The relationship of health beliefs knowledge of disease and social support to health-related quality of life in patients with inflammatory bowel disease

Michael T. Bach

The University of Montana

Follow this and additional works at: https://scholarworks.umt.edu/etd

Let us know how access to this document benefits you.

Recommended Citation

https://scholarworks.umt.edu/etd/6208

This Thesis is brought to you for free and open access by the Graduate School at ScholarWorks at University of Montana. It has been accepted for inclusion in Graduate Student Theses, Dissertations, & Professional Papers by an authorized administrator of ScholarWorks at University of Montana. For more information, please contact scholarworks@mso.umt.edu.
Permission is granted by the author to reproduce this material in its entirety, provided that this material is used for scholarly purposes and is properly cited in published works and reports.

**Please check "Yes" or "No" and provide signature**

Yes, I grant permission  

No, I do not grant permission  

Author's Signature:  

Date: 10/23/00  

Any copying for commercial purposes or financial gain may be undertaken only with the author's explicit consent.

8/98
The Relationship of Health Beliefs, Knowledge of Disease, and Social Support to Health-Related Quality of Life in Patients with Inflammatory Bowel Disease

by

Michael T. Bach
B.S., Northern Michigan University, 1997

Presented in Partial Fulfillment for the Degree of Masters of Arts

The University of Montana

October 2000
Abstract

Bach, Michael T., M.A. October, 2000 Psychology

The Relationship of Health Beliefs, Knowledge of Disease, and Social Support to Health-Related Quality of Life in Patients with Inflammatory Bowel Disease

Director: D. Balfour Jeffrey, Ph.D.

A great deal of research has been done to develop treatments that alleviate the physical symptoms of inflammatory bowel disease (IBD). In addition, the effects of pharmaceutical and surgical interventions on a patient’s health-related quality of life (HRQOL) are currently acknowledged as important considerations. Despite this research, however, and despite interest in the psychological factors that may play an etiological role in IBD, little research has been done to determine the situational and personality variables that contribute to HRQOL in IBD.

The primary hypothesis of this study was that a person’s disease activity, health beliefs, knowledge about IBD, and satisfaction with social support will account for more of the variance in HRQOL scores than will disease activity alone. To test this hypothesis, subjects with IBD were recruited from doctors’ offices, an on-line chat group, and an IBD newsletter, and they completed several questionnaires that measured the above constructs. Stepwise multiple regression and correlational methods revealed that, although disease activity was a significant predictor of all aspects of HRQOL, of the remaining variables, only satisfaction with social support provided additional predictive ability. Post-hoc analyses suggest that social support may be a better predictor of HRQOL in ulcerative colitis patients than in those with Crohn’s disease. Analyses of the HRQOL measurement (the IBDQ) suggest that it is a valid and reliable instrument, but that the four subscales are too highly correlated to be treated as measuring separate components of HRQOL.

Future research should continue to refine the IBDQ and to clarify the conceptual definition of HRQOL. In addition, the question of whether ulcerative colitis and Crohn’s disease patients differ with respect to the role of social support should be addressed, in order to help both groups of patients experience the highest possible degree of HRQOL.
# Table of Contents

Abstract ................................................. ii

List of Tables .......................................... vi

Acknowledgements ...................................... vii

Chapter

1. Introduction

   Overview .............................................. 1

   A Description of IBD ................................ 2

   A Clarification of This Study's Purpose .......... 4

   Research Concerning the Pharmaceutical Treatment of IBD 6

   A Popular Measure of Disease Activity—the CDAI .... 7

   Other Disease Activity Measures ................. 11

   The Chapel Hill Index .............................. 12

   Objective vs. Subjective Measures of Disease Activity .... 14

   Quality of Life and HRQOL: Background and Definitions .... 16

   Criticisms of Generic and Global HRQOL Instruments .... 19

   The IBDQ: A Disease-Specific HRQOL Instrument .... 20

   Other Health-Related Quality of Life Scales ........ 27

   Research Concerning HRQOL in IBD Patients ........ 31

   The Use of HRQOL Instruments as Outcome Measures in Clinical Trials 32

   The Relationship Between Disease Activity and HRQOL .... 34

   Theory About Factors that Influence HRQOL in IBD Patients .... 36

   The Relationship of Health Locus of Control to HRQOL in Other Groups 37

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.
G. Institutional Review Board Proposal. 102
H. Participant Instructions 106
I. IBDQ Items According to Subscale 107
J. Means and Standard Deviations for Scales in the Crohn's Disease and Ulcerative Colitis Groups 109
K. Announcement of Study in IBD Newsletter 110
List of Tables

1. Demographic Features of 62 IBD Patients ........................................... 62
2. Mean, Standard Deviation, Range, and Total Possible of the Scales .......... 63
3. Regression Analyses for IBDQ Subscales and Total Score .................. 65
4. Scale Intercorrelations of the IBDQ ..................................................... 66
5. Probabilities and Partial Correlation Coefficients of Excluded Variables in the Five Regression Equations ........................................... 68
6. Interaction Between Disease Activity and Social Support .................. 69
7. Regression Analyses for Crohn’s Disease vs. Ulcerative Colitis .......... 70
8. Probabilities and Partial Correlation Coefficients for Excluded Variables in Ulcerative Colitis Patients ........................................... 71
Acknowledgements

No work would be complete without a word of thanks to those people who have made it possible. I could never see such a large project through to completion on my own, thus it is only fitting to include such a thanks at its beginning. I would like to thank:

Bal Jeffrey, my thesis advisor, who has made innumerable and valuable suggestions to me and who has consistently shown a keen ability to solve would-be problems.

