he Board of Directors and the 1996 Conference Organizing Committee of the International Society for Quality of Life Research (ISOQOL) would like to extend a cordial invitation to attend its 3rd Annual Conference. The meeting will be held on October 24-27, 1996 in Manila, Philippines.

The purpose of the conference is to support an international exchange of research concerning quality of life, its measurement, and its determinants. Quality of life may be affected by health, housing, socioeconomic status, health care, and the environment. Investigators from different geographic areas of the world will meet to contribute their unique perceptions of quality of life determinants. Through these international exchanges we hope to learn more about the differences and similarities of quality of life characteristics across our globe.

The first International meeting was held in Brussels, Belgium, in February 1994. The founder of the Society, Dr. Maurice Staquet, organized and hosted the event with the assistance from other European investigators. The second meeting was held in Montreal, Canada, in October, 1995. Drs. Monika Bullinger and Sharon Wood-Dauphinee organized and conducted the meeting with help from an international committee.

The forthcoming third conference will be held in Manila, Philippines, on October 24-27, 1996. The International and Local Organizing Committees are led by Drs. Geraldine Padilla and Laurie Ramiro and assisted by other committee members from Europe, the United States, Canada and Asia. Circling the globe promotes the spirit of international research, and makes it easier for investigators from different areas of the world to attend the conferences.

The 1996 ISOQOL International Conference Programme Schedule

October 24:
Concurrent preconference workshops, each lasting 3 hours, will be conducted by experts in their field. Each workshop will provide a course syllabus, readings and outline.

Morning Workshops:
1) Quality of Life Assessment & Interpretation: Introduction, Leader: Sharon Wood-Dauphinee. This workshop will discuss current thinking about quality of life in the health sector, consider factors related to choosing quality of life measures, and examine basic issues involved in conducting quality of life studies. 2) Cross-cultural Perspectives on Quality of Life, Leaders: Donald Patrick and Mona Martin. This workshop focuses on issues and strategies relevant to conceptual and operational definitions of quality of life when culture is taken into consideration. Different methods for developing measures for use cross culturally will be presented. 3) Quality of Life Applications to Health Policy, Leader: Robert Kaplan. This workshop will include issues relevant to the use of quality of life data in formulating health policy. Comparisons of issues common and specific to different geopolitical areas will be considered.

Afternoon Workshops:
4) Quality of Life Assessment & Interpretation: Advanced, Leaders: Eva Lydick, Ron Hays. This workshop will present methods of evaluating and interpreting quality of life measures including a discussion of reliability and validity assessment.
5) Quality of Life in Special Populations - children, Leader: Monika Bullinger. This workshop addresses the concepts, methods, results of research into the Subjective Health or Health-Related Quality of Life in children.
6) Environmental and Socioeconomic Indicators of Quality of Life, Leader: to be named. This workshop will focus on current knowledge concerning environmental and socioeconomic factors that affect quality of life.

Cultural Night and Banquet: The conference will officially open on the evening of October 24 with a welcome ceremony and cultural night banquet.

October 25 and 26:
2-Day Conference Programme

Plenary sessions will include internationally renowned speakers from the Philippines, Japan, Germany and Australia: Dr. Gelia Castillo, «Quality of Life - Beyond Health»; Dr. Kiyoji Kurokawa, «Current Issues and Future Perspectives in Health Care in Japan»; Dr. Monika Bullinger, «The Challenge of International Quality of Life...» (continued on p 2)

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This issue of the QoL Newsletter highlights the evolving interest in quality of life as an outcome measure, not only to demonstrate the efficacy of therapeutic interventions, but also to monitor the effectiveness of healthcare processes. It is therefore encouraging to see pharmaceutical companies investing in multinational studies to monitor quality of life, and the Benefact Database (pages 13, 14) demonstrates the commitment to improving care in clinical oncological practice. This study is similar to the ongoing CORCE study described in a previous issue (Marquis P et al., Quality of Life Newsletter 1996;15:12) which uses quality of life measures to monitor the effect of postoperative care in the rehabilitation of ostomy patients. Both studies aim to improve the quality of care provided to the patients using quality of life as an outcome measure.

A number of articles in this issue address the approach of healthcare providers to monitor the costs and effectiveness of providing health care services and the satisfaction derived by the patients and the impact on their quality of life. More specific studies highlight the use of quality of life assessment in an intensive care situation (page 6), and for disabled patients who are confined to wheelchairs (page 2). These articles serve to demonstrate the increased awareness of the impact of quality of life and its potential as an instrument for improving the effective delivery of healthcare.

One of our aims is to encourage researchers and drug companies to collaborate more on the development of core questionnaires for use in specific disease areas, rather than waste resources recreating existing measures or developing similar measures simultaneously. Without some control over the burgeoning number of quality of life instruments that are currently being developed, how can regulatory authorities, providers and payers interpret quality of life data from clinical trials that do not use standardized measures? Meetings such as the ISOQOL Conferences (see page 1) do much to further research in this area and provide a valuable forum for researchers to exchange ideas and explore new concepts.

We hope that the Newsletter will continue to provide stimulating articles on new methodologies and new approaches to quality of life assessment, and we encourage readers to submit viewpoints, comments or short reports of their research for publication in future issues.

K. Ian Johnson, Editor, QoL Newsletter
Mapi Values, UK.

Commentary

Recent oral presentations and poster sessions will be delivered by a cross section of investigators from Asia, Africa, Europe, North and South America. Topics include: quality of life in children, adolescents, parents, older persons, whole communities; disease targeted application of quality of life such as in persons with cancer, diabetes, mental illness, arthritis, heart problems, AIDS/HIV, and others; new and revised instruments such as the WHOQOL, EORTC-QLQ, SF-36, GHQ; analysis methods and issues (both quantitative and qualitative); mental health and sexual attitudes; cost and environmental issues.

Concurrent interest/study groups and round table discussions are planned as a means of exchanging ideas in an informal atmosphere.

Conference participants are invited to submit their topics to Geraldine Padilla (Fax: +310 206 7433 or E-mail gpadilla@sonnet.ucla.edu). Exhibits by drug companies, publishers, and the Quality of Life Research journal are also planned.

October 25, Friday Evening:
General membership business. Members please attend.

October 27:
Field trips are planned for those interested in learning first hand about the effect that natural disasters such as the volcanic eruption of Mount Pinatubo and socioeconomic conditions have on health-related quality of life.

The number of people with a major ambulatory incapacity, and needing a wheelchair, is continuously increasing, irrespective of the reasons for incapacity (myopathy, traumatic paraplegia, neonatal anoxia). This increase has been met by the development of social support physiotherapy and rehabilitation facilities, equipment, and more recently by the use of specifically educated animals (mainly dogs such as labradors or golden retrievers).

The funding for this support creates a strong demand for assessing these supports, not only in terms of functional or dependency indicators, but also in terms of quality of life. Unfortunately, most health related quality of life measurements include physical activity scales that are not relevant for people in wheelchairs, because of constructs such as running, walking one block (or even less), and climbing up stairs which do not apply to such situations.

One issue is the possibility of constructing other activity scales that can take into account the specific effects of daily living with ambulatory impairment (for example: transfer from bed to chair, or from chair to car). It is also important to differentiate those using an electric wheelchair, from those having cognitive disorders.

Another issue is the ceiling that can be reached by someone moving with a wheelchair: can it be assessed by using the same kind of scale as someone walking, with the same assumptions?

These are difficult tasks that will need a collaborative multicentre approach.

We are in contact with an association promoting support for neurologically deficient patients with educated dogs, and we hope to develop an instrument for health related quality of life for people in wheelchairs. We are therefore keen to learn of other researchers involved in this field in order to explore possible collaboration.

Measuring Quality of Life for People in Wheelchairs

Gerbaud L1, Vernay D2, Biolay S

1 Service d’Epidémiologie, Economie de la Santé et Prévention - Hôtel-Dieu - Clermont-Ferrand
2 Service de Neurologie - Hôpital Nord

France

The new support creates a strong demand for assessing these supports, not only in terms of functional or dependency indicators, but also in terms of quality of life. Unfortunately, most health related quality of life measurements include physical activity scales that are not relevant for people in wheelchairs, because of constructs such as running, walking one block (or even less), and climbing up stairs which do not apply to such situations. One issue is the possibility of constructing other activity scales that can take into account the specific effects of daily living with ambulatory impairment (for example: transfer from bed to chair, or from chair to car). It is also important to differentiate those using an electric wheelchair, from those having cognitive disorders.

Another issue is the ceiling that can be reached by someone moving with a wheelchair: can it be assessed by using the same kind of scale as someone walking, with the same assumptions?

These are difficult tasks that will need a collaborative multicentre approach.

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Methodology

1. Introduction

The objective of the Q-TWiST method, Quality-adjusted Time Without Symptoms of disease or Toxicity of treatment, is to compare treatments in clinical trials in terms of both quantity and quality of life (QOL). The development of the method was motivated in 1986 by a medical controversy over which chemotherapy for breast cancer demonstrated an improvement in disease-free survival, but no overall survival advantage, and had significant side effects. The question then became: does the improved QOL associated with delayed recurrence balance the diminished QOL associated with toxic side effects of the adjuvant therapy? Q-TWiST was designed to evaluate this tradeoff by considering the amounts of time patients spent in the clinical health states of toxicity and recurrence. The technical aspects of Q-TWiST have been described by Gelber and al. The method has been applied to treatment comparisons for patients with node-positive and node-negative breast cancer, rectal cancer, HIV infection, and melanoma.

