Clinically Important Changes in Health-related Quality of Life for Patients with Chronic Obstructive Pulmonary Disease

An Expert Consensus Panel Report

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OBJECTIVE: Without clinical input on what constitutes a significant change, health-related quality of life (HRQoL) measures are less likely to be adopted by clinicians for use in daily practice. Although standards can be determined empirically by within-person change studies based on patient self-reports, these anchor-based methods incorporate only the patients' perspectives of important HRQoL change, and do not reflect an informed clinical evaluation. The objective of this study was to establish clinically important difference standards from the physician's perspective for use of 2 HRQoL measures among patients with chronic obstructive pulmonary disease (COPD).

DESIGN: We assembled a 9-person expert panel of North American physicians familiar with the use of the Chronic Respiratory Questionnaire (CRQ), a disease-specific HRQoL measure, or the generic Medical Outcomes Study Short-Form 36-Item Health Survey (SF-36, Version 2.0) among patients with COPD.

RESULTS: Using 2 rounds of the Delphi process, 1 in-person meeting, and an iterative improvement process for circulating and correcting the final report, the expert panel established small, moderate, and large clinically important change levels for the CRQ and SF-36.

CONCLUSIONS: For this expert physician panel, levels for detecting clinically important differences on the CRQ were equal to or slightly higher than previous studies based on patient-reported differences. Clinically important differences on the SF-36, Version 2.0, were noticeably larger than previous estimates based on cross-sectional differences between clinically defined patient groups.

KEY WORDS: quality of life; COPD; important change; consensus panel; RAND method; Delphi process.

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Chronic obstructive pulmonary disease (COPD) is currently the fourth leading cause of death in the world, and a major cause of chronic morbidity.¹ Unfortunately, clinicians cannot currently offer treatments to most COPD patients that will favorably change the course of this highly prevalent condition. Therefore, the goal of clinical management is to improve patients' health-related quality of life (HRQoL) by relieving symptoms and enhancing functionality.² Structured and validated HRQoL instruments offer the potential of providing an objective framework for the longitudinal evaluation of these important health status measures, which are fundamental to the management of this chronic disease.

Several disease-specific HRQoL instruments have been developed over the past 2 decades to better understand and quantify how COPD affects patients' lives, and to evaluate the effectiveness of treatments designed to manage this often fatal disease.²⁻¹⁵ Of these, the Chronic Respiratory Disease Questionnaire (CRQ) has consistently provided the most responsive measurements of change in individual patients' HRQoL management.¹⁶⁻²⁰ In an effort to understand the changes over time that this instrument captures among patients with chronic airway limitations, the developers defined minimal, moderate, and large differences in the CRQ domains.²¹ They defined a minimal clinically important difference (MCID) as

the smallest difference in a score of a domain of interest that patients perceive to be beneficial and that would mandate, in the absence of troublesome side effects and excessive costs, a change in the patient's management. (p. 408)

Their research design, consisting of an evaluation of the mean domain change within patients anchored on a global assessment of change and a consensus panel of persons familiar with the patients and the instrument, has been replicated by other investigators seeking to understand meaningful intra-individual differences in HRQoL measures.²²⁻²⁴

This approach, however, has been criticized on several grounds. The patients' global change ratings were completely subjective, were based on a single item, and were not evaluated with regard to test-retest reliability.²⁵ In addition, the change levels (minimal, moderate, and large)

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were defined somewhat arbitrarily and were based upon an untested assumption that increases and decreases were symmetric, i.e., that a given level of change (e.g., minimal) can be identified by the same benchmark whether it is an improvement or a decline. Other investigators have questioned the small developmental samples in this study that required the pooling of COPD patients measured by the CRQ with cardiac patients involved in a similar evaluation who were measured by the Chronic Heart Failure Questionnaire (CHQ).^{26,27}

The results from the original CRQ consensus panel have also been challenged.^{26,27} That panel was from a single clinical site, and the published report did not specify the clinical expertise of panel members. In addition, although the CRQ and CHQ instruments are very similar, the results of the consensus panel also involved pooling changes for both the CRQ and CHQ instruments, which assumes that the same change standards should apply to both instruments and both conditions. Recognizing that there were few "clinical" aspects to this investigation, the developers of the CRQ change standards subsequently substituted the term "minimal important difference" for the MCID.²⁸

Despite the many problematic aspects of the CRQ developmental studies, quantifying clinically important increments in HRQoL measures remains an important issue if these instruments are to be routinely and comfortably used by clinicians to enhance their estimation of a COPD patient's disease severity and assessment of the impact on patient care, and ultimately, to improve patient outcomes. Other investigations that tie HRQoL change scores to external evaluations (anchors) of change, and distribution-based studies that use statistical parameters (like the standard deviation) to evaluate individual and group HRQoL changes have appeared in the literature as researchers and practitioners continued to seek standards for assessing important HRQoL differences in COPD-specific measures.²⁹ However, no clinically important change standards have been established for generic HRQoL measures, such as the Medical Outcomes Study Short-Form 36-Item Health Survey (SF-36),³⁰ the most widely-used HRQoL instrument in the world³¹ and one that is frequently used with COPD patients. Although no formal assessments of MCIDs have been performed for the SF-36, studies of cross-sectional differences between clinically defined patient groups have suggested a 3- to 5-point change on any SF-36 scale as clinically important.³²

This report attempts to fill these gaps in the literature by detailing the highly structured process and the resulting clinically important change thresholds for COPD patients established by an expert panel of physicians for the CRQ and the SF-36. Using the consensus development process advanced by researchers at the RAND Corporation, we empanelled 9 physicians from across North America. Each participating physician was experienced in using the CRQ or the SF-36, in addition to other HRQoL questionnaires. The goal of the panel was to reach consensus on how much

change in each domain of these 2 instruments signified small, moderate, and large clinically important differences (CIDs), either improvements or declines, for individuals with COPD.

