1987) emphasizes the growing economic importance of measuring health status. Health care resources are scarce in the sense that it is unrealistic to expect that there will be enough resources to satisfy human wants completely. Clinical research seeks to establish whether treatments or programs do more good than harm, but demonstration of a procedure's success is not a sufficient condition for its adoption. The benefit from applying the procedure, its effectiveness, must be compared with its cost. With respect to liver transplantation, the initial high costs of intensive care unit support, surgeon expertise and operating room expenses must be

weighed against the health years gained and productive living resumed by most transplant recipients.

Health Status Measurement of Liver Transplant Patients

A variety of outcome indicators aimed at assessing general health and functioning have been used with the liver transplant population. However, these indicators vary considerably in terms of their emphasis on physical versus emotional or social health domains. Robinson, Switala, Tarter, and Nicolas (1989) focused on physical recovery. Other investigators have included employment status, quality of the patient's relationship with his/her partner, interest in leisure activities, self worth, financial status, and the presence of tension, depression or anger as measures of transplant outcome (Tarter, Erb, Biller, Switala, & Van Thiel, 1988). Tymstra, Bucking, Roorda, Van Den Heuvel, and Gips (1986) assessed complaints of physical discomfort and life satisfaction, while Williams, Santiago, and Evans (1987) used rates of return to work or school as indicators of health outcome. Although the various measures were useful in describing aspects of functional recovery, the variability makes between study comparisons difficult. In addition, the measurement error of any given indicator may vary substantially within and between studies.

Recently, the SIP has been chosen as an outcome indicator for liver transplant patients. Tarter, Switala, Arria, Plail, and Van Theil (1991) studied the quality of life of liver transplantation patients using the SIP and the Social Behavior Adjustment Schedule (SBAS; Platt, Heyman, Hirsch, & Hewett, 1980). The SBAS is based on an informant's assessment of the patient with regard to disturbed behavior, social

performance and burden they place on other family members. The SBAS and the SIP were administered prior to surgery and again within 2-3 years after surgery. The SIP results indicated that liver transplant recipients (n = 53) improved on average, on the physical dimension scores by 89.5%, and on the psychological adjustment scores by 70.2% from pre-transplant scores. When compared with the control group, the SBAS results for the transplant recipients were not found to be significantly different. The SIP, however, detected residual impairments (on 8 scales) during the post-transplant phase that the SBAS did not. The scales that remained impaired included ambulation, alertness, sleep and rest, work, recreation, eating, social interaction and communication. The SIP, therefore, may be more sensitive to small residual deficits.

Bonsel, Essink-Bot, Klompmaker, and Sloof (1992) employed a longitudinal design to describe the changes in health-related quality of life for liver transplantation candidates and recipients. Several health status measures were applied including the Nottingham Health Profile, a modification of the SIP. Measurements were taken prospectively on transplant candidates (n = 26). These patients, in addition to post-transplant patients who were being followed by this Program (n = 20), were measured post-operatively at 3 months, and then annually for 2 years. Those patients assessed annually included patients who were up to 10 years post-transplant. Results from the pre-transplant group suggested major restrictions in all domains of functioning, including psychological distress, many physical disturbances and a low level of experienced well-being. After transplantation, all indicators showed improvement. Further improvement in the first post-operative year was found to be

comparable to quality of life levels similar to or slightly below the level for the general population. These findings supported the authors' hypothesis that orthotopic liver transplantation contributes positively to the quality of life of surviving patients.

Adams, Ghent, Grant and Wall (1995) used an employment questionnaire, the SIP and the Medical Outcomes Survey to study the factors affecting employment after liver transplantation. Measures were applied retrospectively to a large post-transplantation population. The subscales from the health status measures that predicted employment were identified (ambulation, home management, physical functioning and pain). Demographic factors such as being older in age and being continuously out of the workforce for several years prior to transplantation were predictive of those recipients who were least likely to return to work after liver transplantation.

These studies demonstrate the application of a general health status measure to a specific organ transplantation population. However, Tarter et al. (1991) failed to report biological data on their sample's liver function. As a result, it could not be determined if changes identified by the SIP were associated with improvement in liver functioning. In addition, the retrospective design of some of the studies did not permit examination of the rate or timing of changes in health status which may have implications for the timing of rehabilitative interventions. To improve upon the design and data collection in previous studies, the current study uses a prospective design which includes measurement both pre- and post surgery of functional capacity and liver function.

Psychometric Testing of the Sickness Impact Profile (SIP)

Developed in the late 1970's, the SIP is one of a number of psychometrically-sound health status measures that was developed to provide comprehensive assessment of overall functioning of a circumscribed subgroup or population. Several reviewers have compared these various general health status measures.

Specific to the arthritic population, Deyo and Inui (1984) compared the SIP with the American Rheumatism Association (ARA) functional classification and a patient self-rating scale to assess the sensitivity of these instruments to clinical changes in patient function. When applied to groups of patients, the SIP and the patient self-rating scale were modestly superior to the ARA scale. None of the scales however were sensitive to change on an individual patient level.

Deyo, Inui, Leininger and Overman (1983) compared results obtained by the SIP to functional outcomes obtained by the ARA functional scale and patient self-ratings of function. Scores on the SIP or its subscales showed stronger correlations than the other scales with disease-specific biological measures for arthritic patients (i.e. hematocrit, sedimentation rate, grip strength, morning stiffness, duration of R.A., and anatomic stage). Validity of the SIP was maintained with repeated administrations, and the SIP was found to be more reliable than either of the other measures.

Liang, Larson, Cullen and Swartz (1985) administered five health status instruments to arthritic patients before and after total joint arthroplasty. The 5 instruments included the Functional Status Index (FSI), the Health Assessment Questionnaire (HAQ), the Arthritis Impact Measurement Scales (AIMS), the Index of

Well-Being (IWB) and the Sickness Impact Profile (SIP). All the measures proved to be highly intercorrelated. Inter-instrument differences however, were noted for social and global measures of health. Differences in social functioning were thought to be perhaps due to less refined measurement scales of the HAQ and IWB scale. Another possibility was that different content for the subscale of social functioning in each instrument may have contributed to the poorer correlations. The relative efficiency of the scales to measure global change varied also. The FSI and the HAQ were less efficient than the SIP, AIMS or IWB. Greater consistency was obtained for pain and mobility dimensions. The investigators concluded that no single instrument consistently outperformed the others. Although a health status instrument does not currently exist for the end-stage liver failure disease population, the current study can help establish the inter-correlations between current measures of clinical/biological function and those obtained by self-report and the SIP.

Leighton Read, Quinn, and Hoefer (1987) evaluated the practicality and validity of the General Health Rating Index (GHRI), the Quality of Well-being Scale (QWB) and the Sickness Impact Profile. The tests were administered to a large outpatient population who ranged in functional capacity and morbidity. All three measures demonstrated acceptable content validity, convergent construct validity and discriminant validity. In addition, the SIP was found to be practical for clinical use in terms of interviewer training required, administrative time (20-30 minutes), and respondent burden. Practical information with regard to ease or difficulty in administering the SIP to the pre- and post-operative liver transplantation patient will

be obtained.

Hornberger, Regelmeier, and Petersen (1992) interviewed patients with chronic renal failure undergoing in-centre hemodialysis to determine the level of agreement among six measures of well-being. The measures included the SIP, the Campbell Index of Well-being, Standard Gamble, Time Trade-off, categorical scaling and Kaplan-Bush Index of Well-being. Correlations among these measures were poor and the investigators found that the SIP produced the highest well-being scores compared to the other five measures. The investigators went on to calculate the cost effectiveness of in-centre hemodialysis per quality-adjusted life year to demonstrate the variability associated with the well-being scores that were incorporated into the equation.

Specific to the COPD population, Jones, Baveystock and Littlejohns (1989) concluded that the SIP was not sensitive enough to detect clinically relevant, disease-specific changes in health. In assessing health status of patients with mild to moderate airflow limitations and to detect clinically important changes in health, they recommended the use of a questionnaire where a higher proportion of the content was directly relevant to respiratory symptoms. Whether the SIP captures useful and relevant disease-specific information will become apparent upon completion of the study.

The findings from the above studies demonstrate the convergent-discriminant validity of the SIP when compared to other health status measures. For overall health measurement of the arthritic population, and the arthritic population subsequent to

arthroplasty, the SIP appears equal if not superior to the disease-specific measures for arthritis. When compared to measures of well-being amongst a chronic renal failure group, poorer intercorrelations between measures were described. For COPD patients, one study concluded that the SIP was not sensitive enough to detect clinically relevant changes in respiratory symptoms. Because of the variability in the findings of studies that sought to examine the convergent-discriminant validity of the SIP, it seems particularly important that traditional, disease-specific indicators be used alongside a general health status measure if validity information is sought. The current study collected disease-specific information in addition to SIP scores to assist the validation analysis. Although there is no general health measure currently available for use with end-stage liver disease patients, this study compares the SIP results with patient self-rated, clinician-rated and biological measures of liver function to obtain concurrent validation information to examine the utility of the SIP for use with liver transplant patients.

Utilization of the SIP for Outcome Measurement

Despite the question that some investigators have regarding the SIP's sensitivity to disease-specific changes in health in some patient groups (e.g. COPD), a number of researchers have effectively utilized the SIP as a means to evaluate treatment and program outcomes. The SIP's sensitivity in detecting differences in health of the elderly was found to be superior to the Life Satisfaction Index A and the Self-Rating Depression Scale in a study comparing 2 methods of geriatric care (Yeo, Ingram, Skurnick & Crapo, 1987). Ott et al. (1983) randomly assigned myocardial infarction

survivors to either a control group, an exercise group or an exercise and teaching-counselling group. The SIP was found to be useful in distinguishing the limited physical benefits but significant psychosocial benefits of these programs. Augustinsson, Sullivan and Sullivan (1986) selected the SIP and the Mood Adjective Check List (MACL) to assess overall function, pain and mood disturbance of chronic pain patients. The measures were found to be useful in studying the subjects' response to epidural spinal electrical stimulation. The measures were also able to distinguish those with chronic pain from a control group without chronic pain symptoms. In short, these studies have demonstrated the SIP's capacity to function as a comprehensive and reliable health status measurement tool.

Summary

The advancement of general health status measurement has produced sound, summary measures of overall health. Studies examining the psychometric properties of the Sickness Impact Profile support its ability to assess the physical, social and emotional dimensions of health status. Studies have shown that it is a practical measure that is sensitive to clinically important changes with various sub-populations. Its sensitivity has been shown to exceed that of standard measures of clinical change in some groups (arthritics), but in other groups (COPD) its sensitivity is somewhat debatable. For some diagnostic groups, the SIP has been directly related to biological indicators of health, suggesting that the tool's utility in measuring the impact that biological health has on functional capacity could add to outcome measurement data.