2. Methodology

The application of the Q-TWiST method involves the following three steps.

Defining Clinical Health States:

The first step is to define clinical health states that highlight the differences between the treatments being compared for the specific disease under study. Generally these states include a period of relatively uncompromised QOL, consisting of time spent without symptoms or toxicity (TWiST), representing the best QOL available for the study patients. Other states may include time with treatment toxicity and time with disease progression. Patients progress through the clinical health states chronologically, possibly skipping one or more states, but never backtracking. These states can be defined retrospectively at the time of data analysis or can be specified prospectively in the protocol document in anticipation of performing a Q-TWiST analysis. In the original analysis of adjuvant chemotherapy for breast cancer, the clinical health states were: time spent with treatment toxicity (TOX); time without either symptoms of the disease or toxicity of treatment (TWiST = disease-free survival [DFS]); and time following the diagnosis of systemic spread of the disease or relapse (REL = overall survival [OS] - DFS). The clinical health states, for example TOX and REL, are assigned utility coefficients, uTOX and uREL respectively, to express the value of time in these states relative to TWiST. The values of these utility coefficients are left unspecified, but their effect on the analysis is investigated in the third step using a sensitivity analysis. The utility coefficients are on a scale from 0 = «as bad as death» to 1 = «as good as TWiST». The utility coefficient for TWiST is assumed to be unity because it characterizes a period of relatively perfect health. The Q-TWiST outcome is calculated as the weighted sum of the clinical health state durations and the utility coefficients. For the breast cancer example:

\[ \text{Q-TWiST} = u_{TOX} \times \text{TOX} + u_{TWiST} \times \text{TWiST} + u_{REL} \times \text{REL} \]

Partitioning the Overall Survival:

In the second step, Kaplan-Meier curves for the clinical health state transition times are used to partition the area under the OS curves separately for each treatment group. The average time patients spend in each health state within the median follow-up period is calculated using restricted means.

Comparing treatments using Q-TWiST:

The third step is to compare the treatment regimens using the Q-TWiST formula defined in Step 1 and the mean durations of the clinical health states calculated in Step 2. Treatment comparisons are made in a sensitivity analysis, also called a threshold utility analysis which compares the treatments across all possible values of the utility coefficients. A figure illustrates the values of the utility coefficients for which one treatment yields more Q-TWiST than the other. This provides a Q-TWiST treatment comparison even when estimates of the utility values are not available. The evolution of long-term treatment benefits compared with short-term treatment toxicity can be illustrated longitudinally with a Q-TWiST gain function.

3. An example

To illustrate Q-TWiST, we present an analysis of a randomized clinical trial of adjuvant chemotherapy for resectable breast cancer. Trial V of the International Breast Cancer Study Group (IBCSG) investigated the effectiveness of a short duration (1 month) adjuvant chemotherapy in patients with node-positive breast cancer compared with long duration adjuvant therapy (6 or 7 months). A total of 1,229 patients were randomized to the two treatments, and the median follow-up for this analysis was 7 years.

Figure 1 shows the partitioned survival plots according to treatment group. The areas between the curves give the average amounts of time spent in TOX, TWiST and REL as indicated. The larger area of TOX and the smaller area of REL are characteristics of the long duration treatment in terms of time with reduced QOL. The average amounts of time in TOX, TWiST and REL up to 7 years from randomization are shown in Table 1. The two-right hand columns of the table refer to the treatment differences (long duration minus short duration).

Table 1: Treatment Differences

- TOX: Time spent with treatment toxicity
- TWiST: Time without symptoms or toxicity
- REL: Time with disease progression
- DFS: Disease-free survival
- OS: Overall survival
- uTOX: Utility coefficient for treatment toxicity
- uTWiST: Utility coefficient for TWiST
- uREL: Utility coefficient for relapse

Figure 1: Partitioned Survival Plots. Partitioned survival for the long duration treatment (A) and for the short duration (B) for BCSG Trial V at 7 years of median follow-up. In each graph, the area under the overall survival curve (OS) is partitioned by the survival curves for disease-free survival (DFS) and time with treatment toxicity (TOX). The areas between the survival curves give the average months spent in TOX, TWiST and REL as indicated.

(continued on p 4)
duration minus short duration) for the average amounts of time patients spent in the various states. Our sensitivity analysis indicated that in all cases except \( u_{TOX} < 0.1 \) and \( u_{REL} > 0.9 \), the long duration chemotherapy provided a greater amount of Q-TWiST compared to short duration chemotherapy. This benefit was statistically significant (p<0.05) in all cases where \( u_{TOX} > u_{REL} > 0.3 \). For example, for a patient who values time with toxicity as being at least as valuable as an equivalent amount of time with recurrence (e.g., \( u_{TOX} = u_{REL} = 0.5 \)). The Q-TWiST analysis indicates that the long duration chemotherapy is the preferred treatment (e.g. 5 months of quality-adjusted time gained, confidence interval [2.8]). Conversely, a patient who is particularly averse to the side effects of treatment may place a low value on time with toxicity and a higher value on time relapse (e.g., \( u_{TOX} = 0.2 \) and \( u_{REL} = 0.8 \)). In this case the preferred treatment is not clear since the Q-TWiST comparison is not statistically significant.

4- Q-TWiST applications

The Q-TWiST method can be applied for any treatment comparison involving progressive health states that differ with respect to patients’ QOL. In each disease setting, defining the appropriate clinical health states poses interesting challenges. Close collaboration with clinicians treating the disease is necessary to assure the identification of the tradeoffs that are most relevant.

In an ongoing study evaluating treatment regimens for childhood acute lymphoblastic leukemia (ALL), a major concern is the late adverse effects of toxic treatments. Although prior to the 1960’s ALL was almost uniformly lethal, it currently has a 70-75% cure rate1. Unfortunately, long term survival has been associated with late sequelae, such as cardiac effects, cognitive impairment, growth abnormalities, and second malignancies. The Q-TWiST analysis should incorporate the reduced QOL associated with one or more late toxicities. The Q-TWiST outcome in this disease setting will be modified to include late effects as a separate clinical health state. This study is also directly assessing patient preferences, using the Health Utilities Index5, and the Q-TWiST analysis will incorporate the generated utilities. Small cell lung cancer presents different issues for a quality-adjusted survival analysis. The poor survival associated with this disease focuses extra concern on the acute treatment toxicities which can decrease QOL. Since the treatments being evaluated may not return patients to relatively good health, this may be a situation where TWiST (i.e. time with a tumor response) should be valued with a utility less than one.

A version of Q-TWiST has also been developed for use in meta-analysis and has been applied to the worldwide overview of breast cancer data in analyses of pre- and postmenopausal breast cancer10,11. Parametric estimates for the tails of the survival distributions have been used to project future gains that might be achieved12.

Current research is underway to apply a Q-TWiST analysis for treatment comparisons in other childhood malignancies, colon cancer, lymphoma, multiple myeloma, prostate cancer and brain tumors.

5. Conclusion

As illustrated by the breast cancer example, a Q-TWiST analysis may be performed retrospectively after the completion of a clinical trial. In this case data must be available for partitioning overall survival into the clinically relevant health states. These are often broadly defined, for example using the entire treatment period to represent toxicity.

Alternatively, a Q-TWiST analysis can be planned prospectively as described above in the ALL example. This enables a more precise definition of the clinical health states and provides the opportunity to collect the specific end points required to partition the overall survival time. Patient-derived utilities can also be obtained during the trial. Even when estimates for utility scores are available within a trial, we recommend that the threshold utility analysis be performed to allow the trial results to be interpreted for individual patient preferences.

It has become increasingly important to include QOL considerations in the evaluation of treatment effectiveness in clinical trials. These comparisons are based on weighting clinically relevant health states according to patient preferences. Q-TWiST integrates QOL assessment into a survival analysis to provide a range of treatment recommendations for patient decision making.

Acknowledgment: We are grateful for the partial support provided by an American Cancer Society grant (PBR53E).