METHODS

The consensus development conference process, originally developed by the RAND Corporation to evaluate the appropriateness of medical and surgical techniques, synthesizes the opinions of experts with the available evidence to provide detailed assessments.³³ Since its publication, this method of integrating existing knowledge to establish practice standards has been applied to health-related concerns beyond appropriateness, such as the development of indication guidelines of alcohol abuse in older persons³⁴ and the establishment of priorities for quality of care studies.³⁵ The consensus development conference process³⁶ can be described using its 4 procedural stages: *context*, which encompasses the issue that the conference will explore; *panel composition*, where the qualifications of appropriate panelists are determined and panelists are selected to comprise a balanced board; the *pre-panel process*, where background information and relevant literature research are prepared for presentation to the panelists; and, finally, the *panel meeting*, where, through a variety of ways, all panelists convene and seek to achieve an a priori defined level of consensus among participants on the context issue.

Context

The context for the panel conference was to determine the amounts of change in the domain scores of the CRQ and SF-36, Version 2.0, that reflect small, moderate, and large clinically important improvements and declines in HRQoL among COPD patients. This context was communicated to the panelists, although no specific definition of "clinically important change" was provided.

Panel Composition

We began the panel selection process in October 1999 by conducting literature searches of the MEDLINE database (January 1995 to October 1999) and collecting literature pertinent to HRQoL among patients with COPD. We used the search term for "lung disease, obstructive" as both a key word and as text words (obstructive pulmonary disease), and intersected those results with text words that identified each of the HRQoL instruments (CRQ or the SF-36). In order to cast a wider net, the disease term was also intersected with the key word "quality of life." We then reviewed all of the resulting articles from these searches on the basis of the following criteria. First, the article needed to represent an original longitudinal investigation of HRQoL change using at least 1 of the appropriate HRQoL measures. Second, articles using the CRQ or the SF-36 needed to measure and report changes in all 4 CRQ

domains, or in all 8 SF-36 scales. Because of the small number of articles that met this original criterion of domain-reported changes for the CRQ, this assumption was subsequently relaxed. Articles reporting change in the total CRQ score were included, as well as cross-sectional CRQ articles. Third, at least 1 of the article's authors needed to be a North American physician. We felt that the financial and time constraints associated with travel to a panel meeting by physicians not on the continent prohibited their involvement.

Using these criteria, we identified 10 articles. Each member of the panel planning committee (chaired by WMT, and including KWW, KK, ANB, and FDW) reviewed the articles, and determined that all of the 33 physician authors from these 10 articles were suitable to serve as panel members. We then sent (via overnight express delivery) each of the potential panelists a letter that solicited their interest in serving on the panel of expert physicians. We further explained that because each panel must ultimately represent a balance between generalists and specialists, geographic diversity, etc., panel members would be selected from among those who expressed interest in participating. We also included an overview of the study, and requested a list of available dates for attending a panel meeting from those physicians interested in participating. Of the 33 potential panelists, 13 indicated availability and interest in being considered further. One potential panelist nominated a colleague who had several relevant publications just outside the original search window. After review by the panel planning committee, this potential panelist substitution was allowed. From these 14 physicians, the need for balance between generalists and specialists, and for geographic diversity, as well as the logistics of availability for meeting on a single date, led to the final selection of 9 panelists (see acknowledgments) by the planning committee. From these panelists, the chair of the panel planning committee selected the panel's chair (SDF).

Pre-panel Process

Approximately 2 months prior to the panel meeting, we initiated the pre-panel process with the chosen panelists by sending pertinent literature related to HRQoL change measured by the CRQ and the SF-36 among COPD patients, as well as the instruments themselves (the CRQ and the SF-36, Version 2.0). In an attempt to provide realistic evidence related to clinically important changes in individual patients' HRQoL, we also included several retrospective change scenarios developed from COPD outpatients enrolled in a previous longitudinal study of HRQoL.²⁶

To construct these patient scenarios, we identified 15 patients enrolled in the above-mentioned study²⁶ who had 2 clinical encounters (office visits, etc.) on the day or very close to the day of their HRQoL telephone interviews, which were scheduled every 6 months regardless of any clinic visit

schedules. After examining the HRQoL scores of these patients, we focused on the 9 patients who had changes in most of their HRQoL domains between visits. For these patients, we pulled the medical charts to obtain the visit-specific discharge notes and orders. Complete medical chart data were found in a timely manner for 6 of these patients. Blinded to the patients' HRQoL data, 2 physicians (WMT and KK) reviewed these 6 medical charts and reported lung disease and comorbid diagnoses, current medications, history, physical examination results, treatment plans and changes in treatment for the 2 clinical encounters in questions for each patient. The clinical report for each patient was presented to the panelists at the beginning of the patient scenario, followed by the patient's CRQ and SF-36 domain scores from the telephone interviews on or near the date of the clinical encounters, as well as the change score for each domain. The 6 retrospective change scenarios are presented in Appendix A, available on the *Journal's* web page (<http://www.blackwellscience.com/jgi>).

