

PILOT STUDIES ON AUGMENTING HEALTH UTILITIES INDEX QUESTIONNAIRES TO REFLECT POSITIVE HEALTH AND LIMITATIONS DUE TO BREATHING DIFFICULTIES

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CONFLICT OF INTEREST

It should be noted that David Feeny has a proprietary interest in Health Utilities Incorporated, Dundas, Ontario, Canada. HUInc. owns the copyright to and distributes HUI materials.

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ABSTRACT

Background

Generic measures of health status including the Health Utilities Index Mark 2 (HUI2) and Mark 3 (HUI3) omit elements of "positive" or supra-normal health. The lack of positive health items results in the potential for ceiling effects, especially in the context of assessing population health. Similarly, in clinical studies, the lack of specificity of generic measures may limit their responsiveness.

Objectives

The first objective of the study was to experiment with the inclusion of positive physical and emotional health levels in HUI2 mobility, HUI3 ambulation, HUI2 emotion, and HUI3 emotion. The second objective was to experiment with the effects of including "breathing difficulties" in the description of levels in HUI for mobility, ambulation, and pain and discomfort in a group of patients with chronic obstructive pulmonary disease (COPD).

Methods

The experimental augmented HUI questionnaire was randomly assigned to students known to engage in vigorous physical activity. Similarly, COPD patients were randomized to receive the standard or modified HUI questionnaire.

Results

Positive health levels in mobility and ambulation were frequently selected by students. The augmented questionnaire appears to be less subject to ceiling effects. Similarly, breathing difficulties were endorsed by COPD patients and a higher burden of illness was revealed.

Conclusions

Results from the pilot study are encouraging. Further experimentation with HUI questionnaires appears to be warranted.

INTRODUCTION

A major advantage of generic health profiles, such as the Short-Form 36 (Ware 1996) and multi-attribute utility measures such as the Quality of Well Being (Kaplan and Anderson 1996), EuroQol EQ-5D (Rabin and de Charro 2001), and Health Utilities Index (HUI) (Feeny et al. 1996, 2002; Furlong et al. 2001; Horsman et al. 2003) is that these measures are applicable to virtually all adult populations and permit broad comparisons across diseases and health problems in both clinical and population health settings. The breadth of coverage of these generic measures may, however, attenuate descriptive power and responsiveness in clinical studies of particular diseases and health problems (Guyatt et al. 1993; Wiebe et al. 2003).

Ceiling effects may limit the usefulness of generic measures in population health and ambulatory care settings. If many subjects are classified at the top of the scale provided by a measure, the responsiveness of the measure is likely to be attenuated. Even though subjects may improve, the measure will not be able to capture that improvement. Ceiling effect issues also limit the ability of the measure to distinguish among individuals in relatively healthy groups (Wright et al. 2003). Similarly, floor effect problems can attenuate responsiveness in clinical settings when patients have moderate or severe burdens of morbidity.

A number of investigators have reported on the use of generic measures of health-related quality of life (HRQL) in primary-care settings (Cunningham et al. 2003; Edelman et al. 1999, Lubetkin and Gold 2002, Macran et al. 2003; Rubenstein et al. 1995; Sin et al. 2002; Wasson et al. 1999; Welch 1999). Macran et al. 2003 report that ceiling effect issues were less frequent with HUI (using a non-standard version) and with SF-12 than with the EuroQol EQ-5D. Lubetkin and Gold (2002) report fewer ceiling effect problems with HUI than with SF-12 and EQ-5D. Lubetkin and Gold also report that respondents felt that HUI made the most sense to respondents in terms of how they think about their health relative to the SF-12 and EQ-5D.

Most generic measures are designed to reflect a range of severity of health problems, including minor, moderate, and severe. However, existing generic measures have not been designed to capture "positive" health. Positive or supra-normal health, both physically and mentally, may enhance the ability to cope with stress and threats to health status. Positive health may contribute to resilience. Being able to capture aspects of positive health may also provide

some differentiation among those who report themselves as free of problems and thus reduce ceiling effects.

One of the two primary objectives of this study was to experiment with adding new levels to two generic measures of health-related quality of life, the HUI2 and HUI3, to reflect positive physical and mental health. The resulting modified questionnaire was then administered to a "known group" - - a class of physical therapy and occupational therapy students known to engage in vigorous physical activity and thus likely to endorse positive physical health items.

Generic measures typically cover a wide range of dimensions (domains) of health status. The breadth of coverage enhances the ability to make comparisons across diseases and populations. However, generic measures are often less responsive than specific measures that focus on the particular symptoms and problems associated with a disease and its management (Wiebe et al. 2003).

A standard response to this problem is to administer both generic and specific measures in a study (CCOHTA 1997). An alternative approach is to add disease-specific content to a standard generic measure. The second primary objective of this study was to experiment with adding disease-specific content to HUI2 and HUI3 to reflect the breathing difficulties associated with chronic obstructive pulmonary disease (COPD). A standard HUI questionnaire was modified to include breathing difficulties and administered to a group of patients with moderate or severe COPD.

Material common to both pilot studies is presented first. Then each of the two pilot studies will be discussed separately. In the concluding section of the paper, results from both pilot studies will be discussed.

Measures. Health Utilities Index Mark 2 (HUI2) and Mark 3 (HUI3) Systems.

The HUI2 includes seven health attributes (sensation [vision, hearing, speech], mobility, emotion, cognition, self-care, pain, and fertility) with three to five levels within each attribute for a total of 24,000 unique health states (Feeny et al. 1992, 1996: Furlong et al. 2001; Horsman et al. 2003). Fertility is not addressed in this study and is assumed to be normal. The HUI3 has 8

attributes (vision, hearing, speech, ambulation, dexterity, cognition, emotion, pain) using five or six levels for each attribute for a total of 972,000 unique health states (Feeny et al. 1996, 2002).