Table 1: Average months of time according to quality-of-life endpoint for 1,129 patients in International Breast Cancer Study Group Trial 3. Q-TWiST is given for two hypothetical utility coefficient scenarios

<table>
<thead>
<tr>
<th>End Point</th>
<th>Chemotherapy Treatment</th>
<th>Long Duration</th>
<th>Short Duration</th>
<th>Difference</th>
<th>95% C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOX</td>
<td>6</td>
<td>1</td>
<td>5</td>
<td>4.9 to 5.1</td>
<td></td>
</tr>
<tr>
<td>TWIST</td>
<td>54</td>
<td>47</td>
<td>6</td>
<td>3 to 10</td>
<td></td>
</tr>
<tr>
<td>OS</td>
<td>69</td>
<td>64</td>
<td>5</td>
<td>2 to 8</td>
<td></td>
</tr>
<tr>
<td>DFS</td>
<td>59</td>
<td>48</td>
<td>11</td>
<td>8 to 15</td>
<td></td>
</tr>
<tr>
<td>Q-TWiST</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>uTOX = 0.2</td>
<td></td>
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<tr>
<td>uREL = 0.8</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Q-TWiST</td>
<td>62</td>
<td>60</td>
<td>2</td>
<td>1 to 5</td>
<td></td>
</tr>
</tbody>
</table>

For more information, please contact: Shari Gelber, Frontier Science Technology and Research Foundation, 303 Boylston Street, Brookline, MA 02146, USA. Tel: +1 617 632 3603 - Fax: +1 617 632 2444 - E-mail: sharip@jimmy.harvard.edu
Data collection is currently underway for a research program to describe and track changes in the quality of life (QOL) of adults recovering from adult respiratory distress syndrome (ARDS). ARDS is a lung disorder characterized by severe lung failure requiring intensive care and ventilatory support. It is a relatively rare condition estimated to occur in approximately 5-8 persons per 100,000 population each year. ARDS is defined as moderate or severe lung injury or non-cardiogenic pulmonary edema, with appropriate antecedent history. Typically, ARDS is preceded by traumatic injury or sepsis. While ARDS may develop as a complication subsequent to surgery or in the presence of a major debilitating chronic illness, it can also occur subsequent to pneumonia or accidents such as near drowning or road traffic accidents. ARDS serves as a paradigm for intensive care since it may occur in the chronically ill or previously healthy, has an uncertain course, and requires extensive health care resources.

Until recently, the focus of ARDS outcome studies has been survival; the case-fatality rate frequently approaches 50% or higher. Other parameters most often monitored in recovery are lung function laboratory tests. While there is no denying the validity of the current American Lung Association slogan «when you can’t breath, nothing else matters», to paraphrase John Ware, «there’s more to life than breathing». The value of assessing health status and QOL after ARDS has only recently been noted in the literature12. Descriptive evaluations of QOL are important to prepare health care providers, patients and families for the challenges of recovery and life after ARDS. Clinical trials in ARDS using QOL outcomes are also important to ensure that innovative therapies aimed at improving the case-fatality rate do not do so at the cost of reducing the QOL of survivors.

As part of an NIH funded Specialized Center for Research in Acute Lung Injury (Grant P50HL150152, P Bitterman, PI) we have been studying the QOL of individuals with ARDS. Initial pilot study aims were to identify patient concerns and perceptions of problems subsequent to ARDS. Additional aims include identifying the clinical correlates and predictors of QOL outcomes.

The definition and model of QOL which have guided us in this work were drawn from several sources13. Our conceptual model of QOL follows a pathway from antecedent demographic and clinical factors through symptoms, mental and physical functioning to patient perceptions and ultimately to QOL defined as a valuing of one’s overall life satisfaction and well-being.

Two pilot studies have been completed. The first was a focus group and series of interviews with survivors of ARDS. Focus group participants had moderate or severe ARDS, diagnosed and treated 6 months to 3 years earlier. The focus group was conducted to identify the most salient symptoms and concerns of ARDS survivors. In response to the question «How is ARDS affecting you now?», participants reported depression, frustration, anger, fatigue, avoidance behaviours, flashbacks, concerns about memory problems and a lack of understanding about ARDS. In some ways, patient concerns paralleled those noted by individuals suffering from post traumatic stress syndrome, and in other ways they closely modelled those reported by persons with asthma. For example, several patients report avoiding activities such as fuelling the car or gardening. The stated rationale for these behaviours were to avoid the strong smells or moulds that could cause lung problems. However, comments also suggested the possibility that when situations trigger coughing or other lung symptoms these may also trigger flashbacks or disturbing memories about the ICU.

Issues raised by the focus group (memory problems, avoidance behaviours, flashbacks) were converted into questions and used to supplement disease-specific measures, such as shortness of breath and lung symptoms in a self-report QOL battery developed for a study of lung transplant patients2. The modular battery also contains a generic HRQOL profile, a depression scale, and indices of overall QOL. This battery was then pilot tested on a group of 24 ARDS survivors, some of whom participated in the focus group. Patient responses to the battery indicated that the items identified by the focus group were common complaints. Additional findings suggested that ARDS survivors have substantial limitations in their HRQOL across several domains, continuing through the first year after ARDS.

An additional outcome of this research was the recognition of the lack of educational material about ARDS written specifically for patients and families. The educational needs of this patient group is quite unique, given that they may experience partial or complete amnesia for prolonged periods of time during and subsequent to extubation and ICU care. Much of the conversation, teaching and information that they have received is forgotten and patients report a great frustration not understanding what they have experienced and what they may expect. Our team is developing a patient information brochure which can be referred to by patients and families during the ICU course and post ICU rehabilitation.

ARDS patients experience common symptoms such as fatigue or lack of stamina, and depression. They also report less common problems and symptoms such as hearing loss, change in the quality of their laughter, loss of ability to sing, while flashbacks and nightmares cause panic, anxiety and fear. The complexity of this disorder makes it difficult to determine whether or not it is ARDS or other factors such as ICU stress, drug side effects, brain damage, or the underlying risk factor that promoted ARDS that cause these problems. Current research by our group includes the prospective identification of ARDS patients, and follow-up with concurrent pulmonary function test results and QOL self reports.

For further information about the SCOR ARDS study, contact: Cynthia Gross at the College of Pharmacy, University of Minnesota, USA. FAX: 612 625 9931 or Email: gross002@maroon.tc.umn.edu.

1 - McHugh LG et al. Recovery of function in survivors of the acute respiratory distress syndrome. Am J Respir Crit Care Med 1996;150:50-54
Quality of Life after Intensive Care Treatment

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The Munich study group on quality of life after intensive care (ICU) treatment currently addresses different populations of long term survivors after intensive care treatment, e.g. patients after acute lung failure, survivors of septic shock and patients after coronary artery bypass grafting.

Although both entities are closely related, we believe that an exact definition of the patient group under study is very important when looking at health related quality of life (HRQOL) in long term survivors after intensive care. Functional outcome in different ICU populations (e.g. patients after multiple trauma or cancer) is very different and probably not comparable.

Acute lung failure is a common complication after severe trauma or generalized and severe infections. Lungs are essential organs and until lately, less than 40 % of patients with acute pulmonary failure survived despite often long-lasting and costly intensive care treatment based on the management of the underlying disease and artificial ventilation. Recent data, however, indicate that the survival rate of patients with acute lung failure can be increased by newer and highly sophisticated therapeutic approaches such as the continuous inhalation of pulmonary vasoactive drugs or even the use of extracorporeal lung support system. This technology is based on an artificial lung which ensures adequate gas exchange and oxygenation preserving the function of other essential organs while the patient’s lungs take time to heal. This type of treatment is extremely expensive and limited to 12 specialized centres in Europe, which achieve survival rates of up to 70 % in these critically ill patients.

Despite this impressive progress in medical management and the increasing allocation of health care resources to treatment of acute lung failure, surprisingly little is known about quality of life in long-term survivors of this devastating disease. The evaluation of new and expensive medical technology in intensive care must include measures of outcome other than pure survival. To achieve this, we are currently using the Medical Outcomes Study SF-36 questionnaire and contact all long term survivors of acute lung failure treated in our unit at 6 months after discharge from the ICU in a prospective design. After informed oral consent, they receive the SF-36 by mail. In a second study, we retraced and contacted 80 long-term survivors of acute pulmonary failure treated between 1985 and 1995 and compared the HRQOL of these patients to healthy controls of identical age and sex who completed the SF-36. The intensive care treatment in these patients lasted between 10 and 235 days, and 14 were treated with the extracorporeal lung support system for up to 29 days. All of these long-term survivors described themselves as ambulatory and independent. The majority of patients reported a high level of perceived quality of life on multiple health concepts of the SF-36 with relatively small differences when compared to the healthy controls. Patients after acute lung failure had a somewhat lower perception of their general health, were least satisfied with physical functioning, and showed a higher incidence of chronic pain. When compared to patients with more common diseases such as hypertension (medically controlled) or migraine whose HRQOL was evaluated using the SF-36, these long-term survivors of pulmonary failure showed a comparable quality of life, with the exception of higher pain scores in patients with migraine. This is corroborated by the fact that most patients after an episode of severe pulmonary failure returned to their previous lifestyles and employment. Forty-nine of our patients classified themselves as being in full- or part-time employment (61.3 %), and only 15 (18.8 %) as disabled. When retired patients were excluded, 52 of 75 long-term survivors (69.3 %) had paid employment or were homemakers and the majority worked in the same profession they held before intensive care treatment. The vast majority of patients were highly satisfied with the nursing and medical care they received during their severe illness.

Medical investigations assessing quality of life outcomes after intensive care are increasingly important and this study demonstrates that even desperately ill patients with acute failure of vital organs are able to recover almost completely and to achieve good physical and social functioning including a high rate of employment. Although a true cost-benefit analysis in patients after intensive care treatment is difficult to perform, this study suggests that expensive high technology interventions in patients with acute lung failure could, in addition to pure ethical benefits, even be cost effective.