Employing a 2-round Delphi process,³⁷ panelists completed 2 tasks using these materials in Round 1. First, they read and reviewed the selected literature and the actual patient scenarios and indicated what they believed constitutes a minimal, moderate, or large clinically important change (improvement or decline) in HRQoL within each domain of the CRQ and the SF-36. Second, they indicated additional pertinent literature that should be included in the next mailing to all panelists.

We compiled the results and comments from Round 1 and obtained copies of the requested literature. These materials were distributed in a second mailing to the panel, and provided an opportunity for each panelist to survey the field with regard to the other panelists' opinions on the context issues. After reviewing the Round 2 information, panelists again completed the task of reviewing the newly identified literature and indicating what they believed constitutes a minimal, moderate, or large clinically important change (improvement or decline) in each domain of both HRQoL instruments. Prior to the panel meeting, we sent the results from Round 2 to the panelists using the same process.

Panel Meeting

At a 4-hour meeting, the panelists focused on achieving consensus on clinically important change thresholds for small, moderate, and large individual improvement and decline in the domains of the CRQ and the SF-36, Version 2.0. Although panelists did attempt to achieve unanimity, the a priori criterion for consensus required only a substantial majority (all but 2 panelists). Both audiotapes and videotapes of the meeting were made and subsequently transcribed. The meeting transcripts were presented to the panel chair, who drafted a consensus report for circulation to all panelists. Panel members then iteratively modified this report until all accepted it as an accurate reflection of the panel's conclusions. The panel conference activities

received approval from all appropriate Institutional Review Boards.

RESULTS

The panel met in St. Louis, Missouri on June 15, 2000 after reviewing the results of the 2 Delphi rounds of the pre-panel process. Initially, each panelist briefly described his/her method for determining CIDs for the CRQ. Although most of the panel members assigned similar values to small, moderate, and large changes, there was some variation in their approaches. Their methods fell into 4 camps: 1) the consideration of patient score change data from their own successful respiratory rehabilitation or pharmaceutical interventions; 2) the application of a proportion (e.g., 20%, 40%, and 60%) to each measure's scoring range; 3) a triangulation of results from 3 previous investigations,^{21,26,28} where minimal change standards for the CRQ converged at nearly the same levels, and then an extraction of these CRQ results to the SF-36; and 4) the application of Cohen's effect size criteria (0.2, 0.5, and 0.8 standard deviations) for evaluating change.

The panel then discussed the course they would adopt for assigning final values to each scale. It was unanimously agreed that the CIDs should be symmetric so that positive and negative changes in the same category (e.g., a small decline or a small improvement) would uniformly be of the same magnitude. It was also unanimously agreed that the increases from small to moderate and from moderate to large should be arithmetic, increasing incrementally by the value of a small change. Furthermore, there was general agreement that it was usually best to err on the side of accepting a smaller change as important rather than overlooking an important change in an individual patient. Finally, it was noted that, ideally, the smallest CID should be greater than the intrinsic variability of a domain or scale.

The group began with the dyspnea dimension of the CRQ. They first reviewed the results of their earlier Delphi rounds and information about the statistical properties of the scale in several samples of COPD patients. They also considered the number of items in the domain (i.e., 5) and the number of those items that would have to change by the minimal amount to be considered clinically important. For all CRQ dimensions, 1 point represents the smallest possible score change on any item in the domain. The panel came to adopt the term *state change* to describe this minimal movement on a single item. After extensive discussion, the panel reached a consensus for the dyspnea dimension: 3 points represented a small CID, 6 points a moderate CID, and 9 points a large CID. The group then proceeded to apply this process to determine the CIDs for the remaining 3 dimensions of the CRQ (Table 1). For several of the dimensions, however, the panel deliberated with considerable discussion before achieving a consensus.

The panel then proceeded to discuss CID standards for the SF-36, Version 2.0. The panel chair provided a brief

Table 1. Clinically Important Differences* for the Chronic Respiratory Disease Questionnaire (CRQ)

CRQ Dimension (Number of Items) [†]	Small Change	Moderate Change	Large Change
Dyspnea (5)	3	6	9
Fatigue (4)	2	4	6
Emotional function (7)	5	10	15
Mastery (4)	3	6	9

* Clinically important differences are reported for total domain score changes, not the average change per item.

[†] The value of a single state change for all items in all dimensions is 1.

background on prior studies of clinically important changes as measured by the SF-36, Version 1.0. Again, the panel reviewed the number of items and the different values for state changes on each SF-36 scale, as well as the modal responses from the panel members during the Delphi process. There was also discussion about individual panelists' experiences with the use of the SF-36 and with the known standard deviations and standard errors of measurement for each of the 8 SF-36 scales among samples of COPD patients. After attaining initial consensus on the SF-36 scales, the panel then reviewed all the results once again to ensure that they had been consistent among scales in selecting the CIDs shown in Table 2. Small changes on the SF-36, Version 2.0 scale scores ranged from 8.3 to 12.5, while moderate changes ranged from 16 to 25 and large changes ranged from 25 to 37.5 points on these 0–100 scales.