The SIP is particularly suitable for use with the transplantation population

because it has the capacity to evaluate a specific health program aimed at a circumscribed subgroup. As a reliable general health measure, the SIP is useful for assessing multiple domains of health outcome (physical, social and emotional status) that would otherwise necessitate a battery of domain-specific measures. Consequently, the SIP offers a more consistent measurement of the domains of interest and reduces respondent burden.

To date, the use of the SIP with transplantation populations has been limited and its appropriateness for use with liver recipients has yet to be firmly established. This study sought to improve upon previous work undertaken with this organ transplant group by establishing the concurrent validity of the SIP with three other measures of health status. In addition, the outcome of the transplantation procedure was assessed at specific time intervals to demonstrate the rate of recovery of functional ability post-surgery. This will improve upon Tarter et al.'s (1991) study which measured outcome 2-3 years post-transplant, an interval that may overestimate the duration required for most transplant patients to demonstrate significant recovery in the physical, social and emotional domains of health.

CHAPTER III

METHODS AND PROCEDURES

Sample

A sample of liver transplantation candidates and recipients from the University of Alberta Hospitals Liver Transplant Program were asked to participate in a study involving the assessment of their functioning before and after liver transplantation. The subjects' participation involved completing two health surveys, permitting the researcher to access their liver function test results, and allowing the Liver Transplant Recipient Coordinator to complete a patient health rating. Health ratings were obtained once pre-operatively and at two intervals post-operatively. The data were analyzed to examine the concurrent validity and sensitivity of the SIP in this situation and to quantify/describe the functional health status of subjects before and after liver transplantation.

Patients were excluded from the study if they were under the age of 16 years; the literature to date has only involved adminstration of the SIP to adult subjects. Additional exclusion criteria were (1) a degree of illness which interfered with administration of the SIP; (2) the patient did not speak or read English; or (3) the patient declined to participate. Calculations indicated that a sample of 20-30 subjects was required to provide adequate statistical power (Appendix A).

Of 43 patients who were approached to participate in the study, three proved to be ineligible to participate. One patient refused to provide consent, one was too

encephalopathic to provide informed consent and one patient did not speak English. Six other patients were assessed pre-operatively but four were not transplanted within the data collection period, one patient died prior to being transplanted and the last patient asked to be removed from the transplant list. As a result, data was collected on 34 patients. Table 4 summarizes the demographic characteristics of the 9 non-participants.

Instruments

The Sickness Impact Profile (SIP)

Description of the SIP

The Sickness Impact Profile is a standardized general health status questionnaire that was developed in the late 70's and underwent rigorous psychometric testing in the early 80's. It was designed to be broadly applicable across types and severities of illness and across demographic and cultural subgroups. The lack of cultural bias, however, has been recently refuted by Patrick and Deyo (1989). The investigators demonstrated that the construct validity of the Mexican-Spanish version of the SIP was lower among patients using this version than among those using the American-English version.

The SIP is a 136 item, standardized questionnaire that addresses 12 categories of health status. The items in the SIP are grouped into 2 dimensions: The Physical Dimension is broken down into the categories of ambulation, mobility, and body care and movement. The Psychosocial Dimension encompasses social interaction,

alertness behavior, emotional behavior, and communication. The remaining categories are considered independent and include sleep and rest, eating, work, home management, and recreation/pastimes. Behaviorally-anchored statements were chosen because behaviors are assumed to be observable manifestations of the overall impact of illness (Bergner, Bobbitt, Carter & Gilson, 1981).

There are two administration formats available. There is one set of instructions for the interviewer-administered format, and another set for the self-administered version. The items that follow the instructions, however, are identical. For the interviewer-administered version of the SIP, the items are read aloud to the subject. The subject is then asked to respond only to items which he is sure describe him on the day of the interview, and are related to his health. For the self-administered version of the SIP, the subject completes the survey after reading the instructions. The self-administered version allowed the survey to be mailed to the subject for completion. This feature of the survey reduced respondent burden because some of the subjects did not reside in the Edmonton area. Even for those subjects who lived in Edmonton, the self-administered version eliminated the necessity for an additional visit to the hospital.

Each of the statements in the SIP are weighted and assigned a value. To obtain an overall SIP percent score, the values for each statement that were endorsed by the subject are added together, then divided by the sum total of all the values. The product is then multiplied by 100. The higher the percent score, the greater the functional impairment. Scores for each category are calculated in a like manner.

That is, the weighted values of all items endorsed within a category are summed, divided by the sum of the values of all items in the particular category and multiplied by 100 (Appendix B).

Intended Application and Purpose

One of the SIP's intended purposes is to permit evaluation of a specific health program aimed at a circumscribed subgroup (University of Washington, 1978). The University of Alberta Hospitals Liver Transplant Program is one such program. A relatively consistent group of health care workers, specialists and a surgeon deliver specialized care to liver transplant candidates and recipients.

The subjects used in the development of the SIP varied in disease severity. A subgroup of apparently healthy people were used to establish the tool's sensitivity to detect subtle manifestations of impaired function. These features are particularly relevant to this study. Patients presenting for liver transplantation vary in etiology, comorbidity, severity of symptoms and the impact these factors have on function. Post-operatively, a recipient's functional capacity may vary in significant ways from his/her pre-operative state. A measure that assesses a range of functional abilities and is sensitive to subtle functional changes represents a useful outcome tool for a liver transplant population.

Validation Procedures

Table 2 summarizes the results of the field trials that examined the concurrent validity of the SIP with respect to selected criterion measures (Bergner, Bobbitt, Kressel, Pollard, Gilson, & Morris, 1976; Bergner, Bobbitt, Pollard, Martin, &

Gilson, 1976; Bergner, Bobbitt, Carter, & Gilson, 1981). The field trials demonstrated the concurrent validity of the SIP relative to other measures of health dysfunction. A direct relationship between the self-assessment of dysfunction and the subject's SIP score also provided preliminary evidence of the instrument's validity. The current study seeks to establish evidence of concurrent validity via patient self-rated reports and SIP scores.

Table 3 summarizes the results of validity studies examining the relationship between SIP scores and specific clinical measures as applied to three condition-specific patient populations. The results indicated that the SIP was related to biological/clinical measures in the assessment of health status across different patient groups. The liver transplant population provides an opportunity to establish the relationship between biological liver function data and SIP scores.

Reliability

The reliability of the SIP has also been demonstrated (Pollard, Bobbitt, Bergner, Martin & Gilson, 1976). Test-retest reliability after a 24 hour delay was $r = .88$, $p < .001$, for overall SIP scores, and $r = .75$, $p < .01$, averaged across all 12 category scores. Internal consistency (Cronbach's alpha) was .94. The sample size for reliability testing was 119.

The SIP was administered at all time intervals.

The Self-Rating of Dysfunction Scale

This scale was used in the original validation studies of the SIP (Bergner et al., 1976) with patient groups of different diseases and disease severities. Subjects rated

their relative level of dysfunction in each category of activity represented in the SIP (Appendix C). The 7-point scale ranges from "minimally dysfunctional" to "maximally dysfunctional". Subjects also rated their overall level of dysfunction using the same 7-point scale. Although specific reliability and validity data on this and the Clinician Rating of Dysfunction are not available, the scales were used extensively in two field trials involving eight different patient populations (Bergner et al., 1976; Gilson et al., 1975). The self-rating of dysfunction was administered at all time intervals.

The Clinician Rating of Dysfunction Scale

The Recipient Coordinator rated each subject's level of dysfunction in each of the SIP categories (Appendix D). The Recipient Coordinator also provided an overall rating of dysfunction for each subject. This scale was administered to pre-operative patients only.

The Child-Pugh Classification of Liver Function

The Child-Pugh Classification of Liver Function was used to categorize the extent of each subject's liver dysfunction. Measurements of each subject's total bilirubin level, albumin level, PT INR, and degree of encephalopathy were recorded. These measurements were used at all time intervals (Appendix E).

Study Design

A one group pretest/posttest design was used to obtain the health status information. Health information was collected from a group of liver transplant

candidates prior to their transplant and the same group of patients were reassessed at two time intervals subsequent to their surgery. The Liver Transplant Recipient Coordinator notified the researcher of liver transplant candidates. Appointments were arranged by the Recipient Coordinator for the researcher to meet with the candidate to determine their eligibility and interest in participating in the study. During the initial meeting the researcher provided the candidate with verbal and written information with regard to the study (Appendix F). If the candidate agreed to participate, a written consent form was completed (Appendix G). If the candidate declined the invitation to participate or was ineligible to participate, the researcher included them on a list of non-participating candidates and they were eliminated from the subject pool.

Once the participating candidates completed the consent process and bloodwork had been drawn or was scheduled to be drawn within 24 hours, the Sickness Impact Profile and the Self-Rating of Dysfunction Scale were administered. The Clinician Rating of Dysfunction Scale was provided to the Recipient Coordinator to complete. If the participating candidate had not had bloodwork drawn within 24 hours, the instructions for completing the SIP and Self-Rating of Dysfunction Scale were reviewed with the candidate. Once the bloodwork was drawn, the candidate completed the health assessments and the researcher asked the Recipient Coordinator to complete the Clinician Rating of Dysfunction Scale.

Once each candidate had undergone liver transplantation, they were contacted at two months and again at six months post surgery and asked to complete the Self-

Rating of Dysfunction and the Sickness Impact Profile within 24 hours of bloodwork being drawn. Given that most subjects had been discharged home by the two month post-transplant date, they were contacted by mail and received a letter with instructions and the surveys to complete. They were asked to return the surveys to the researcher, indicating the date they were completed.

Research Objectives

Objective # 1 was to establish whether SIP scores correlate with the scores obtained from the 3 other health measurements (concurrent validity). Three research questions were asked:

a) To what extent do SIP scores correlate with patient-rated health assessments?

b) To what extent do SIP scores correlate with clinician-rated health assessments?

c) To what extent do SIP scores correlate with biological measures of health?

Objective #2 was to identify the inter-instrument correlation of health assessments (convergent-discriminant validity). The research question was:

a) Which pairs of health assessments show the greatest and weakest correlations?

Objective #3 was to establish whether inter-instrument correlations are maintained at each of the 3 time intervals. The research question was:

a) What is the extent of the inter-instrument correlations at each of the 3 time intervals?

Objective #4 was to quantify the health of liver transplant patients at each time interval (outcome measurement). The research question was:

a) What were the scores obtained by subjects on each of the health measures at each time interval?

Objective #5 was to evaluate the change in health status over time (outcome measurement). The research questions were:

a) Are there significant changes in health status from Time 1 to Time 2, from Time 2 to Time 3 or from Time 1 to Time 3 as measured by any of the health assessments?

b) What was the relationship between change scores as measured by the SIP and those obtained by the other health measures (sensitivity)?

Procedures

Timetable

Data collection occurred over a 25 month period (August 1994 to September 1996). As patients underwent evaluation and were found suitable for liver transplantation, the researcher assessed the pre-operative health status of consenting subjects. As subjects proceeded through the liver transplantation process, they were assessed at 2-months and 6-months post surgery.