My committee members, John Klocek, David Schulberg, and Sharon Uhlig, for the excellent suggestions made at my prospectus meeting and for allowing me some flexibility with the sample size.

Dr. Noren, for without your willingness to participate, I would never have begun the study.

Dr. Morris, Dr. Murney, and Dr. Travis for allowing me to place questionnaires in your offices.

All the nurses who did the actual distributing of questionnaires.

Cathy Michalec of the Crohn’s and Colitis Foundation of America, who enthusiastically suggested a posting of the study in the Foundation’s newsletter and distribution of questionnaires to support groups.

John Caruso, for taking the time to consult with me regarding several statistical analyses.

Tom and Barb Bach, who encouraged me to excel not only academically, but in all areas of my life through their instruction and example.

My wife Jen, who has encouraged me to continue despite the tremendous sacrifice of time and energy. If I didn’t feel your support, I wouldn’t have finished.

Alaina. You haven’t been alive as long as this project has been underway, but you have shown much interest in the printing of rough drafts.

Lastly, but certainly not in the least, the LORD, for giving me the peace of mind necessary to accomplish tasks in this life, and a sure hope for the life to come.
The Relationship of Health Beliefs, Knowledge of Disease, and Social Support to Health-Related Quality of Life in Patients with Inflammatory Bowel Disease

Chapter 1

Introduction

Overview

This study will attempt to clarify how several different factors are related to health-related quality of life in patients with inflammatory bowel disease, or IBD. First, this disease will be described, and research concerning its pharmaceutical treatment will be discussed. It will then be argued that symptom description alone, as measured by current disease activity indices, does not fully capture the patient’s experience; health-related quality of life is also important.

After discussing the definitions of quality of life and health-related quality of life (HRQOL), literature describing what is known about HRQOL in IBD patients will be presented. Because current research indicates that disease activity alone does not fully account for variance in HRQOL scores, the relationship between disease severity and HRQOL will also be addressed. Based on a literature review, the following additional factors HRQOL appear worth investigating: health locus of control; patient knowledge of disease; and satisfaction with social support.

To answer the question “How do the above factors relate to health-related quality of life in IBD patients?” questionnaires were filled out by subjects seeing gastroenterologists in Marquette, MI and Missoula, MT. Additional subjects were also recruited by posting a study announcement on an Internet message board and in an IBD newsletter. All patients filled out the questionnaires at home, then mailed them to the
experimenter in Montana. The relationship between the above variables and HRQOL was determined by calculating several multiple regression equations and correlation coefficients. In addition, the internal consistency and intercorrelation of the subscales of the HRQOL instrument were computed.

A Description of IBD

Inflammatory bowel disease affects about 400,000 people in the United States (Mendeloff, 1980) and millions of people worldwide. Consisting of two different illnesses, Crohn’s disease and ulcerative colitis, IBD is a lifelong condition characterized by periods of activity and remission that continue throughout a person’s life. Although its genetic and environmental precursors have been studied, the etiology of IBD is presently unknown (Reif, Klein, Lubin, Farbstein, Hallak, & Gilat, 1997). Men and women are affected roughly equally by IBD, and it is usually diagnosed before they are 30 (Mendeloff, 1980). Although Crohn’s disease and ulcerative colitis share some of the same symptoms, such as diarrhea and abdominal pain, the two present themselves differently to both patients and clinicians.

Crohn’s disease can inflame any part of the alimentary tract, from the mouth to the anus, although this inflammation occurs primarily in the small and large intestines (Whitehead, 1980). During an exacerbation, its sufferers can experience severe abdominal pain, weight loss, fatigue, and diarrhea (Myren, Bouchier, Watkinson, Softley, Clamp, & deDombal, 1984), as well as joint pain and complications in the perianal area (Kornbluth, Salomon, & Sachar, 1993). Examination often reveals scar tissue, which may narrow the intestines in different areas. The inflammation caused by Crohn’s
disease is typically deeper than the first layer, or mucosa, of the intestines, and can lead to fistulae, abnormal passages between internal organs (Kornbluth, Salomon, & Sachar, 1993). There is currently no cure for Crohn's disease and, although surgery can be used to remove inflamed sections of intestine, the condition usually returns, bringing continued symptoms (Farmer, Easley, & Farmer, 1992).

The inflammation involved in ulcerative colitis, by contrast, is limited to the large intestine, and typically involves the rectum (Morson, 1980). The disease is marked by frequent and bloody diarrhea, which may lead to anemia (Myren et al., 1984, Jewell, 1993). Other symptoms during an exacerbation include abdominal pain, fever, nausea, weight loss, joint pain and eye irritation (Jewell, 1993). The damage done to the large intestine is usually limited to the mucosa (Morson, 1980). Currently, the only cure for the disease is removal of the colon (Morson, 1980), which occurs in about 30% of patients.

Despite the differences in the severity and location of inflammation in Crohn's disease and ulcerative colitis, the two have many similarities and are categorized under the common heading of IBD. As mentioned above, both diseases are caused by unknown factors, and have a clinical course of exacerbation and remission. Although they are reliably distinguished from each other today (Myren et al., 1984), the similar symptoms made the two easily confused by physicians until about 40 years ago, when examination of the colon became more common (Taylor, 1980).