For both the HUI2 and HUI3 single attribute utility scores are on a scale in which the most highly impaired level is 0.00 and normal is 1.00. Standard HUI2 overall scores are on a scale in which the score for the all-worst HUI2 health state is -0.03, dead has a score of 0.00 and perfect health is 1.00 (Torrance et al. 1996). Standard overall scores for the HUI3 are on a scale in which the all-worst HUI3 state has a score of -0.36, dead is 0.00, and perfect health is 1.00.

Questionnaires

Two forms of questionnaires, standard and modified, were used. The standard survey contains 15 questions designed to capture respondents functional capacity in each of the health attributes covered by the Health Utilities Index Mark 2 (HUI2) and Mark 3 (HUI3) systems. The modified questionnaire was augmented to capture positive health in emotion, ambulation, and mobility and to provide respondents an opportunity to consider breathing problems in their responses on ambulation, mobility, pain and discomfort questions. Positive health levels were identified as 0; normal health is level 1 and higher levels within each attribute imply increasing disability. Further detail is provided in the description of each of the pilot studies.

Ethics Approval

Ethics approval for both surveys was obtained from the University of Alberta Health Research Ethics Board, Panel B.

PILOT STUDY NUMBER 1: POSITIVE HEALTH METHODS, POSITIVE HEALTH

Students

Physical and occupational therapy students attending a rehabilitation course at the University of Alberta November 2001 were approached with a request to participate in the study to assess positive health modifications to the questionnaire. The students, most of whom are actively engaged in physical fitness, were randomly assigned to the two forms of the questionnaire.

To reflect positive mental health, new levels ("0" normal is level 1) were added to HUI2 and HUI3 emotion. Level 1 HUI2 emotion is "generally happy and free from worry." The description for level 0 that was added is "very happy and fully confident that I can deal with whatever life has in store for me." The description for level 1 HUI3 emotion is "happy and interested in life." The description for level 0 HUI3 emotion is "extremely happy and living life to its fullest."

Level 1 HUI2 mobility is "able to walk, bend, lift, jump, and run normally for age." Level 1 HUI3 ambulation is "able to walk around the neighbourhood without difficulty, and without walking equipment." To reflect positive physical health, level "0" was added to HUI2 mobility and HUI3 ambulation as "able to engage in vigorous physical activity." A definition of vigorous physical activity was provided as follows: "vigorous physical activity involves continuous and rhythmic motion of your legs and your breathing is much harder than walking (e.g., running)."

Single-Attribute Utility Scores and Overall Utility Scores for Positive Health

Standard multi-attribute utility functions provide overall and single-attribute utility scores for the HUI2 (Torrance et al. 1996) and HUI3 (Feeny et al. 2002) systems. The highest score, 1.00, is attached to normal (perfect) health. Dead is assigned a score of 0.00. Standard single-attribute utility score scales range from 0.00 (lowest level - - most impaired - - on that attribute, for instance blind for vision) to 1.00 (level 1, normal). In the absence of a proper study to assess the value attached to supra-normal levels, the following arbitrary single-attribute and overall utility scores were adopted to facilitate quantitative analyses. The guesstimated single-attribute scores

for the supra-normal levels (levels 0) for HUI2 mobility, HUI2 emotion, HUI3 ambulation, and HUI3 emotion were obtained by adding one half of the difference between the single-attribute utility scores for levels 1 and 2 of that attribute, rounded up to the closest one hundredth. For instance for HUI2 mobility in the standard system the score for level 1 is 1.00 and the score for level 2 is 0.92. The difference is 0.08; one half of that equals 0.04 so the single-attribute utility score for level 0 HUI2 mobility is 1.04. Overall scores were computed assuming the attribute weights from the standard multiplicative multi-attribute utility functions for HUI2 and HUI3 but with the new single-attribute score for the supra-normal levels. Although in the absence of a legitimate preference-elicitation survey it is difficult to know what the scores for the supra-normal levels would be, the method adopted here is likely to have underestimated the scores - underestimated the gap between the value attached to the normal versus supra-normal level.

Sing	Overall score	
HUI2 Mobility	1.04	1.02
HUI2 Emotion	1.07	1.04
HUI3 Ambulation	1.09	1.04
HUI3 Emotion	1.05	1.03

Study Design, Positive Health

As mentioned above, a known groups approach was used. It was hypothesized that highly physically active respondents would endorse the positive physical health levels frequently. A class of physical therapy and occupational therapy students known to engage in regular vigorous physical activities was used to assess the usefulness of adding positive physical health levels to the standard HUI systems. The degree of participation in physical activities was also documented in terms of frequency, intensity, and energy expended using the Godin Leisure Time Physical Activity Questionnaire (Godin and Shepard 1985).

Students attending class in November 2001 were randomized to receive the standard HUI questionnaire or the modified one that included positive health levels and explicit statements about breathing difficulties. There were no *a priori* hypotheses about the selection of positive

mental health levels.

Statistical Analyses, Positive Health

The number of unique vectors within each group between the standard and modified questionnaires is compared. Mean single-attribute and overall utility scores within each group and between the two forms are compared. Independent sample t-tests between the standard and modified surveys are conducted for mean single-attribute utility scores for ambulation, mobility, emotion, and pain and overall scores in the HUI2 and HUI3 for the students.

Results, Positive Health

Response Rate and Student Characteristics. The class enrollment was 120 students. Eighty-seven students attended class on the day that the questionnaires were administered. Three questionnaires were returned blank. The response rate was 96.6%. Students were randomly assigned to the standard or modified questionnaire.

