Almost exactly two years ago, an editorial in this journal put two questions: (1) has QoL research actually helped to improve anyone’s QoL? (2) does it pay enough attention to quality of life in what is still disparagingly called the Third World? The author invited readers to comment, considering that the questions would have failed in their purpose if no one did so.

No one did, and this editorial therefore witnesses the failure of the first.

Did its readers (if any) consider the answers to be so complacently self-evident that there was no need for comment? The terrible events of September 11, 2001 and thereafter cannot be condoned in any circumstance. But the steadily deteriorating relationships between poor and rich, East and West, Islam and so-called Christianity both before and afterwards require the questions to be put again:

1. Has QoL research paid enough attention to the quality of life of the poor and otherwise disadvantaged of the world?
2. Has QoL research improved quality of life?

If the answer to the first two questions is at best a qualified “no”............

3. WHY NOT?

This final question is not to be taken as a suggestion for yet another workshop, seminar, symposium, congress, summit or other international gab-feast. As a West-of-England precept puts it: “Do summat! Do good if ‘e can: but do summat!” (“Do something, do good if you can, but DO something!”)

Dick Joyce, Department of Psychology, Royal College of Surgeons in Ireland, Dublin, Ireland. E-Mail: crbjoyce@freesurf.ch

Asthma and COPD are both chronic public health diseases. The primary goal of treatment includes symptom control and care taking to optimize patients’ functioning and well-being, i.e., their health-related quality of life (HRQL). Thus, outcome can better be assessed by changes in the total burden of disease and its consequences than in terms of pulmonary function tests or biochemical markers.

**Our objective** was to write a health technology assessment report by performing a systematic and critical review of the scientific basis for the various types of treatment for asthma (children and adults) and COPD and include HRQL as one primary outcome measure. The mission was to synthesize evidence and grade conclusions about benefits, risks and costs for the medical community, regulatory agency, governmental departments and society. Areas in need of further research were listed.

**Methods**

Four primary outcome measures were selected for the review (no rank order): HRQL, symptoms, need for acute care (increased medication, emergency visits or hospital admissions), and mortality from asthma or COPD. Studies of high quality were included, i.e., RCT, CCT, meta analysis or a quality-controlled, systematic review of such studies. Report on at least one of the four outcome measures was demanded and use of a treatment period of 3 months or more. Around 350 studies passed these criteria and were assessed and graded re. strong, moderate, weak, and little or no support. Secondary outcome measures included traditional clinical endpoints, care consumption and costs. Rigorous diagnostic criteria were applied. Literature search strategy comprised lung diseases, obstructive or asthma and for quality of life focus on questionnaire.

**Results**

Treatments reviewed comprised preventive interventions, physical training and patient education, alternative therapies, pharmacological treatment (beta-2
stabilisers and anticholinergics, theophylline, glucocorticoids, cromoglycate, antileukotrienes, antihistamines, cough medicines, immunosuppression, specific immunotherapy with allergen extracts, antibiotic treatment for acute exacerbations in chronic bronchitis, oxygen therapy at home, cardiovascular drugs in COPD, volume-reducing lung surgery for emphysema, reflex treatment, and antioxidants). Both disease-specific and generic HRQL instruments contributed to the evidence tables, most importantly for rehabilitation by physical training in COPD, pharmacological treatment in asthma, e.g., inhaled steroids, and lung surgery for emphysema. Most valuable specific instruments were St. Georges’ Respiratory Questionnaire (asthma/ COPD), Chronic Respiratory Questionnaire (COPD), Asthma Quality of Life Questionnaire (adult, pediatric and caregiver versions), and Living with Asthma Questionnaire, and among generic measures, the SF-36 Health Survey.

Conclusions

To assess the treatment of asthma and COPD, it is essential to use outcome measures that reflect the impact of the disease on an individual’s life (HRQL, symptoms, need for acute care, and mortality). Patient-reported outcome of treatment efficacy is nowadays adequately standardized for scientific reviews according to the conventional criteria of evidence-based medicine. Refinement of implications of HRQL however still remains re. design (power calculations for each measure), analysis (hypotheses re. domains close vs. distant to the condition and its treatment), and interpretation (clinical significance of change, distribution-based measures e.g., effect size calculations and criterion-related measures, e.g., threshold change scores).

Adapted from an Abstract accepted as an oral presentation at the 9th International Cochrane Colloquium, October 9-13, 2001 at the Palais des Congrès, Lyon, France

For more information, please contact Marianne Sullivan, Health Care Research Unit, Sahlgrenska University Hospital, SE-413 45 Göteborg, Sweden. E-mail: marianne.sullivan@medicine.gu.se.
self-image and esteem (“when you look at yourself in the mirror”, “when you think about your qualities”). It is interesting to see that the item “when you practise sport” is also clearly correlated to this 4th factor as well as the item dealing with leisure in general.

The internal reliability
measured by the Cronbach coefficient is satisfactory at 0.76.

The scale’s sensitivity
was observed by studying the replies obtained in particular in relation to sex, age and different settings.

• Profiles of the replies

Figure 1 shows the replies profile.

About one third of the items (N=9) obtained a score higher than 1. Most of these items are related to leisure. The items with lower ratings relate to medical care, school, but also future and relationship with adults. We also noted that these young subjects are very pessimistic concerning «what is going on in the surrounding world», a result that was always found with adults.

• Modulating factors

In order to study the impact of various factors on adolescents’ quality of life, we computed a global score from the sum of all items scores. This sum was divided by the number of items. Variance Analysis (see table 2) shows that sex has a clear effect (the mean global score is .58 in males and .48 in females p=. 01). It is the same for age combined to two groups of schools (favourable area N=249, unfavourable area N=105); for adolescents less than 16 yrs, there is a difference between the two class groups, the global score is better in unfavourable neighbourhood (.67 vs. .42). We already observed that kind of paradoxical results (better quality of life in more precarious social conditions) but only in young adults, or students (as if a good QOL in adolescents could also mean a better ability to complain).

We also looked at the effects of these modulating factors on the items, which make up the 4 factors computed from ACP (table 3). While no effect was observed on factors 2 and 3, a clear influence of sex and social environment was observed on items of factors 1 and 4. As far as factor 1 is taken into consideration, for the younger adolescents (group 1), the items of factor 1 have a higher value in the less favourable environment (1.04 vs .67 p=. 04). The reverse is observed for the eldest girls: they have a better QOL in the more favourable environment (1.11 vs .62 p=. 02).

Table 2 ANOVA: impact of various factors on Adolescents global quality of life score (dependent variable)

<table>
<thead>
<tr>
<th>Independent variable</th>
<th>Test F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>5.36</td>
<td>.01</td>
</tr>
<tr>
<td>Age 1</td>
<td>.27</td>
<td>NS</td>
</tr>
<tr>
<td>Class 2</td>
<td>3.20</td>
<td>.07</td>
</tr>
<tr>
<td>Age x Sex</td>
<td>.77</td>
<td>NS</td>
</tr>
<tr>
<td>Age x Class</td>
<td>3.14</td>
<td>.04</td>
</tr>
<tr>
<td>Sex x Class</td>
<td>.72</td>
<td>NS</td>
</tr>
<tr>
<td>Sex x age x class</td>
<td>.05</td>
<td>NS</td>
</tr>
</tbody>
</table>

1: age: 3 groups are considered: group 1 less than 16 (N=73); Group 2=16 yrs (N=186); group 3 >=17yrs (N=95).
2: 2 groups are considered: schools located in a favourable area N=249, schools located in a less favourable area (N=105).

Table 3 ANOVA: Impact of various factors on the items making up factors 1 and 4 (dependent variable)

<table>
<thead>
<tr>
<th>Factor 1: relationship and leisure (sum of 6 items)</th>
<th>Independent variable</th>
<th>Test F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>0.64</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Age 1</td>
<td>.67</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Class 2</td>
<td>0.01</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Age x Class</td>
<td>4.60</td>
<td>.01</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Factor 4: self esteem (sum of 4 items)</th>
<th>Independent variable</th>
<th>Test F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent variable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex x age</td>
<td>16.7</td>
<td>.0002</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Age and sex see table 2

As far as factor 4 is taken into consideration, we found a better esteem among boys (.90 vs .49 p <. 0001), and in the less favourable environment (.94 vs .61, p=. 0002).

Discussion

It appears feasible to interview adolescents about their QOL. Their answers are both relevant and consistent as shown by the validation studies:

1) the acceptability is excellent;
2) the construct validity is appropriate, principal component analysis highlighting adolescents specific domains such as relation with youngsters, school, family, self image;
3) the internal consistency of the scale reaches values generally accepted for psychological measurement scales in the human sciences (Cronbach alpha around 0.70).