Other studies are currently addressing the effects of traumatic experiences of patients undergoing ICU treatment (e.g. anxiety, respiratory distress, nightmares or pain) on HRQOL in long term survivors. Preliminary results suggest a definite influence of these adverse experiences on psychosocial components of HRQOL and the SF-36 seems to be sufficiently sensitive to detect such effects. This indicates that optimal management of analgesia and sedation of patients undergoing ICU treatment could improve HRQOL outcome.

For further information, please contact: Christian H Stoll, MD or Gustav Schelling, MD, Institute of Anesthesiology, Ludwig-Maximilians-University, Marchioninistr. 15, Munich 81377, Germany. Tel: +49 89 70 95 -1 (Beeper 07/160) - Fax: +49 89 70 95 -28 22 - E-mail: u711Lam@ana.med.uni-muenchen.de
WORK IN PROGRESS

U.K.

Evaluation of Specialist Outreach Clinics in Primary Care in England.
Alison Aber, Matthew Bond, Ann Bowling, Marie McCay, Gerard Pope.
Centre for Health Informatics and Multiprofessional Education, Health Services Research Team, University College London Medical School, London, UK.

Summary
A two year evaluative study of specialist outreach clinics in primary care in England is currently being undertaken by a research team at CHIME headed by Professor Ann Bowling. The study aims to gather and analyse information on the process costs of the outreach service as well as the satisfaction with, and effectiveness of, the service for purchasers, providers and recipients. Amongst the data collected is quality of life data. This relates to the health status of participants specific to the condition for which they are seeing the specialist.

Background
The current changes in the structure of the NHS have seen a shift in the locus of care towards the primary healthcare system. Within this framework we are seeing the proliferation of specialist outreach clinics, hospital based consultant clinics in non-hospital settings, across England. In 1994 ninety-six such clinics were identified from a survey of fifty provider units. Thus far there has been little systematic research of these services, evaluating it in terms of cost-effectiveness in comparison with equivalent hospital out-patient services. The CHIME team are currently evaluating outreach services in centres across England following six month pilot studies from this team and a team at the University of Manchester.

Support and Funding
The study is funded by the Department of Health and NHS Executive. Ethical approval of the study has come from the Royal College of General Practitioners and Local Research Ethics Committees in all study areas.

Hypotheses
Specialist outreach clinics in primary care will:
1. Improve access to specialist care and reduce waiting times for appointments. This in turn will improve both short term outcomes and satisfaction for patients.
2. Improve continuity of specialist care for the individual. Specialist consultation will improve case awareness and develop a rapport with patients.
3. Improve communication between the specialist and GPs. This will offer educational and skill development opportunities for practitioners and the potential for shared care. This in turn may enhance professional satisfaction.
4. Decrease GP referrals to outpatient care enabling the out-patient service to become more responsive to urgent referrals. This has implications on workload for both GPs and specialists.
5. Decrease the cost to patients both financially and in terms of time.
6. Optimise resources for both the GP Fundholders and NHS Trusts in terms of cost of care and use of time.

Aims
The study aims to: evaluate the costs, processes and effectiveness of specialist outreach clinics in primary care in comparison with out-patient controls; determine the appropriate indications for referral to outreach clinics, identify the different models of provision of outreach clinics and identify successful and cost effective practice as well as the provision of quality care.

Methods
The study pairs each specialist's outreach and outpatient clinics with a target sample size of sixty participating patients per site. Patients who consent to participate initially complete a two part questionnaire and return it by FREEPPOST. This should yield a study sample size of two thousand participants. Patients returning completed questionnaires are then followed up after six months to evaluate any changes in treatment, care and service satisfaction. Clinical sheets completed after the specialist consultation offer data on costs, condition, severity and expected outcome.

(continued on p 8)
Data is also being collected on GPs and specialists' attitudes and experiences of the outreach service. The practice managers and Hospital Trusts assist in the comparative cost analysis with outpatient services by providing details on running costs.

### Measures used in the questionnaires

The patient questionnaires collect data on the satisfaction with, and experience of, the clinics attended as well as the costs to the patients in terms of time and travel. Data is also collected on the patients health and well-being as well as their expectations of treatment outcome. Several measures are utilised in the structure of the questionnaire to elicit information on satisfaction and quality of life. The main measures are as follows.

- Ware's Consumer Satisfaction Questionnaire (visit specific)
- Rand Medical Outcomes Study batteries on disease impact
- Health Status Questionnaire 12 (HSQ12) - shortened SF36
- Adaptation of Duke Severity Scale
- Questions on attitudes and processes were developed from existing items and collaboration with Professor Wilkin and Mary Black at University of Manchester
- Questions on cost were developed by cooperation with Universities of Manchester and York (T. Gosden and B. Leese) and Queen Mary and Westfield College, University of London (I. Jones).

### Data collected

Data collected falls into four categories; costs, process, satisfaction and outcome. The cost data relates to running costs, treatment costs and costs to the patient. Process data includes treatment and referral patterns, waiting times and the quality of the relationship between the specialist and the patient. The satisfaction data collected refers to patient and doctor satisfaction and attitudes to the outreach/outpatient service. Outcome measures relate to health status at baseline and followup and the patterns of discharge, follow-up and referrals for surgery.

### Results

The study is due for completion in November 1997. Preliminary papers on the pilot study are due for journal publication in the near future.

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**Quality Assurance in Health Care**

Quality assurance in health care is one of the main research topics of the Department of General Practice and Primary Health Care of the University of Ghent, Belgium.

A health interview survey was conducted in 1995. A sample of 4800 persons was selected in two regions in Belgium, one in the North (Aalst) and one in the South (Luik). The sample was stratified with respect to age, sex, health insurance agency and region. A general, non-institutionalized, population of 45 and older was envisaged.

Functional status indicators (SF-36 and WONCA-COOP charts) were used to evaluate quality of life. Chronic illnesses were elicited in an open question and in a closed question by means of a list of chronic diseases. A list of complaints to evaluate psycho-social and somatic problems was also available.

Utilization of care of the 4800 people in the survey was evaluated by means of registration data from 1994 and 1995, produced by the two largest health insurance agencies in Belgium.

The main objective is to analyse the relation between continuity of care in general practice and the level of utilization of health care controlled for functional status.

Results will be available in December 1996.

This research is made possible by means of a grant from the National Health Insurance Institute.

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**Health Services Research Unit (University of Oxford)**

The Health Services Research Unit supports a wide variety of projects concerned with the measurement of health status and quality of life. Current projects include: the evaluation of the SF-36 in a variety of patient groups; the development of the UK summary scores from the SF-36; the development and testing of the SF-12; the development and validation of Parkinson's specific health status measures; the evaluation of laparoscopic versus open surgery for hernia repair in a randomised trial; the evaluation of laser prostatectomy versus TURP for BPH; outcomes assessment in plastic surgery; comparison of a variety of health status measures (e.g. SF-36, Functional Limitations Profile, EuroQol EQ-5D, COOP Charts etc) in a variety of chronic illnesses (e.g. sleep apnoea, rheumatoid arthritis, congestive heart failure).

The unit supports a WWW site containing information on these and other projects, http://hsru.dphpc.ox.ac.uk/

A UK SF-36 Manual and interpretation guide is available from the Unit. Order forms are available from the Administrator.

Tel: +44 1865 224141
Fax: +44 1865 228418.

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The Seattle Angina Questionnaire (SAQ) is a 19 item instrument developed to quantify 5 clinically relevant domains of coronary artery disease. Nine items define the limitations in patients’ physical capacity due to symptoms of angina pectoris. Two items assess the frequency of anginal symptoms and an additional item defines whether a change in the precipitants of symptoms and an additional item defines the limitations in patients’ physical capacity due to symptoms of angina pectoris. Two items describe patients’ satisfaction with the treatment of their coronary artery disease and 3 items explore how much patients’ coronary artery disease has impacted their quality of life.

Each of the 5 scales of the SAQ has been individually validated. Furthermore the reliability and responsiveness of each scale has also been independently determined. As others have postulated the responsiveness of this disease-specific questionnaire is greater (i.e. more sensitive to change) than the generic SF-36, which also captures limitations due to other comorbid conditions. Because of its rigorous development and evaluation, the SAQ has recently been endorsed by the Medical Outcomes Trust as a worthy disease-specific functional status measure for ongoing and future applications.

### Applications of the Seattle Angina Questionnaire

Serving as an outcome measure for clinical trials, as a measure of quality of care and as an aid in patient management are examples of the possible applications for functional status assessment. In view of its validity, reliability and responsiveness, the SAQ has been selected to serve each of these roles in ongoing research investigations.

### An Outcome Measure in Clinical Trials

Because it provides a clinically meaningful description of patients’ functioning in several domains and because it affords an endpoint on each participant in the trial, the SAQ has been chosen as an outcome measure in several ongoing clinical investigations. The Quality of Life in Angina Research Trial is a randomized study of once-daily vs. multi-dosing anti-anginal medications that has successfully employed serial administration of the SAQ to define the quality of life differences between these 2 strategies for treating patients with chronic stable angina. Similarly, the OPUS trial is comparing optimal angioplasty with intracoronary stenting to define the quality of life differences between these 2 strategies of percutaneous coronary revascularization.