The exact medication used depends on the severity of the disease and the response of the individual, however, both diseases are treated with similar drugs (Jewell, 1993; Kornbluth, Salomon, & Sachar, 1993). Although symptoms can be severe during relapse,
most patients experience periods of remission during which they are able to perform daily activities without significant interference (Drossman, Lesserman, Mitchell, Zhiming, Zagimi, & Patrick, 1991; Joachim & Milne, 1987). Because of these similarities, the two diseases are frequently grouped together in studies (Farmer, Easley, & Farmer, 1992; Irvine et al., 1994; Martin, Leone, & Naccarato, 1995), and they will also be grouped together in this study.

**A Clarification of the Purpose of This Study**

Before examining the outcome research of drug therapy for IBD, it is necessary to clarify the focus of the present study. Although psychological factors and their relationship to disease activity are of interest, no assumption is made that these factors contribute to the development or severity of the disease. Many studies have posited a link between personality and IBD, going as far as stating that IBD (especially ulcerative colitis) is caused by certain psychological liabilities.

Aronowitz and Spiro (1988) traced the development of this interest to a paper by Murray that appeared in 1930. In this paper, Murray noted that patients with ulcerative colitis were characterized by a personality style that included fearfulness, conflict and dependence. This idea was further refined in 1950 when Franz Alexander, a psychoanalyst, proposed the specificity hypothesis: certain psychological conflicts (such as the desire to be independent and the desire to be cared for) lead to specific patterns of arousal in the autonomic nervous system. This arousal then causes damage to particular areas of tissue (the colon in the case of ulcerative colitis). Many psychodynamic studies followed, with the general agreement that some event (perhaps a narcissistic wound)
preceded the exacerbation or occurrence of symptoms, which served as a substitute for direct aggression or action (Chessick, 1995). Although researchers have searched for a personality style common to those with Crohn’s disease, this illness has received less attention than ulcerative colitis. This is most likely due to the fact that Crohn’s disease was described at a later time than was ulcerative colitis (North and Alpers, 1994).

Although researchers developed complex psychosomatic theories explaining the etiology of IBD (particularly ulcerative colitis), their study methodologies have been criticized on many grounds, for example, sampling bias, lack of control groups, unsystematic collection of data in a retrospective manner, and the use of cross-sectional rather than longitudinal designs (North and Alpers, 1994; Zuckerman and Briones, 1989). Two recent reviews concluded that there is no “IBD personality” and that patients with ulcerative colitis do not have a higher than normal rate of psychiatric diagnosis (North and Alpers, 1994; Zuckerman and Briones, 1989). Although some studies have found that Crohn’s patients have more diagnoses of anxiety and depression than patients with ulcerative colitis (North and Alpers, 1994; Sheffield and Carney, 1976), it is not clear whether these symptoms precede the disease or if they are a reaction to it (Addolarato, Stefanini, Capristo, Caputo, Gasbarrini, and Gasbarrini, 1996). In summary, whether or not the onset or course of IBD is influenced by stress or other emotional factors is unclear at this time. Although these unanswered questions remain, the purpose of this study is not to investigate the mental or emotional liabilities of people with IBD, but rather to examine the psychological strengths that may assist them in adapting to the illness.
Research Concerning the Pharmacological Treatment of IBD

Although patients with both diseases may require surgery, their symptoms are usually managed with some type of pharmaceutical therapy (Jewell, 1993; Kornbluth, Salomon, & Sachar, 1993). In a two-year study involving over 400 patients with Crohn’s disease (Malchow, Ewe, Brandes, Goebell, Ehlms, Sommer, & Jedinsky, 1984), patients were randomly assigned to six-week treatments of either 6-methylprednisolone alone, 6-methylprednisolone combined with sulfasalazine, sulfasalazine alone, or a placebo. Disease activity was measured with Crohn’s Disease Activity Index (CDAI; Best, Becktel, Singleton, & Kern, 1976) and the van Hees index (van Hees, van Elteren, van Lier, & van Tongeren, 1980), which will be discussed below. The disease activity of patients who responded to treatment was measured for up to two years. Analysis of the treatments revealed that, overall, 6-methylprednisolone was the most effective regimen. It was also superior at reducing disease activity in previously treated patients and in subgroups with inflammation in the small intestine only, or in both the small and large intestines. The combination therapy was most effective for previously untreated patients, and for those with inflammation in the large intestine only.

Powell-Tuck, Bown, & Lennard-Jones (1978) investigated two types of corticosteroid treatment for patients with ulcerative colitis. Corticosteroids had been shown efficacious in this population (Truelove & Witts, 1955), but a comparison of single vs. divided dosages had not been made. Powell-Tuck et al. randomly assigned 45 patients to one of two groups. Twenty-three patients received a treatment of 40 mg. of prednisolone in the morning, and 22 received the same total amount in four separate administrations each day. The authors reported no differences among the treatments in
terms of disease activity, speed of response, or side effects, and recommended that
patients be given the more convenient single dosage.