4) regarding questionnaire’s sensitivity, we note that sex, age and social context have a real impact on the results.

Next step will involve the use of the questionnaire in different therapeutic approaches.

Acknowledgments: We wish to thank the teachers who gave us the opportunity to collect the information: Anouk Boulakia, Claude Jamet, Jean-Luc Labouche, Yves Perier-Muzet, Colette Zederman.

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Interest in the application of health-related quality of life (HRQOL) measures as indicators of population health has recently emerged. HRQOL measures can facilitate the tracking of health trends, identify discrepancies in health, and guide efforts to improve the health of populations. Previous investigations of population health have focused on rates of homicide, infant mortality, and age-adjusted mortality (all causes) as well as the number of physicians per capita as social determinants of health. These investigations, however, have returned mixed results. In an effort to expand investigations, however, have returned mixed results. In an effort to expand investigations, determinants of health. These physicians per capita as social (all causes) as well as the number of health have focused on rates of homicide, infant mortality, and age-adjusted mortality (all causes) as well as the number of physicians per capita as social determinants of health. These investigations, however, have returned mixed results. In an effort to expand investigations, however, have returned mixed results.

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The PedsQL™ 4.0 Generic Core Scales have resulted from a programmatic instrument development effort by Varni and colleagues during the past 15 years. The PedsQL™ 4.0 measures the core health dimensions (physical, mental, and social) as delineated by the World Health Organization, as well as role (school) functioning. It includes child self-report for Young Children (ages 5-7), Children (ages 8-12), and Adolescents (ages 13-18) and parent proxy-report for these age groups as well as for Toddlers (ages 2-4). The inclusion of child self-report as well as parent proxy-report reflects the commitment to measuring children’s perceptions of their HRQOL for the broadest age range possible, while also recognizing the importance of parents’ perceptions of their children’s HRQOL in directly influencing health care utilization.

The PedsQL™ 4.0 is comprised of 23 items that encompass the 4 scales: 1) Physical Functioning (8 items), 2) Emotional Functioning (5 items), 3) Social Functioning (5 items), and 4) School Functioning (5 items). The parent proxy-report forms are parallel to the child self-report forms, and are designed to assess the parent’s perceptions of their child’s HRQOL. The items for each of the forms are essentially identical, differing only in developmentally appropriate language, or first or third person tense. The instructions ask how much of a problem each item has been during the past one month.

### Table 1. Means and Internal Consistency Reliability* for Child Self-Report and Parent Proxy-Report Total Scores on the PedsQL™ 4.0 Generic Core Scales: Comparisons between Population-Based and Hospital-Based Samples

<table>
<thead>
<tr>
<th>Scale</th>
<th>N</th>
<th>Total Score Means</th>
<th>Internal Consistency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Child Self-Report</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Sample</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population-Based</td>
<td>5972</td>
<td>82.76</td>
<td>0.89</td>
</tr>
<tr>
<td>Hospital-Based</td>
<td>960</td>
<td>79.62</td>
<td>0.88</td>
</tr>
<tr>
<td>Healthy Groups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population-Based</td>
<td>5079</td>
<td>83.81</td>
<td>0.89</td>
</tr>
<tr>
<td>Hospital-Based</td>
<td>401</td>
<td>83.00</td>
<td>0.88</td>
</tr>
<tr>
<td>Chronic Health Conditions Groups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population-Based</td>
<td>574</td>
<td>74.04</td>
<td>0.89</td>
</tr>
<tr>
<td>Hospital-Based</td>
<td>367</td>
<td>77.19</td>
<td>0.87</td>
</tr>
<tr>
<td><strong>Parent Proxy-Report</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Sample</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population-Based</td>
<td>10,066</td>
<td>81.38</td>
<td>0.92</td>
</tr>
<tr>
<td>Hospital-Based</td>
<td>1622</td>
<td>80.87</td>
<td>0.90</td>
</tr>
<tr>
<td>Healthy Groups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population-Based</td>
<td>8709</td>
<td>82.32</td>
<td>0.92</td>
</tr>
<tr>
<td>Hospital-Based</td>
<td>717</td>
<td>87.61</td>
<td>0.88</td>
</tr>
<tr>
<td>Chronic Health Conditions Groups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population-Based</td>
<td>831</td>
<td>73.18</td>
<td>0.91</td>
</tr>
<tr>
<td>Hospital-Based</td>
<td>662</td>
<td>74.22</td>
<td>0.89</td>
</tr>
</tbody>
</table>

*Scales with reliabilities of 0.70 or greater are recommended for comparing patient groups whereas a reliability criterion of 0.90 is recommended for analyzing individual patient scale scores. Note: The three school-related questions asked of parents of toddlers were not included in the calculation of Internal Consistency Reliability.
A 5-point Likert response scale is utilized (0 = never a problem; 1 = almost never a problem; 2 = sometimes a problem; 3 = often a problem; 4 = almost always a problem). Items are reverse-scored and linearly transformed to a 0-100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0), so that higher PedsQL™ scores indicate better HRQOL. To create the Total Scale Score, the mean of all 23 items is computed as the sum of the item responses divided by the number of total items. A Total Scale Score is not computed if greater than 50% of the items are not completed.

The PedsQL™ as a Measure of Pediatric Population Health

The PedsQL™ was recently field-tested on a large population-based sample to examine its utility as a measure of pediatric population health. These scores were then compared to a previously published hospital-based database in order to determine the utility of the PedsQL™ as a measure of pediatric population health.

Hospital-Based Comparison Sample

The hospital-based sample consisted of 1,677 families (963 child self-report ages 5-18 and 1,629 parent proxy-report for children ages 2-18) recruited from local pediatric health care settings for the field trial of the PedsQL™ 4.0. The measure was administered in English or Spanish, and was conducted in person or by telephone. The sample included children with a chronic health condition (as reported by the child's parent; n = 683), children with an acute health condition (n = 207), and healthy children (n = 730; parent report did not identify presence of a chronic health condition). The percentage of missing item responses for this sample was 1.54% for child self-report and 1.95% for parent proxy-report.

Population-Based Sample

The PedsQL™ 4.0 Generic Core Scales were administered in a large state with a total population of approximately 33 million residents. The sample was comprised of 10,241 families (5,972 child self-report for ages 5-16 and 10,067 parent proxy-report for children ages 2-16) who were surveyed as part of a statewide program evaluation. While the PedsQL™ can be administered for children ages 2-18, this sample included only children ages 2-16 in order that a 2-year follow-up can be conducted (children ages 16 will be 18 at the time of the final assessment). The measures were administered in one of five languages – English, Spanish, Vietnamese, Chinese, or Korean. A nationally recognized survey administration firm was contracted to conduct the mail survey. The overall return rate with one mailing and no follow-up contact was 51% (10,241 families completed the PedsQL™ at home and mailed back the survey from an initial mailing to 20,031 families).

Of the total pediatric population sample, data were collected on 5332 (52.07%) males and 4909 (47.93%) females. The sample included 8,836 children whose parents did not report the presence of a chronic health condition (86.3%), 847 children whose parents reported the presence of a chronic health condition (8.3%), and 558 children for whom this information was not reported (5.4%).

Population-Based Findings

To assess the feasibility of the PedsQL™ as a population health measure, the percentage of missing values was calculated.11,12,13 The percentage of missing item responses for all scales was minimal, ranging from 1.1% for child self-report to 2.5% for parent proxy-report (ages 5-16 only). The percentage of missing values on the parent proxy-report for the School Functioning scale for toddlers (ages 2-4) was 52%, due to the fact that many children ages 2-4 did not attend school. Scale internal consistency reliability was determined by calculating Cronbach’s coefficient alpha.14 The alpha coefficients demonstrate that the PedsQL™ child self-report and parent-proxy report forms are reliable measures of HRQOL in the population-based sample, and are comparable to hospital-based sample (see Table 1). The means of the PedsQL™ Total Scale Score for both the population-based and the hospital-based samples are also shown in Table 1. Both child-self and parent-proxy report scores indicate better HRQOL for healthy children than for children with chronic health conditions, demonstrating known groups validity.15,16 Pearson correlations between child self-report and parent-proxy report indicate that healthy children and their parents responded consistently for the PedsQL™ Total Scale Score $r = .596, p < .001$. Children with chronic health conditions and their parents also responded consistently on the PedsQL™ $r = .685, p < .001$.