DISCUSSION

Standards for establishing the amount of change over time needed in a HRQoL measure in order for that change to be considered important or relevant can be determined empirically by within-person change studies. However, such anchor-based methods incorporate only the patients' perspectives of important change, and do not reflect an informed clinical evaluation of HRQoL change. As stated in 1998 by Carolyn Clancy and John Eisenberg in *Science*, "Additional work to enhance the interpretability of outcome measures, particularly in terms of clinical significance, is needed to increase the usefulness of these tools. Clinicians are unlikely to use patient-reported outcome measures routinely unless the reports are as familiar to them as blood pressure and other physiological measures." (p. 256)³⁸ As a first step in developing standards for "clinically important differences" for the disease-specific CRQ and the generic SF-36, Version 2.0 when used in patients with COPD, we assembled a 9-person expert panel of North American physicians familiar with the use of at least 1 of these HRQoL measures among patients with COPD. Using 2 rounds of the Delphi process, 1 in-person meeting, and an iterative improvement process for circulating and correcting the final

Table 2. Clinically Important Differences and State Changes for SF-36, Version 2.0

SF-36 Scale	Small Change	Moderate Change	Large Change	Value of Each State Change
Physical functioning	10	20	30	5
Role-physical	12.5	25	37.5	6.25
Bodily pain	10	20	30	10
General health	10	20	30	5
Vitality	12.5	25	37.5	6.25
Social functioning	12.5	25	37.5	12.5
Role-emotional	8.3	16.7	25	8.3
Mental health	10	20	30	5

SF-36, Medical Outcomes Study Short-Form 36-Item Health Survey.

report of the panel meeting by the respective panel chairman, CIDs from an expert panel were established for each HRQoL measure.

Our panel's levels for detecting CIDs on the CRQ were on average slightly higher than previously investigated change levels for the CRQ based on patient-perceived differences. In the 1989 study by Jaeschke et al., an average change per item of 0.5 was considered a minimal (small) important difference in the dyspnea, fatigue, and emotional function dimensions of the CRQ.²¹ When multiplied by the number of items in each dimension, this equates to small CID thresholds of 2.5, 2.0, and 3.5, respectively, in dyspnea, fatigue, and emotional function. In contrast, this expert panel reached consensus on small CID thresholds of 3, 2, and 5, respectively, which are attainable integer change scores for individuals. However, similar to the Jaeschke et al. results, the panel incremented these small CIDs by multipliers of 2 and 3 to set the moderate and large CID standards.²¹ The panel also set CID levels for the mastery dimension, which had been excluded from the Jaeschke et al. investigation because of the lack of a similar domain in the simultaneously studied CHQ. When we applied these new standards for the evaluation of CRQ dimensional change scores among 393 outpatients with COPD in the a previous HRQoL Study²⁶ and compared the classifications (no change, small, moderate, or large) with the cutpoints reported by Jaeschke et al., 51 (13%) of these outpatients were classified differently in the dyspnea dimension, while 107 (27%) had different classifications in the emotional function domain.

Determining CIDs for the SF-36 scales proved to be a more challenging task for the panel that was complicated by the instrument's differing scale increments (i.e., the numeric value of a state change). Nonetheless, the panel adopted an informed and practical approach by considering the possible score changes that can result on each SF-36 scale (noted in the state change column of Table 2). They then compared these state changes to their own experiences with COPD patients, as well as to distribution-based methods that have been used to interpret HRQoL change, and agreed on the reported levels. The magnitude of these change levels (≥ 8.3 points) should shed light on

the widely held but poorly substantiated belief that a 3- to 5-point change on an SF-36 scale indicates a clinically important intra-individual difference. This belief stems from a 1989 report of SF-20³⁹ cross-sectional data collected from a large study of patients with and without chronic health conditions.³² In those data, the predicted average on the health perceptions scale (mean = 69.1) for the hypertension group ($N = 2,708$) was 3.5 points lower and statistically different ($P < .001$) from the respective scale average (mean = 72.6) for those participants with no self-reported chronic conditions ($N = 2,595$), after controlling for age, gender, education, and income. The "significance" of this cross-sectional difference, however, was driven by very large sample sizes, and was not determined using data that assessed patient change over time.

It is important to note that we did not provide definitions of *clinically important differences* or the magnitudes of change (*small, moderate, and large*) to the panelists. Instead, we hoped that the physician panelists, each experienced in the use of these measures, would come to their own understanding of these terms. Although prior work by Jaeschke et al. attempted to define a *minimally clinically important difference*, that definition has some shortcomings.²¹ First, it directly speaks to score differences that are perceived *beneficial* to the patient, but does not address detrimental changes. Even if one considers an appropriate interpretation of this definition to include avoiding deterioration as a benefit, the patient with no perceived change is not properly recognized or classified. Second, even when the clinician and the patient agree that an important improvement or decline in HRQoL has occurred, this may not necessarily "mandate a change in the patient's management," especially if such a change would be detrimental to the care of the patient,²⁴ or if all clinical options have been exhausted. We were pleased that our panelists, who are experienced in both providing clinical care for and performing research among patients with COPD as well as being experienced in the use of these HRQoL measures, came to their own interpretations of CIDs and the magnitude of those differences. Moreover, their interpretations converged when the panelists quantified these changes in the CRQ and SF-36 domains.