### A Measure of Quality Care for Quality Improvement Projects

As health care resources in the United States have tightened, increasing pressure is applied to the suppliers of health care services to maximise the quality and efficiency of the care that they provide. Several projects have used functional assessment tools to quantify the status of the patients served and to monitor improvements in patients’ health status associated with innovations in health care delivery.

One application of this approach is the CABG Outcomes Assessment Team, a physician-led effort to gain improved insight into the functional status outcomes of coronary bypass surgery. In a pilot project, almost all cardiothoracic surgery groups (n=12) in the state of Washington have prospectively enrolled up to 130 patients each into a study that will quantify the outcomes of each group in the state. This information will then be presented blindly to the entire surgical community and allow a process of reflection and discussion to better define how to select and manage patients with advanced coronary artery disease.

Another such project involves a ‘natural history’ experiment in a Veterans Affairs general internal medicine clinic. In this project a sample of 100 patients with stable coronary artery disease were
Quality of Life and Pharmacoeconomics in Clinical Trials

At the start of this review I would like to share with you my multiple biases; I do this tongue-in-cheek. First of all, I have had the pleasure of knowing Bert Spilker personally for many years, having worked professionally with him at the then Burroughs Wellcome Co. in Research Triangle Park, North Carolina, USA. Second, I consulted with Bert in his plans to revise, expand and update this book. And finally, were the previous two admissions not sufficient to disqualify me from an objective review of this Second Edition, I co-authored two of its chapters!

Having noted these biases I can honestly declare that I am impressed with the outcome of Spilker's editorial (and writing) acumen. Those of you familiar with the first Edition of this book, published in 1990, will observe that Spilker has included a number of news sections in this volume, including those on health policy, cross-cultural issues and pharmacoeconomics, among others. These timely additions to a volume that was already chockablock with vital and relevant - if at times redundant - information will likely assure the work's place as the bench book of choice for researchers involved in outcomes research in general and quality of life assessment in particular.

Without going into a chapter by chapter analysis, the value of the book is found in its breadth, depth and ease of access to cross-disciplinary issues. With respect to the work's breadth, the 127 chapters - authored by a virtual who's who of researchers from the social, medical and health care science disciplines - are organized into 11 sections. The titles of these sections are as follows: (1) Introduction to the Field of Quality of Life Trials; (2) Standard Scales, Tests, and Approaches to Quality of Life Assessments; (3) Specific Scales, Tests, and Measures; (4) Choosing and Administering Tests and Treatments; (5) Analyzing, Interpreting, and Presenting Data; (6) Special Perspectives on Quality of Life Issues; (7) Cross-Cultural and Cross-National Issues; (8) Health Policy Issues; (9) Special Populations to Assess Quality of Life; (10) Specific Problems and Diseases; and (11) Pharmacoconomics.

An arbitrary selection of chapter topics reveals a range from the basic how to (for example, How to Develop and Validate a HRQL Instrument, by Guyatt et al.); to a discussion of underlying philosophy (for example, Ethical and Medical Basis of Health Care Rationing, by Bjork); to special considerations (for example, Anthropological Perspectives: The Importance of Culture in the Assessment of HRQL, by Guarnaccia); to the future (for example, The Future of Pharmacoconomics, by Drummond). A range of descriptive and patient preference HRQL scales, tests and measures are reviewed (section III), as are specific populations and diseases in which assessments are often times undertaken (sections IX and X, respectively). Instruments include the very well-known - the SF-36 Health Survey and the Nottingham Health Profile, for example - and the less well-known - the Derogatis Affects Balance Scale, for example.

The depth of the book is found in the intensity of cutting-edge topics authored by a wide range of contributors; these contributors include academic, industry and government scientists, health services researchers, physicians, nurses, pharmacists, statisticians and others. (It is difficult to fathom the personal energy Spilker must have expended to corral these 202 individuals into agreeing to write these chapters, let alone getting them to adhere to the book's publishing deadline). Examples of up-to-date - if at times esoteric - topics are especially prevalent in the sections on health policy and pharmacoconomics. In the health policy section (section VIII), the thought processes and rigor by which scientists evaluate new health care technologies are discussed by Eddy in Rules for Evaluating Medical Technologies; while Patrick and Erickson review how various types of health outcomes data and methodologies can be employed to inform decision makers achieve a more objective allocation of health care resources in a chapter entitled the Applications of Health Status Assessment to Health Policy.

All of the chapters contained within the pharmacoconomics section (section XI) are enlightening. However, as an industry outcomes research scientist, I found especially useful Problems in Undertaking Pharmacoeconomic Assessments in Phase III Clinical Trials, by Drummond et al; and Threats to the Validity of Pharmacoeconomic Analyses Based on Clinical Trial Data, by Rittenhouse and O'Brien. These three economists are among the top in the economics field, and one can see why upon reading these chapters. One would more likely expect to find this type of information within a professional journal; the fact that it is found within Spilker's compendium is a testament to the editor's desire to publish a genuine state-of-the-art textbook. In this he unquestionably succeeded.

The final point I wish to make regarding this work was made by Ann Cull in her review of Spilker's First Edition (Cull, A Quality of Life Research 1993; 2(1): 85-86); to wit, continued progress in methodologic issues within the HRQL field is dependent upon «cross-fertilisation (sic) of ideas across specialities». Most will agree that specialties relevant to HRQL measurement include, at a minimum, the social sciences - psychology, economics and anthropology, in particular; the mathematical sciences - measurement theory and statistics; and the health care sciences - public health, medicine and nursing. Within the Second Edition the ease of access to cross-disciplinary issues and respective fields - regardless of one's personal training or interest - is perhaps the most attractive feature of Spilker's effort.

In conclusion, this book will be of interest - it may even be essential - to a wide variety of outcomes researchers regardless of whether their affiliation is within academia, industry or government. With the able assistance of over 200 experts, Spilker has produced a valuable resource on the state-of-the-art of quality of life and pharmacoeconomic assessment within, and in many cases external to, the context of clinical trials.

Dr Rick Berzon, Health Economics, Bayer Pharmaceuticals, West Haven, Connecticut, USA.
Schizophrenia is a serious mental illness which, in Canada, affects 1 person in 100. In the last 15 years, there has been a growing field of Canadian research on the quality of life of individuals with severe mental illness such as schizophrenia. Multidimensional and psychometrically sound tools to assess quality of life of this population are urgently needed for use: 1) in the community-based programs which are being implemented to assist those suffering from this disease; 2) in clinical trials of new drugs; 3) in clinical research on innovative and standard treatments; 4) in clinical interventions to assess clients’ needs and guide clinical treatment decisions. This multi-centered study will evaluate Canadian editions (French and English) of the recently developed Wisconsin Quality of Life Questionnaires (client, care givers, family) to assess its suitability for clinical practice and research in Canada. The original edition of these Quality of Life Questionnaires was developed at the University of Wisconsin by Marion Becker and her team. The English language edition has been modified for Canada’s health care and social services environment, and a French language edition has been developed concurrently by the principal investigators of this proposal*. A supplementary questionnaire has also been developed for Canada by Deborah Tamlyn to assess the practical usefulness of the questionnaires from the perspective of doctors and other care givers who would be its potential users in health care settings.

**Objectives:**

The objectives of the proposed study are to evaluate the validity and reliability of the Canadian editions of the Wisconsin Quality of Life Questionnaires in samples of people with schizophrenia from both major urban centres and other areas of Nova Scotia, Prince Edward Island and Quebec; to obtain norms for use in the three provinces by utilizing random samples from the general populations, both urban and non-urban; and to evaluate clinicians’ perceptions of the usefulness of the instrument in assessing patients’ needs and in guiding clinical treatment decisions. An additional inherent objective is to assess the semantic and conceptual equivalencies of the French and English versions developed for use in Canada.

(continued on p 12)

**Instruments**

The Seattle Angina Questionnaire

(continued from p 9)

Finally, Mapi Research Institute has recently undertaken to adapt the SAQ into 12 different languages and cultures. This will enable broader international use of a validated, reliable and responsive instrument for defining the functional status and quality of life of patients with coronary artery disease.

For further information, please contact: John Spertus, University of Missouri Medical School, 2301 Holmes Street, Kansas City, Missouri, USA.
Tel: +1 816 556 3000 - E-mail: jspertus@ctcr.umkc.edu.


**An Aid in Patient Management**

Since self-administered questionnaires can accurately describe important clinical information, they can be scored and tracked over time to plot the course of a patients’ condition. In coronary artery disease, the progression of symptoms can often be insidious since patients modify their activities to minimize the frequency and severity of their symptoms. In general internal medicine clinics, when physicians need to attend to a wide variety of comorbid conditions, both the doctor and the patient may fail to recognize that the symptoms of coronary artery disease have worsened. A description of the clinical status of patients’ coronary artery disease, as provided by the SAQ, may prove to be a valuable aid to generalist physicians who manage patients with coronary disease. An 8 center Veterans Affairs trial has recently begun to test this hypothesis in 16 general internal medicine units.