Benefits of the PedsQL™ as a HRQOL Measure of Pediatric Population Health

The findings suggest several benefits of utilizing the PedsQL™ 4.0 as a measure of pediatric population health. First, the measure is brief, easy to complete by children and parents at home or in healthcare settings, is easy to administer and score, and can be used to assess HRQOL in healthy children and children with acute and chronic health conditions ages 2-18. The measure also provides important information relevant to the health outcomes of pediatric populations by including domains that are influenced by health or illness. Second, the PedsQL™ has been readily translated into multiple international languages, increasing the feasibility of measuring HRQOL in numerous language groups across states and nations. Third, the measure has demonstrated minimal missing values in both local samples and a large population sample, further supporting the utility of the instrument. Fourth, the PedsQL™ has demonstrated internal consistency reliability, validity, sensitivity, responsiveness, and an impact on clinical-decision-making,17,18,19,20 further supporting its application as a measure of HRQOL in pediatric population health. Finally, the PedsQL™ performed in both the population-sample and the hospital-based sample as would be expected: healthy children report higher HRQOL than children with chronic health conditions, scores for the healthy children were similar in the population-based and the hospital-based samples, and scores for children with chronic health conditions were similar in both the population-based and the hospital-based samples.

NSTRUMENTS

The PedsQL™ as a Population Health Measure: Implications for States and Nations

(continued from p 4)
Expert Review of Pharmacoeconomics & Outcomes Research

Published by Future Drugs, Expert Review of Pharmacoeconomics & Outcomes Research was launched in October 2001 and is published bi-monthly. The journal provides commentary and analysis on the growing relationship between economic factors and clinical prescribing decisions, offering a practical background to informed prescribing decisions and allocation of healthcare resources.

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- Expert opinion – a personal commentary on the most effective or promising strategies
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Policy Implications for States and Nations

The feasibility of the PedsQL™ 4.0 as a measure of pediatric population health has important implications for states and nations. As mentioned previously, the information provided by the measure can be used to influence public policy initiatives. For example, the PedsQL™ might be used to identify specific subgroups of children at risk for health problems or to determine factors that may contribute to the health of a population, which can influence how state and federal healthcare funds are allocated. The PedsQL™ might also be used to evaluate the effectiveness of state and federal healthcare programs, and inform legislation on the allocation of resources to healthcare initiatives. Finally, the PedsQL™ can be used in large pediatric populations to study the effectiveness of health promotion and disease prevention within a specified pediatric population (e.g., different age and language groups, children with chronic health conditions).

For further information, please contact James W. Varni, PhD, Professor and Senior Scientist, Center for Child Health Outcomes, Children’s Hospital and Health Center, 3020 Children’s Way, MC 5053, San Diego, CA 92123. Tel: +(858) 966-4907 - Fax: +(858) 966-7478 - Email: jvarni@chsd.org.

The PedsQL™ is available at http://www.pedsq.org.

4. Varni, JW, Seid, M, Kurtin, PS. The PedsQL™ 4.0: Reliability and Validity of the Pediatric Quality of Life Inventory® Version 4.0 Generic Core Scales in Healthy and Patient Populations. Medical Care 2001;39:800-812.
ew health status and quality of life instruments exist that focus on the positive aspects of adolescence, incorporate adolescents’ perspectives and language, apply to both general and vulnerable populations, and tap perceptions or feelings. Previous work in Nordic countries with general survey measures indicated that adolescents with disabilities report a lower quality of life than those without chronic conditions or disabilities. Public health, social services, and clinical interventions are often designed with the aim of improving the health and quality of life of adolescents, particularly those who are vulnerable through health, economic, or other difficulties and disadvantages. With the goal of capturing the perception and voice of adolescents, we used inductive grounded theory qualitative methods to develop the Youth Quality of Life Instruments (YQOL).

In developing YQOL instruments, we adapted the World Health Organization Quality of Life working group (WHQOL) general definition of QoL as people’s perceptions of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns. This definition requires that youth themselves define the important concepts and items, that the measure employ subjective self-report whenever possible, and that items be developmentally appropriate. Our goal was to produce an instrument that is brief, cross-culturally comparable at least within the United States, has a generic core applicable to all youth, and has specific modules containing non-overlapping content for population subgroups. Finally, it is hoped that the QoL paradigm with its positive assets approach will help identify sources of resilience and strategies of coping, which are rarely disclosed in deficit-oriented approaches.

The YQOL generic quality of life (QoL) instruments are designed for all youth ages 12-18, including those with and without health conditions or disabilities. They are easy-to-understand, self-administered questionnaires constructed for adolescents at a U.S. fourth grade reading level (age 9). Two versions of the generic YQOL have been developed, a long version for program evaluation and research (YQOL-R, 72 items), and a short version for surveillance (YQOL-S, 13 items). The YQOL-R is divided into three, self-contained sections, one containing 28 contextual items that can be reported on by others and compared, one containing 42 perceptual items that can be reported only by the adolescents themselves, and one containing two individual-level items which assess the facets of quality of life the youth feel are most important and those that they would most like to change. The YQOL-R perceptual items can be used as a stand-alone instrument. The items comprising the YQOL-S were selected from the YQOL-R as representative of issues judged by the authors to be of most potential importance to policy makers.

In addition to a total score, four domains have been identified from the YQOL-R: Sense of Self, Social Relationships, Culture and Community, and General Quality of Life. The YQOL-S is designed for monitoring leading indicators of QoL in adolescent populations, and is not scored by domain, as each question is regarded as a social indicator in itself. The YQOL scores are transformed to a 0-100 scale for easy interpretability, higher scores indicating better QoL.

The YQOL instruments include the most important concerns of youth, and were developed through three types of data: (a) in-depth interviews with youth ages 12-18 with and without disabilities, from many different settings, asking what was important to their life; (b) focus groups with youth ages 12-18 with and without disabilities, with primary caregivers of youth with and without disabilities, and with youth health and welfare professionals; and (c) consultation with existing assessment instruments, such as the National Longitudinal Adolescent Health Survey (ADD Health). To the maximum possible extent, the content of the measures is defined by adolescents themselves and written in their language. The YQOL-R is an appropriate tool for evaluating the effectiveness of programs that are designed to improve the lives of young people. A major application of the YQOL-R will be to assess the effectiveness of interventions for adolescents with physical and other disabilities, including attention-deficit hyperactivity disorder (ADHD). The instrument takes 15 minutes to complete. Psychometric validation of the YQOL-R for cross-sectional studies has shown it to have good reliability and validity, and has been shown to discriminate between typical, ADHD, and mobility disability groups.

The YQOL-S instrument was used in conjunction with the Teen Assessment Survey to assess the association between health-risk behaviors and self-perceived quality of life among adolescents. The framework of QoL proved useful in evaluating the risk of adolescent use of tobacco, alcohol, illicit drugs, and engaging in high-risk sexual behavior. For health providers and educators who want to know about high-risk health behaviors, QoL may be more valuable in identifying teens than direct questions about drugs, alcohol, and sex because it is less confrontational and less likely to yield socially-acceptable responses.

Asking adolescents themselves what is important to their QoL, we attempt to keep the model youth-centered, developmentally appropriate, and based upon subjective self-report. Soliciting both positive and negative aspects of QoL in the adolescent interviews, we hope to correct for the negative bias in (continued on p 8)
The Institute for Health & Productivity Management (IHPM), the premier global resource on the impact of employee health on productivity, announces the availability of a groundbreaking new book — *Measuring Employee Productivity: A Guide to Self-Assessment Tools*. The unique tool guide was presented and discussed during the IHPM’s National Conference – “Putting Health and Productivity to Work” – held in Orlando, Florida, on September 24-26. The conference brought together 150 employer and managed care executives and physician leaders to advance the field of health and productivity management and its impact on organizational performance.

Developed and written for the IHPM by Wendy Lynch, Ph.D., a consultant with William M. Mercer, Inc., and John E. Riedel, MPH, MBA, of Riedel & Associates Consultants, Inc., the guidebook was funded by a grant from Schering-Plough Corporation.

The new *Measuring Employee Productivity* guidebook provides critical information on the leading available self-assessment measurement tools, plus background on important worker health and productivity measurement issues.

**INSTRUMENTS**

**USA**

*Youth Quality of Life: A New Measure Incorporating the Voices of Adolescents* (continued from p 7)

many existing instruments. Finally, including respondents from a diverse set of backgrounds and circumstances, we encompass as comprehensive a description of QoL as practically possible, applying to adolescents with and without disabilities.