Despite the extensive efforts we undertook to obtain reliable and accurate results in this study, potential shortcomings remain and warrant mention. First, we employed only a single panel of physicians. Studies by RAND with several physician panels demonstrated substantial heterogeneity in their assessments of the appropriateness of different medical procedures.⁴⁰ However, the panel employed in the present study was comprised only of physicians who had substantial clinical and research experience with the task at hand, while this was not the case in the RAND studies. Second, it is possible that panelists were biased by the results of prior research and might have arrived at different conclusions had they been unfamiliar with that literature. Using experienced physicians, such exposure to earlier studies was unavoidable. Moreover, the widely varying approaches employed by different panelists at the start of the process strongly suggest that few were biased in this fashion. Third, when there are limited clinical data, clinicians may require a greater change in the data that are available before judging that a clinical change has occurred. That is, when clinical information is minimal, the recognition of clinical change will be conservative. And finally, although we made every effort to maintain the integrity of the consensus process, the possibility remains that some members of the panel succumbed to well-known influences of group process.⁴¹ Coupled with this, there was no measure of the reliability of the panelists' judgments about clinically significant change. While the expert panel process is designed to add validity to such judgments, we cannot report a measure of actual agreement.

Establishing clinical change standards for HRQoL measures requires both clinical insight into the etiology, symptoms, and progression of the disease, as well as patient insight related to living with the chronic disease. Using the RAND consensus method for integrating the expert physicians' opinions with the available evidence, our results provide clinicians with usable standards for assessing change in the HRQoL of COPD patients seen in clinical practice, and in doing so, enhance their estimation of a COPD patient's disease severity and assessment of impact on patient care, and ultimately, improve patient outcomes. These results also provide COPD researchers with standards for evaluating the results of HRQoL research investigations among patients with COPD. However, these panel results reflect the judgment of only 1 group of physician experts. We must now compare the expert physicians' estimates of important change to the change estimates of patients with COPD. Moreover, additional insight on CIDs can be obtained from the physicians who routinely treat these COPD patients and who can directly observe their HRQoL changes.⁴² Contrasting these physicians' assessments of HRQoL changes with those of their COPD patients will further elucidate how clinically important differences and patient-perceived differences in HRQoL compare.

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APPENDIX A

Retrospective Change Scenario for COPD Disease Patient No. 1

Basic Information:**Age:** 61**Sex:** female**Disease diagnosis:** COPD**Comorbid diagnoses:**

hypertension

anemia

obesity

osteoarthritis

chest pain

Current medications:

acetaminophen

benazepril

ecotrin

ibuprofen

isosorbide

nitroglycerine

Visit No. 1: 6/23/95**Clinical information:**

History: Patient without complaints. Losing weight (walking, eating less). Weight down 8 lbs. Denies chest pain or dyspnea on exertion. Says she walked about 6 miles last month after visiting her daughter across town. Right knee doing better; ran out of ibuprofen 2 weeks ago, which she was using twice a day. Tylenol helps some as well. No GI symptoms. Patient is a non-smoker.

Physical exam: BP 125/58, pulse 70. Weight 211 lbs. Lungs clear bilaterally. Heart with 2/6 systolic ejection murmur at apex and left lower sternal border, without radiating to carotids. Abdomen obese, non-tender. No lower extremity edema. Distal pulses 2+.

Test results: PFTs more consistent with restrictive disease.

Treatment plan: Check A7 today. Encouraged to continue weight loss for obesity. Continue isosorbide for questionable history of CAD. Use PRN NSAIDs for osteoarthritis, but encourage use of Tylenol as much as possible. Mammogram before next visit.

Follow-up in 6 months to Medicine Clinic.

Changes in treatment: None.

Visit No. 2: 1/5/96**Clinical information:**

History: No chest pain. Not using inhalers except as needed. Has dyspnea after 4-5 blocks of walking. Complaints of decreased mobility and mild pain in right third and fourth fingers, worse in the morning but gets better during the day. Not affecting daily activities. Blood pressure stable on benazepril. Patient requesting disability forms to be completed.

Physical exam: BP 125/58, heart rate 62, weight 211 (unchanged). Lungs clear bilaterally. Heart shows 2/6 systolic ejection murmur at left lower sternal border without radiation. Extremities: right third PIP joint tender to palpation, no catching or crepitus. No edema.

Test results: Old stress test negative.

Treatment plan: Continue same antihypertensive medication. Continue prn albuterol inhaler for questionable COPD (begun in Medicine Clinic 1/5/96). Continue prn ibuprofen for osteoarthritis. Follow questionable early trigger finger on right hand.

Follow-up in 6 months to Medicine Clinic.

Changes in treatment: Discontinue isosorbide and follow chest pain symptoms, but continue prn nitroglycerin and daily aspirin.