Many other studies have been done to test different drug treatments for IBD (for
e.g., Archambault, Feagan, Fedorak, Groll, Irvine, Kinnear, Laupacis, McDonald,
Rochon, Saibil, 1991; Truelove & Witt, 1955; Yacyshyn, Bowen-Yacyshyn, Jewell,
Tami, Bennett, Kisner, & Shanahan, 1998). They have typically involved great
methodological rigor, using valid and reliable outcome measures of disease activity and
placebo control groups. Subjects have been randomly assigned to groups, and both they
and the medical staff were blind to treatment condition. Despite the care put into these
studies, however, criticisms have increased recently regarding the outcome measures
used—measures that ignore HRQOL (Garrett & Drossman, 1990; Martin, Leone, Fries,
& Naccarato, 1995; Talal & Drossman, 1995). These criticisms will be discussed later,
but first several disease activity scales will be described.

A Popular Measure of Disease Activity—The CDAI

Many researchers have attempted to quantify disease activity so that different
drug treatments of IBD can be evaluated. The earliest measure of disease activity in
Crohn’s disease was the Crohn’s Disease Activity Index (CDAI; Best et al., 1976). The
CDAI contains a patient-completed questionnaire that asks about symptoms such as
abdominal pain, feelings of well-being, and the number of loose stools per week. The
patient fills out this questionnaire over a one-week period. The physician then adds
information and a score is calculated. The CDAI was designed to be convenient,
sensitive to change, and to correlate with physician assessments of disease activity.
Scores of less than 150 are defined as inactive disease, while scores above 450 indicate very severe activity.

Gastroenterologists from 13 universities and medical centers designed the CDAI. Through discussion, they chose 18 factors they thought were important for assessing disease activity. This list was later reduced to eight, which will be described below. Data was gathered from 112 outpatients who had previously been diagnosed with Crohn's disease and who recorded data on a one-week diary card that was turned in at each visit (total of 187 visits). About 75% of the subjects were receiving medical treatment for their Crohn's disease.

A multiple regression equation was used to predict the physician assessment. The categories of physician assessment of the patient's health and the number assigned to them were: (1) very well; (3) fair to good; (5) poor; or (7) very poor. When patients returned for a follow-up visit, the physicians also gave a rating of the patient's change since the last visit. These ratings were: much better; slightly better; the same; slightly worse; or much worse. In addition to these physician ratings, the patient diary cards containing information about abdominal pain, feelings of well-being, and the number of loose stools per week were collected at each visit.

Once all the data were collected, the number of independent variables was reduced from 18 to 12 using multiple regression with stepwise deletion. Further deletion reduced this number to eight. These are, in the order they appear on the final CDAI: number of liquid or very soft stools per week; sum of seven daily abdominal pain ratings; sum of seven daily ratings of general well-being; the presence of various extraintestinal symptoms (e.g., arthralgia, mouth lesions, skin rash, etc); whether or not the person was
taking opiates for diarrhea; the presence or absence of an abdominal mass; hematocrit value; and bodyweight.

The authors displayed a figure showing the relationship between the computed CDAI score and the physician rating of disease. Although no statistics regarding the agreement between the two ratings were reported, the authors note that, "increasingly unfavorable subjective physician's ratings are associated with tendencies toward increasingly higher CDAI values, but moderate overlap of ranges occurs" (p. 442). A later publication stated that the correlation between the CDAI score and the physician assessment was .70 (Sandler, Jordan, & Kupper, 1988).

Test-retest data was not reported for the CDAI. Instead, the authors reported retest data from 13 patients with 18 visits whose therapy was unchanged during the data collection period. Most of the physician ratings of change were "the same." The reported pooled standard deviation of the repeated administration was 45.5 CDAI units. The authors did not discuss whether they thought this finding provided evidence of the CDAI's reliability. Another study, however, reported a test-retest correlation (eight week period) of .66 (Irvine et al., 1994). It should be noted, however, that the disease activity in Crohn's disease can change substantially in eight weeks, which may explain the moderate correlation.

deDombal and Softley (1987) also examined the CDAI, and they reported considerable observer variation in the scores of various disease activity indices, including the CDAI. They had seven physicians who used the CDAI in daily practice assign CDAI scores to 10 construed case histories. A figure showing the distribution of CDAI scores for each case was referred to and, although no statistical procedures were described, the
authors noted "considerable discrepancy" (p. 476). They also observed that much of this
discrepancy seemed attributable to one or two of the observers who may have been less
familiar with the CDAI. A table revealed a smaller range of scores when the more
extreme high and low values were eliminated. Examples of the means and ranges were:
132, with a range of 108-162; 261, with a range of 235-310; 305, with a range of 280-
330; and 391, with a range of 373-472. Again, no statistics were used to describe the
table.

The items that caused the most disagreement concerned what defined a liquid
stool, what factors were considered extraintestinal, the hematocrit value, and the
calculation of ideal body weight. The authors noted that small discrepancies were
multiplied in the calculation of the final CDAI score. They recommended that the
variables in the CDAI be clarified in order to increase inter-observer reliability.