Table 1 presents the student characteristics. Of the 84 students who completed questionnaires, 75 were female and 9 were male, with a mean age of 25. Most of the students are actively engaged in physical activities. On average both student groups engaged in mild, moderate, and strenuous exercise 5, 3, and 3 times a week respectively. If one sums the frequency of each physical activity and multiplies it by the corresponding MET values of 9, 5, and 3 the total amount of energy expended per week had a mean score of 54 as measured by the Godin Leisure Time Physical Activity Questionnaire (Godin and Shephard 1985).

Table 2 displays descriptive statistics for single-attribute and overall utility scores between the two forms. As expected in a group of healthy students, overall mean scores for both the standard and modified questionnaires were high.

Comparing the Standard and Modified Forms

The range of overall scores in the standard format HUI2 (0.64 - 1.00) is larger than the range for modified format (0.73 - 1.06). For the standard format HUI3 the range of overall scores (0.24 - 1.00) was larger than for the modified format (0.58 - 1.10). The mean overall score for

the standard format HUI2 (0.90) is lower than for the modified format HUI2 (0.95); the difference is statistically significant (see Table 3). The mean overall score for the standard format HUI3 (0.86) is lower than for the modified format HUI3 (0.96); again the difference is statistically significant. The lowest mean single attribute utility scores were observed for sensation and emotion for HUI2 (both formats) and vision, emotion, and pain for HUI3 (both formats). Differences for emotion were statistically significant; differences for pain were not (Table 3).

The mean overall HUI2 and HUI3 scores of the modified format are higher than for the standard format. In fact all single attribute mean scores of the modified survey are greater than or equal to the standard scores; see Table 2. Most of the students are engaged in physical fitness activities. Among students receiving the modified format questionnaire, those who participated in strenuous physical activities more times per week were more likely to endorse level "0" (positive health) than those who engaged in strenuous activities fewer times per week. The addition of a new level in the modified format captured higher health levels and resulted in higher utility scores. This positive health level is not included and therefore not reflected in the scores from the standard form.

Unique Vectors

Tables 4 and 5 display the number of unique vectors between the standard and modified questionnaires. For HUI2 there were 13 unique vectors for the standard form and 21 for the modified form. For HUI3 there were 19 vectors for the standard from and 22 for the modified form. Deficits in sensation and vision were common.

The modified survey has a larger number of unique vectors compared to its standard counterpart. The addition of a positive health level increased the potential number and combination of vectors compared to the standard questionnaire.

Discussion, Positive Health

Adding positive health levels for physical health affects the reporting of health status. A large proportion of the students endorsed the new levels. The modified questionnaire was able to

distinguish among healthy respondents more readily than the standard questionnaire.

Further experimentation with positive health levels appears to be warranted. More important, it would be useful to employ the modified questionnaire in a longitudinal survey to determine if positive health has prognostic value in predicting future health.

Pilot Study Number 2: Breathing Difficulties

As noted above, the objective of pilot study number 2 was to determine if inviting respondents to consider breathing difficulties in answering questions on mobility, ambulation, and pain and discomfort would affect reports on health status and utility scores. A known group, patients with chronic obstructive pulmonary disease (COPD) was selected to assess the feasibility and usefulness of the questionnaire in the context of breathing difficulties.

Clinical Features

COPD includes two entities: chronic bronchitis and emphysema, that share a common pathophysiological feature of progressive expiratory airflow obstruction. The assessment of FEV1, forced expiratory volume in 1 second, is important in monitoring and guiding treatment and valid for grading the severity of this condition. The disease is characterized by airflow limitation that is not fully reversible. The airflow limitation is usually both progressive and caused by inflammatory response of the lungs to noxious particles or gases, commonly cigarette smoking. The diagnosis should be considered in any patient who has: cough, sputum production or dyspnea, and a history of exposure to risk factors for the disease.

The diagnosis is confirmed by spirometry. The value of a bronchodilator FEV1< 80% of the predicted value in combination with an FEV1 and forced vital capacity (FVC) ratio < 70% confirms that the airflow limitation is not reversible. Patients with COPD typically experience limitations in mobility and are sometimes emotionally depressed.

Methods, Breathing Difficulties

COPD patients were selected to assess modifications on breathing difficulties.

Patients

A standardized chart review of patients registered at the COPD Clinic, University of Alberta Hospital, Edmonton, was completed by a trained health professional who was not directly involved in patient care. All patients seen in the clinic during the period 1997 through 2002 with moderate or severe (for criteria see below) COPD were selected as possible participants in the study. One hundred eleven patients with moderate or severe COPD were identified. Exclusion criteria included mild severity, involvement in other studies and incomplete medical charts.

Modification of Questionnaire, Breathing Difficulties

To reflect limitations due to breathing difficulties, existing level descriptions in HUI2 mobility, HUI3 ambulation, HUI2 pain and discomfort, and HUI3 pain and discomfort were modified to include explicit reference to limitations due to breathing. The stem for the pain and discomfort questions for HUI2 and HUI3 were revised by including "(e.g., difficulty in breathing)" in the standard stem so that it read as follows: "which one of the following best describes the pain and discomfort (e.g., difficulty in breathing) you have experienced during the past week?" The stem of the questions and HUI2 mobility and HUI3 ambulation were revised to include: "please think about your ability to walk or engage in vigorous physical activity and your breathing".

Study Design, Breathing Difficulties

Patients with documented moderate or severe COPD under the care of one of two pulmonary specialists (PM, DS) were approached to participate in the study. Patients were randomized to receive the standard HUI questionnaire or the modified one that included positive health levels and explicit statements about breathing difficulties. It was hypothesized that patients who received the modified questionnaire and thus were asked explicitly to think about breathing difficulties when asked about mobility, ambulation, and pain and discomfort would report more problems than patients who received the standard questionnaire. Patients were randomly allocated to either the standard or modified version of the questionnaire.