In terms of the conceptual model, we hypothesize that the effects of social relationships and environment are mediated by the outlook of the individual, i.e., how the individual interprets his or her context/situation (as per the WHOQOL definition). Of course, social relationships and environment have an effect upon individual outlook, but the nature of the individual’s outlook may be the key factor in determining QoL. Although an adolescent may live in a negative physical, social, and/or cultural context, he or she may yet experience a relatively good QoL, depending upon his or her coping strategies and capacities in relation to that context. Alternately, an adolescent with ample socioeconomic resources and good psychological health might evaluate his or her position in life as relatively poor. Again, this model provides a means for programs to assess the strengths and resiliency of young people in adopting coping strategies in the face of adversity.

In conclusion, we found that it is possible for adolescents to articulate their views on the quality of their lives, from both a positive and negative perspective. The grounded theory method is useful for avoiding making assumptions about the determinants of adolescent QoL, and allowing the adolescents’ own voices to be heard.

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E-mail: donald@u.washington.edu

For information regarding use of the YQOL instruments, please consult our website at http://www.yqol.org

E-mail:yqol@u.washington.edu


**PUBLICATI ON**

*Measuring Employee Productivity: A Guide to Self-Assessment Tools*

The *Institute for Health & Productivity Management (IHPM)*, the premier global resource on the impact of employee health on productivity, announces the availability of a groundbreaking new book — *Measuring Employee Productivity: A Guide to Self-Assessment Tools*. The unique tool guide was presented and discussed during the IHPM’s National Conference – “Putting Health and Productivity to Work” – held in Orlando, Florida, on September 24-26. The conference brought together 150 employer and managed care executives and physician leaders to advance the field of health and productivity management and its impact on organizational performance.

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It includes:

• How to choose the right tool for a company’s or organization’s specific objectives
• Detailed descriptions of seven self-assessment tools
• Specific productivity factors measured by each tool
• Psychometric testing of each tool
• Actual tools and instructions for their use

*Measuring Employee Productivity: A Guide to Self-Assessment Tools* will help you:

• Determine the impact of health problems on work performance
• Compare the impact of different health problems on work performance
• Identify areas of opportunity for health interventions
• Assess the potential productivity gains from various alternative health improvement strategies and evaluate their actual impact
• Monitor the impact of improvements in clinical care quality on work performance
• Create a business case for investing in employee health

For additional information or to order the *Measuring Employee Productivity* guidebook, please visit www.ihpm.org or call 804-527-1905 and ask for Crystal Smith.
The large and growing burden of chronic disease worldwide is presenting new challenges in health assessment. For example, demand has grown recently for information concerning the impact that chronic health problems have on a population’s ability to work, and its work productivity. Several survey instruments are now available, which focus specifically on employment. In this article, we present information on a new self-administered, self-report survey instrument, the Work Limitations Questionnaire (WLQ).

The WLQ

The WLQ is an easy to use questionnaire, measuring the degree to which employed individuals are experiencing limitations on-the-job due to their health problems and health-related productivity loss. The WLQ has 25 items that ask respondents to rate their level of difficulty or ability to perform specific job demands (Figure 1). The job demands, which are contained in the WLQ’s items, have four defining features: 1) they occur among a variety of jobs; 2) many different physical and emotional health problems may interfere with their performance; 3) they are considered important to the job from the worker’s perspective; and 4) problems performing them are frequently related to productivity. The WLQ’s 25 items are aggregated into four scales. The Time Management scale contains five items addressing difficulty handling time and scheduling demands. The six-item Physical Demands scale covers a person’s ability to perform job tasks that involve bodily strength, movement, endurance, coordination and flexibility. The Mental-Interpersonal Demands Scale has nine items addressing cognitively job tasks and on-the-job social interactions. The fourth scale is the Output Demands Scale and it contains five items concerning diminished work quantity and quality. Scale score range from 0 (limited none of the time) to 100 (limited all of the time) and represent the reported amount of time in the prior two weeks respondents were limited on-the-job. Additionally, using an algorithm, WLQ scale scores can be converted into an estimate of productivity loss.

Development Process

The WLQ development process began in 1994 with a grant from Glaxo-Wellcome, Inc. WLQ research has also been supported by Pharmacia, Inc., and the National Institute of Mental Health. Prior to the WLQ’s development, there had been a very limited amount of detailed information available on the work experience of the employed, chronically ill population. Much of the information was gleaned from global indicators, such as the activity limitation and disability day items appearing within the US National Health Interview Survey, and the role disability scales of health assessment questionnaires. The WLQ itself evolved from a qualitative and quantitative research process. Early in that process, we convened multiple focus groups consisting of employed patients with chronic disease. Our interactions with working patients helped us to better understand how the work activities, associated with various jobs, were influenced by different conditions and their treatments. For example, we found that several physical and mental conditions made it difficult for individuals to perform their job tasks effectively throughout the workday according to an established or expected work schedule. Another important finding was that work productivity was a sensitive topic for many of the chronically ill workers we interviewed, and we learned how, in a non-threatening manner, to ask about work productivity. We also found that the act of recalling information about work productivity, and the effects of health problems on productivity, constituted a relatively difficult response task. These general findings helped to shape our measurement approach. A period of cognitive testing followed, in which items and item groupings were evaluated for content validity (relevance to work and to illness), clarity, and respondent burden. Finally, a series of psychometric tests, conducted on
resulting questionnaire forms, led to the current 25-item version. Within both patient and employee populations, this version of the WLQ has demonstrated excellent scaling properties, as well as construct and criterion validity. Scale alpha’s exceed the recommended level of .70 in both patient and employee populations. Construct validity tests have shown that WLQ scale scores vary with personality, type of chronic condition, and severity within condition groups, such as depression and osteoarthritis. In a study of depression patients, Swindle and colleagues found that the energy level, a hallmark depression symptom, predicted WLQ scores. Low energy corresponded to decreased work productivity both cross-sectionally and longitudinally. Criterion validity tests have been performed in several settings. For example, within a sample of private short-term disability claimants with back pain, baseline WLQ scores obtained within four weeks of the claim predicted the duration of the disability until return to work. In a study of patients with rheumatoid arthritis and in a second with a fibromyalgia sample, Wolfe and colleagues found that WLQ scores predicted patient income level.

We conducted a work-site study involving repeat measures of approximately 900 employees, to determine whether WLQ scores were significantly related to objectively-measured employee-level work productivity. We found that scores were related in the hypothesized manner. Using results generated within this study, we developed an approach to scoring the WLQ, which enables the user to translate scale scores into a single estimate of productivity loss. Table 1 demonstrates how the data can be used to quantify the difference in productivity from a relatively ‘healthy’ employee (WLQ scale scores = 0), and to calibrate the productivity impact of various chronic conditions. For example, the average WLQ index score for an employee sample with depressive symptoms was approximately 15.

**Table 1. The Work Limitations Questionnaire: Estimated Productivity Impact of Health-Related Work Limitations Based on WLQ Index Score**

<table>
<thead>
<tr>
<th>WLQ Index Score</th>
<th>% decrease in productivity (compared to healthy)</th>
<th>% increase in work hours to compensate for productivity loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>4.9</td>
<td>5.1</td>
</tr>
<tr>
<td>10</td>
<td>9.5</td>
<td>10.5</td>
</tr>
<tr>
<td>15</td>
<td>14.1</td>
<td>16.2</td>
</tr>
<tr>
<td>20</td>
<td>18.1</td>
<td>22.1</td>
</tr>
<tr>
<td>25</td>
<td>22.1</td>
<td>28.4</td>
</tr>
<tr>
<td>30</td>
<td>25.9</td>
<td>34.9</td>
</tr>
<tr>
<td>35</td>
<td>29.5</td>
<td>41.9</td>
</tr>
<tr>
<td>40</td>
<td>32.9</td>
<td>49.2</td>
</tr>
<tr>
<td>45</td>
<td>36.2</td>
<td>56.8</td>
</tr>
<tr>
<td>50</td>
<td>39.4</td>
<td>64.9</td>
</tr>
</tbody>
</table>


**New Research**

In 2002, we will begin a new two-year project, which is designed to make WLQ data and other health and work productivity indicators highly accessible and easy to interpret. We have been awarded a grant from Pharmacia, Inc., under the auspices of the Aetna Academic Medicine and Managed Care Initiative, to collect and disseminate normative data on health and work productivity from a representative household sample within the United States. Data will be collected by the National Opinion Research Center. We will publish normative data for subgroups defined by major demographics, health status, occupation, and industry.