Summary of Procedures

Data collection procedures are summarized as follows:

Time 1: Pre-Transplant

Consent, SIP, The Self-Rating of Dysfunction Scale, The Clinician-Rating of Dysfunction Scale, The Child-Pugh Classification of Liver Function

Time 2: 2 months Post-Transplant

SIP, The Self-Rating of Dysfunction Scale, The Child-Pugh Classification of Liver Function

Time 3: 6 months Post-Transplant

SIP, The Self-rating of Dysfunction Scale, The Child-Pugh Classification of Liver Function

Methods for Protecting Against Rater Bias

Prior to the commencement of data collection, the researcher thoroughly reviewed the SIP administration and scoring materials and instructions (Conn, Bobbitt & Bergner, 1973). The researcher reviewed the Clinician-Rating of Dysfunction with

the Liver Transplant Recipient Coordinator. The Coordinator and the researcher were blinded to the subject's scores on the Self-Rating of Dysfunction and the SIP.

Ethical Considerations

Potential study subjects met with the researcher and were provided with verbal and written information about the purpose of the study. The requirements for participation were discussed. A written Information Sheet was provided and informed consent was obtained prior to participation. The informed consent procedures ensured voluntary participation, confidentiality and the right to withdraw without consequence.

Patient data were not reported as independent data, but rather as group results so that anonymity was ensured. The research proposal was accepted by the Ethics Review Committee of the University of Alberta Hospitals (Appendix H)

Data Analysis

Data was analyzed using the computerized Statistical Package for the Social Sciences (SPSS) program. To obtain data for objectives 1, 2, 3, and 4, the descriptives function and Pearson r correlation function was used. To obtain data for objective 5, the ANOVA function using the General Linear Model for repeated measures was used to compare the means obtained at the Time 1 to Time 3 and Time 2 to Time 3 intervals.

The data was also analyzed with the cases that died, removed from the data set. There were no statistically or clinically significant differences between the two sets of data. The results contained hereafter, reflect data from all cases.

CHAPTER IV

RESULTS

Participant Demographic Characteristics

The participant demographics and characteristics are listed in Table 5. Of the 34 patients who entered the study, fifty-six percent of the participants were male. The mean age of the participants upon entry to the study was 50.18 years (range = 35 - 71). Thirty-two percent of the participants were between 40 - 44 years old.

With respect to the medical status of the participants at the time of transplantation, 73% (n=25) were classified as Status 1, indicating that they were at home. Fifteen percent (n=5) of the participants were Status 2, in hospital in stable condition. Six percent (n=2) were Status 3, in the intensive care unit but not on mechanical support. Six percent (n=2) were Status 4, in the intensive care unit requiring intubation due to severe liver disease.

Cirrhosis of the liver due to Hepatitis B, C or D, alcohol-induced, or cryptogenic cirrhosis accounted for 68% (n=23) of the primary diagnoses assigned to the participants. The other diagnostic indications for transplantation included Primary Biliary Cirrhosis (n=4), fulminant hepatic failure (n=2) and one case each of Alpha 1 antitrypsin deficiency, Budd-Chiari, Chronic Autoimmune Hepatitis, hepatic artery thrombosis and Primary Sclerosing Cholangitis. Ten of the participants were assigned a secondary diagnosis. In addition to their primary diagnosis 3 patients had alcohol-induced cirrhosis, 2 patients had Hepatitis B, 2 had a hepatocellular tumor, 1 had Alpha 1 antitrypsin deficiency, 1 had Budd-Chiari and one had a portal vein

thrombosis.

Five participant deaths occurred during the data collection period (see Table 6). Two of the participants died after being transplanted and before the 2-month post-transplant period. Three more participants died after the 2-month data collection phase but before the 6-month data collection phase.

The results will be presented according to each of the five research objectives.

Research Objective #1

Objective #1 was to establish whether SIP scores correlate with the scores obtained from the other health measurements (concurrent validity). The three research questions were:

a) To what extent do SIP scores correlate with patient-rated health assessments?

The relationships between overall SIP scores and overall patient-rated health scores were assessed with Pearson correlation coefficients (see Table 7). SIP scores were highly correlated with patient-rated health assessments at Time 1 ($r = .76$, $p < .01$), Time 2 ($r = .84$, $p < .01$) and at Time 3 ($r = .75$, $p < .01$).

b) To what extent do SIP scores correlate with clinician-rated health assessments?

Clinician-rated health assessments were collected at Time 1 only (see Table 8). The correlation between SIP scores and clinician-rated health assessments was $r = .68$ ($p < .01$). Clinician ratings were more strongly correlated with the physical dysfunction component of the SIP ($r=.75$, p , .01) than the psychosocial dysfunction component ($r=.40$, p , .05). Clinicians may receive fewer observable clues about a

patient's psychosocial health than are available through observation about a patient's physical state of health. This may be an explanation for this pattern of correlations. SIP scores were moderately correlated with clinician-rated health assessments, however not as strongly as the patient-rated health assessments.

c) To what extent do SIP scores correlate with biological measures of health? (see Table 9)

At Time 1, overall SIP scores were highly correlated with encephalopathy scores ($r = .62$, $p < .01$), bilirubin values ($r = .52$, $p < .01$) and PT INR values ($r = .41$, $p < .05$) but not with albumin values.

At Time 2, overall SIP scores were highly correlated with encephalopathy scores ($r = .71$, $p < .01$), bilirubin ($r = .45$, $p < .01$) and albumin values ($r = -.61$, $p < .01$) but not PT INR values.

At Time 3, overall SIP scores were moderately correlated with bilirubin values ($r = .41$, $p < .05$). No other relationships between SIP and biological variables were found to be significant at this time interval.

Bilirubin values were the only value to be significantly correlated with overall SIP scores at all three time intervals. In decreasing order of correlational strength, overall SIP scores were related with patient-rated health assessments, clinician-rated health assessments, bilirubin values and stages of encephalopathy. Albumin and PT INR values were least strongly correlated with overall SIP scores.

Research Objective #2

Objective #2 was to identify the inter-instrument correlation of health assessments

(convergent-discriminant validity). The research question was:

a) Which pairs of health assessments show the greatest and weakest correlations?

Correlation matrices were constructed to depict the inter-instrument correlations of health assessments. One table for each time interval was constructed (see Tables 11-13). The highest correlations at all time intervals were between the overall SIP score and the patient-rated health score. At Time 1 the correlation was $r = .76$, ($p < .01$), at Time 2 the correlation was $r=.84$ ($p < .01$) and at Time 3 the correlation was $r=.75$ ($p < .01$). At Time 1, albumin values demonstrated the weakest correlations with all of the other measures. At Time 2 and Time 3, PT INR scores correlated with all other measures the most poorly. The range of correlations between PT INR and all other variables at Time 2 were -.15 to .22 and at Time 3 were -.05 to .33. Table 10 describes the patients scores when categorized by the Childs-Pugh Classification of Liver Disease. Most patients pre-operatively, had significantly abnormal liver function values. At Time 1, 28 patients had at least stage 1 encephalopathy, 31 patients had bilirubin values of greater than 25 umol and 29 patients had albumin values of less than 35 gm/L. Most patients, at all time intervals had PT INR values of 1.3 - 2.0 secs. Encephalopathy scores could not be correlated with the other measures at Time 3 because the values had returned to zero (absence of encephalopathy) for all patients. The greatest improvements in liver function occurred by Time 2, and were maintained or continued to improved when measured at Time 3. At Time 2, only 2 patients had a stage 1 or greater level of encephalopathy, 14 patients had a bilirubin level greater than 25 umol and 12 patients

had albumin values less than 35 gm/L.

Research Objective #3

Objective #3 was to establish whether inter-instrument correlations are maintained at each of the 3 time intervals. The research question was:

a) What is the extent of the inter-instrument correlations at each of the 3 time intervals?

There were fewer statistically significant inter-instrument correlations as the measurements proceed from Time 1 to Time 3. Of the 36 possible intercorrelations at Time 1, 26 were significantly correlated (72%). At Time 2, 16 of 28 possible intercorrelations were significant (57%) and by Time 3 only 9 of 28 possible intercorrelations were significant (32%). Overall, the biological measures became less intercorrelated as well as showing less relationship with the other measures as time progressed.

Research Objective #4

Objective #4 was to quantify the health of liver transplant patients at each time interval (outcome measurement). The research question was:

a) What were the scores obtained by patients on each of the health measures at each time interval?

Table 14 summarizes the scores obtained by patients at each time interval. The mean SIP variable scores indicate the percentage of dysfunction the participant experiences in each of the categories. Higher scores indicate greater dysfunction. Lower scores indicate improved, less dysfunctional performance. SIP variable scores

show an obvious downward trend indicating improved function as time progresses from pre-operative (Time 1) to post-operative (Time 2 and 3) intervals.

The most dramatic impairments in function pre-operatively (Time 1) as measured by the SIP were in the areas of sleep and rest where the average percent dysfunction score was 61.7% for all patients. This indicated that many patients were spending a great deal of time resting, napping, sleeping, or less alert. The next most dysfunctional areas were work (mean = 57.2%) which meant that many patients were not working and those that were, required their work to be modified. The mean score for recreation was 49.9% which indicated that many patients were unable or limiting their participation in physical recreation or activities because of their health. The mean score of 41.9% for alertness behavior indicated that many patients identified impairments with concentration, attention, reasoning and problem solving. The mean score for home management was 40.3 % which meant that many patients were doing less of the regular daily work around the house and many were unable to do any of the heavy work around the house because of their health.

The SIP variables showing the greatest percent differences from Time 1 to Time 3 in descending order were sleep and rest (51.3% difference), recreation (32.1% difference), home management (29.0% difference), mobility (28.5% difference) and alertness behavior (25.5% difference). This meant that significant improvements in functioning were identified by patients with regard to their need for sleep and rest, their ability to participate in previous pasttimes and hobbies, and their ability to undertake homemaking tasks. They were better able to move around independently

both indoors and from place to place, and their mentation and ability to attend to tasks and respond efficiently had improved. The SIP variables showing the least residual dysfunction in ascending order at Time 3 were eating (2.7%), mobility (4.7%), communication (5.1%), and body care and movement (5.2%). These results indicated that only a few patients responded to items that indicated a limitation in their functioning that could be attributable to their health with regard to eating or the desire to eat, ability to move from room to room or to get around outdoors, make themselves understood when speaking, or perform self care tasks such as dressing or bathing. Those variables that showed the greatest residual dysfunction by Time 3 were work (37.1%), recreation (17.8%) and alertness behavior (16.3%). With regard to work, Table 15 summarizes the work status of patients by time interval. By Time 3, there were as many patients not working as there were working. The SIP assigns a dysfunctional percent score of 70.1% to all patients who are not working. A score of 0% is given to those that have returned to work and do not check off any of the items that indicate that modifications have been made to the job such as working shorter hours, not acomplishing as much as usual at work, or doing only light work. Retired patients are assigned a 0% score because although they are not working, it is not because of their health.