Randomization was performed with the assistance of a computer program (SPSS) which generated the random sequence of patients. Questionnaires were mailed from June 7 to 26, 2002.

Non-respondents to this initial mailing were followed up a month later and a second set of surveys were mailed in order to increase the response rate.

Statistical Analyses, Breathing Difficulties

The number of unique vectors within each group between the standard and modified questionnaires is compared. Mean single-attribute and overall utility scores within each group and between the two forms are compared. Independent sample t-tests between the standard and modified surveys are conducted for mean single-attribute utility scores for ambulation, mobility, emotion, and pain and overall scores in the HUI2 and HUI3 for the patients. Scores from both forms of the questionnaires were re-calculated with the attribute levels for mobility, emotion, and pain reset to 1 (normal) in order to compare overall scores between the standard and modified forms focusing solely on morbidity burdens in the other attributes.

Results, Breathing Difficulties

One hundred eleven patients with moderate or severe COPD were identified. 77 patients were chosen randomly to receive questionnaires but only 26 patients returned them (34% response rate). Eleven questionnaires were returned as undeliverable and current addresses could not be determined. Three patients had died since last being seen in the clinic. Twenty-six of a feasible 63 patients returned complete questionnaires (response rate 41.3%). Table 6 shows the patient demographics. For the 77 patients only gender and age were recorded. For the 26 patients, the mean age is 69 and 35% are female, 15 out of 25 patients were retired and only 3 individuals were still employed full time.

Clinical Characteristics

Most patients had co-morbidities (Table 7). The most frequent co-morbid condition was hypertension, with 16 patients diagnosed (62%). Arthritis, asthma and diabetes shared the same frequency with 46%.

The mean age for moderate and severe patients is given in Table 8. For the 13 patients who received the modified questionnaire the mean FEV1 % predicted was 48.92%, higher than the mean for the 13 patients who received the standard questionnaire, 46.53%.

HUI.

Table 9 shows the descriptive statistics for single-attribute and overall utility scores for the COPD patients for two forms of the questionnaire. The poor health of the patients was demonstrated by their low overall mean scores for the standard version (HUI2 0.77; HUI3 0.57). The mean overall HUI2 and HUI3 scores for the modified version are lower still (0.59; 0.39).

Comparing Standard and Modified Forms

The overall range of scores for the standard form HUI2 (0.42 - 1.00) is smaller than the range for the modified form (0.30 - 1.00). The range for the standard version of HUI3 (0.21 – 1.00) is smaller than the range for the modified version (0.09 - 1.00). The mean overall score for the standard version of HUI2 (0.77) is greater than the mean score for the modified version (0.59); the difference is statistically significant (Table 10). Similarly, the mean overall score for the standard version of HUI3 (0.57) was greater than the mean for the modified form of HUI3 (0.39); again the difference is statistically significant. For both the standard and modified forms, the lowest mean single-attribute utility scores were for HUI2 mobility and HUI3 ambulation. For both HUI2 and HUI3, mean single-attribute utility scores for emotion were statistically significantly different when comparing the two forms but were not statistically significantly different for pain or mobility/ambulation.

Attributes levels for both forms of the questionnaires for mobility, emotion, and pain were reset to 1 (normal) with the objective of comparing the overall scores for the standard and modified forms reflecting morbidity burdens in attributes other than mobility or ambulation, emotion, and pain and discomfort. For the standard form, the mean overall score for HUI2 (0.93) was higher than the mean for the modified form for HUI2 (0.87). For the standard form for HUI3 the mean overall score (0.88) was higher than the mean for the modified form of HUI3 (0.74). For both forms mean overall scores were much higher than the scores obtained when deficits in mobility or ambulation, emotion, and pain and discomfort were not ignored. The differences in mean scores between standard and modified and standard forms for HUI2 and HUI3 reflect differences in health states between the two groups in attributes other than mobility/ambulation, pain, and emotion. Even though patients were randomized to receive the

standard or modified questionnaire, it appears that those who received the modified questionnaire were, on average, less healthy than those who received the standard questionnaire. This is confirmed in Table 7 which reports a mean number of other chronic conditions of 4.5 for patients receiving the standard-format questionnaire and 5.6 for those receiving the modified format; the difference is not statistically significant.

Unique Vectors

Tables 11 and 12 display the number of unique vectors in the standard and modified forms for the 26 patients. For HUI2 there were 12 unique vectors for both the standard and modified forms. For HUI3 there were 13 unique vectors for each form. Each vector describes the health status of a person at a particular point in time. The HUI2 vectors for the standard form patients indicate that 10 out of 13 (76.9%) patients had problems in sensation and mobility and that 9 patients out of 13(69.2%) had problems with pain. The HUI2 vectors for the modified form patients indicate that all patients had problems with sensation and all but one patient had problems with mobility.

The HUI3 vectors for the patients who received the standard form indicate deficits in vision (84.6%), ambulation (84.6%), emotion (38.5%) and pain (77%). For HUI3 for the modified version deficits were in vision (92.3%), ambulation (92.3%), emotion (100%), and pain (69.2%).

Discussion, Breathing Difficulties

It is evident that asking respondents to think about breathing difficulties when answering questions on mobility, ambulation, and pain and discomfort affected the reporting of health status by patients with COPD. Unfortunately randomization in a small cohort of COPD patients did not work perfectly. It would seem that by chance those who were randomized to the modified questionnaire were less healthy than those who were randomized to the standard questionnaire. That those who received the modified questionnaire reported more problems reflects both the effects of the modification of the questionnaire and the greater incidence of problems in the group. Nonetheless, it appears that further testing of the modified questionnaire is warranted.

Several substantial study limitations should be noted. First, the sample of COPD patients is

small and is not necessarily representative of patients with COPD. Second, although the study included known groups for breathing difficulties (COPD patients) and vigorous physical activity (physical and occupational therapy students), a known group for positive emotional health was not included and the performance of the modified format in that context remains untested. The generalizability of the results is unclear.