**Future Directions**

Currently, several additional projects will permit further evolution of the SAQ. Recently, funding has been obtained to convert the SAQ into a health state utility. If successful, this project will define which self-administered instruments are needed to define patients’ health state utilities. Furthermore, if the SAQ can be transformed into a health state utility, then decision analyses and economic analyses will be able to be efficiently performed in studies that use the SAQ as an outcome measure.
Compendium of Quality of Life Instruments Working Group

The Medicines Research Unit at the University of Wales, Cardiff in collaboration with the Centre for Medicines Research, is currently involved in a project to compile a comprehensive Compendium of Quality of Life Instruments. The aim is to provide a sourcebook of original questionnaires and related information for those working and/or interested in the field of health-related quality of life. This will be an ongoing project and the Compendium will be updated at regular intervals.

At present the Working Group is contacting all authors of instruments inviting them to submit copies of their questionnaire, data on the instrument and a short bibliography of related articles. The compendium will be of tremendous use to anybody interested in this field or involved in clinical evaluation of medical treatments (e.g. comparing treatment modalities or treatment regimes; monitoring therapeutic outcomes; assessing quality of life in disease management). Information on the original instrument and its cross-cultural adaptations will be featured.

The fact that there are such a large number of measures available shows that there is no single instrument that would satisfy all users and be appropriate for all purposes. The purpose of this Compendium is to present as many instruments as possible to facilitate the selection of an instrument likely to be suitable or requiring adaptation to specific clinical work or, when the work in question requires a new approach, facilitate the examination of existing knowledge and experience.

A patient's quality of life is an important outcome variable of any medical intervention. Assessment of quality of life can only become more important in the future and its potential uses are likely to expand as more research leads to a better understanding of the values such measurement can bring.

We hope to publish the first edition of the Compendium in Autumn 1997. If you have not been contacted concerning your instrument please write to us at the following address:

Dr Sam Salek, Medicines Research Unit, Redwood Building, King Edward VII Avenue, Cardiff, CF1 3XF, UK. Tel: +44 1 222 874783 - Fax: + 44 1 222 874535 - Email: SalekSS@Cardiff.ac.uk

Research plan

This study will focus on six groups of individuals receiving psychiatric services following a diagnosis of severe mental illness (schizophrenia): 1) 80 persons living in the community and receiving outpatient services in English in Halifax, Nova Scotia; 2) 80 persons living in the community and receiving outpatient services in English in other area(s) of Nova Scotia; 3) 30 persons living in the community receiving services in Charlottetown, Prince Edward Island; 4) 30 persons living in the community receiving services in other area(s) of Prince Edward Island; 5) 80 persons receiving outpatient services in French in Montreal, Quebec; and 6) 80 persons receiving outpatient services in French in other area(s) in Quebec. For each client, a care giver and a family member (if available, and with client's consent) will be recruited.

The first phase of the study will evaluate the validity and the reliability (internal consistency and inter-rater) of the Wisconsin Quality of Life Questionnaire with the six patient groups in the three provinces, members of the clients' families, and care givers who have been actively involved in care of the patients. Semantic and conceptual equivalencies of the French version will also be assessed.

The second phase will evaluate the test-retest reliability of the form for patients through retesting of two randomized sub-samples of 40 patients/clients each, one English-speaking, one French-speaking, within a two-week period.

If phases one and two indicate the presence of acceptable psychometric properties, the third phase will be to use the client questionnaire with random samples of the control populations of the three provinces aged 18-65 years, (Nova Scotia n=160; Quebec n=160; PEI N=60). This will be done on a single occasion to provide benchmark data.

The concluding phase will assess the usefulness of the Wisconsin QOL instruments from the perspective of care givers involved in phase one of the research. Participating care givers from Nova Scotia, Prince Edward Island and Quebec will be surveyed by interviewers working under the direction of the research team.

Once this has been completed, subsequent studies will assess responsiveness to change, by using the Wisconsin Quality of Life Questionnaires in quasi-experimental studies.

*Principal Investigators

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Nova Scotia Team Pablo Diaz, MD, FRCP Lise Manchester, PhD Michael Ross, PhD Deborah Tamlyn, PhD P.E.I. Team Joann Waish, MS, RN Quebec Team Céline Mercier, PhD Raymondne Hackey, MA Raymond Tempplier, PhD


Despite the rapid growth of interest in measuring quality of life (QOL) in oncology clinical trials, there has been almost no formal integration of QOL assessment in oncology clinical practice. Reasons for this are many, including lack of appreciation of the value of such an activity, and lack of an available technology to facilitate data collection and case review. Now, with the advent of the Benefact, a new international QOL assessment program, clinicians around the world can submit QOL assessment records of a consecutive sample of 100 patients from their outpatient practice. In turn, they will receive summary printouts of QOL reported by their patients, including how their patients compare to other patients in their country, and to an international sample. This will in essence provide enabling them to evaluate how their patients compare to those around their country, and across the world.

Benefact is the name given to this worldwide QOL database. It is a multinational project sponsored by Glaxo Wellcome Pharmaceuticals. The Benefact program features the Functional Assessment of Cancer Therapy (FACT) Measurement System, specifically the general (FACT-G) instrument. The FACT-G has been translated and validated in 9 languages, making it immediately available for use into Benefact application in 22 of the 38 countries that have expressed an interest. A list of currently participating and pending countries is provided in Table 1. Continuing translation and validation work will see the availability increase throughout the coming months, until all interested countries are equipped with properly translated and pretested questionnaires.

Benefact is an innovative project designed to help physicians improve patient care. The utility of such a database lies primarily in its ability to aid physicians who treat cancer patients in identifying areas in which their patients QOL could be improved (i.e. through more psychosocial interventions or better pain and symptom management), thereby affording opportunities to enhance the quality of their care. Pre-testing of the concept in six countries (England, France, Germany, Italy, Spain, and the United States) yielded important information regarding physicians’ interest in and support of the creation of an international QOL database. Nearly 80% responded favourably to the concept, citing the need to better equip themselves to assess, monitor and improve the QOL of their patients as pivotal to the advancement of cancer care. Current obstacles included physicians feeling under-qualified and ill-equipped to adequately evaluate and track quality of life status.

Encouraging results from the pre-testing have helped substantiate the need and value of increasing QOL awareness in oncology clinical practices, prompting Glaxo Wellcome to initiate and underwrite the creation of this world-wide database. Overall, the database will serve to consolidate QOL data and generate meaningful feedback gathered from multiple institutions in over 30 countries. Participating physicians will recruit and complete essential sociodemographic and treatment information on 100 cancer patients (post-diagnosis), each of whom will be asked to complete a QOL questionnaire. All patient data is confidentially submitted to an independent data management team which will enter and summarize the information.

The FACT-G was selected for use in this project because it is a well-validated, easy to administer, multilingual questionnaire which allows the calculation of both domain-specific (physical well-being, social/family well-being, emotional well-being, functional well-being, and relationship with the doctor) and global QOL scores. Calculated subscale and global scores generated from Benefact will enable physicians to quantify psychosocial, physical, functional, and treatment satisfaction aspects of their patients easily and quickly. They will also allow for comparison with sociodemographic and treatment variables, allowing physicians to explore meaningful relationships.

Standard Benefact reports will consist of the raw data, descriptive statistics, summary reports, and graphic representations of patient responses as compared with national and international norms for each of the five QOL domains and the total score. Physicians will have access to four customized reports to begin as soon as 20 patients have been accrued. Comparative reports, contingent on already defined standards for sufficient national and international accrual, will be generated periodically. The confidential nature of this project assures that the funding company will not have access to individual patient responses or individual physician reports.

Table 1: Glaxo Wellcome Benefact Database Participants (9/96)

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* Mainland China will use the simplified character Chinese, Hongkong and Singapore will use the traditional character Chinese.

Level 1: Countries for which a conceptually and semantically equivalent pretested questionnaire exists. These countries can move directly to introduce their national program.

Level 2: Translation methodology is underway to develop valid pretested translations of the questionnaire.

Level 3: Some preliminary work has been done to translate questionnaire. More effort will occur in the coming months.
The potential for this project is enormous. Short term benefits include potential physician-patient rapport building throughout the duration of the project by highlighting concerns that may otherwise receive inadequate attention. It is proposed that doctors offer to discuss the completed questionnaire with the patient, viewing it as a basis for interventions. Participating patients may benefit by having the chance to assess their current QOL in a comprehensive yet simple way, and appreciate the opportunity to discuss specific physical, social or emotional concerns with their doctor.

Longer term benefits include the fostering of QOL awareness and the promotion of a more comprehensive conceptual understanding amongst clinicians. Not only will physicians be able to better communicate with their cohorts regarding quality of life concepts, but they will be better prepared to assess and address quality of life issues with their patients. The feedback provided from the database may furnish physicians with a host of relevant information about their patients and the quality of their care. Interpretation can provide an objective means of distinguishing specific areas within clinical practices that could be improved (i.e. pharmacological or psychosocial interventions, pain and symptom management, the addition of alternative therapies). Furthermore, it is hoped that participating physicians will be motivated by using the Benefact assessment and will ultimately incorporate QOL evaluation routinely into their clinical practice. The knowledge to be gained throughout this effort to quantify and compare QOL data on a truly international basis will likely benefit the QOL international field in general.