The results of patient-rated health variables are summarized in Table 16. Patients rated their perceived level of dysfunction on a 7-point Likert scale. Higher scores indicated greater dysfunction. The domain demonstrating the most dysfunction in the pre-operative stage was work (5.8) which meant that patients felt that their ability to

work was very greatly impaired by their health. Health domains that were identified as being greatly impaired by their health were recreation (5.2), sleep and rest (4.9) and home management (4.8) domains . By Time 3, the areas showing the least residual dysfunction were body care and movement (1.5) and communication (1.7). This meant that patients' ability to function in those domains were not at all, or very slightly, affected by their health. All categories, except sleep and rest, show a downward trend as patients proceed from pre-operative to post-operative stages, indicating that they are experiencing less and less dysfunction over time. The variables showing the greatest residual dysfunction by Time 3 were work (3.7), recreation (3.0) and home management (3.0). With regard to work, these results meant that patients felt that their ability to work was moderately impaired by their health. Patients felt that their ability to participate in recreational activities and ability to perform homemaking tasks were slighly impaired by their health.

The results obtained through biological indices are summarized in Table 17. All means during the pre-operative stage are significantly abnormal, but by six months post-operatively, the means for all categories had returned to normal values.

Research Objective #5

Objective #5 was to evaluate the change in health status over time (outcome measurement). The research questions were:

a) Are there significant changes in health status from Time 1 to Time 2, from Time 2 to Time 3, or from Time 1 to Time 3 as measured by any of the health assessments?

Table 18 summarizes the findings of the analysis of variance which was conducted to determine whether the mean scores were significantly different at each time interval. The results indicate statistically significant F values for comparisons made between Time 1 and Time 2 for the overall SIP score ($F = 50.25$, $p < .000$), physical dysfunction dimension scores of the SIP ($F = 23.36$, $p < .000$), psychosocial dysfunction dimension scores of the SIP ($F = 36.87$, $p < .000$) and patient-rated dysfunction scores ($F = 24.27$, $p < .000$). As well, statistically significant F values for comparisons made between Time 1 and Time 2 for all biological indices were obtained. The F value for encephalopathy was 30.33 ($p < .000$), for bilirubin the F value was 6.63 ($p < .023$), for albumin the F value was 15.35 ($p < .002$) and for PT INR the F value was 7.93 ($p < .002$). Comparisons between Time 2 and Time 3, however, did not result in significant means differences; change was maintained from the first post-operative time interval until the second post-operative time interval.

b) What was the relationship between change scores as measured by the SIP and those obtained by the other health measures (sensitivity)?

Change scores were defined by an effect size calculation: the difference between the two time intervals being compared, divided by the standard deviation of the earlier period. Effect sizes of .8 or greater are considered large, and effect sizes of .5 moderate. The change scores make it possible to compare the quantity of change that occurred as measured by the SIP, by patients and by the biological indices using an equivalent means of comparison - standard deviation of the variable. Table 19

summarizes the change scores of the SIP and patient-rated variables. All but one measure (psychosocial dimension score as measured by patient assessment) showed a large effect size when comparing Time 1 to Time 3, as measured by the SIP and patient-ratings. Large effect sizes were also found from Time 1 to Time 2 for overall SIP score, sleep and rest, and recreation as measured by the SIP and patient-ratings. Moderate effects from Time 1 to Time 2 were evident for physical dimension scores, eating, and home management. Overall, similar change scores were obtained by the SIP and patient-ratings, suggesting that the SIP is comparably sensitive to functional changes when compared to the functional changes that the patient identifies.

As for change scores as measured by the biological indices (see Table 20), large effect sizes were apparent from Time 1 to Time 2 for encephalopathy (1.11) and albumin (-1.42), and moderate effect sizes for bilirubin (0.60) and PT INR (0.78). Likewise, from Time 1 to Time 3, even larger effect sizes were noted for encephalopathy (1.33) and albumin (-1.90) and moderate effect sizes for bilirubin (0.72) and PT INR (0.78). Relatively small effect sizes were evident between Time 2 and Time 3 for all biological indices.

Overall, change scores indicate moderate to large effects occurring from Time 1 to Time 2, small to moderate changes occurring from Time 2 to Time 3, and the largest changes occurring when Time 1 and Time 3 scores are compared.

CHAPTER V

DISCUSSION AND CONCLUSIONS

Limitations of the Study

The limitations of this study are as follows:

1. Not all patients who were transplanted during the study period participated in the study. It is not possible to know whether the functional capacity and psychosocial well-being of those who did not participate differed significantly from those who did participate.
2. The SIP proved to be a somewhat time consuming tool to administer to encephalopathic patients. As patients' level of consciousness worsened, their capacity to accurately self-report diminished. The SIP, therefore, may not be the most appropriate tool to use with patients with a Grade 2 or higher encephalopathy score.
3. Data was collected in the post-operative and rehabilitative stages of recovery. Important aspects of health and well-being that occur subsequent to this period of recovery were not captured by this study.
4. Variables such as family support and community services which may have impacted the patients' health status and everyday functioning during the transplantation process were not incorporated into the design of the study.
5. The Time 2 and Time 3 outcome results reflect the general health status of the participants who survived and could be assessed at those time intervals. The outcome results do not adjust for mortality.

Discussion and Clinical Implications

Overall, the study provided support for the utility of using the SIP as an outcome indicator for liver transplant patients. However, some caveats do apply to its use with this population. The psychometric properties of the SIP that were evaluated included concurrent validity, convergent-discriminant validity and sensitivity. With regard to concurrent validity, the SIP scores were highly correlated with patient-rated health scores, and these strong correlations were maintained at all time intervals. It was anticipated that SIP scores would be correlated with patient-rated scores at $r=.50$ ($p < .05$). The results demonstrated correlations of $r=.76$ ($p < .01$), $r=.84$ ($p < .01$) and $r=.75$ ($p < .01$) for Time 1, 2 and 3 respectively. Thus patient-rated scores correlated in expected ways with the SIP. More specifically, there was agreement as to the health categories that were most impaired pre-operatively. Both the SIP and the patient-rated measure identified sleep and rest, work, recreation and home management to be the most dysfunctional areas. At Time 3, 2 of the 4 variables that were identified as least dysfunctional were the same as measured by the SIP and identified by patients' self report (communication and body care and movement). This provided evidence that there was strong agreement in health assessments as measured by the SIP and by the patient at each time interval.

The aspect of convergent-discriminant validity was supported by the strength and patterns of correlations obtained. Physical dimension scores were highly correlated with overall SIP scores at all time intervals. Psychosocial dimension scores were also significantly correlated with overall SIP scores at all time intervals but not as strongly

as the physical dimension scores. This would be expected because the independent categories are more physically based variables. The overall SIP score is more heavily represented by physically based variables than psychosocial ones.

It was anticipated that patient-rated scores would correlate more strongly than clinician-rated scores with SIP scores. This was expected because studies have shown that patients are capable, reliable and accurate in evaluating their health status in terms of its impact on their everyday functioning. Patients have been shown to be able to evaluate their health more accurately than an observer or a clinician. The results confirmed this finding in that although the clinician ratings were significantly correlated with SIP scores ($r=.68$), physical dimension scores ($r=.75$) and psychosocial dimension scores ($r=.62$), the results were not as strongly correlated as the patient-rated scores were. This gives support to the importance and continued use of patient-rated health scales for outcome measurement.

The biological variables were also found to correlate in expected ways with physical and psychosocial dimension scores. At Time 1 and 2, 6 of the possible 8 correlations between biological indices and the physical dimension score are statistically significant. At Time 1 and 2, only 3 of the possible 8 correlations between biological indices and the psychosocial dimension are statistically significant. It would be expected that specific biological indices would align more closely with the physical dimension than the psychosocial dimension scores.

By Time 3, however, the biological indices are significantly correlated with few of the other measures. This may be due to the fact that for many patients their liver

function had normalized by Time 3, but overall functioning and recovery was not yet complete. Specific biological indices may not produce data that represents the general functioning and overall well-being of a patient. Another factor affecting biological measures includes the effect that transfusing albumin would have on normalizing albumin values and the effect that fresh frozen plasma has on PT INR.

The more abnormal the liver function results were, the more strongly they correlated with SIP scores, physical dimension scores, psychosocial dimension scores and patient ratings of function. All of the measures provide information with regard to abnormal functioning, so as health and functioning improved, the correlations weaken. The correlation matrices revealed that PT INR values were only statistically correlated with the other health measures when the PT INR values were elevated (abnormal). Bilirubin was the only biological value that was statistically correlated with the SIP scores and physical dimension scores at all 3 time intervals. The strength and patterns of correlations obtained support the view that the SIP is a valid instrument with regard to its convergent-discriminant qualities when applied to a liver transplant population.

The last psychometric property of the SIP to be evaluated by this study was sensitivity. Results from the SIP, patient-rated variables and biological indices consistently showed that the largest changes in functioning and biological health occurred from Time 1 to Time 3, moderate changes from Time 1 to Time 2 for a number of variables, and small changes from Time 2 to Time 3. The consistent pattern and similar strength of change scores as measured by all three indices, gives

evidence to substantiate the sensitivity of the SIP to detect and measure changes in overall health and functioning over time. The SIP appeared to detect clinically relevant, disease-specific changes in health such as pre-operative impairment of sleep and rest patterns and level of alertness. The post-operative results confirmed what clinicians observe clinically with regard to return of functioning. The study quantified the early post-operative recovery that many transplant patients make. This adds to the outcome information that Tarter et al. (1991) collected in that his study examined transplant patients at the 2-3 year post-transplant period. The findings of this study support the claims of the developer of the SIP as well as other investigators that found the SIP to be a valid and sensitive instrument for quantifying health and well-being of a circumscribed population.

The other component of the SIP that was evaluated by the study was its utility as an outcome indicator with regard to its capacity to comprehensively describe and quantify the health of transplant candidates and recipients in terms of global health domains and everyday functioning. The SIP was valuable in that a broad range of debilitation and health could be captured by the instrument. This aspect was particularly pertinent with a liver transplantation group because of the range of health and illness that can exist among the group at pre- and post-operative stages. The results of this study can be summarized as follows. Overall, by Time 3, many patients are experiencing few functional limitations with regard to self-care, ambulation, and getting around the community as reflected by the physical dimension score. In terms of the psychosocial health domain, most patients do not identify

symptoms that indicate impairments with their ability to communicate or interact socially. Few report emotional symptoms that are indicative of ill health. The one health category of the psychosocial domain which shows some residual dysfunction is the alertness behavior category. Items in this category indicate symptoms of decreased concentration, forgetfulness and confusion. In terms of the independent health categories, few patients indicate any symptoms reflecting difficulties with eating or appetite. Residual impairments in terms of sleep and rest patterns (needing to lie down in order to rest, or needing to sit during much of the day) was minimal for most patients. Overall impairments in the home management domain were also minimal. This meant that many patients had resumed much of the regular daily work around the house such as light housecleaning, laundry, shopping, and taking care of personal or household business affairs. Heavy work and repair work around the house, however, continued to be limited at the Time 3 interval. Many patients has resumed community activities, going out for entertainment and some had resumed their physical recreational activities, although full participation levels had not yet been achieved. The one category showing the greatest residual impairment at Time 3 was the work category. Equal numbers of patients were working as were not working. Very few patients had returned to full-time work. Those that had returned to work had modified their work schedule or work demands.