**WLQ Users**

Clinical researchers, the pharmaceutical industry, employers, managed care organizations, and public health professionals are all seeking accurate information concerning the work impact of chronic disease. The pharmaceutical industry requires sensitive and specific work disability and productivity indicators for use in its clinical trials. Employers are requesting data to assess the impact of changing employee demographics on health and productivity. Some firms are evaluating the need for, and effectiveness of, employee health improvement strategies, such as disease management programs. Managed care organizations are being asked to demonstrate value to customers, including purchasers, who are interested in improving employee function and limiting the indirect costs of illness. Finally, public health officials have widened their surveillance and prevention efforts to include disability due to chronic disease. The WLQ can contribute information to all of these initiatives.

**Availability**

The WLQ is available royalty-free for non-commercial applications; commercial users are charged a fee. Information about the WLQ, and copies of the instrument, are available free by request from WLQ@Lifespan.org.

For further Information, please contact Debra Lerner, M.S., PhD, The Health Institute Division of Clinical Care Research, New England Medical Center, Box 345, 750 Washington Street, Boston, MA 02111, USA. Tel: (+1) 617-636-8636 Fax: (+1) 617-636-8351

Email: WLQ@Lifespan.org


Results

Quality of Life in Diabetic Patients Treated by Insulin Pumps

Eric Renard, MD, PhD, Dominique Apostol, MD, Dominique Lauton, MD, Françoise Boulet, MD, and Jacques Bringer, MD
Endocrinology Department, Lapeyronie Hospital, Montpellier, France

Background — — — — — — — —
Like most chronic diseases requiring lifelong daily treatment, type 1 (insulin-dependent) diabetes mellitus (T1DM) induces significant consequences on self-perceived quality of life (QOL). Beside the debilitating fluctuations of blood glucose level and the progressive development of chronic complications affecting eyes, kidneys, nerves, heart and blood vessels, the burden of insulin treatment also affects QOL. Management of insulin treatment represents a heavy load because it combines self-monitoring of capillary blood glucose, performance of daily insulin injections and permanent adjustment of insulin doses according to measured blood glucose, food ingestion and scheduled life activities. Moreover, the quest for near-normal blood glucose control in order to prevent diabetes-related-chronic complications is associated with unavoidable side effects such as hypoglycemic reactions and a tendency of weight gain, also further impairing QOL. The technical progress in insulin delivery devices, namely portable and implantable insulin pumps, allows improvements in metabolic control and increased flexibility in diet and activities. However, these therapeutic modalities require reinforced involvement of the patient in blood glucose monitoring and more sophisticated skills in insulin use. Moreover, the constant carriage of portable systems or the presence of an artificial implant both modify body appearance and increase disease awareness in everyday life. Beside assessment of metabolic impact of insulin pumps, consequences of these treatments on QOL need to be specifically estimated to allow a more global evaluation of these technical changes in diabetes care.

Objectives — — — — — — — —
The goal of the present study was to estimate the effects on health-related QOL of long-term use of portable and implantable insulin delivery systems for the treatment of T1DM. The control group included patients with similar disease conditions as patients using insulin pumps, but being treated with conventional insulin injections.

Methods — — — — — — — —
T1DM patients included in this cross-sectional study were all treated in the same Diabetes Care Unit as ambulatory patients. All of them gave their informed consent to participate in the study. None of them experienced recent personal events that might alter their QOL. The patients with implantable pumps constituted the reference group for the enrollment of patients using portable pumps or conventional injections. The patients with implants had all been previously treated by portable systems for at least six months. They moved to implantable devices as volunteers to participate in a study assessing long-term feasibility of this treatment mode. Briefly, implanted pumps are disc-shaped devices surgically settled in a subcutaneous pocket of the abdominal wall under general anesthesia. Insulin is delivered from a refillable reservoir in the peritoneal cavity through a peritoneal catheter connected to the pump outlet. Insulin is delivered at a variable rate according to patient adjustments by the mean of an external programmer using telemetry transcutaneous transmission. Patients perform at least 4 daily capillary blood glucose measurements to assess metabolic efficacy of insulin infusion and modulate infusion rate. Implants used at the time of the study were Minimed Implantable Pumps model 2001 (Minimed Inc, Sylmar, CA, USA) with a battery-life expectancy of 36 months. Patients with portable pumps were enrolled among consecutive patients attending the Diabetes Care Unit for routine visits so that they grossly matched with patients using implanted devices for age, sex, diabetes history, level of diabetic complications and metabolic control. Patients under conventional insulin treatment used multiple daily insulin injections and were enrolled among consecutive patients attending the Diabetes Care Unit for routine visits, too. They were also selected in order to match with the patients using pumps for the above-mentioned parameters (Table 1).

QoL was assessed by a version of Diabetes Quality of Life (DQOL)1 questionnaire, validated in French language2. Psychometric properties of this transculturally-adapted version of the original questionnaire designed by Jacobson et al have been previously documented by a specific study performed by the EVADIAC Study Group3. Briefly, DQOL is a self-administered specific questionnaire for diabetes, designed for the Diabetes Control and Complications Trial (DCCT), including 46 items rated on a 5-point Likert-type scale, assessing satisfaction (15 items), impact (20 items), social/vocational worry (7 items) and diabetes worry (4 items).

(continued on p 12)
A complementary question on general well-being rated on 5 is also included in the questionnaire. Raw scores calculated for the 4 main topics are transformed to a 100-point scale, with the higher score level meaning higher level of QOL. A total score can be calculated from the results of the 4 specific scales.

DQOL data are presented as means ± SD. Comparisons of scores between groups were assessed using non-parametric statistical tests because of the non normal distribution of data. A p value below 0.05 is required for statistical significance.

Results — — — — — — — — — —

The DQOL scores in the three groups of patients are presented in Table 2. Significant differences between patients using pumps and patients with conventional treatment were present for satisfaction and diabetes worry scales. Of note, well-being scores tended to be higher in pump-treated patients, although statistical significance was not reached. Interestingly, patients using implantable pumps showed a higher satisfaction score whereas they had the longer history of diabetes and presented the highest rate of complications. In spite of this higher level of satisfaction with implantable pumps, the impact of diabetes and complications remains unaffected by this therapeutic mode.

Social and vocational worry tended to be higher in users of portable pumps, while diabetes worry was significantly higher in both groups of pump users. Total DQOL scores were similar in the three studied groups. However, patients using portable pumps tended to have a lower total score.

Discussion — — — — — — — — — —

Although cross-sectional, this assessment of QOL using a French version of DQOL is able to indicate significant differences in QoL among T1DM patients according to treatment regimen. These data are valuable since the psychometric properties of the adapted questionnaire in French language have been previously validated.

Thus, French-DQOL has shown reliability, reproducibility and both clinical and concurrent validity vs. SF-36 and SQLP questionnaires.

Satisfaction with implanted pumps has already been shown in T2DM patients included in a randomized clinical trial comparing prospectively these devices with multiple daily insulin injections. The previously reported reductions of glycemic variability and incidence of severe hypoglycemia in patients using intraperitoneal insulin delivery are likely involved in this improved satisfaction with implanted pumps. The increased flexibility in life activities allowed by this treatment as well as the reduced time dedicated to treatment performance are also likely playing a role in this positive effect on QoL. The formal demonstration of a benefit in satisfaction when using implantable devices for insulin delivery adds a new dimension to the metabolic evaluation of this treatment mode. This more global positive effect for the patient is crucial to be pointed out since the necessity of surgery and the eventual incidents related to this technique as well as the specific cost due to this treatment appear to be favorably counterbalanced. Although providing relative flexibility and reduced blood glucose fluctuations versus insulin injection regimen, portable pumps require the use of cumbersome external materials that may explain the limits in the level of satisfaction.

The lack of measurable effect of pump use on disease impact may be related to the high rate of diabetic complications in the studied patients. The presence and the level of diabetic complications are well known to have a strong effect on the impairment of QoL. Only more drastic changes in the modalities of diabetic treatment such as pancreatic graft have been shown to be able to have a positive effect on health-related QoL in complicated diabetic patients.

Social and vocational worry score appears as non-significantly affected by pump treatment. This observation must be interpreted with caution in patients aged 35 to 50 because their familial and professional projects are often already strongly established. Whatever their treatment regimen, their worry in these domains cannot be easily altered. A specific assessment in younger subjects might indicate different results, owing to the improved satisfaction mentioned above.

Results of diabetes worry score are somewhat puzzling at first glance. A first interpretation may be deleterious for the pump option because it may be concluded that pumps could increase patient concerns on having diabetes. Alternatively, these results might indicate that worried patients for their diabetes could self-select for pump use. Pump therapy requires high compliance to treatment and self-blood glucose monitoring, which is more likely accepted by worried patients. Only prospective studies assessing changes in diabetes worry score before and after pump initiation could answer these two hypotheses.