CONCLUSIONS

Incorporating positive health levels appears to be feasible and promising. Similarly, disease or problem specific modifications to standard wording also seem to enhance the sensitivity and applicability of a generic measure in a particular clinical context.

It will be important to conduct additional studies to assess the usefulness of including positive health levels and modifying level descriptions to reflect the burdens of specific diseases or health problems. If the results of additional studies highlight the usefulness of modifying the standard HUI systems and questionnaires, it may then be worthwhile to contemplate revisions to the measures and the development of new scoring functions to accommodate the new levels. It will also be important to identify a known group for positive emotional health so that the usefulness of those new levels may be assessed. Further exploration of these approaches is important.

REFERENCES

- 1. Canadian Coordinating Office for Health Technology Assessment, "Guidelines for Economic Evaluation of Pharmaceuticals: Canada, 2nd Edition." Ottawa: Canadian Coordinating Office for Health Technology Assessment, November, 1997.
- 2. Cunningham, William E., Terry T. Nakazono, Kai Li Tsai, and Ron D. Hays, "Do Differences in Methods for Constructing SF-36 Physical and Mental Summary Measures Change Their Association with Chronic Medical Conditions and Utilization?" *Quality of Life Research*, Vol. 12, No. 8, December, 2003, pp 1029-1035.
- 3. Edelman, David, Rhys Williams, Margaret Rothman, and Gregory P. Samsa, "A Comparison of Three Health Status Measures in Primary Care Outpatients." *Journal of General Internal Medicine*, Vol. 14, No. 12, December, 1999, pp 759-762.
- 4. Feeny, David H., George W. Torrance, and William J. Furlong, "Health Utilities Index," Chapter 26 In Bert Spilker, ed. *Quality of Life and Pharmacoeconomics in Clinical Trials*. Second Edition. Philadelphia: Lippincott-Raven Press, 1996, pp 239-252.
- 5. Feeny, David, William Furlong, George W. Torrance, Charles H. Goldsmith, Zenglong Zhu, Sonja DePauw, Margaret Denton, and Michael Boyle, "Multi-Attribute and Single-Attribute Utility Functions for the Health Utilities Index Mark 3 System." *Medical Care*, Vol. 40, No. 2, February, 2002, pp 113-128.
- 6. Furlong William J., David H. Feeny, George W. Torrance, and Ronald D. Barr, "The Health Utilities Index (HUI) System for Assessing Health-Related Quality of Life in Clinical Studies." *Annals of Medicine*, Vol. 33, No. 5, July, 2001, pp 375-384.
- 7. Guyatt, Gordon, H., David H. Feeny, and Donald L. Patrick, "Measuring Health-Related Quality of Life." *Annals of Internal Medicine*, Vol. 118, No. 8, April 15, 1993, 622-629.
- 8. Horsman, John, William Furlong, David Feeny, and George Torrance, "The Health Utilities Index (HUI®): Concepts, Measurement Properties and Applications." *Health and Quality of Life Outcomes* (electronic journal) (Vol. 1: 54, October 16, 2003), http://www.hqlo.com/content/1/1/54
- 9. Kaplan, Robert M., and John P. Anderson, "The General Health Policy Model: An Integrated Approach," in Bert Spilker, ed., *Quality of Life and Pharmacoeconomics in Clinical Trials*. Second Edition. Philadelphia: Lippincott-Raven Publishers, 1996, pp 309-322.
- 10. Lubetkin, Erica I., and Marthe R. Gold, "Comprehensibility of Measures of Health-Related Quality of Life in Minority and Low-Income Patients." *Journal of the National Medical Association*. Vol. 94, No. 5, May, 2002, pp 327-335.
- 11. Macran, Susan, Helen Weatherly, and Paul Kind, "Measuring Population Health: A

- Comparison of Three Generic Health Status Measures." *Medical Care*, Vol. 41, No. 2, February, 2003, pp 218-231.
- 12. Rabin, Rosalind, and Frank de Charro, "EQ-5D: A Measure of Health Status from the EuroQol Group." *Annals of Medicine*, Vol. 33, No. 5, July, 2001, pp 337-343.
- 13. Rubenstein, Lisa V., J. Michael McCoy, Dennis W. Cope, Pamela Anne Barrett, Susan H. Hirsch, Karen S. Messer, and Roy T. Young, "Improving Patient Quality of Life with Feedback to Physicians about Functional Status." *Journal of General Internal Medicine*, Vol. 10, No. 11, November, 1995, pp 607-614.
- Sin, Don D., Irvin Mayers, Godfrey C. W. Man, Ali Ghaary, and Lawrence Pawluk, "Can Continuous Positive Airway Pressure Therapy Improve the General Health Status of Patients with Obstructive Sleep Apnea?" Chest, Vol. 122, No. 5, November 2002, pp 1679-1685.
- 15. Torrance, George W., David H. Feeny, William J. Furlong, Ronald D. Barr, Yueming Zhang, and Qinan Wang, "Multi-Attribute Preference Functions for A Comprehensive Health Status Classification System: Health Utilities Index Mark 2." *Medical Care*, Vol. 34, No. 7, July 1996, pp 702-722.
- Ware, John E., Jr., "The SF-36 Health Survey," Chapter 34 In Bert Spilker, ed. Quality of Life and Pharmacoeconomics in Clinical Trials. Second Edition. Philadelphia: Lippincott-Raven Press, 1996, pp 337-345.
- 17. Wasson, John H., Therese A. Stukel, Julia E. Weiss, Ron D. Hays, Anne M. Jette, and Eugene C. Nelson, "A Randomized Trial of the Use of Patient Self-Assessment Data to Improve Community Practices." *Effective Clinical Practice*, Vol. 2, No. 1, January/February, 1999, pp 1-10.
- 18. Wiebe, Samuel, Gordon Guyatt, Bruce Weaver, Suzan Matijevic, and Casey Sidwell, "Comparative Responsiveness of Generic and Specific Quality-of-Life Instruments." *Journal of Clinical Epidemiology*, Vol. 56, No. 1, January, 2003,pp 52-60.
- 19. Wright, Marilyn J. Victoria Galea, and Ronald D. Barr, "Self-Perceptions of Physical Activity in Survivors of Acute Lymphoblastic Leukemia in Childhood." *Pediatric Exercise Science*, Vol. 15, 2003, pp 191-201.