One way by which the results could be used to describe outcome would be to suggest score ranges that correspond to descriptive anchors to describe clinical improvement or deterioration. Table 21 offers one possible format for describing

clinical outcome as obtained by SIP scores. The difference in SIP scores between each time interval were calculated for each patient. These scores were assigned categories to describe the degree to which scores indicated improvement or deterioration. This format of the results describes the incidence of mortality as well as the course of clinical change of surviving patients. The Time 1 to Time 2 column describes the moderate and significant improvements that patients make from the pre-operative to early post-operative time interval. The Time 2 to Time 3 interval demonstrates that about one third of the patients show minor deterioration and another third show minor improvements during the 2-month to 6-month post-operative period. The Time 1 to Time 3 interval demonstrates that of those patients who survive the procedure, 22% show improvement, 22% show moderate improvement and 41% show significant improvement.

The implications of this study with regard to the practice of occupational therapy include that the focus of pre-operative interventions be on minimizing the negative effects of the areas identified as being of greatest dysfunction (sleep and rest, work, recreation, alertness and home management). Continued patient education with regard to energy conservation and the prescription of assistive devices to save energy or simplify tasks appears indicated. The impact that the patient's physical and cognitive symptoms have on the energies and capacities of the caregivers deserves equal attention. Caregivers need to be alerted to signs that may indicate that they need further support either through home care or respite services. Discussing the demands that an end-stage liver disease patient can have on the family or spouse may help to

circumvent caregiver burnout by encouraging that caregiver support be arranged early on.

The occupational performance areas where residual dysfunction was identified post-operatively, which included work, recreation and home management, could also be the focus of rehabilitation efforts. Identifying community resources that could assist patients in resuming work roles or helping to facilitate return to work strategies with employers could be a means to assist recovery. Discussing patient goals in the context of health domains are a further means by which the health information from this study could be applied clinically.

Other implications with regard to this study include that occupational therapists can be useful in assisting liver transplant programs in evaluating their program efficacy as it relates to the general health status measurement of patients. The SIP proved to be useful in describing the health or the impact of illness that patients experienced during the various stages of transplantation. The 12 health domains captured information about the impact that health has on everyday functioning and intra- and interpersonal well-being. The ability to collapse 3 of the variables to produce a physical dimension score, and 4 of the variables to produce a psychosocial dimension score as well as having an overall score, allows the level of detail to vary according to the purpose of an analysis or the intent of a report. The SIP produces data in an understandable format for administrators, health workers, patients and the public. Outcome information obtained from the SIP could also be useful in clarifying program goals and expected outcomes. The outcome data could be used to respond to

requests for information with regard to the functional outcome of our patients. Comparison of SIP results obtained from different Transplant Centres or different patient populations could be additional ways to use health data generated by the SIP.

Among the encephalopathic pre-operative patients, however, the instrument was not an efficient tool to obtain data. The format of the SIP relies on the patient to agree or disagree with statements about their current state of health. The confusion, impaired judgment, and fluctuating level of consciousness that occurs among the more encephalopathic patients (stage 2 encephalopathy) affects the patient's capacity to answer the questions accurately and quickly. Therefore, a shorter instrument or one that relies on clinical observation rather than self-report may be more appropriate. A shorter instrument would also be advantageous for the ongoing, systematic measurement of the health and well-being of transplant patients over time. The MOS 36-Item Short-Form Health Survey (SF-36) is one such instrument that would be worth considering (SF-36; Ware & Sherbourne, 1992). It is quicker to administer, thereby reducing respondent burden. To allow for pre-operative information to be gathered from encephalopathic patients, a volunteer could be trained to administer or to assist patients in completing the survey. Surveys could be completed at regular intervals, 3-months, 6-months and then annually on post-transplant patients. Tracking other factors that may be predictive of improved health or efficient recovery such as demographics, severity of illness pre-operatively and co-morbidities could also be collected at regular intervals. Following trends over time with regard to transplant patients everyday functioning, intra- and inter-personal well-being and adaptation to

their health maintenance regime may provide information needed to demonstrate treatment efficacy. Comprehensive health information could also provide data for cost effectiveness or cost-benefit analyses.

Summary

The sophistication of outcome measurement has improved with the development of general health status measures. Outcome measurement information about new and costly procedures such as liver transplants must be comprehensive and understandable to administrators, patients and the public. This study evaluated the utility of a general health status measure, the Sickness Impact Profile (SIP) as an outcome indicator for liver transplant patients. Health assessments were made of liver transplant patients before, and at two intervals after transplant surgery. The data was analyzed to assess concurrent validity, convergent-discriminant validity and sensitivity. As well, the data was used to quantify the health and recovery of pre- and post-transplant patients. The results supported the claims of the developer of the SIP as well as other investigators who found the SIP to be a valid and sensitive instrument for quantifying the health and well-being of a circumscribed population. The only caveat to its use with liver transplant patients was that the SIP may not be appropriate to obtain health information from patients with a Stage 2 or greater level of encephalopathy.

TABLES

Table 1: Actuarial Survival of Albertan Liver Transplant Patients*

Time	Adult Patient Survival
0	100
3 mos.	89.3
6 mos.	86.5
1 year	84.9
2 years	83.0
3 years	79.3
4 years	75.7
5 years	73.0

* From University of Alberta Hospitals (1996)

Table 2: Correlation of Overall SIP Scores and Selected Criterion Measures*

Criterion Measure	1974 Field Trial (N = 272)[a]	1976 Field Trial (N = 696, N = 199)[b]
Self Assessment of Dysfunction	.52	.69
Clinician Assessment of Dysfunction	.49	.50
NHIS	.61	.55
ADL	.46	N/A

*Adapted from Bergner, M., Bobbitt, R.A., Carter, W.B., and Gilson, B.S. (1981). All coefficients are significant at $p < .001$.

Note NHIS = National Health Interview Survey Index of Activity Limitation, Work Loss and Bed Days; ADL = Activities of Daily Living Index

[a] Sample consisted of rehabilitation medicine patients (n = 73), speech pathology patients (n = 48), out-patients with chronic problems (n = 80) and group enrollees (n = 75).

[b] Sample consisted of random sample of prepaid group practice patients (n = 696) and subjects who considered themselves to be sick, sampled from a family medicine clinic (n = 199).

Table 3: Correlation of SIP Scores and Clinical Measures*

Population & Clinical Measure	Overall SIP Score	Physical Dimension	Pyschosocial Dimension
Total Hip Replacement			
Harris Analysis of Hip Function	-.81	.84	.61
Hyperthyroidism			
Adjusted T_4	.41	.21	.35
Rheumatoid Arthritis			
Activity Index	.66	.66	.56

*Adapted from Bergner, M., Bobbitt, R.A., Carter, W.B., and Gilson, B.S. (1981).

Table 4: Non-participant Demographic Characteristics (n=9)

Characteristic	Frequency	Percent
Gender		
Male	4	44
Female	5	56
Age (years)		
31-40	1	11
41-50	3	33
51-60	1	11
61-70	4	44
Mean Age 52.7 years		
Age Range 36-63 years		
Status at Time of Transplant		
1 - patient at home	2	50
2 - patient in hospital	2	50
Primary Diagnoses		
Cirrhosis - Alcohol-induced	1	11
Cirrhosis - Hepatitis B	2	22
Cirrhosis - Hepatitis C	2	22
Non A/B/C - sub-fulminant liver failure	1	11
Primary Biliary Cirrhosis	3	33
Secondary Diagnoses		
Cirrhosis - Hepatitis C	1	11
Tumor - Hepatocellular Cancer	1	11

Table 5: Participant Demographic Characteristics (n=34)

Characteristic	Frequency	Percent
Gender		
Male	19	56
Female	15	44
Age at Entry to Study		
35-39	3	9
40-44	11	32
45-49	3	9
50-54	5	15
55-59	4	12
60-64	6	18
65-69	1	3
70-74	1	3
Status at Time of Transplant		
1 - pt. at home	25	73
2 - pt. in hospital, stable	5	15
3 - pt. in ICU, not intubated	2	6
4 - pt. in ICU, intubated	2	6
Primary Diagnoses		
Alpha 1 antitrypsin deficiency	1	3
Budd-Chiari	1	3
Chronic Autoimmune Hepatitis	1	3
Cirrhosis - Alcohol-induced	6	18
Cirrhosis - Hepatitis B	3	9
Cirrhosis - Hepatitis C	11	33
Cirrhosis - Hepatitis D	2	6
Cirrhosis - Cryptogenic	1	3
Hepatitic Artery Thrombosis	1	3
Non A/B/C Hepatitis - fulminant hepatitic failure	2	6
Primary Biliary Cirrhosis	4	12
Primary Sclerosing Cholangitis	1	3
Secondary Diagnoses		
Alpha 1 antitrypsin deficiency	1	3
Budd-Chiari (previous transplant)	1	3

Table 5: Participant Demographic Characteristics Contd. (n=34)

Characteristic	Frequency	Percent
Cirrhosis - Hepatitis B	2	6
Cirrhosis - Alcohol-induced	3	9
Portal Vein Thrombosis	1	3
Tumor - Hepatocellular Cancer	2	6

Table 6: Participant Survival By Time Interval

Time Interval	Frequency	Percent
Time 1 (pre-transplant)	34	100.0
Time 2 (2 months post-op)	32	94.1
Time 3 (6 months post-op)	29	85.3

Table 7: Correlation of SIP Scores with Patient-Rated Health Scores by Time Interval

Time Interval	Correlation
Time 1 (pre-transplant)	.761, $p < .01$
Time 2 (2 months post-op)	.844, $p < .01$
Time 3 (6 months post-op)	.754, $p < .01$

Table 8: Correlation of Clinician-Rated Health Scores with SIP Scores

Variables	Correlation
Clinician-Rating and Overall SIP Score	.68, $p < .01$
Clinician-Rating and Physical Dysfunction	.75, $p < .01$
Clinician-Rating and Psychosocial Dysfunction	.40, $p < .05$

Table 9: Correlation of SIP Scores with Biological Measures of Health

	Biological Measure			
Time Interval	Encep	Bili	Alb	PTINR
Overall SIP Score Time 1	.62**	.52**	-.10	.41*
Overall SIP Score Time 2	.71**	.45**	-.61**	-.12
Overall SIP Score Time 3	.00	.41*	-.20	-.34