Table 2. Quality of life assessed by DQOL scores according to treatment regimen

<table>
<thead>
<tr>
<th>Treatment Regimen</th>
<th>Insulin Injections</th>
<th>Portable Pumps</th>
<th>Implantable Pumps</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>30</td>
<td>49</td>
<td>29</td>
</tr>
<tr>
<td>Satisfaction score</td>
<td>71 ± 14</td>
<td>74 ± 13</td>
<td>79 ± 13*</td>
</tr>
<tr>
<td>Impact score</td>
<td>62 ± 11</td>
<td>62 ± 8</td>
<td>61 ± 11</td>
</tr>
<tr>
<td>Social worry score</td>
<td>76 ± 16</td>
<td>69 ± 19</td>
<td>76 ± 15</td>
</tr>
<tr>
<td>Diabetes worry score</td>
<td>70 ± 15</td>
<td>50 ± 18*</td>
<td>53 ± 13*</td>
</tr>
<tr>
<td>Total score</td>
<td>68 ± 11</td>
<td>65 ± 9</td>
<td>69 ± 9</td>
</tr>
<tr>
<td>Well-being score</td>
<td>2.39 ± 0.50</td>
<td>2.49 ± 0.77</td>
<td>2.55 ± 0.63</td>
</tr>
</tbody>
</table>

Mean ± SD. Scores are rated on 100, except well-being score rated on 5.
* p<0.05 vs. “insulin injections”  ** p<0.001 vs. “insulin injections”
INTRODUCING

A New Project of the Mapi Research Institute’s Foundation, Boston, MA, USA: the Directory of PRO Databases

1V Vetsmany, 2MP Emery, 3K Conway

1Mapi Research Institute’s Foundation, Boston, USA 2Mapi Research Institute, Lyon, France

We are pleased to announce the establishment of the Mapi Research Institute’s Foundation based in Boston, MA, USA. Besides reinforcing our links with our collaborators and clients on the American continent, the Foundation will continue to support and promote the use of Patient Reported Outcomes (PRO) in clinical research and clinical practice through collaborative research projects.

One of the first projects of the Foundation will aim to facilitate access to useful information on data generated from PRO evaluation. The Directory of Databases (DDB) Project will be structured to identify, locate and describe existing worldwide databases created from the collection and centralisation of PRO data from clinical studies.

In collaboration with the developers and the users of PRO measures, this project will create a descriptive grid per questionnaire that will list information such as database location, contact details, conditions of access and general structure about surveyed population(s) in studies where the questionnaire has been used. The DDB will not include reference values and clinical data from studies, but will give some practical information on existing databases to researchers and companies using a PRO measure.

Moreover, this project will be connected to the new QOLID.org (Quality of Life Instruments Database) website which provides detailed descriptive information on over 300 instruments as well as copies of the questionnaire if available (220 questionnaires included). For each questionnaire, information on the existence of a database will be collected from the authors and a link may be established between the QOLID.org website and the DDB.

In order to collect preliminary information on the existing PRO databases, we have already sent a questionnaire in the last issue of the Quality of Life Newsletter. The answers to this questionnaire from developers, academic researchers and pharmaceutical companies confirm the need and the interest in such a directory.

Your support and comments are very welcome at this early stage of our DDB project.

For more information, please contact: Vilayvanh-Céline Vetsmany, Pharm.D., M.S., Project Manager, Mapi Research Institute, Inc., 15 Court Square, Suite 400, Boston, MA 02108 USA. Tel: +1.617.723.7153 ext206 - Fax: +1.617.523.7322 Email: vvetsmany@mapi.fr

RESULTS

France

Quality of Life in Diabetic Patients Treated by Insulin Pumps

(continued from p 12)

However, from a structural point of view of DQOL, one must take into account that diabetes worry score only relies on four items. Moreover, one of these items assess whether the patient worries about his body looking different because of diabetes. This topic definitely arises worry when one wears an external device or has an abdominal subcutaneous implant. For us, diabetes worry scale should be differently designed for patients using portable or implanted devices for diabetes care and/or cautiously interpreted because of this ambiguous item for them and the considerable effect it may have on calculated score since it rates for one fourth in the calculation of the diabetes worry score.

The relative discrepancy between total DQOL score and general well-being score according to the various treatment regimens suggests that the four scales taken into account for the calculation of total score of DQOL may miss some elements contributing to diabetes-related QoL, at least for patients using specific treatment modalities like pumps.

Conclusion — — — — — — — — —

The assessment of QoL by a specific questionnaire provides an original sight in the assessment of new treatment modalities of diabetes mellitus that usefully completes data collected on more conventional end-points. We think that instruments to measure diabetes-related QOL should be more widely used in the procedures aiming at the validation of new therapeutic approaches in this field. Besides, more sophisticated questionnaires should be developed in the future to avoid misinterpretations that may arise with new treatment options.

For further information, please contact Eric Renard, MD, PhD, Endocrinology Department, Lapeyronie Hospital, 34295 Montpellier cedex 5, France - Tel: +33 4 67 33 83 82 - Fax: + 33 4 67 04 13 56 or + 33 4 67 33 74 16 - E-mail: e.renard@chu-montpellier.fr

Background and objectives
Over the last 20 years, a large number of Patient reported outcome (PRO) instruments have been developed and are increasingly used in multinational research and clinical practice. The success of PRO studies highly depends on the choice of an appropriate instrumentation. The instruments have to be selected according to the domains they measure, the population they are dedicated to as well as their specificity to a pathology. Practical issues such as the availability of different translations, the copyright issues, and the conditions of access to the instruments are also major criteria in the choice of the instruments.

From these observations and according to Mapi Research Institute’s policy to support and promote the evaluation of PRO, the project of a Quality of Life Instruments Database (QOLID) has been launched to provide all those involved in health care evaluation with a comprehensive and unique source of information on PRO measures available through the Internet.

QOLID is a collaborative project between the Information Resources Centre of Mapi Research Institute, Lyon, France and Marcello Tamburini, Istituto Nazionale Tumori, Milan, Italy. Through the structured presentation of synthesized, reliable and updated information, the aim of the QOLID database is:
- To provide an overview of existing PRO instruments
- To provide relevant information on PRO instruments
- To provide easy access to the instruments and their developers
- To facilitate the choice of an appropriate PRO instrument

Content and structure
The QOLID.org database, which is available on the Internet at the address www.qolid.org lists 1,000 PRO instruments and provides detailed information on over 300 of them, either generic or domain-, disease- or population-specific. For each instrument, the information is structured in two levels:
- The first level of access (Fig. 1) is available to all visitors free of charge and contains for each of the 300 instruments the following descriptive information:
  - full and abbreviated name of the questionnaire,
  - author(s),
  - objective,
  - pathology,
  - disease,
  - type of instrument,
  - population,
  - mode of administration,
  - original language,
  - list of available translations.
- The second level (Fig. 2) based on yearly subscriptions provides subscribers with practical information on the 300 instruments and their access:
  - full and abbreviated name of the questionnaire,
  - contact information for use of the original questionnaire and its translations,
  - copyright information,
  - copy of over 170 original questionnaires
  - copy of 100 translations,
  - copy of over 50 user manuals,
  - bibliographic references,
  - related websites.

Subscriptions are proposed to universities, hospitals, associations, as well as pharmaceutical and profit companies.

Information search
Information on the instruments presented in QOLID may be obtained through different menus available on the search page:
- alphabetical list of the abbreviated name of the instruments
- therapeutic areas
- specific dimensions, populations or conditions
- search engines

(continued on p 15)
QOLID: a New Quality of Life Instruments Database available on the Internet
www.QOLID.org

Update and future development
Any information included in the database is approved by, and updated twice a year in collaboration with, the authors of each instrument. The update will give us the opportunity to increase QOLID with new information as well as new instruments. By the end of 2002, information available on each instrument will be expanded with:
- the number of items
- the time for completion
- the existence of a database
- the existence of a user manual, and descriptions on new instruments will be added.

Conclusion
Its facilitated and unique access through the Internet makes QOLID the first source of accurate, reliable, and regularly updated information providing all those involved in PRO evaluation with an overview of the existing instrumentation. We strongly invite developers of instruments interested in our project to submit their questionnaires for inclusion in QOLID.org. By providing your instrument, you are supporting the development of the premier web-source of information on PRO.