Table 1. Student Demographics, n=84 students

Sex, male, $n = 9$; % male	11
Age, mean years (Std. Dev.)	25 (4.7)
Weight, mean kgs (Std. Dev.)	62 (9.9)
Height, mean cm (Std. Dev.)	167 (7.2)
Education, % completed	
High School, $n = 84$	100
Some university, $n = 46$	55
Bachelor degree, $n = 31$	37
Physical activity, mean frequency per week	
Mild exercise	5
Moderate exercise	3
Strenuous exercise	3
Godin Leisure Time Physical Activity, mean score. (Std Dev.)	54 (30)

Table 2. Single-Attribute and Overall Utility Scores for Students for Standard and Modified Questionnaire

	Minimum	Maximum	Median	Mean	Std Dev
	Std. Mod.				
HUI2					
Sensation	0.65, 0.65	1.00, 1.00	0.87, 0.91	0.89, 0.91	0.08, 0.08
Mobility	1.00, 0.92	1.00, 1.04	1.00, 1.04	1.00, 1.03	0.00, 0.03
Emotion	0.60, 0.60	1.00, 1.07	0.93, 1.00	0.92, 0.97	0.09, 0.10
Cognition	0.86, 0.86	1.00, 1.00	1.00, 1.00	0.97, 0.98	0.06, 0.05
Self-Care	1.00, 1.00	1.00, 1.00	1.00, 1.00	1.00, 1.00	0.00, 0.00
Pain	0.75, 0.95	1.00, 1.00	1.00, 1.00	0.98, 0.98	0.04, 0.03
Overall Score	0.64, 0.73	1.00, 1.06	0.91, 0.97	0.90, 0.95	0.08, 0.07
HUI3					
Vision	0.95, 0.95	1.00, 1.00	0.95, 0.95	0.96, 0.97	0.02, 0.02
Hearing	1.00, 1.00	1.00, 1.00	1.00, 1.00	1.00, 1.00	0.00, 0.00
Speech	0.67, 0.67	1.00, 1.00	1.00, 1.00	0.99, 0.99	0.06, 0.05
Ambulation	1.00, 0.83	1.00, 1.09	1.00, 1.09	1.00, 1.07	0.00, 0.06

Dexterity	1.00, 0.88	1.00, 1.00	1.00, 1.00	1.00, 1.00	0.00, 0.02
Emotion	0.33, 0.73	1.00, 1.05	1.00, 1.00	0.94, 0.98	0.13, 0.08
Cognition	0.70, 0.70	1.00, 1.00	1.00, 1.00	0.96, 0.98	0.09, 0.06
Pain	0.00, 0.77	1.00, 1.00	0.92, 1.00	0.92, 0.95	0.16, 0.08
Overall Score	0.24, 0.58	1.00, 1.10	0.92, 1.00	0.86, 0.96	0.18, 0.11

Std=Standard

Mod=Modified

Note: Modified single-attribute utility scores for HUI2 mobility range from 0 (level 5) to 1.0 (level 1) to 1.04 (level 0). For HUI2 emotion the range is 0 to 1.07. Overall HUI2 scores range from -0.03 to 1.06. For the modified HUI3 ambulation single-attribute utility scores range from 0 to 1.05 and overall scores range from -0.36 to 1.10.

Table 3. Independent Sample T-Tests for Mean Single-Attribute and Overall Utility Scores for Students for Standard and Modified Questionnaires

	T-valu	e
HUI2		
Mobility	7.82	i.
Emotion	2.27	
Pain	0.47	
Overall Score	3.09	
HUI3		
Ambulation	8.14	
Emotion	1.7	
Pain	1.09	
Overall Score	2.95	

Note: The critical value for the t-statistics with alpha = 0.05 and 83 degrees of freedom, one-tailed test, is 1.660.

Table 4. Number of Unique Vectors in the Standard Questionnaire for Students

Standard									
HUI2	Affected Attributes	Score	n	%	HUI3	Affected Attributes	Score	n	%
111111	0	1.00	5	12	11111111	0	1.00	5	12
111112	1	0.97	3	7	11111112	1	0.95	2	5
112112	2	0.90	2	5	11111113	1	0.86	1	2
112211	2	0.88	1	2	11111131	1	0.93	1	2
211111	1	0.95	11	26	11111212	2	0.88	2	5
211112	2	0.92	2	5	21111111	1	0.97	9	21
212111	2	0.88	4	10	21111112	2	0.92	7	17
212112	3	0.85	5	12	21111113	2	0.84	1	2
212211	3	0.83	3	7	21111132	3	0.85	1	2
212212	4	0.80	3	7	21111135	3	0.33	1	2
212213	4	0.70	1	2	21111211	2	0.91	2	5
312111	2	0.79	1	2	21111212	3	0.85	2	5
313211	3	0.64	1	2	21111243	4	0.58	2	5
					21111312	3	0.73	1	2
					21111331	3	0.71	1	2
					21111332	4	0.67	1	2
					21111342	4	0.54	1	2
					21211111	2	0.89	1	2
					21311442	5	0.24	1	2

13 vectors 19 vectors

HUI2 attributes are sensation, mobility, emotion, cognition, self-care, and pain HUI3 attributes are vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain.