* $p < .05$
** $p < .01$

Table 10: Child-Pugh Classification of Liver Function - Frequency by Category

Variable	Time 1	Time 2	Time 3
Encephalopathy			
None	6	29	29
Stage 1	18	2	0
Stage 2	6	0	0
Stage 3	4	1	0
Deaths	0	2	5
Missing Data	0	0	0
Bilirubin			
< 25 umol	3	18	22
25 - 40 umol	10	9	4
> 40 umol	21	5	7
Deaths	0	2	5
Missing Data	0	0	0
Albumin			
35 gm/L	4	20	22
28 - 34 gm/L	7	8	5
< 28 gm/L	22	4	1
Deaths	0	2	5
Missing Data	1	0	1
PT INR			
1.3 - 2.0 secs.	28	30	18
2.1 - 2.8 secs.	3	0	0
> 2.8 secs.	3	0	0
Deaths	0	2	5
Missing Data	0	2	10

Table 11: Inter-instrument Correlations at Time 1

	PHYSD	PSYCHS	PT.RATE	CL.RATE	ENCEP	BILI	ALB	PTINR
SIP	.93**	.85**	.76**	.68**	.62**	.52**	-.10	.41*
PHYSD	1.00	.63**	.76**	.75**	.64**	.56**	-.05	.45**
PSYCHS		1.00	.62**	.40*	.35*	.25	-.05	.22
PT.RATE			1.00	.48**	.52**	.44**	-.02	.41*
CL.RATE				1.00	.71**	.55**	-.06	.58**
ENCEP					1.00	.65**	-.19	.61**
BILI						1.00	-.11	.79**
ALB							1.00	-.16
PTINR								1.00

* $p < .05$; ** $p < .01$

SIP = Sickness Impact Profile Score; PHYSD = Physical Dysfunction Score of the SIP; PSYCHS = Psychosocial Score of the SIP; PT.RATE = patient's self-rating score; CL.RATE = clinician's rating score; ENCEP = stage of encephalopathy; BILI = bilirubin value; ALB = albumin value.

Table 12: Inter-instrument Correlations at Time 2

	SIP	PHYSD	PSYCHS	PT.RATE	ENCEP	BILI	ALB	PTINR
SIP	1.00	.95**	.86**	.84**	.62**	.49*	-.60**	-.07
PHYSD		1.00	.69**	.78**	.67**	.50**	-.64**	.00
PSYCHS			1.00	.72**	.44*	.35	-.36*	-.15
PT.RATE				1.00	.57**	.36	-.52**	.22
ENCEP					1.00	.94**	-.30	.10
BILI						1.00	-.19	.14
ALB							1.00	.01
PTINR								1.00

* $p < .05$
** $p < .01$

SIP = Sickness Impact Profile; PHYSD = Physical Dysfunction Score of the SIP; PSYCHS = Psychosocial Score of the SIP; PT.RATE = patient's self-rating score; ENCEP = stage of encephalopathy; BILI = bilirubin value; ALB = albumin value.

Table 13: Inter-instrument Correlations at Time 3

	SIP	PHYSD	PSYCHS	PT.RATE	ENCEP	BILI	ALB	PTINR
SIP	1.00	.82**	.83**	.75**	.	.41*	-.20	-.34
PHYSD		1.00	.48*	.52**	.	.47*	-.46*	-.37
PSYCHS			1.00	.72**	.	.22	.10	-.18
PT.RATE				1.00	.	.26	.04	-.34
ENCEP					1.00	.	.	.
BILI						1.00	-.26	-.05
ALB							1.00	.33
PTINR								1.00

* $p < .05$
** $p < .01$

SIP = Sickness Impact Profile; PHYSD = Physical Dysfunction Score of the SIP; PSYCHS = Psychosocial Score of the SIP; PT.RATE = patient's self-rating score; ENCEP = stage of encephalopathy; BILI = bilirubin value; ALB = albumin value.

Table 14: Mean, Range and Standard Deviations of SIP Variables

Variable	Time	n	Mean	Range	Std. Deviation
Overall SIP	1	34	32.4	7.5-67.4	14.3
Score	2	30	15.5	1.2-53.5	14.8
	3	27	9.3	0.0-22.1	7.8
Physical	1	34	28.4	0.0-79.0	21.0
Dimension	2	30	14.9	0.0-77.6	22.1
Score	3	27	6.1	0.0-25.4	7.7
Body Care &	1	34	27.3	0.0-97.9	25.9
Movement	2	30	14.9	0.0-91.6	26.8
	3	27	5.2	0.0-23.8	7.5
Mobility	1	34	33.2	0.0-84.7	24.5
	2	30	14.6	0.0-75.5	20.3
	3	27	4.7	0.0-33.7	9.6
Ambulation	1	34	27.0	0.0-57.4	13.6
	2	30	15.3	0.0-66.4	18.3
	3	27	9.4	0.0-38.6	12.1
Psychosocial	1	34	28.9	5.3-68.1	16.2
Dimension	2	30	10.0	0.0-35.7	9.3
Score	3	27	8.3	0.0-32.2	9.4
Emotional	1	34	24.0	0.0-71.6	19.5
Behavior	2	30	8.7	0.0-51.9	12.3
	3	27	5.8	0.0-20.9	7.7
Social	1	34	30.1	3.5-92.6	18.5
Interaction	2	30	9.9	0.0-35.6	10.5
	3	27	6.7	0.0-36.5	9.4
Alertness	1	34	41.9	0.0-100.0	34.0
Behavior	2	30	12.0	0.0-60.0	16.2
	3	27	16.3	0.0-81.7	23.3

Table 14: Mean, Range and Standard Deviations of SIP Variables Contd.

Variable	Time	n	Mean	Range	Std. Deviation
Communication	1	34	15.7	0.0-61.1	18.7
	2	30	8.8	0.0-66.9	15.9
	3	27	5.1	0.0-43.6	11.2
Independent Categories					
Sleep & Rest	1	34	61.7	0.0-100.0	27.3
	2	30	23.5	0.0-78.0	24.7
	3	27	10.4	0.0-38.5	12.0
Eating	1	34	13.7	0.0-39.6	8.9
	2	30	7.0	0.0-39.7	9.7
	3	27	2.7	0.0-11.3	3.7
Work	1	34	57.2	0.0-70.1	24.2
	2	30	47.7	0.0-70.1	29.1
	3	27	37.1	0.0-70.1	32.2
Home	1	34	40.3	0.0-85.3	22.2
	2	30	23.6	0.0-91.9	29.4
	3	27	11.3	0.0-41.2	13.8
Recreation	1	34	49.9	4.0-90.8	20.9
	2	30	24.5	0.0-70.9	21.0
	3	27	17.8	0.0-49.8	18.4

Table 15: Work Status by Time Interval

Time	Not Working	Working	Retired	Deaths
1, n = 34	23	6*	5	0
2, n = 32	16	11**	3	2
3, n = 32	12	12**	3	5

* = modified or part-time work

** = full-time, part-time or modified work

Table 16: Mean, Range and Standard Deviations of Patient-Rated Variables

Variable	Time	n	Mean	Range	Std. Deviation
Overall Pt-Rated Score	1	34	4.6	2 - 7	1.4
	2	29	3.1	1 - 7	1.7
	3	27	2.8	1 - 5	1.3
Body Care & Movement	1	34	2.8	1 - 7	1.7
	2	29	1.9	1 - 7	1.7
	3	27	1.5	1 - 4	1.0
Mobility	1	34	4.6	1 - 7	1.8
	2	29	3.0	1 - 7	1.9
	3	27	2.6	1 - 6	1.6
Ambulation	1	34	3.9	1 - 7	1.8
	2	29	3.0	1 - 7	1.8
	3	27	2.9	1 - 6	1.8
Emotional Behavior	1	34	4.0	1 - 7	1.7
	2	29	2.4	1 - 6	1.5
	3	27	2.6	1 - 6	1.7
Social Interaction	1	34	3.3	1 - 6	1.8
	2	29	2.3	1 - 5	1.4
	3	27	2.3	1 - 4	1.2
Alertness Behavior	1	34	3.8	1 - 7	1.9
	2	29	2.6	1 - 6	1.4
	3	27	2.5	1 - 5	1.3
Communication	1	34	2.4	1 - 7	1.6
	2	29	1.7	1 - 6	1.3
	3	27	1.7	1 - 5	1.1
Sleep & Rest	1	34	4.9	1 - 7	1.4
	2	29	2.8	1 - 5	1.5
	3	27	2.9	1 - 5	1.5

Table 16: Mean, Range and Standard Deviations of Patient-Rated Variables Contd.

Variable	Time	n	Mean	Range	Std. Deviation
Eating	1	34	4.1	1 - 7	1.5
	2	29	2.5	1 - 7	1.7
	3	27	2.4	1 - 6	1.6
Work	1	31	5.8	1 - 7	1.6
	2	29	4.4	1 - 7	1.9
	3	25	3.7	1 - 7	1.9
Home	1	34	4.8	1 - 7	1.6
	2	29	3.8	1 - 7	1.6
	3	27	3.0	1 - 6	1.6
Recreation	1	34	5.2	1 - 7	1.5
	2	29	3.3	1 - 7	1.8
	3	27	3.0	1 - 6	1.6

Table 17: Mean, Range and Standard Deviations of Biological Indices

Variable	Time	n	Mean	Range	Std. Deviation
Stage of Encephalopathy	1	34	1.2	0 - 3	0.9
	2	32	0.2	0 - 3	0.6
	3	29	0.0	0 - 0	0.0
Bilirubin	1	34	127.5	12.0-646.0	147.0
	2	32	39.1	6.0-453.0	78.9
	3	29	21.9	5.7-111.0	21.0
Albumin	1	33	26.5	15.0-38.0	6.2
	2	32	35.3	21.0-47.0	6.7
	3	28	38.3	25.0-45.0	4.6
PT INR	1	34	1.7	0.9 - 5.1	0.9
	2	30	1.0	0.8 - 1.3	0.1
	3	19	1.0	0.8 - 1.2	0.1

Table 18: ANOVA of SIP Scores, Physical, Psychosocial and Patient-Rated Dysfunction Scores and Biological Indices by Time Interval

Variable	SS	df	MS	F	p value
SIP Score	7066.05	2	3533.02	45.85	.000*
T1 vs T2	8873.64	1	8873.64	50.25	.000*
T2 vs T3	246.49	1	246.49	2.18	.153
Physical Dysfunction	5796.25	2	2898.12	25.57	.000*
T1 vs T2	6564.24	1	6564.25	23.36	.000*
T2 vs T3	436.81	1	436.81	3.06	.093
Psychosocial Dysfunction	6934.00	2	3467.00	29.70	.000*
T1 vs T2	10277.90	1	10277.90	36.87	.000*
T2 vs T3	1.44	1	1.44	0.01	.916
Patient-Rated Dysfunction	41.09	2	20.54	17.80	.000*
T1 vs T2	60.84	1	60.84	24.27	.000*
T2 vs T3	.01	1	.01	.005	.942
Encephalopathy	10.05	2	5.02	28.28	.000*
T1 vs T2	14.00	1	14.00	30.33	.000*
T2 vs T3	.07	1	.07	1.00	.336
Bilirubin	81227.00	2	40613.50	6.74	.004*
T1 vs T2	117504.00	1	117504.00	6.63	.023*
T2 vs T3	149.18	1	149.18	2.39	.146

Table 18: ANOVA of SIP Scores, Physical, Psychosocial and Patient-Rated Dysfunction Scores and Biological Indices by Time Interval Contd.