In conclusion, the Glaxo Wellcome sponsored Benefact database is a large, international descriptive QOL database. It features QOL assessment using the Functional Assessment of Cancer Therapy-General (FACT-G), and will allow physicians who treat cancer patients around the world the opportunity to compare patients in their clinical practice to other patients in their country and around the world. It will allow physicians to look specifically at their own patient QOL records to determine problem areas that might require intervention. Usage of this database may reflect the current acceptability, and feasibility of using QOL data to influence clinical practice, an important new direction in the expanding field of health-related quality of life research.
An increasing use of Quality of Life (QOL) assessment in oncological research has been observed in the last years. This has led to a proliferation of QOL instruments, self-administered, multidimensional questionnaires, with the aim of assessing all the domains of the QOL potentially impacted by disease and therapies.

Despite the subjective nature of QOL perception, it has become generally recognised and accepted, although less attention has been paid to the process of selecting domains and sub-domains to be explored with questionnaires. The approach used for defining the conceptual framework for QOL and selecting domains and sub-domains is often made by a panel of experts. As an example, a consensus group of 39 experts, set up by the Italian Society of Psycho-Oncology, identified 12 sub-domains from 4 well known QOL domains.

It is not known whether the domains identified are relevant for patients. Moreover questionnaires developed in «foreign» countries may not be culturally sound or relevant for patients living in different cultural backgrounds. The cultural adaptation of some questionnaires requires the attribution of different weights to the questions. In order to explore what really contributes to the quality of life of Italian patients, a survey was conducted with the aim of identifying any dimension of QOL that is positively or negatively affected by the illness and its treatments.

Materials and methods

Two hundred and eighty cancer patients with specified characteristics were previously identified. The inclusion characteristics were: place of residence (north, centre and south of Italy), primary tumour (breast, lung, digestive organs, genital organs, urinary system, head and neck tumours, and others) and stage of disease (follow-up with no evidence of disease vs patients undergoing therapy).

Patients were asked to complete an «open-ended» questionnaire in which some of the questions were derived from a study by Padilla et al. The questions were:

- What does the term quality of life mean to you?
- In your opinion what contributes to a good quality of life?
- In your opinion what contributes to a poor or bad quality of life?
- Which physical or psychological symptoms interfere with your QOL?
- Please state any positive or negative change in your life, due to illness or treatments.

Data analysis

- The 248 questionnaires were transcribed and subsequently broken down in phrases on a form that allowed coding. A phrase was defined as a group of two or more grammatically related words that represented a concept.
- Three raters (a research nurse, a specialist in oncology and a clinical psychologist), performed a content analysis of the transcript, using as conceptual framework the list of domains and sub-domains identified by the Italian Society of Psycho-Oncology. Any concept not represented in the original classification was added to the list. In order to derive new items and subcategories, a sample of 30 questionnaires was jointly coded by the 3 coders. A list of 94 items was thus identified.
- Fifty questionnaires were independently coded by each rater and each item attributed to one of the 94 categories previously identified. If a unit of analysis represented more than one concept, it was split into two or more sentences; if more units of analysis represented the same concept, they were considered as a single unit of analysis. Attention was paid to avoid interpretation: the interscanner agreement was evaluated and any disagreement was discussed and the definition of different domains and sub-domains thus refined. The procedure was repeated on different sets of 10 questionnaires, until an acceptable agreement between raters was obtained.

Seventy-five questionnaires were coded by the 3 raters and finally, on the last set of 6 questionnaires, an absolute agreement on 58.1% of the items identified and on 67.3% of domains. The true misclassification was
after five years of industry-sponsored research and development, we are pleased to announce the upcoming publication of the Child Health Questionnaire (CHQ) and Manual.

The CHQ yields a profile of 14 health concepts and two summary measures of physical and psychosocial functioning and well-being for children five years of age and older. Both positive and negative health states and a wide range of objective and subjective ratings are represented. The 50-item parent completed version (CHQ-PF50) has been normed in a representative sample of US children, tested in several condition groups, clinical trials, and population-based monitoring efforts, and translated/adapted into 10 languages. A 28-item version of the parent form (CHQ-PF28) has also been normed and tested for large-population based studies.

The analogous child completed version of the CHQ consists of 87 items, is designed for self-completion by children of at least 10 years of age, and has been tested in three condition groups, a school-based population and is currently being fielded in an NIH-sponsored trial. Royalty-free permission to use and reproduce the CHQ is routinely granted to individuals and organizations upon completion of a user’s agreement.

The manual is a user-friendly guide to the administration and scoring of the CHQ-P50, CHQ-PF28 and CHQ-CF87 Health Profiles. In addition, preliminary scoring documentation for physical and psychosocial summary indices are provided for the two parent forms. The manual has clear instructions and several features that facilitate use, including: well-labelled tabs, an index, a list of tables and graphs, and a glossary. The manual also provides:

- Results from tests of scaling and scoring assumptions and reliability estimates from 14 studies
- Results from tests of empirical validity
- Norms for a representative sample of US children and by child and parent characteristics.
- Benchmark data for chronic condition groups
- Processing options for CHQ forms
- Scoring diskette and test dataset using SPSS and SAS statistical software programs.

About the Manual

The Child Health Questionnaire (CHQ): A User’s Manual
Jeanne M. Landgraf, Linda Abetz, and John E. Ware, Jr.
The Health Institute, New England Medical Center, Boston, USA

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* Appendices: Copies of CHQ forms including scannable versions and interviewer scripts and SPSS and SAS statistical software scoring programs
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Work in Progress

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limited to 7 items (7.1%). A pair agreement was reached in all the other cases: the third coder rated some of the items coded by the other two as ‘Not Classified’.

- When the entire data were coded, the original categories were reviewed and categories overlapping were joined together. The final result was a list of 43 categories and a disease specific symptoms checklist.

**Conclusion**

The present study shows the possibility of defining the content domain of quality of life attributes for cancer patients, using patients as experts. This approach allows the determination of the content representation of the domains identified. A content relevance evaluation of each category has to be performed in a larger sample of cancer patients.

5. - The European Group for Quality of Life and Health Measurement. European Guide for the Nottingham Health Profile. 1989

For further information, please contact: E. Mencaglia, Division of Psychology, National Cancer Institute, Via Venezian, 1, 20133 Milano, Italy. Tel: +39 2 239 0554 - Fax: +39 2 239 0761.
Introduction

A number of clinical and biological variables exist for the assessment of HIV patients including survival, disease free interval, CDC staging, CD4 count, and viral load.

Nowadays, in the developed countries, these variables are simple to use in the evaluation of the efficacy of therapies. The preliminary studies using health related quality of life measures to assess antiretroviral drugs efficacy seem to be replaced by a regular utilization of clinical and biological measures. However, the assessment of a patient’s health related quality of life remains an important issue: the clinical and biological variables do not represent a patient’s point of view, and are not useful for evaluating the increased efforts in social, psychological, support and alternative to hospitalization (home care, hospital day care).

These efforts represent a significant amount of money and volunteer work, and it is important to assess its efficacy in terms of improvement in patients’ quality of life.

As a result, we decided to conduct a study with two main objectives:
- To assess the health related quality of life (HRQOL) in HIV patients using a self-administered short form questionnaire.
- To test its acceptability and its sensitivity to patients’ condition by evaluating the changes in the health status during a one year period.

Study Design

We used a questionnaire translated into French by INSERM, based on the RAND SF-36 together with the HIV specific items of the HIV-MOS SF-30. These two questionnaires had each shown various psychometric properties in previous studies among AIDS Patients. The HIV MOS SF-30 is now based on the MOS SF-20, which is replaced by the MOS SF-36 in most studies, while the MOS SF-36 does not have any HIV specific scales.

Each patient receiving ambulatory care is asked to complete a form at the beginning of the study (first point) and then every 3 months for the ARC and AIDS patients, or every 6 months. Clinical and biological data are provided by the patient’s physician at each time point. The data are collected anonymously, and participation is not compulsory.

Data analyses are performed using both EPIINFO and SAS software. Since the study is still ongoing, we can only present the preliminary results here.

Preliminary Results

Acceptability:
A total of 133 patients have been asked to participate: there were 2 immediate refusals and 108 completed the questionnaire (82.4%). 68 patients have reached the sixth month evaluation and 56 completed the questionnaire (82.4%).

Response rates and scores:
At the first time point, response rates vary from 87.0% to 98.1%. The scores scales are shown in Table 1.

Changes in clinical and biological variables:
We have only conducted the analysis at the first time point. The main changes are linked to the occurrence of disease related to stage IV, both ARC and AIDS (see graph I). There are few changes in CD4 count and these are not directly correlated to the real number of CD4 cells (see graph II).

After 6 months we compared the intra-patient changes by computing each patients’ difference using paired t tests. The only significant changes are increasing scores in physical and cognitive functioning (see table II).

Conclusion

The assessment of the psychometric properties (notably reliability, internal consistency) will be performed at the end of the data collection, and a test-retest is planned on a random sample of patients at the end of the study.