Finally, Goebell, Wienbeck, Schomerus, & Malchow (1990) analyzed data
concerning the CDAI that were gathered from a large study (described above) of Crohn’s
disease patients (Malchow et al., 1984). In addition to completing the CDAI, three
gastroenterologists who were blind to the CDAI score gave each patient a disease rating
of 1 (not active), 2 (slight), 3 (moderate), 4 (severe), or 5 (very severe). An inter-rater
reliability coefficient was not reported, but the authors stated that in 78% of the cases all
three physicians gave the same score. A single clinical rating was then calculated from
these ratings. The correlation between the CDAI and the clinical rating in this study was
.88. It should be noted, however, that because of its subjective nature, the general well-
being category of the CDAI was omitted.
In conclusion, these results and those of the above studies suggest that, although the CDAI has limitations (such as moderate reliability), it is probably as trustworthy as the rating by a medical expert; that is, it taps into domains that gastroenterologists consider important when making judgements about their patients' disease activity. The difficulty of finding a "gold standard" for the validation of disease activity measures, which is discussed below, has likely contributed to the popularity of the CDAI in research (Malchow et al, 1984; Yacyshyn et al, 1998).

Other Disease Activity Measures

Disease activity scales have also been designed for use with ulcerative colitis patients. Truelove and Witt's (1955) scale for ulcerative colitis uses objective factors such as body temperature, resting heart rate and hemoglobin count. Although widely used, this instrument is not sensitive to small degrees of change in activity because of its categorical classification scale—mild, moderate or severe (Singleton, 1987). In attempts to improve Truelove and Witt's scale, a number of new indices for ulcerative colitis have been created. These include the St. Mark's index (Powell-Tuck, Bown, & Lennard-Jones, 1978), an instrument designed by Seo, Okada, Yao, Ueki, Arima, & Okumura (1992), and another measure that is a modification of Truelove and Witt's scale (Gomes, duBoulay, Smith, & Holdstock, 1986). These scales produce numerical severity scores based on a number of objective and subjective factors.

Some researchers have criticized the CDAI as unreliable and lacking objectivity because of the influence of subjective—patient-reported—factors on its score (Crama-Bohbouth, Pena, Biemond, Verspaget, Blok, Arndt, Weterman, Pauwels, & Lamers,
1989; van Hees, et al., 1980). Efforts to make improvements over the CDAI have generally consisted of either simplifying it, or including objective parameters. Harvey and Bradshaw’s (1980) scale is simpler to administer than the CDAI, but correlates highly with it. The Dutch (van Hees et al., 1980) and Cape Town indices (Wright, Marks, & Parfitt, 1985) were created to assess the more objective aspects of the illness.

**The Chapel Hill Index**

The Chapel Hill Index (CHI; Sandler et al., 1988) was designed to produce scores comparable to the CDAI without the need for a physical exam or laboratory work. It was originally designed for survey research with Crohn’s patients, but has also been used to assess disease activity in subjects with ulcerative colitis. Because it will be used in this study, it is described in detail below.

The CHI was designed based on data from a trial of sulfasalazine as a treatment for Crohn’s disease (Singleton, Summers, Kern, Becktel, Best, Hansen, & Winship, 1979, as cited in Sandler et al., 1988). Eight centers gathered data on 1082 visits by 89 patients. At each visit, information on the variables that make up the CDAI score, as well as a physician rating of disease activity were recorded. The physician rating was used as the dependent variable in a regression analysis, and had the following categories: 1 (very well); 3 (fair to good); 5 (poor); and 7 (very poor).

To reach their goal of developing a self-report survey instrument, the authors did not use the independent variables from the CDAI that required an examination or labwork. The remaining variables were liquid stool frequency, well-being, abdominal pain, use of opiates for diarrhea, and body weight. Several data sets of 89 observation
each were formed by randomly selecting one visit from each of the 89 patients. The authors then carried out “informal examinations of regression results” (p. 454), and decided to keep only the following independent variables: the number of liquid stools in a week, amount of abdominal pain, and general well-being.

One hundred samples of 89 visits (one randomly chosen visit per subject) were then generated. For each of the three variables, partial regression coefficients were calculated for predicting the CDAI score. To facilitate interpretation of their scale, the authors multiplied these coefficients by a constant, so that the mean (138.4) and standard deviation (97.2) of the scale were comparable to the CDAI.

To test the utility of the CHI, it and the CDAI were used to calculate activity scores for each of the 1082 patient visits. These scores were divided into quartiles, and the agreement between the quartiles of each index was quantified. Another 100 random samples of 89 visits, one from each patient, were then generated. An activity score was calculated using each index, and the Pearson correlation coefficients between the CDAI and the CHI were calculated. The sensitivity of the CHI was also examined by determining its and the CDAI’s baseline score as a quartile. The agreement between the instruments (e.g., higher quartile, same quartile, lower quartile) on subsequent visits was then examined. The authors found that when each index was used to place patients into a quartile, the agreement between the two was 64% (Kappa=.517). Agreement within one quartile was 94% (Kappa=.838), which was reported as very high.

Using all 1082 visits, the correlation between the scores of the two instruments was .866 (p<.0001). In approximately 61% of the cases, the CHI and the CDAI were in agreement (by quartile) about change in disease activity. Agreement within one quartile
occurred 97% of the time. The authors acknowledged that, because the CHI was not validated with an independent sample, their results could be biased. However, they concluded that the CHI is promising in survey research because of its simplicity, its high correlation with the CDAI, and its sensitivity to change.

Drossman et al. (1991) used the CHI to survey 320 patients with ulcerative colitis and 671 patients who had Crohn’s disease as part of a study of HRQOL. In addition, Irvine, Zhou, & Thompson (1996) used the CHI to quantify disease activity in 45 patients with ulcerative colitis and 150 who had Crohn’s disease in a validation study of a shortened form of a HRQOL instrument. In the CHI, the subject’s responses are multiplied by three different values (three for the number of loose stools, ten for abdominal pain, and eight for general well-being) and then added together, producing scores that range from 0-650. Scores less than 150 indicate that the disease is in remission. The CHI has only three questions, and takes less than five minutes for the patient to complete.