Variable	SS	df	MS	F	p value
Albumin	1225.00	2	612.50	22.09	.000*
T1 vs T2	1400.00	1	1400.00	15.35	.002*
T2 vs T3	87.50	1	87.50	8.40	.012*
PT INR	5.47	2	2.74	7.93	.002*
T1 vs T2	8.38	1	8.38	8.11	.014*
T2 vs T3	0.04	1	0.04	.46	.508

* = significant at $p < .05$ level

Table 19: Summary of Change Scores of SIP and Patient-Rated Variables

Variable	Time	SIP Change Score	Pt-Rated Change Score
Overall SIP Score	1 to 2	1.18	1.07
	2 to 3	0.42	0.18
	1 to 3	1.62	1.29
Physical Dimension Score	1 to 2	0.64	0.64
	2 to 3	0.40	0.17
	1 to 3	1.06	0.81
Psychosocial Dimension Score	1 to 2	1.17	0.64
	2 to 3	0.18	-0.02
	1 to 3	1.27	0.62
Independent Categories			
Sleep & Rest	1 to 2	1.40	1.50
	2 to 3	0.53	-0.07
	1 to 3	1.88	1.43
Eating	1 to 2	0.75	1.07
	2 to 3	0.53	-0.07
	1 to 3	1.24	1.13
Home	1 to 2	0.75	0.63
	2 to 3	0.42	0.50
	1 to 3	1.31	1.13
Recreation	1 to 2	1.22	1.27
	2 to 3	0.32	0.17
	1 to 3	1.54	1.47
Work	1 to 2	0.39	0.88
	2 to 3	0.04	0.37
	1 to 3	0.83	1.31

Table 20: Change Scores of Biological Indices

Variable	Time	Change Score
Encephalopathy	1 to 2	1.11
	2 to 3	0.33
	1 to 3	1.33
Bilirubin	1 to 2	0.60
	2 to 3	0.22
	1 to 3	0.72
Albumin	1 to 2	-1.42
	2 to 3	-0.45
	1 to 3	-1.90
PT INR	1 to 2	0.78
	2 to 3	0.00
	1 to 3	0.78

Table 21: Clinical Description of Overall SIP Change Scores

Description and Change Score	Time 1 to 2* (%)	Time 2 to 3** (%)	Time 1 to 3* (%)
Death	2 (6.3)	5 (16.7)	5 (12.5)
Significant Deterioration (< -20)	1 (3.1)	1 (3.3)	
Moderate Deterioration (-11 to -20)	1 (3.1)		
Deterioration (-1 to -10)		8 (26.7)	
No Change	1 (3.1)	2 (6.7)	
Improvement (1 to 10)	5 (15.6)	9 (30.0)	7 (21.9)
Moderate Improvement (11 to 20)	10(31.3)	3 (10.0)	7 (21.9)
Significant Improvement (> 20)	12(37.5)	2 (6.7)	13(40.6)

* n = 32, 2 surveys not returned, ** n = 30, 4 surveys not returned

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APPENDICES

APPENDIX A
Sample Size and Power Calculation

The sample size calculaation was based on the results obtained in Tarter, Switala, Arria, Phail and Van Thiel's (1991) study of the quality of life of liver transplantation patients. The magnitude of improvement that they demonstrated across all of the SIP scales from pre-operation to post-operation was 73.9%. The mean and standard deviations of pre-operation measures was estimated from graphed material in the results section.

The mean SIP score pre-operatively was 30.1 (SD = 31). A 73.9% improvement would place the post-operative mean at 7.7 because lower SIP scores indicate less functional impairment.

$$\frac{n}{\text{group}} = 2\sigma^2 \times \frac{f(\alpha, \beta)}{(\mu_2 - \mu_1)}$$

where σ = standard deviation for μ_1
μ_1 = mean pre-op score
μ_2 = mean post-op score

f value (for alpha = .05, beta = .8) = 7.9

$$\frac{n}{\text{group}} = \frac{2(31)^2}{(22.4)^2} \times 7.9$$

$$= \frac{1922}{501} \times 7.9$$

$$= 3.8 \times 7.9 = 30 \text{ subjects}$$

Therefore, 30 subjects would be required to obtain 80% power. Collecting data on 20 subjects would result in approximately 60% power.

APPENDIX B

Sickness Impact Profile Summary Sheet

Physical Dimension	**Client Score**					
Ambulation	_____	=	___	÷ 84.0 X 100	=	___ %
Mobility	_____	=	___	÷ 71.9 X 100	=	___ %
Body Care/Move	_____	=	___	÷ 200.3 X 100	=	___ %
Physical Score		=	___	÷ 356.4 X 100	=	___ %

Psychosocial Dimension	**Client Score**					
Social Interaction	_____	=	___	÷ 145.0 X 100	=	___ %
Alertness	_____	=	___	÷ 77.7 X 100	=	___ %
Emotional Behav.	_____	=	___	÷ 70.5 X 100	=	___ %
Communication	_____	=	___	÷ 72.5 X 100	=	___ %
Psychosocial Score		=	___	÷ 365.7 X 100	=	___ %

Independent Categories	**Client Score**					
Sleep and Rest	_____	=	___	÷ 49.9 X 100	=	___ %
Eating	_____	=	___	÷ 70.5 X 100	=	___ %
Work	_____	=	___	÷ 51.5 X 100	=	___ %
Home	_____	=	___	÷ 66.8 X 100	=	___ %
Recreation	_____	=	___	÷ 42.2 X 100	=	___ %
Overall Score		=	___	÷ 1003 X 100	=	___ %

APPENDIX C
Self-Rating of Dysfunction Scale

1. To what extent is your functioning affected by your health today, specific to the area of home management (heavy work, light work)? For example, if your health prevents you from being able to perform many of your home management tasks, you would give yourself a higher number. If your health does not interfere with your abilities in this area, you would give yourself a lower number.

   1 - not at all
   2 - very slightly
   3 - slightly
   4 - moderately
   5 - greatly
   6 - very greatly
   7 - extremely

2. To what extent is your functioning affected by your health today, specific to the area of ambulation (walking, using stairs, climbing slopes)?

   1 - not at all
   2 - very slightly
   3 - slightly
   4 - moderately
   5 - greatly
   6 - very greatly
   7 - extremely

3. To what extent is your functioning affected by your health today, specific to the area of mobility (going out to do errands, etc.)?

   1 - not at all
   2 - very slightly
   3 - slightly
   4 - moderately
   5 - greatly
   6 - very greatly
   7 - extremely

Self-Rating of Dysfunction Scale Contd.

4. To what extent is your functioning affected by your health today, specific to the area of body care and movement (dressing, bathing)?

   1 - not at all
   2 - very slightly
   3 - slightly
   4 - moderately
   5 - greatly
   6 - very greatly
   7 - extremely

5. To what extent is your functioning affected by your health today, specific to the area of social interaction (interaction with family, friends)?

   1 - not at all
   2 - very slightly
   3 - slightly
   4 - moderately
   5 - greatly
   6 - very greatly
   7 - extremely

6. To what extent is your functioning affected by your health today, specific to the area of alertness behavior (restlessness, lability)?

   1 - not at all
   2 - very slightly
   3 - slightly
   4 - moderately
   5 - greatly
   6 - very greatly
   7 - extremely

Self-Rating of Dysfunction Scale Contd.

7. To what extent is your functioning affected by your health today, specific to the area of emotional behavior?

    1 - not at all
    2 - very slightly
    3 - slightly
    4 - moderately
    5 - greatly
    6 - very greatly
    7 - extremely

8. To what extent is your functioning affected by your health today, specific to the area of communication (rate of speech, understandability)?

    1 - not at all
    2 - very slightly
    3 - slightly
    4 - moderately
    5 - greatly
    6 - very greatly
    7 - extremely

9. To what extent is your functioning affected by your health today, specific to the area of sleep and rest (dozing off or interrupted sleep cycle)?

    1 - not at all
    2 - very slightly
    3 - slightly
    4 - moderately
    5 - greatly
    6 - very greatly
    7 - extremely

Self-Rating of Dysfunction Scale Contd.

10. To what extent is your functioning affected by your health today, specific to the area of eating (appetite, special diet)?

    1 - not at all
    2 - very slightly
    3 - slightly
    4 - moderately
    5 - greatly
    6 - very greatly
    7 - extremely

11. To what extent is your functioning affected by your health today, specfic to the area of work (job modifications)?

    1 - not at all
    2 - very slightly
    3 - slightly
    4 - moderately
    5 - greatly
    6 - very greatly
    7 - extremely

12. To what extent is functioning affected by your health today, specific to the area of recreation/pasttimes (participation, type)?

    1 - not at all
    2 - very slightly
    3 - slightly
    4 - moderately
    5 - greatly
    6 - very greatly
    7 - extremely

13. Overall, on the same 1-to-7 scale, to what extent does your health impair your functioning? _____

APPENDIX D

Clinician Rating of Dysfunction - 1

People's states of health sometimes affect the way they function, in other words, the way they carry out their life activities. They don't do things in the usual way: they cut some things out, they do some things for shorter lengths of time, they do some in different ways. Now, we would like to know how _____ functioning is affected by his/her health today, specific to the areas of functioning outlined below. Circle the number which best describes _____.