HEALTH-RELATED QUALITY OF LIFE DATA

Domains of the CHQ	Interview 1 Date: 6/30/95	Interview 2 Date: 1/05/96	Change (T2 – T1)
Dyspnea	35	25	-10
Fatigue	25	18	-7
Emotional Function	38	44	6
Mastery	26	26	0
Domains of the SF-36			
Physical Functioning	0.00	45.00	45.00
Role-Physical	100.00	75.00	-25.00
Bodily Pain	72.00	52.00	-20.00
General Health Perception	72.00	67.00	-5.00
Vitality	75.00	25.00	-50.00
Social Functioning	50.00	25.00	-25.00
Role-Emotional	100.00	0.00	-100.00

Retrospective Change Scenario for COPD Disease Patient No. 2

Basic Information:**Age:** 52**Sex:** male**Disease diagnosis:** COPD**Comorbid diagnoses:**

peripheral vascular disease
 diabetes with retinopathy
 hypertension
 above-the-knee amputation

back pain
 venous stasis

Current medications:

albuterol inhaler
 benazepril
 Darvon-N
 ferrous sulfate
 furosemide
 insulin (NPH and regular)
 KCl
 nifedipine XL

Visit No. 1: 3/25/96**Clinical information:**

History: (Nurse visit for blood pressure check) Benazepril was increased to 20 mg/day the previous week in Medicine Clinic when he was also found to not be doing his Accuchecks for his diabetes. Had Eye exam in June. Had an ulcer on his left foot and had been seen in Orthopedics Clinic the previous week.

Physical exam: Done on the physician's visit the previous week showed BP 184/94, pulse 86, weight not recorded due to patient's being in a wheelchair. Noted to be obese. Neck without venous distension or masses. Chest with soft crackles, but otherwise clear. Heart without murmurs. Extremities show right stump clean with 1+ edema. Left foot bandaged and not examined. BP on 3/25/96 was 170/100.

Test results: Sodium 144, potassium 3.6, chloride 104, bicarbonate 30 (elevated). BUN 14, creatinine 1.9, glucose 111, glycated hemoglobin 8.3.

Treatment plan: Continue same blood pressure medication on 3/25/96. The previous week, the physician planned to check a glycated hemoglobin, lipid profile, urinalysis, and do home blood glucose monitoring. Follow-up at Medicine Clinic in 1 week for blood pressure check.

Changes in treatment: Increase benazepril to 20 mg/day.

Visit No. 2: 9/23/96**Clinical information:**

History: (Nurse visit for diabetes) Started new insulin dose after Medicine Clinic visit the previous week (9/16/96) when he had a regular physician visit. The physician noted that the patient had not been able to check his blood sugar at home because he lost his Accucheck meter 2 months previously. Also has not checked blood pressure at home. Left foot ulcer was healed. No increase in leg swelling. Not taking his furosemide at night because it makes him urinate frequently. On 9/23/96, the blood sugars checked at home remained elevated. Continues to have inconsistent schedule of meals and insulin injections.

Physical exam: BP on 9/16/96 was 192/94, pulse 84, with no weight recorded. Patient was in no acute distress with quiet respirations. Lungs were clear. Heart was without murmurs. Abdomen obese but otherwise unremarkable. Left leg showed a healed ulcer on his foot and non-pitting edema.

Test results: None.

Treatment plan: On 9/16/96: replace glucometer, check blood sugars at home, and schedule for diabetic teaching. On 9/23/96: reinforced importance of regular meals and treatment with insulin. Patient will get an alarm clock to help him maintain his insulin schedule. Consider starting metformin on next visit. Follow-up in 1 week to Medicine Clinic for glucose check.

Changes in treatment: Increase insulin dose.

HEALTH-RELATED QUALITY OF LIFE DATA

Domains of the CHQ	Interview 1 Date: 3/27/96	Interview 2 Date: 9/25/96	Change (T2 – T1)
Dyspnea	16	23	7
Fatigue	13	18	5
Emotional Function	30	36	6
Mastery	11	20	9
Domains of the SF-36			
Physical Functioning	15.00	18.75	3.75
Role-Physical	0.00	0.00	0.00
Bodily Pain	31.00	51.00	20.00
General Health Perception	15.00	35.00	20.00
Vitality	55.00	60.00	5.00
Social Functioning	50.00	87.50	37.50
Role-Emotional	33.33	100.00	66.67
Mental Health	56.00	80.00	24.00

Retrospective Change Scenario for COPD Disease Patient No. 3

Basic Information:**Age:** 66**Sex:** female**Disease diagnosis:** COPD**Comorbid diagnoses:**

Schizophrenia

hypertension

knee pain

positive PPD

Current medications:

albuterol inhaler

pseudoephedrine

Maxzide

trifluoperazine

Visit No. 1: 4/11/95**Clinical information:**

History: Patient seen in Medicine Clinic one month previously for runny nose, productive cough with yellow sputum, and dyspnea on exertion. Oxygen saturation at that time was 93% (FIO₂ not specified). On previous visit, she had end-expiratory wheezes without crackles. Patient was given the diagnosis at that visit of bronchitis with COPD exacerbation, and treated with amoxicillin, pseudoephedrine, and albuterol inhaler prn. Also scheduled pulmonary function studies. On 4/11/95, patient complained of swelling in her abdomen and feeling a "knot" in her right lower quadrant. She had a history of cervical and breast cancer.