For any information on QOLID, please contact: Marie-Pierre Emery, Director of the Information Resources Centre, 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 82 - Email : mped@mpli.fr

Design and Analysis of Quality of Life Studies in Clinical Trials
Diane L. Fairclough

Publication Date: 26 March 2002

More and more frequently, clinical trials include the evaluation of Health-Related Quality of Life (HRQoL), yet many investigators remain unaware of the unique measurement and analysis issues associated with the assessment of HRQoL. At the end of a study, clinicians and statisticians often face challenging and sometimes insurmountable analytic problems.

Design and Analysis of Quality of Life Studies in Clinical Trials details these issues and presents a range of solutions. Written from the author’s extensive experience in the field, it focuses on the very specific features of QoL data: its longitudinal nature, multidimensionality, and the problem of missing data. The author uses three real clinical trials throughout her discussions to illustrate practical implementation of the strategies and analytic methods presented.

As Quality of Life becomes an increasingly important aspect of clinical trials, it becomes essential for clinicians, statisticians, and designers of these studies to understand and meet the challenges this kind of data present. In this book, SAS and S-PLUS programs, checklists, numerous figures, and a clear, concise presentation combine to provide readers with the tools and skills they need to successfully design, conduct, analyze, and report their own studies.

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Education of disabled children in France is conducted either in institutions or in ordinary schools. In the latter case, the child’s quality of life (QoL) is a relevant criterion by which the benefit of this integration can be assessed.

We conducted a study to describe the QoL of disabled children going to school in the department of Rhône (a French territorial division in the Southern part of France). 224 children, aged 5-10, were concerned, some of them going to school without any specific help during school time, the others being helped at school by an assistant helper.

Questionnaires were given to teachers, assistant helpers, parents and children when they were able to understand and fill out a self-report form. Children’s QoL was assessed using the AUQUEI questionnaire, a pictured self-administered questionnaire. Parents filled out the same questions about their child.

Teachers and assistant helpers gave their own opinion about the child’s feelings in various school situations, as well as their view about the child’s evolution.

Study population

Data from 151 children were collected (response rate: 67%). The average age was 6 years 3 months, and 60% were boys. Most of them (88%) had learning difficulties, one half presented behavioral disorders, a third of them did not communicate with language, 12% needed technical help for moving.

One third of them was in full time education, 49,5% in half time education, and 17% went to school less than 3 half days per week. 75% of the children benefited from an assistant helper.

Results

Teachers

They assessed favorably both feelings of the children during school time and the children’s evolution. They assessed the children’s well being:

- lower during schoolwork or school activities in a group,
- better when the children arrive at school, during playtime, lunch, school outings, - and intermediate during motor activities.

When children presented behavioral disorders, well-being seemed to be significantly less favorable during schoolwork, school activities in a group or school outings.

The children’s evolution was rather favorable in all fields: relation with peers, mood, behavior, speech, physical autonomy, knowledge, participation in school activities, and self-confidence.

There were significant differences in this evolution according to children’s characteristics. Evolution seemed better concerning speech and knowledge when the child was able to talk; it seemed less favorable concerning relation with peers, participation in school activities, behavior and mood when the child presented behavioral disorders.

When an assistant helper supported the child, 78% of teachers estimated that school attendance could not be possible without this help. They said that the assistant helper was essential to schoolwork, and facilitated the child’s comfort and relations with peers.

85% of teachers also said that receiving a disabled child at school is beneficial to other children, and 92,5 % of them said that the other schoolchildren’s parents welcomed this integration.

The point of view of assistant helpers concerning feelings and evolution of the children was very close to the teachers'. However, it was always more optimistic.

Parents assessed their children’s evolution more favorably than the school professionals. They were rather satisfied by school attendance. Nevertheless, 50% of them experimented some difficulties with school integration. They mentioned the insufficiency of school time, the lack of assistant helpers, the inappropriateness of schools and the lack of institutions, as well as teachers’ insufficient knowledge about their child disability.

The Children’s QoL could be directly assessed using AUQUEI questionnaire in 70 children. Their answers in the structured format scale (either the global score or the answers profile) did not differ significantly compared to general population children.

On the other hand, their open answers were different. Among the reasons given for feeling satisfied or dissatisfied, they less often gave answers concerning relationship with peers, restrictions or duties, and their environment. There were no differences in the frequency of answers concerning free time activities, body or achievement.

When parents assessed the same questions, their answers were not correlated with the children’s one, even though the answer profile was similar (see figure 1).

Teachers and assistant helpers agreed about the role of the assistant helper, ranking first help for schoolwork, then helping for moving, helping for group activities, and last psychological support.

Parents expected more psychological support from the assistant helper, even if they also ranked first help for schoolwork. In conclusion, school integration for disabled children appears to be assessed rather favorably both by school professionals and parents, even though difficulties remain in its implementation.

Quality of life assessed by children and parents is also favorable. Both parents and teachers appreciate the help from an assistant helper.

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Death and dying may seem the antithesis to research about quality of life. However, there is a sizable literature about what constitutes quality of dying — and it is part of the continuum of the work of healthcare outcomes research. Palliative and hospice care are interventions that improve the experience of dying for patients and their family members. Research about quality of palliative care for children is still an underdeveloped area. In contrast to adults at end of life, there are no instruments to measure quality of care, satisfaction with care, and the quality of death for children. A landmark article by Holmes and Rae in the late 1960s introduced the idea of a quantifiable and extreme level of stress following family member’s death, and was followed by confirmation in different cultures, and especially for parents of children with life-limiting illness and death. Hence the quality of the child’s death impacts the ongoing quality of the bereaved parent’s life. However, in European and North American societies, compared to the death of adults, the death of a child is relatively uncommon. Approximately 53,000 children die each year in the United States; about half of these children die in the first year of life. 75 to 85% of childhood deaths occur in hospitals. In the United Kingdom, 1 in 10,000 children die from a chronic illness. In addition to the children who die, 1 to 1.7 per 1000 children live with a potentially life limiting illness. Perhaps the uncommon nature of child death, in conjunction with our death-denying cultures, have provided us with few details to inform best medical practice for dying children and their families. The American Academy of Pediatrics recommended further clinical research concerning the effectiveness and benefits of pediatric palliative care interventions and models of service provision. Research will require appropriate evaluation tools, for children, when possible, but also for their parents. In 1998, the Robert Wood Johnson Foundation (RWJ USA web site http://www.promotingexcellence.org) announced a nationwide initiative entitled “Promoting Excellence in End-Of-Life-Care.” The overall goal of the program is to identify “best practices” and through education, to extend those to society at large. Our program FOOTPRINTS(SM) from Cardinal Glennon Children’s Hospital in St. Louis, USA was one of the 22 chosen, and one of only two pediatric programs funded in this initiative. The FOOTPRINTS(SM) clinical program utilizes a model of advanced care planning and care coordination for children living with life limiting illnesses and their families. The goals of the program are threefold: (1) the development of processes for identifying children whose illnesses or injuries may be life limiting and for whom a model advanced care planning is appropriate, (2) educating health care providers and the public on the needs of dying children and their families and the skills necessary to meet the needs, and (3) the development of research/outcome evaluation tools that will help caregivers to evaluate and improve the quality of care and satisfaction with care provided to these children and families. (Additional information about the FOOTPRINTS program is available at http://www.footprintsatglennon.org) A fundamental barrier to improving the quality of pediatric palliative care is the lack of process and outcomes measurement tools. In our planning process, we found substantial help from existing programs, publications, and the literature concerning adult end-of-life, and quality-of-life in children with chronic illness. However, we found few published research or clinical care resources for children living with life limiting illnesses, and those receiving or eligible for palliative care. Our additional challenges included developing appropriate methods to conduct the research and the need to develop and/or adapt existing tools for our evaluation of the program. As others have noted, qualitative research makes a very important contribution to palliative care research but quantitative research also is needed to understand a broad range of potential outcomes of health care for dying children. We included a qualitative research stage to design an appropriate protocol, choose among potential published validated instruments, and construct additional questions about quality of care for the quantitative phase. For example, how soon after the child’s death should we wait before contacting parents for an interview? The literature on palliative care research for adults varies, for example recommending waiting 3 to 6 months. Consequently, the first step entailed conducting a series of focus groups to better understand end-of-life care issues salient to families who have lost a child. The purpose of the focus groups was to seek input by those adults intimately involved in the care of the dying child so that our clinical, educational, and research program met their needs. Participants included family members (n=61), healthcare providers in the home, community, and hospital settings (n=30), and pastoral and social service providers (n=23). We have selected, adapted, and developed tools for use with parents and care providers, described below in more detail. Our research methods also were adapted based on focus group feedback, including our decision to approach parents only after the death of a child, not during palliative care. Currently, we wait about six months before contacting parents. However, one of the unanticipated challenges has been the rapid transition of living arrangements following a child’s death, especially to single parents and those in extreme poverty. About 50% of our potential families are lost to follow-up, but after contact, 32% accept these interviews. We asked parents for their opinions about the burden and applicability of existing surveys and instruments on children’s quality of life, end-of-life care, grief, and spirituality. Parents who had participated in the focus groups evaluated and provided feedback on the sensitivity, burden, and appropriateness of several questionnaires. Questionnaires they evaluated were: • Quality of Care Tools: Evaluation with Care Survey & Nurse Parent Support Tool• Spirituality Tools: Spiritual Well Being & Spiritual Involvement & Beliefs Scale• Grief Tools: The Texas Revised Inventory of Grief & The Anticipatory Grief Scale(continued on p 18)
Instruments we evaluated, and those we developed, are described in more detail at http://www.promotingexcellence.org/navigate/frameset60.html. Based on information from both parent and health care provider focus groups, we chose to use two published instruments for evaluation.11,15