Physical Dimension

Ambulation

Impact on Function	
1 - not at all	
2 - very slightly	Pt. walks more slowly or requires a cane
3 - slightly	Pt. walks shorter distances or stops to rest often
4 - moderately	Pt. does not walk up or down hills
5 - greatly	Pt. walks only with the help of someone
6 - very greatly	Pt. needs to use a wheelchair
7 - extremely	Pt. is unable to walk

Mobility

Impact on Function	
1 - not at all	
2 - very slightly	
3 - slightly	Pt. does not go out as often (i.e. for groceries, to visit)
4 - moderately	Pt. is not able to use public transportation
5 - greatly	Pt. stays away from home only for brief periods of time
6 - very greatly	Pt. stays home most of the time
7 - extremely	Pt. stays within one room

Body Care and Movement

Impact on Function	
1 - not at all	Pt. does not have trouble with personal self-care activities
2 - very slightly	Pt. dresses him/herself, but does so very slowly
3 - slightly	Pt. kneels, stoops or bends down only by holding on to something
4 - moderately	Pt does not bathe him/herself completely, i.e., requires assistance
5 - greatly	Pt. stands only with someone's help
6 - very greatly	Pt stays lying down most of the time
7 - extremely	Pt. does not have control of their bowel and/or bladder

---

Psychosocial Dimension

Social Interaction

Impact on Function	
1 - not at all	
2 - very slightly	Pt. is cutting down the length of their visits with friends
3 - slightly	Pt. is going out less to visit people
4 - moderately	Pt. talks less with those around them
5 - greatly	Pt. is not doing the things they usually do to take care of their children or family
6 - very greatly	Pt. isolates him/herself as much as possible from the rest of the family
7 - extremely	Pt. has frequent outbursts of anger at family members

---

Clinician Rating of Dysfunction - 2

Alertness Behavior

Impact on Function	
1 - not at all	No change in level of alertness
2 - very slightly	Pt. reacts slowly to things that are said or done
3 - slightly	Pt. can't keep their attention on any activity for long
4 - moderately	Pt. forgets alot, i.e., things that happened recently, where they put things etc.
5 - greatly	Pt. has difficulty doing activities involving concentration and thinking
6 - very greatly	Pt. has difficulty reasoning and solving problems i.e., making plans, making decisions
7 - extremely	Pt behaves as if they were confused or disoriented in place or time

---

Emotional Behavior

Impact on Function	
1 - not at all	
2 - very slightly	
3 - slightly	Pt. acts nervous or restless
4 - moderately	Pt. laughs or cries suddenly
5 - greatly	Pt. acts irritably and impatiently - talks badly about themselves, swears at themselves, blames self
6 - very greatly	Pt. talks about the future in a hopeless way
7 - extremely	

Communication

Impact on Function	
1 - not at all	
2 - very slightly	Pt. speaks slightly more slowly or responds with slight hesitation
3 - slightly	Pt. has difficulty speaking, i.e., slurs words, gets stuck
4 - moderately	Pt. doesn't write except to sign his/her name
5 - greatly	Pt's speech is understood only by a few people who know them well
6 - very greatly	Pt. communicates mostly by gestures (nodding head, pointing)
7 - extremely	No satisfactory means by which to communicate can be identified

---

Independent Categories

Sleep and Rest

Impact on Function	
1 - not at all	
2 - very slightly	
3 - slightly	Pt. sleep cycle is occasionally interrupted
4 - moderately	Pt. lies down more often during the day in order to rest
5 - greatly	Pt. spends much of the day lying down in order to rest
6 - very greatly	Pt. sleeps or dozes most of the time (day and night)
7 - extremely	

Eating

Impact on Function	
1 - not at all	
2 - very slightly	Pt. does not have his/her usual appetite
3 - slightly	Pt. is eating much less than usual

Clinician Rating of Dysfunction - 3

4 - moderately	Pt. feeds him/herself but only by using specially prepared food or utensils
5 - greatly	Pt. is not eating food, fluids only
6 - very greatly	Pt. cannot feed themselves, but must be fed
7 - extremely	Pt's nutrition is taken through tubes or I.V.

If patient is not working and it is <u>not</u> because of his/her health, skip the next section and go to the section "Home Management"

Working

Impact on Function

1 - not at all	
2 - very slightly	Pt. works their usual job but with some changes (uses different tools, trades some tasks with other workers
3 - slightly	Pt. works shorter hours
4 - moderately	Pt. does only light work
5 - greatly	Pt. is not able to do their job as carefully or accurately as usual
6 - very greatly	Pt. acts irritably toward work associates
7 - extremely	

Home Management

Impact on Function

1 - not at all	
2 - very slightly	
3 - slightly	Pt. does not do the heavy work around the house
4 - moderately	Pt. does the work around the house only for short periods of time or rests often
5 - greatly	Pt. is not doing <u>any</u> of the shopping that they would usually do
6 - very greatly	Pt. is not doing <u>any</u> of the regular daily work around the house that they would usually do
7 - extremely	

Recreation/Pastimes

Impact on Function

1 - not at all	
2 - very slightly	Pt. does their hobbies and recreation for shorter periods of time
3 - slightly	Pt. is cutting down on <u>some</u> of their usual physical recreation or activities
4 - moderately	Pt. is doing more <u>inactive</u> pastimes <u>in place</u> of their other usual activities
5 - greatly	Pt. is not doing <u>any</u> of their usual physical recreation or activities
6 - very greatly	Pt. is not doing <u>any</u> of his/her <u>inactive</u> recreation and pastimes (T.V., playing cards, reading etc.)
7 - extremely	

Overall, what rating on the above scale would you assign to the impact that this patient's functioning is affected by their health today? ____

APPENDIX E

Child-Pugh Classification of Liver Function

	1 Minimal	2 Moderate	3 Advanced
Stage of Encephalopathy	none	1 and 2	3 and 4
Bilirubin (umol)	< 25	25-40	> 40
Albumin (gm/L)	35	28-34	< 28
PT INR (secs)	1.3-2.0	2.1-2.8	> 2.8

APPENDIX F
INFORMATION SHEET

Title: Evaluating the Utility of the Sickness Impact Profile (SIP) As An Outcome Indicator For Liver Transplantation Patients

Principal Investigator: Dr. N.M. Kneteman Phone: 492-3118

Co-Investigator: Martha Loadman Joyce Phone: 492-6203

Background: There are different ways to measure the benefits of a surgical procedure. One way is to measure the impact that the surgical procedure has had on a person's physical and social capacity and their emotional well-being. A measure of health called the Sickness Impact Profile is meant to measure these aspects of a person's health. We want to know if this measure is a useful one to measure the impact that liver transplantation has on people who are undergoing the procedure.

Purpose: You are being asked to participate in a research study that measures various aspects of your health. The purpose of the study is to see whether the Sickness Impact Profile is an appropriate measure to describe the health of people who are waiting for and have undergone liver transplantation.

Procedures: Participating in this study will involve:

a) 3 sessions with Martha Joyce. The first session will be scheduled while you are waiting for your transplant. The second session will be scheduled for 2 months after your transplant and the third session at 6 months after your surgery. Each session will take approximately 1 hour. Therefore the total amount of time that will be required of you beyond that needed for standard pre- and post-operative procedures is approximately 3 hours.

At each session:

b) You will be interviewed by Martha Joyce who will administer a questionnaire to you (takes about 20-30 mins). You will then be asked to fill out a rating scale that indicates how well you feel you are functioning (5-10 mins).

c) If you have not had a blood sample drawn within 24 hours, a sample will be taken and the results will be used to rate your health.

d) During your first session, you will also be seen briefly by the Transplant Coordinator who will fill out a rating scale (5-10 mins).

INFORMATION SHEET CONT.

Title: Evaluating the Utility of the Sickness Impact Profile as an Outcome Indicator for Liver Transplantation Patients

Possible Benefits:

The possible benefits to you for participating in this study are that you can provide information that will help to identify what health indicators are most appropriate for use with people undergoing liver transplantation.

Possible Risks:

There are no known risks to participating in this study.

Confidentiality:

Personal records relating to this study will be kept confidential. Any report published as a result of this study will not identify you by name.

You are free to withdraw from the research study at any time, and your continuing medical care will not be affected in any way. If the study is not undertaken or if it is discontinued at any time, the quality of your medical care will not be affected. If any knowledge gained from this or any other study becomes available which could influence your decision to continue in the study you will be promptly informed.

If you have any questions or concerns about this study, feel free to contact any of the individuals identified below:

Dr. N.M. Kneteman 492-3118
Transplant Surgeon and Associate Professor of Surgery

Martha Joyce
Occupational Therapist and Graduate Student 492-6203
453-2964

APPENDIX G

CONSENT FORM

Title of Project: Evaluating the Utility of the Sickness Impact Profile (SIP) As An Outcome Indicator For Liver Transplantation Patients

Principal Investigator:	Dr. N. M. Kneteman	Phone Number: 492-3118
Co-Investigator:	Martha Loadman Joyce	Phone Number: 492-6203

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care?	☐	☐
Has the issue of confidentiality been explained to you, and do you understand who will have access to your medical records?	☐	☐
Do you want the investigators to inform your family doctor that you are participating in this research study?	☐	☐

Who explained this study to you? _____

CONSENT FORM CONT.

Title of Project: Evaluating the Utility of the Sickness Impact Profile As An Outcome Indicator for Liver Transplantation Patients

	Yes	No
I agree to take part in this study:	☐	☐

Signature of Research Subject

_____

(Print Name)

_____

Date: _____

Signature of Witness

_____

Signature of Investigator and Designee

_____

APPENDIX H

ETHICS REVIEW FORM

University of Alberta
Edmonton
Canada T6G 2R7

Office of the Dean
Faculty of Medicine
2J2.00 WC Mackenzie Health Sciences Centre
Telephone (403) 492-6621
FAX: (403) 492-7303

RESEARCH ETHICS BOARD

ETHICS APPROVAL FORM

Date:May 1994

Name(s) of Principal Investigator(s): Dr. N. Kneteman

Department: Surgery

Title: Evaluating The Utility Of The Sickness Impact Profile (SIP) As An Outcome Indicator For Liver Transplantation Patients

The Research Ethics Board (REB) has reviewed the protocol involved in this project which has been found to be acceptable within the limitations of human experimentation. The REB has also reviewed and approved the patient information materials and consent form.

Specific Comments:

Signed - Chairman of Research Ethics Board

for the Faculty of Medicine
University of Alberta

This approval is valid for one year.

Our File #1572

University of Alberta
Edmonton

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Faculty of Medicine

Canada T6G 2R7

2J2.00 WC Mackenzie Health Sciences Centre
Telephone: (403) 492-6621
Fax: (403) 492-7303
E-mail: _____@dean.med.ualberta.ca

RESEARCH ETHICS BOARD

ETHICS APPROVAL FORM

Date: May 1995

Name(s) of Principal Investigator(s): Dr. Norman Kneteman

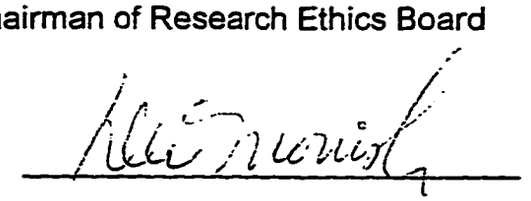
Department: Surgery

Title: Evaluating The Utility Of The Sickness Impact Profile (SIP) As An Outcome Indicator For Liver Transplantation Patients

The Research Ethics Board (REB) has reviewed the protocol involved in this project which has been found to be acceptable within the limitations of human experimentation. The REB has also reviewed and approved the patient information materials and consent form.

Specific Comments:

Signed - Chairman of Research Ethics Board



for the Faculty of Medicine
University of Alberta

This approval is valid for one year.

Our File #1572