**Objective vs. Subjective Measures of Disease Activity**

The above studies reveal a debate concerning the use of objective (observed by the clinician) or subjective (self-reported) factors to measure disease activity. Objective measures of disease activity have at least an intuitive advantage over their subjective counterparts. For example, a hemoglobin count is more stringently defined than “mild” vs. “moderate” abdominal pain. Both types of measurements, however, appear to assess different, yet equally valid aspects of disease activity. Although knowing the degree of inflammation in the intestines is important, it does not always correspond with the
patient's experience of pain or discomfort. The presence of minimal inflammation can produce severe impairments in functioning and, conversely, people with highly inflamed intestines may report little discomfort (Goebell et al., 1990; Singleton, 1987; Talal & Drossman, 1995). In addition, obtaining “objective” measurements like hematocrit value can lead to disagreement (deDombal and Softley, 1987). The lack of a gold standard for disease activity validation has caused some to argue that patient ratings should not be considered less important in the management of IBD than the results of lab tests (Garrett & Drossman, 1990). Their suggestion is to view both types of ratings as complementary, each adding important information for diagnosis, because any particular activity scale describes only a certain aspect of the disease.

However, both types of scales have also been criticized as failing to provide important information about the patient’s perception of functioning outside the realm of his/her physical symptoms. The awareness that IBD affects more than just a person’s bathroom habits and that it extends in its impact to the social and emotional domains has increased (Farmer, Easley, & Farmer, 1992; Guyatt et al., 1989). It has become clear that the current disease activity scales, while providing valuable data, fail to gather some important information, because even patients whose IBD is in remission (defined by their score on an activity scale) may have diminished satisfaction with their functioning (Love, Irvine, & Fedorak, 1992). This knowledge has paved the way for the formation of scales that measure health-related quality of life.
Quality of Life and HRQOL: Background and Definitions

At this point it is necessary to discuss some of the difficulties in defining the construct of HRQOL. First, however, the more general concept of quality of life (QOL) will be examined. Musschenga (1997) points out that QOL became an important consideration in medicine after certain interventions, such as the administration of antibiotics, were discovered. These treatments led to the prolonging of life, but sometimes in a diminished capacity compared to pre-illness functioning. Because different treatments have differential efficacy and side effects (kidney transplantation vs. kidney dialysis, for example), other considerations than simply whether the patient would survive became important. Quality of life is now considered an important outcome in medicine, as evidenced by the development of measuring scales for quality of life in illnesses such as cancer, asthma, epilepsy, rheumatoid arthritis, angina, diabetes and AIDS (Bowling, 1995).

Despite the importance of knowing how a treatment will affect a person’s life, there has been great difficulty in formulating a definition of QOL (Anderson and Burckhardt, 1999; Farquhar, 1995). Farquhar has suggested that one reason for this lack of consensus is that many different disciplines are interested in the construct, each employing a definition that captures the components most interesting to them. Related to this reason, different standards of QOL such as objective (number of hours worked) or subjective (enjoyment of activities) are often used across and within disciplines.

Using the term QOL without consistency makes comparing different studies difficult, and it can be confusing when terms such as functional status are used interchangeably with QOL. Anderson and Burckhardt (1999) defined functional status as
"individuals' abilities to meet their basic needs, fulfill roles and maintain well-being (p. 302)," and they add that, although functional status influences QOL, it does not serve as a synonym for it.

Based on a literature review, Farquhar (1995) described three types of QOL definitions. The first type is the global definition, which includes all possible areas of a person's life, from family to work, health, and emotional life. Also included in this definition is the concept of happiness vs. unhappiness. Farquhar provides an example of a global definition: "the degree of satisfaction or dissatisfaction felt by people with various aspects of their lives (p. 503)." Although all areas of a person's life are included in this definition, it is unclear both how to operationalize it and what areas of a person's life are particularly important.

Component definitions, the second type, include only certain dimensions that are claimed to be central to QOL, such as freedom of choice and emotional well-being. An advantage to this approach is easier operationalization and measurement. A downfall, however, is that the dimensions are chosen arbitrarily, based on the interests of the researchers.

Finally, focused definitions are those that use only one or a few components of quality of life, rather than claiming to measure the entire construct. The most common example is those addressing the component of health. Farquhar (1995) suggests that, when this approach is used, it is least confusing when there is explicit acknowledgement that only a part of QOL is being addressed—hence the term HRQOL.

Based on these definitions, it is clear that HRQOL is a focused definition that is not intended to encompass all aspects of a person's experience. Before providing a
specific definition of HRQOL, however, it should be noted that this construct has been criticized. Anderson and Burckhardt (1999) disagree with the assumption, central to HRQOL, that "people make distinctions between some part of their life that is influenced by health, and some parts that are not so influenced (p. 302)." They suggest that, in most studies, the term is simply composed of variables related to the disease of interest (i.e., physical symptoms).