Physical exam: BP 172/89, pulse 89, weight 166 (increased 6 lbs over past month). Abdomen obese without masses or organomegaly. No other examination documented.

Test results: FEV1 1.29 liters (63% of predicted), FVC 2.18 (78% of predicted).

Treatment plan: Continue inhalers. Obtain CT scan for questionable abdominal mass. Follow-up in 1-2 months to Medicine Clinic.

Changes in treatment: Restart Maxzide for hypertension.

Visit No. 2: 10/17/95**Clinical Information:**

History: Patient doing well. Out of blood pressure medications. Only 1 episode of wheezing in the last few months.

Physical exam: BP 168/80, pulse 84, weight 181 (increased 15 lbs). Lungs clear. Neck without bruits. Heart with an S4 gallop, but no S3.

Test results: CT scan showed renal cyst and ventral hernia.

Treatment plan: Continue albuterol as needed for COPD/reactive airways disease. Continue isradipine for hypertension. Follow-up in 6-7 months to Medicine Clinic; get mammogram at that time.

Changes in treatment: Discontinue Maxzide for hypertension.

HEALTH-RELATED QUALITY OF LIFE DATA

Domains of the CHQ	Interview 1 Date: 4/17/95	Interview 2 Date: 10/17/95	Change (T2 – T1)
Dyspnea	35	31	–4
Fatigue	18	25	7
Emotional Function	36	39	3
Mastery	20	27	7
Domains of the SF-36			
Physical Functioning	60.00	33.33	–26.67
Role-Physical	100.00	100.00	0.00
Bodily Pain	100.00	100.00	0.00
General Health Perception	78.33	87.00	8.67
Vitality	70.00	65.00	–5.00
Social Functioning	100.00	100.00	0.00
Role-Emotional	100.00	100.00	0.00
Mental Health	60.00	76.00	16.00

Retrospective Change Scenario for COPD Disease Patient No. 4

Basic Information:**Age:** 74**Sex:** female**Disease diagnosis:** COPD**Comorbid diagnoses:**

atrial fibrillation
 congestive heart failure
 hypertension
 obesity
 renal insufficiency
 CAD

Current medications:

albuterol inhaler and nebulized solution	ipratropium inhaler
beclomethasone inhaler	KCl
benazepril	nifedipine XL
digoxin	TheoDur
furosemide	warfarin

Visit No. 1: 3/17/95**Clinical information:**

History: Recently discharged after COPD exacerbation requiring mechanical ventilation. Has been doing well since then. Breathing comfortably. No cough, fever, or chills. Still losing weight with Slim Fast. Plays Eucre once a week and asking if he can have an occasional beer.

Physical exam: BP 108/46, pulse 68, weight 268 lbs. Lungs clear. Heart shows 2/6 systolic ejection murmur at left lower sternal border. Abdomen unremarkable. Extremities show 1+ pitting edema.

Test results: Many from recent hospitalization, but none commented upon in note.

Treatment plan: Continue inhaled steroids, bronchodilators, and TheoDur for reactive airways disease. Continue diuretics, afterload reduction, and inotropes for left ventricular dysfunction. Continue coumadin for atrial fibrillation. Try to obtain hospital bed through Social Work. Follow-up to obtain INR in 1 week, call if INR >3 or <2. Follow-up to Medicine Clinic in 4-6 months.

Changes in treatment: None.

Visit No. 2: 9/15/95**Clinical Information:**

History: In for routine office visit. Complains of occasional dyspnea on exertion and cough productive of whitish sputum. No fevers. Has dry, irritated eyes.

Physical exam: BP 101/56, pulse 86, weight 266 (down 2 lbs). HEENT normal except 2X2 cm non-tender moveable supraclavicular lymph node. Lungs clear. Heart shows 2/6 systolic ejection murmur, but no gallops. Abdomen unremarkable. There is a trace of lower extremities edema.

Test results: None.

Treatment plan: Continue inhaler regimen for COPD. Check INR. Consider giving artificial tears for dry eyes. Consider Eye appointment in the future. Follow-up on INR check in 4 weeks, Medicine Clinic in 2 months.

Changes in treatment: None.

HEALTH-RELATED QUALITY OF LIFE DATA

Domains of the CHQ	Interview 1 Date: 3/22/95	Interview 2 Date: 9/15/95	Change (T2 – T1)
Dyspnea	18	15	–3
Fatigue	19	6	–13
Emotional Function	33	18	–15
Mastery	16	11	–5
Domains of the SF-36			
Physical Functioning	68.75	30.00	–38.75
Role-Physical	100.00	0.00	–100.00
Bodily Pain	80.00	10.00	–70.00
General Health Perception	20.00	6.25	–13.75
Vitality	50.00	5.00	–45.00
Social Functioning	100.00	62.50	–37.50
Role-Emotional	66.67	100.00	33.33
Mental Health	76.00	28.00	–48.00