Table 5: Number of Unique Vectors in the Modified Questionnaire for Students

					_				
Modified									
HUI2	Affected Attributes	Score	n	%	HUI3	Affected Attributes	Score	n	%
100111	0	1.06	1	2	11101011	0	1.10	1	2
100112	1	1.03	1	2	11101111	0	1.05	3	7
100211	1	1.01	1	2	11101112	1	1.00	4	10
101111	0	1.02	3	7	11101113	1	0.91	1	2
101112	1	0.99	2	5	11101131	1	0.98	1	2
102112	2	0.92	4	10	11101212	2	0.93	2	5
120112	2	0.98	1	2	11121013	2	0.81	1	2
122112	3	0.87	1	2	11121113	2	0.78	1	2
200111	1	1.01	5	12	21101011	1	1.07	5	12
200112	2	0.98	2	5	21101012	2	1.01	1	2
201111	1	0.97	6	14	21101111	1	1.03	8	19
201112	2	0.94	2	5	21101112	2	0.97	2	5
201211	2	0.92	2	5	21101113	2	0.89	1	2
201212	3	0.89	1	2	21101132	3	0.90	2	5
202111	2	0.90	3	7	21101211	2	0.96	2	5
202112	3	0.87	2	5	21101221	3	0.85	1	2
202211	3	0.85	1	2	21101231	3	0.89	1	2
203211	3	0.73	1	2	21101331	3	0.76	1	2
210111	1	0.99	1	2	21102312	4	0.71	1	2
212212	4	0.80	1	2	21111111	1	0.97	1	2
301111	1	0.87	1	2	21111243	4	0.58	1	2
					21301211	3	0.81	1	2
21 vectors					22 vectors				

HUI2 attributes are sensation, mobility, emotion, cognition, self-care, and pain.

HUI3 attributes are vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain.

Table 6. COPD Patient Demographics

	n=26	n=77 (sent questionnaires)	n=111 (chart review)
Gender, % female	35	41	37
Age, mean years (Std. Dev.)	69 (9.2)	70 (11.2)	71(11.1)
High School, % complete	46	n.a.	n.a.
Employment status, % retired	60	n.a.	n.a.
Weight, mean kg	75	n.a.	n.a.
Height, mean cm	168	n.a.	n.a.

Note: n.a. = not available.

Table 7. Co-morbidities, n = 26 COPD patients

	Patients Affected	% Patients Affected
Arthritis/Rheumatism	12	46
Arthritis/Back problems	9	35
Osteoporosis	8	31
Hypertension	16	62
Heart Disease	9	35
Asthma	12	46
Chronic Bronchitis:		
Emphysema	24	92
Diabetes	12	46
Thyroid problems	3	12
Urinary incontinence	5	19
Difficulty in Hearing	6	23
Cataracts	5	19
Other allergies	9	35
Sinusitis	8	31

The mean number of other chronic conditions per patient for the 26 patients was 5.1. For the 13 patients receiving the standard-format questionnaire, the mean was 4.5; for the 13 who received the modified format the mean was 5.6.

Table 8. Age and Severity of COPD in COPD Patients

Moderate

Severe

Questionnaire	# patients	Mean Age	# patients	Mean Age
		(Std. Dev.)		(Std. Dev.)
Modified.	7	66 (10.7)	6	72.5 (12.4)
Standard	6	73.5 (6.4)	7	64.7 (4.3)

Table 9. Single-Attribute and Overall Utility Scores for COPD Patients for Standard and Modified Questionnaires

	Minimum	Maximum	Median	Mean	Std Dev
	Std. Mod.				
HUI2					
Sensation	0.65, 0.65	1.00, 0.87	0.87, 0.87	0.87, 0.79	0.08, 0.11
Mobility	0.34, 0.34	1.00, 1.00	0.92, 0.61	0.79, 0.69	0.21, 0.22
Emotion	0.86, 0.00	1.00, 0.86	1.00, 0.86	0.96, 0.71	0.07, 0.25
Cognition	0.86, 0.66	1.00, 1.00	1.00, 0.86	0.94, 0.90	0.07, 0.10
Self-Care	1.00, 0.85	1.00, 1.00	1.00, 1.00	1.00, 0.98	0.00, 0.06
Pain	0.42, 0.42	1.00, 1.00	0.95, 0.85	0.89, 0.83	0.16, 0.17
Overall Score	0.42, 0.30	1.00, 0.85	0.77, 0.57	0.77, 0.59	0.13, 0.17
HUI3					
Vision	0.95, 0.38	1.00, 1.00	0.95, 0.95	0.96, 0.89	0.02, 0.17
Hearing	0.32, 0.48	1.00, 1.00	1.00, 1.00	0.93, 0.91	0.20, 0.19
Speech	1.00, 0.67	1.00, 1.00	1.00, 1.00	1.00, 0.95	0.00, 0.12
Ambulation	0.00, 0.16	1.00, 1.00	0.83, 0.67	0.70, 0.64	0.29, 0.26

Dexterity	0.73, 0.73	1.00, 1.00	1.00, 1.00	0.95, 0.95	0.08, 0.10
Emotion	0.73, 0.33	1.00, 0.91	1.00, 0.91	0.94, 0.77	0.10, 0.21
Cognition	0.92, 0.32	1.00, 1.00	1.00, 0.92	0.96, 0.85	0.04, 0.20
Pain	0.00, 0.48	1.00, 1.00	0.92, 0.77	0.77, 0.82	0.29, 0.15
Overall Score	0.21, 0.09	1.00, 0.82	0.58, 0.34	0.57, 0.39	0.21, 0.24

Table 10. Independent Sample T-Tests for Mean Single-Attribute and Overall Utility Scores for COPD Patients for Standard and Modified Questionnaires

	T-value
HUI2	
Mobility	1.17
Emotion	3.42
Pain	0.89
Overall Score	2.91
HUI3	
Ambulation	0.49
Emotion	2.67
Pain	-0.59
Overall Score	1.99

Note: The critical value for the t-statistic with an alpha of 5% and 12 degrees of freedom, one-tailed test is 1.708.