Although this criticism may have some validity, it is also clear that an illness will impact some areas of a person's life more than others (e.g., occupational role vs. family relationships). In addition, because quality of life includes a potentially infinite number of components (Farquhar, 1995), restricting the definition to include only those areas most affected by the illness (HRQOL) not only allows for more accurate measurement, but also for the promise of utility to patients who are choosing between alternative treatments. These considerations lead to the following definition of HRQOL: "the functional effect of an illness and its treatment on a patient, as perceived by the patient" (Ferry, 1999, p.S15). Note here that "functional effect" does not mean the same thing as functional status, but refers to a global effect on a person's life. Based on this definition, two points should be noted.

First, HRQOL refers to a person's subjective experience of IBD, as opposed to various laboratory measures that a patient is not directly aware of, such as hemoglobin count, platelet count, or erythrocyte sedimentation rate (Guyatt, Mitchell, Irvine, Singer, Williams, Goodacre, & Tompkins, 1989). Second, the experience of HRQOL goes beyond the physical symptoms of IBD (diarrhea, pain, etc.) to its impact on other areas of a person's life (Maunder, Cohen, McLeod, & Greenberg, 1995). A basic premise of this
article is that, until recently, HRQOL has largely been ignored in IBD research. Based on this view of HRQOL, several instruments designed to measure this construct will be described. First, however, three types of HRQOL instruments will be discussed.

Criticisms of Global and Generic HRQOL Instruments

Health-related quality of life measurements can be classified as global, generic, or disease-specific (Irvine, 1997). Irvine states that global assessments may give an overall description of a patient's functioning, but they fail to describe specific areas of impairment. In addition, these measures often yield only categorical scores, such as good, fair, or poor. Generic questionnaires, by contrast, produce a quantitative score, and can be used in a variety of patient groups.

Irvine (1995), however, criticized generic HRQOL instruments by stating that these measures are subject to systematic error due to possible differences between the populations that are sampled. For example, patients with inflammatory bowel disease tend to be younger and have more mobility than do arthritic patients, and socioeconomic and marital statuses between them may also differ. Thus, differences in scores between the two groups may be due to factors other than health status, such as age.

In addition, generic instruments can be insensitive to differences within a single population. Irvine (1997) described a study in which a generic HRQOL questionnaire did not discriminate between ulcerative colitis patients who had undergone surgery and a group of healthy controls (Provenzale, Phillips-Bute, & Shearin, 1995). As an alternative to global and generic HRQOL scales, Irvine recommends the use of disease-specific questionnaires—those designed for use in a particular group of patients.
The IBDQ—A Disease-Specific HRQOL Instrument

Recognizing the weaknesses of global and generic questionnaires, several groups have developed HRQOL instruments specific to IBD. The widely used Inflammatory Bowel Disease Questionnaire (IBDQ; Guyatt et al., 1989) was designed to be an outcome measure in clinical trials. This measurement will be used in this study, and it is described in detail below.

The first step in the development of the IBDQ was the formation of 150 items that described problems faced by IBD patients (Mitchell et al., 1988). These were generated through an open-ended questionnaire administered to several doctors and clinicians, and to 77 patients from outpatient settings. Patients who had proctitis alone, or who had ileostomies, were excluded from this rating procedure. In their description of this process, the authors stated that the items formed five different dimensions: bowel symptoms, systemic symptoms, functional impairment, social impairment, and disturbances of emotional function. They did not, however, describe the way that these dimensions were formed.

The 150 items were then rated by 97 IBD patients (43 with ulcerative colitis and 54 with Crohn’s disease) according to importance (“not very important” to “extremely important”). This produced a reduced list of 30 items. After additional feedback from several clinicians, two more items were added. These 32 questions form the IBDQ, which can be completed in approximately 20 minutes. Scores for each item range from 1 (worst function) to 7 (best function), for a range of 32-224. In Crohn’s patients who are experiencing remission, the average IBDQ score is 169 (Irvine, 1997). A similar score
has been reported for patients with ulcerative colitis (Han, McColl, Steen, Barton, & Welfare, 1998). These compare to a mean score of 211 for individuals without IBD (Irvine et al., 1994).

In a separate study, Guyatt and colleagues (1989) tested the validity and reliability of the IBDQ. They described four subscales into which the IBDQ was divided, but did not describe the process used to form these subscales. The first subscale relates to bowel disturbances and has ten items. It asks questions such as, "How often in the last two weeks have you been troubled by cramps in your abdomen?" The second subscale inquires about systemic symptoms—physical symptoms not directly related to the gastrointestinal tract—and contains five questions. An example is, "How much energy have you had in the last two weeks?" The emotional function subscale contains 12 questions, such as, "How often during the last two weeks have you felt frustrated, impatient, or restless?" Finally, the social function subscale has five questions, such as, "How often during the last two weeks have you had to cancel a social engagement because of your bowel problem?" Considering the above discussion of conceptual difficulties associated with HRQOL, the IBDQ operationalizes HRQOL by referring to the physical, emotional, and social effects of IBD. A possible criticism at this point is a confounding of physical symptoms with HRQOL. Below, the IBDQ will be compared to three other instruments designed to measure HRQOL in IBD.

Guyatt et al. (1989) then administered the IBDQ to 61 patients with IBD (38 with ulcerative colitis, 23 with Crohn's disease) from both inpatient and outpatient settings to establish an average baseline score. They readministered it to them one month later to obtain a follow-up score. After the second administration, the subjects were divided into
two groups based on their self-reported change in disease activity. The 19 patients who reported no change in disease activity were referred to as the stable group. The unstable group was composed of thirty-three patients who reported improvement, and nine who said that they had deteriorated. To determine the IBDQ's reliability, the scores of the 19 stable patients (whose disease activity had not changed) were examined.