We also needed a more extensive quality of care assessment, and developed the Bereaved Parent/Caregiver After Death Interview. The After Death Interview is based on parents’ advice on important domains that were not included fully in existing instruments. Briefly, these domains included child physical well-being and functioning, psychosocial well-being, and family functioning, spiritual well-being, family well-being and perceptions (before and after child’s death), grief, and continuity of care. The goal of the After Death Interview is to assess the religious/social/cultural values of the family as well as evaluate the child’s care and parents’ satisfaction with care received at our hospital.

We developed several provider surveys concerning aspects of a “good death” and their perceptions of a child’s care. During focus groups with health care providers, we identified the need to collect additional information regarding the dying child’s end-of-life-care from them in addition to our interviews with parents. Our program conducts a Quality Assurance End of Life Care Survey to assess the care at the time of death of children who die in the hospital. Questions ask about issues like successful pain management, child and family wishes, and other end-of-life-care. All key health care professionals (e.g. physicians, nurses, social service, pastoral care) involved in caring for the dying child complete this survey. Thus, we are able to obtain perspectives from several different health care providers. What have we learned?

Preliminary analysis show that our health professionals are doing a really good job in discussing pain management and treatment options with families. However, we need to focus our efforts on addressing spiritual, cultural, and ethnic issues, involvement and preparations of the siblings, and discussions about hospice or home care, where appropriate. Medical residents would like more guidance on the logistics surrounding death of a child. Health care providers suggested that additional psychosocial counseling would be welcomed.
MEETINGS

April 17-20, 2002
The Qualities of Aging
To be held in Rome, Italy
The programme will focus on the many factors that affect mental HRQoL for our aging population, such as physical health, environmental compatibility, social integration with others, cognitive competence, treatment and intervention availability.
For more information, please contact IPA secretariat, 550 Frontage Road, #2820 Northfield, IL 60093 USA. Tel: +1 (847) 784 1701 – Fax: +1 (847) 784 1705 – Email: iipa@ipa-online.org. Website: www.ipa-online.org

August 31, 2002
Health-Related Quality of Life Education in Diabetes*
To be held in Budapest, Hungary
The training session is divided into two courses. The morning course, chaired by Prof. Clare Bradley, will provide information on PROs Assessment in Diabetes in general, whereas the afternoon course, chaired by Prof. Frank Snoeks, will be more specific on PROs Assessment in Depression in Diabetes. Experts in the field of PROs with experience in the assessment of patients’ HRQoL with Diabetes will meet to share their knowledge to the participants of these courses. They will provide information on disease-specific and generic PROs instruments, implementation of these instruments in daily clinical practice, scoring of instruments, interpretation and exploitation of results, to ameliorate patient outcomes and translate these results into socio-economic benefits.
For more information please contact Stéphanie Muller, Mapi Research Institute
Tel : +33 (0) 472 13 66 67 - Fax +33 (0) 472 13 69 50 – E-mail: smuller@mapi.fr
*sponsored by the European commission

May 19-22, 2002
ISPOR – 7th Annual International Meeting
To be held in Arlington, USA. Please see announcement on p 18.

August 17-22, 2002
10th World Congress on Pain
To be held in San Diego, California, USA.
Programme and Registration at www.iasp-pain.org

August 18-22, 2002
16th International Epidemiological Association (IEA) World Congress of Epidemiology
To be held in Montreal, Canada
The congress will focus on: Global health concerns for epidemiology, International health and international epidemiology. Epidemiology as a multi-disciplinary science, Molecular and generic epidemiology. Also featured: language-based symposia and workshops of regional interest (planned for Latin America, Eastern Mediterranean, Africa, and ADELFA French language).
IEA 2002 Congress Secretariat, c/o Events International Meeting Planners, 759 Victoria Square, Suite 300, Montreal, Quebec, Canada H2Y 2J7. Tel: +1 514 286 0855 – Fax: +1 514 288 7945 – E-mail: iea2002@eventsintl.com.

July 17-18, 2002
Health Outcomes 2002: Current Challenges and Future Frontiers 8th Annual Conference
To be held in Canberra, Australia
Conference sessions will cover:
• the development, selection, use and interpretation of health outcome indicators and HRQoL measures, multidimensional scaling and item response theory, and maintaining consistency and consensus in measurement;
• developing data sets for use in health outcomes evaluation and for comprehensive health assessment for particular population groups;
• statistical and research design issues in health outcomes evaluation (response shift and response bias, repeated measures, survivorship, comorbidity, effect sizes etc.);
• developments in the National Health Priority Areas, with sessions on asthma, CVD, cancer, diabetes, mental health and injury, with a particular focus on both risk factors and routine assessment in relation to these areas;
• health outcomes and population health, health differentials, health inequalities and burden of disease;

* sponsored by the European commission
September 13, 2002
Health-related Quality of Life Assessment in Asthma and COPD
To be held in Stockholm, Sweden
As previously done in the past two years, Prof. Elizabeth Juniper will coordinate a new course on asthma and COPD, in collaboration with experts in the field: Paul Jones, Sonia Bust, Martin Keech and Isabelle Mear.
For more information please contact Martine Moully, Mapi Research Institute, Tel.: +33 (0) 472 13 66 67 - Fax: (0) 472 13 69 50 - E-mail: mmoully@mapi.fr
* sponsored by GlaxoSmithKline

October 30 - November 2, 2002
ISOQOL Annual Meeting
To be held in Orlando, Florida, USA
Dates to Remember: April 24, 2002: Abstracts Due; June, 2002 (Date TBD): Notifications sent about Abstracts; July, 2002 (Date TBD): Confirmation due from Presenters/Early Registration Deadline. ISOQOL, 6728 Old McLean Village Drive, McLean, VA 22101-3906 USA. Tel: +1 (703) 556-9222 - FAX: +1(703) 556-8729 - Email: info@isoqol.org

November 3-5, 2002
ISPOR – 5th European Congress
To be held in Rotterdam, The Netherlands
Abstract Submission Deadline: June 24, 2002
ISPOR, 3100 Princeton Pike, Building 3 Suite D, Lawrenceville, NJ 08648 USA. Tel: +1 (609) 219-0773 - Fax: +1 (609) 219-0774 - E-mail: info@ispor.org

November 5-8, 2002
19th International Conference of the International Society for Quality in Health Care
To be held in Paris, France
The main themes of the conference are related to some of the main streams in the conference programme. Presentations will address one of the topics listed in the following streams: 1) Improving quality by measuring health care performance, 2) Improving quality by empowering consumers, 3) Improving quality by collaboration and teamwork, 4) Implementation of quality improvement.
Secretariat: Level 9, Aikenhead Centre, St Vincent’s Hospital, 41 Victoria Parade, Fitzroy Victoria 3065 Australia. Tel: +61 3 9417 6971 - Fax: +61 3 9417 6851 - Email: isqua@isqua.org.au Website: www.isqua.org.au

Call for Papers
QoL Newsletter 29
Deadline for submission: 17 June 2002

Any news and information on Quality of Life are invited (e.g. short articles on ongoing Quality of Life research, announcements of publications, meetings, websites etc.)
Please refer to Mapi Research Institute website at www.mapi-research-inst.com for submission information.
Please send your paper by post, fax or E-mail to Caroline Anfray, Mapi Research Institute, 27 rue de la Villette, 69003 Lyon, France. Fax: +33 (0)4 72 13 66 82 - E-mail: canfray@mapi.fr

The primary goal of Mapi Research Institute’s Quality of Life Newsletter is to encourage and facilitate the rapid dissemination and exchange of information on health outcomes within the scientific community. The views expressed in this Newsletter are those of the authors and do not necessarily represent those of Mapi Research Institute.