Retrospective Change Scenario for COPD Disease Patient No. 5

Basic Information:**Age:** 72**Sex:** male**Disease diagnosis:** COPD**Comorbid diagnoses:**

pleural effusion
decubitus ulcer
laryngeal cancer, s/p resection

Current medications:

albuterol inhaler
ipratropium inhaler
triamcinolone inhaler
metoclopramide

ranitidine
Robitussin
acetaminophen with codeine

Visit No. 1: 10/24/95**Clinical information:****History:** Presents for follow-up. He feels better. On antibiotics for bronchitis.**Physical exam:** BP 125/70, pulse 89, weight 167 lbs. S/P vocal chord excision on exam. Lungs show bibasilar rhonchi. Distant heart sounds. Unremarkable abdomen.**Test results:** None.**Treatment plan:** Continue same meds for stable COPD. Follow-up at ENT clinic for laryngeal cancer; 6 months to Medicine Clinic.**Changes in treatment:** None.**Visit No. 2: 7/2/96****Clinical Information:****History:** Had follow-up with ENT the previous week. Complains of pain in left shoulder and hands. Otherwise feels pretty well.**Physical exam:** BP 118/70, pulse 76, weight 174 (up 7 lbs). In no acute distress. Lungs show a few crackles in the right lung. Heart exam normal. Left shoulder and hands tender but no head, redness, or swelling.**Test results:** None.**Treatment plan:** Continue acetaminophen for shoulder and hand pain. Give pneumovax. Follow-up in 6 months at Medicine Clinic.**Changes in treatment:** None.**HEALTH-RELATED QUALITY OF LIFE DATA**

Domains of the CHQ	Interview 1 Date: 10/24/95	Interview 2 Date: 7/02/96	Change (T2 – T1)
Dyspnea	22.50	26.67	4.17
Fatigue	16	16	0
Emotional Function	28	34	6
Mastery	18	19	1
Domains of the SF-36			
Physical Functioning	55.00	50.00	–5.00
Role-Physical	66.67	100.00	33.33
Bodily Pain	84.00	51.00	–33.00
General Health Perception	50.00	35.00	–15.00
Vitality	50.00	50.00	0.00
Social Functioning	62.50	62.50	0.00
Role-Emotional	100.00	66.67	–33.33
Mental Health	64.00	48.00	–16.00

Retrospective Change Scenario for COPD Disease Patient No. 6

Basic Information:**Age:** 65**Sex:** male**Disease diagnosis:** COPD**Comorbid diagnoses:**

positive PPD

CAD

colon polyp

gout

vocal cord polyp

weight loss

glaucoma

Current medications:

albuterol inhaler

aspirin

nitroglycerine

multivitamins

pilocarpine eye drops

betaxolol eye drops

Visit No. 1: 1/29/96**Clinical information:****History:** No complaints. No other comments or history given.**Physical exam:** BP 124/69, pulse 75, weight 114 lbs. Lungs clear. No other examination documented.**Test results:** None.**Treatment plan:** Continue current medications. Follow-up in 6 months to Medicine Clinic.**Changes in treatment:** None.**Visit No. 2: 7/29/96****Clinical information:****History:** Follow-up for multiple complaints. "Anxiety attacks" manifested by episodic non-exertional dyspnea. Lasts 10-15 minutes. No chest pain, dizziness, etc., but he takes nitroglycerine for relief. Also notes urinary frequency with nocturia every hour, but no pain. Abdominal pain in mornings, relieved by eating. Decreased oral intake due to finances. Smokes 1 cigarette every 2-3 days now. Denies alcohol or IV drug abuse. Feels down, but denies suicidal thoughts.**Physical exam:** BP 119/73, pulse 79, weight 113 (down 1 lb). In no acute distress. Lungs clear except for questionable left upper lobe rub. Heart: 3/6 holosystolic murmur with a diastolic murmur also present. No lower extremity edema.**Test results:** Hemoglobin 14.9, WBC 6.0. Electrolytes normal except for a bicarbonate of 33. BUN and creatinine normal. SMA-12 normal except for SGOT/ALT of 47 (elevated). Urinalysis shows 2-5 white blood cells and 5-10 red blood cells per high power field. EKG shows clockwise rotation consistent with either pulmonary disease or prior anterior myocardial infarction.**Treatment plan:** Multiple unrelated complaints with labs not revealing. Suspect depression or other emotional component along with medical problems. Refer to Midtown Mental Health. Try doxazosin for urinary frequency, and check UA. Follow-up in 2 weeks to Medicine Clinic.**Changes in treatment:** Add doxazosin for presumed BPH. Add nutritional supplements.**HEALTH-RELATED QUALITY OF LIFE DATA**

Domains of the CHQ	Interview 1 Date: 1/23/96	Interview 2 Date: 7/30/96	Change (T2 – T1)
Dyspnea	5	5	0
Fatigue	23	8	-15
Emotional Function	39	23	-16
Mastery	19	10	-9
Domains of the SF-36			
Physical Functioning	20.00	10.00	-10.00
Role-Physical	100.00	0.00	-100.00
Bodily Pain	100.00	61.00	-39.00
General Health Perception	45.00	40.00	-5.00
Vitality	70.00	5.00	-65.00
Social Functioning	62.50	37.50	-25.00
Role-Emotional	100.00	33.33	-66.67
Mental Health	100.00	68.00	-32.00