Table 11. Number of Unique Vectors in the Standard Form for COPD Patients

Standard

Affected Attributes	Score	n	%	HUI3	Affected Attributes	Score	n	%
0	1.00	1	8	11111111	0	1.00	1	8
3	0.76	1	8	11133132	4	0.58	1	8
3	0.77	1	8	21121132	4	0.77	1	8
3	0.81	1	15	21121213	4	0.70	1	8
4	0.84	1	8	21121315	4	0.21	1	8
4	0.82	2	15	21122132	5	0.71	1	8
4	0.71	1	15	21122314	5	0.41	1	8
3	0.76	1	8	21131133	4	0.62	1	8
4	0.72	1	8	21141112	3	0.57	1	8
5	0.42	1	8	21141234	5	0.31	1	8
3	0.55	1	8	21161211	3	0.37	1	8
2	0.81	1	8	23122113	5	0.58	1	8
				25111131	3	0.57	1	8
	Attributes 0 3 3 4 4 4 5 3	Attributes 0 1.00 3 0.76 3 0.77 3 0.81 4 0.84 4 0.82 4 0.71 3 0.76 4 0.72 5 0.42 3 0.55	Attributes 0 1.00 1 3 0.76 1 3 0.77 1 3 0.81 1 4 0.84 1 4 0.82 2 4 0.71 1 3 0.76 1 4 0.72 1 5 0.42 1 3 0.55 1	Attributes 0 1.00 1 8 3 0.76 1 8 3 0.77 1 8 3 0.81 1 15 4 0.84 1 8 4 0.82 2 15 4 0.71 1 15 3 0.76 1 8 4 0.72 1 8 5 0.42 1 8 3 0.55 1 8	Attributes 0 1.00 1 8 11111111 3 0.76 1 8 11133132 3 0.77 1 8 21121132 3 0.81 1 15 21121213 4 0.84 1 8 21121315 4 0.82 2 15 21122132 4 0.71 1 15 21122314 3 0.76 1 8 21131133 4 0.72 1 8 21141112 5 0.42 1 8 21141234 3 0.55 1 8 21161211 2 0.81 1 8 23122113	Attributes 0 1.00 1 8 11111111 0 3 0.76 1 8 11133132 4 3 0.77 1 8 21121132 4 3 0.81 1 15 21121213 4 4 0.84 1 8 21121315 4 4 0.82 2 15 21122132 5 4 0.71 1 15 21122314 5 3 0.76 1 8 21131133 4 4 0.72 1 8 21141112 3 5 0.42 1 8 21141234 5 3 0.55 1 8 21161211 3 2 0.81 1 8 23122113 5	Attributes 0 1.00 1 8 11111111 0 1.00 3 0.76 1 8 11133132 4 0.58 3 0.77 1 8 21121132 4 0.77 3 0.81 1 15 21121213 4 0.70 4 0.84 1 8 21121315 4 0.21 4 0.82 2 15 21122132 5 0.71 4 0.71 1 15 21122314 5 0.41 3 0.76 1 8 21131133 4 0.62 4 0.72 1 8 21141112 3 0.57 5 0.42 1 8 2114124 5 0.31 3 0.55 1 8 21161211 3 0.37 2 0.81 1 8 23122113 5 0.58	Attributes 0 1.00 1 8 11111111 0 1.00 1 3 0.76 1 8 11133132 4 0.58 1 3 0.77 1 8 2112132 4 0.77 1 3 0.81 1 15 21121213 4 0.70 1 4 0.84 1 8 21121315 4 0.21 1 4 0.82 2 15 21122132 5 0.71 1 4 0.71 1 15 21122314 5 0.41 1 3 0.76 1 8 21131133 4 0.62 1 4 0.72 1 8 2114112 3 0.57 1 5 0.42 1 8 21141234 5 0.31 1 3 0.55 1 8 21161211 3 0.37 1 2 0.81 1 8 23122113 5 0.58 1

12 vectors 13 vectors

HUI2 attributes are sensation, mobility, emotion, cognition, self-care, and pain.

HUI3 attributes are vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain.

Table 12. Number of Unique Vectors in the Modified Form for Patients

Modified

HUI2	Affected Attributes	Score	n	%	HUI3	Affected Attributes	Score	n	%
232112	4	0.70	1	8	21131313	4	0.51	1	8
212213	4	0.70	1	8	21111343	4	0.48	1	8
243212	5	0.49	1	8	21152233	6	0.30	1	8
235213	5	0.30	1	8	21131443	5	0.18	1	8
222112	4	0.80	1	8	21121211	3	0.82	1	8
332111	3	0.65	1	8	51141211	3	0.34	1	8
222111	3	0.85	1	8	21121211	3	0.80	1	8
233313	5	0.45	1	8	21131353	5	0.16	1	8
322212	5	0.70	1	8	34131433	6	0.09	1	8
333223	6	0.43	1	8	22321231	6	0.58	1	8
222214	5	0.49	1	8	21333343	7	0.20	1	8
342123	5	0.45	1	8	21123234	6	0.39	1	8
					14151213	4	0.24	1	8

12 vectors 13 vectors

Note: One patient skipped an item and as a result there was complete data for only 12 HUI2 vectors. HUI2 attributes are sensation, mobility, emotion, cognition, self-care, and pain. HUI3 attributes are vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain.

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