Table 1: Response rate and mean score at the first point

<table>
<thead>
<tr>
<th>Scale</th>
<th>Response rate</th>
<th>Mean score</th>
<th>Std Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>92.6%</td>
<td>81.1</td>
<td>23.6</td>
</tr>
<tr>
<td>Physical health</td>
<td>94.4%</td>
<td>60.7</td>
<td>42.0</td>
</tr>
<tr>
<td>Mental health</td>
<td>96.1%</td>
<td>64.4</td>
<td>44.2</td>
</tr>
<tr>
<td>Pain</td>
<td>90.5%</td>
<td>72.1</td>
<td>27.2</td>
</tr>
<tr>
<td>Emotional well-being</td>
<td>97.0%</td>
<td>50.1</td>
<td>21.2</td>
</tr>
<tr>
<td>Energy</td>
<td>97.2%</td>
<td>49.1</td>
<td>21.3</td>
</tr>
<tr>
<td>General health perceptions</td>
<td>94.4%</td>
<td>47.6</td>
<td>23.6</td>
</tr>
<tr>
<td>Social well-being</td>
<td>97.2%</td>
<td>64.8</td>
<td>26.8</td>
</tr>
<tr>
<td>Cognitive functioning</td>
<td>97.2%</td>
<td>70.3</td>
<td>24.7</td>
</tr>
<tr>
<td>Depression</td>
<td>93.5%</td>
<td>61.0</td>
<td>26.1</td>
</tr>
<tr>
<td>Activities of daily living</td>
<td>98.1%</td>
<td>64.1</td>
<td>44.6</td>
</tr>
<tr>
<td>General well-being</td>
<td>93.5%</td>
<td>46.6</td>
<td>16.1</td>
</tr>
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</table>

Graph 1: Score changes with disease stage
Acceptability seems to be acceptable since the questionnaire completion takes less than 20 minutes, and response rates are over 80%. Although the occurrence of clinical events has an important impact on quality of life scores (graph I), as shown previously, the few changes after six months and the very low sensitivity to CD4 decrease are surprising.

At the first time point, patients with CD4 counts of less than 200 have better QOL scores than patients with CD4 counts between 200 and 400. This may be due to antiretroviral therapy: at the beginning of the study, guidelines recommended treating only patients with CD4 counts 400. This may be due to antiretroviral therapy: at the beginning of the study, guidelines recommended treating only patients with CD4 counts under 200. The impact of these therapies may explain the better score for a lower CD4 count.

After six months, the only significant changes are an increase in physical and cognitive functioning. This may be a sample effect, since only 51% of the patients have reached this point. We have also to take into account the effect of the radical changes in antiretroviral therapies: currently, patients are given a combination of two or three antiretroviral drugs which are known to considerably decrease the viral load, and to improve the CD4 counts.

In consequence, consideration of the antiretroviral therapy, duration, combination strategies and doses will be important issues in the final analysis.

Nevertheless, these preliminary results give us good hope for building a tool for the evaluation of additional medical care, such as psychological and social support as an alternative to hospitalization.

**Discussion**

It is now generally accepted that both the physical and the mental domains, with a multitude of factors included in physical, cognitive, emotional, social, relational and economic dimensions, contribute to QOL. In most QOL instruments, each of these dimensions is explored by questions on a set of selected items. However, the extent to which each of the dimensions or items contributes to overall QOL, remains controversial i.e. their weight in individuals, and average weights in populations. Linking each item by a question about its importance is theoretically correct, but unlikely to help. Firstly, it may make questionnaires intolerably unwieldy. Secondly, who can choose which is most important between e.g. sleep, eating, having no pain, sex, economic comfort, or being able to work? The weights of most items remain immeasurable by questionnaires, since ultimately most individuals are not aware of the importance of something until it is no longer there.

A further problem with questionnaires is that they can never be comprehensive. Generic questionnaires that are chosen for the purpose of comparability of data inevitably omit some items that may be very important for specific populations in specific circumstances. Even when disease-specific modules are added to generic questionnaires, the problem is not solved: one needs to modify instruments according to other important variables such as age, sex, education, religion, or culture, thereby...
Quality of Life as an Emergent Concept
(continued from p 18)

losing their genericity and practicability. For all these reasons, it can be argued that multi-dimensional, multi-item questionnaires generate profiles, but no indices, and describe, but do not measure QOL, either in individuals or in populations. At best, the profiles generated by multi-item QOL questionnaires identify 1) the subjects problems and 2) the manner (improved or deteriorated) in which these problems are influenced by interventions, but do not tell us to what extent overall QOL is modified. At worst, they allow no conclusion on overall QOL at all. The difficulties in interpreting QOL results obtained with multi-item instruments arise from the fact that overall QOL can be reliably measured by the questionnaires only if scores are available on all contributing items, dimensions and domains for each item has its individually determined weight, and if interactions between the contributing elements are taken into account: clearly an unsumountably complex set of requirements. The fundamental difficulty is that questionnaires are of necessity 1) generic and 2) reductionist, whilst QOL is in reality 1) an individual and 2) emergent construct, the result of a multitude of individual factors, generic factors with individual weights and individually specific interactions between these factors. Thus, the abstract concept 'QOL' is of the same order as e.g. 'freedom', 'security' or 'love'. Emergent concepts, whilst possibly having great importance, cannot be precisely defined, and can be captured only by holistic means. Similarly, emergent constructs can be captured only by global assessment.

Using both a multi-item questionnaire (which identifies the subject's problems), and a global assessment (which reflects their impact on overall QOL) would allow an estimate of the average weights of the dimensions and items, and thereby identify those in whom an improvement would most contribute to an improved QOL. Such a combined approach is likely to enhance the utility and efficacy of interventions at the (micro) individual, meso (population) and macro (societal) levels.

Quality of Life as an emergent concept
ISOQOL, Manila 1996, discussion group session

Saturday October 26th.
15:40 - 17:00, Tindalo Room, Manila Hotel
Themes:
- Is QOL an emergent concept?
- Is individual QOL an emergent construct?
- If so, can it be estimated by global assessment instruments?
- Experience with global QOL instruments.
- Joint use of itemised and global QOL instruments to estimate the weights of QOL factors in order to maximise the efficiency of QOL interventions.

The above summary paper is proposed as a discussion paper.

A more complete version is available from J. BERNHEIM, who will act as a moderator.
Contact address: Chemin du Foriest B-1420 Braine'Alleud, Belgium.
Tel: +32 2 386 25 33 Fax: +32 2 386 24 00
Contributions are welcomed.
**MEETINGS**

October 24-27, 1996
The Third International Conference for Quality of Life Research.
To be held in Cebu City in Manila, Philippines.
It will be hosted and organized by the University of the Philippines, Manila. The conference will focus on the relevance of quality of life research to health policy development although the cross-cultural perspectives of QOL research will still be an important component. (see program schedule on front page)
For further information, please contact: Pr. Laurie S. Ramiro, College of Arts and Sciences, University of the Philippines Manila, Rizal Hall, Ermita, Manila, Philippines. Tel: +63 2 56 55 26 - Fax: +63 2 522 3235 or contact ISOQOL Board of Directors, c/o Riverwood Associates, 8916 20th Ave NE, Seattle, WA 98115 USA. Tel: +1 206 989 9025 Fax: +1 206 517 2867 - E-mail: Riverwood@eoar.com

November 5-8, 1996
4-day session on the use of QoL instruments in clinical trials: EuroQol, SEIQOL, SLPQ, EORTC
To be held in Washington D.C., USA.
This interactive 4-day course will provide you with all the necessary information on these QoL instruments to make the best use in clinical trials. It will allow you to be in direct contact with the developers of each instrument and to obtain personalized responses to your specific requests.

November 5, 1996
The EuroQol EQ5D - a new measure for use in the clinical and economic evaluation of health care.

November 6, 1996
Use of the Schedule for the Evaluation of Individual Quality of Life (SEIQOL) conducted by A. Dazord.

November 7, 1996
Use of the Subjective Quality of Life Profile (SQPL) conducted by A. Dazord.

November 8, 1996
Use of the EORTC QLQ C30 and modules in clinical trials.

For further information, please contact: Ms Katrin Conway or Ms Caroline Anfray, Mapi Research Institute, 27 rue de la Villette, 69003 Lyon, France. Tel: +33 (0)4 72 13 66 67 - Fax: +33 (0)4 72 13 66 68 - E-mail: institut@mapi.fr

May 12-13, 1997
Fourth Annual Symposium of Contributed Papers - Quality of Life Evaluation
To be held in Charleston Place, Charleston, South Carolina, USA.
The objective for this meeting is to provide a forum for the exchange of information on quality of life evaluation. Abstracts of approximately 300 words are requested for identification of potential oral and poster presentations. Please consider contributing to this very important meeting. Papers will be accepted in the following categories, subject to blinded peer review:
- Development, Validation and interpretation, Quality of Life and Economic Evaluation, Quality of Life in Intervention Trials, Quality of Life in Observational, Quality of Life in Medical Care
- Please respond with your abstract by November 20, 1996. You may mail it to EVA LYDICK at Smithkline Beecham Pharmaceuticals, 1250 South Collegeville Road, UP4205, Collegeville, PA 19426-0989, USA or telex to +1 610 917 4818. For further information please contact the DIA by phone +1 215 628 2288.

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