Guyatt et al. (1989) did not report a test-retest correlation for the scores of the 19 stable patients. Instead, they calculated the average differences between baseline and follow-up for each subscale. They then calculated the standard deviations of these differences. The standard deviation for each subscale was then divided by that subscale's average score (baseline plus follow-up divided by two), which yielded a coefficient of variation for each subscale. These coefficients were: bowel symptoms, .07; systemic symptoms, .15; emotional function, .11; and social function, .06. No coefficient was reported for the IBDQ total score. The authors claim that, compared to other questionnaires, these are relatively small coefficients (Guyatt, Thompson, & Berman, 1985, as cited in Guyatt et al., 1989) and conclude that the IBDQ is a reliable instrument.

The IBDQ's responsiveness (sensitivity to change) was tested by comparing the average difference score (baseline minus follow-up) for each subscale in the unstable group to the average difference score in the stable group. The average difference score for each subscale in the unstable group was divided by the standard deviation of the difference scores of the corresponding subscale in the stable group. For example, the average difference score of the bowel subscale in the unstable group was 11.1 points and the standard deviation of the bowel subscale in the stable group was 3.7. The resulting ratio, (11.1/3.7=3.0) is a z-score. The authors explained that, because the number of
subjects (nine) whose disease activity had deteriorated was too small for a separate analysis, the sign of their difference scores (baseline minus follow-up) was reversed. Their scores were then included with the 33 patients whose scores had increased, for the analysis just described.

The ratios for the other scales were: systemic symptoms, 1.8; emotional function, 1.4; and social function, 1.7. The authors claim that, since this ratio is greater than 1.0, the IBDQ is a responsive measure. Guyatt et al. (1989) note, however, that the IBDQ was more responsive to changes in HRQOL in ulcerative colitis patients than it was in Crohn’s disease patients. The responsiveness of the IBDQ in Crohn’s patients will be discussed below.

Guyatt et al. (1989) also reported on the IBDQ’s validity. Convergent evidence (Messick, 1980) for its validity was looked for in the 42 subjects with changes in the self-reported global rating of disease activity. Some of the notable results follow. The correlation between the patient’s global rating of change in tiredness and change in the systemic subscale was .36 (p<.05). The correlation between the patient’s global rating of change in emotional function and change in the emotional subscale was .52 (p<.05). The correlation between the change in the emotional function subscale of the Rand questionnaire (a generic measure of physical and emotional functioning; Ware, Brook, & Davies-Avery, 1980) and change in the emotional subscale was .76, (p<.05). Finally, the patients’ global rating of change in disease activity related moderately well with the changes in the bowel subscale of the IBDQ (.42, p<.05). No correlations concerning the IBDQ’s social functioning scale were reported.
As mentioned above, the IBDQ was not as responsive to changes in HRQOL in Crohn’s disease patients as it was in ulcerative colitis patients. To assess this aspect of the IBDQ in the former group in greater detail, Irvine et al. (1994) described data from a study of 305 Crohn’s patients at 11 different hospitals (Archambault et al., 1991). These patients were randomly assigned to a group receiving either low-dose cyclosporin or a placebo. Subjects were administered the IBDQ and two measures of disease activity—the Crohn’s Disease Activity Index (CDAI; Best et al., 1976), and the Harvey-Bradshaw index (HB; Harvey & Bradshaw, 1980)—at two-month intervals for eighteen months. In addition, subjects and physicians made global assessments of changes in patient bowel function, emotional function, and tiredness at each visit. These assessments were made on a one (a great deal worse) to seven (a great deal better) scale.

To assess responsiveness, Irvine et al. (1994) divided the patients into two groups: those who experienced a relapse in disease activity during the trial (171 patients), and those who remained stable (134 subjects). Relapse was defined as an increase of 100 points in the CDAI and a change in steroid therapy. Two measurements, the baseline score and the lowest score obtained in the trial, were then compared.

The authors reported that the patients who relapsed had low scores (lowest obtained in the trial) that differed significantly from patients who had stable disease activity; that is, the IBDQ total score decreased more in patients whose disease activity worsened than in stable patients. This fact gives evidence for the IBDQ’s responsiveness in Crohn’s patients. In addition, the bowel and systemic subscales were more responsive than the emotional and social subscales, causing the authors to suggest that the latter scales measure something different than the first two scales.
The authors stated that there is not a gold standard of HRQOL against which they could compare the IBDQ. In lieu of such a standard, they predicted that the disease activity measures would correlate more highly with the bowel subscale than with the social and emotional function subscales; no prediction was made concerning the systemic subscale. Correlations were reported between the IBDQ and the activity indices at the time of initial measurement (all were significant). The correlation between the IBDQ overall score and the CDAI was -.67; thus a higher HRQOL score was associated with lower disease activity. As predicted, the emotional and social function subscales had lower correlations (-.50 and -.56, respectively) with the CDAI than did the bowel subscale (r= -.71). The same pattern was observed between HB scores and the IBDQ total and dimensional scores. The authors did not state why predictions were not made concerning the systemic subscale.

Reliability data in this study were reported in terms of intraclass correlation coefficients between IBDQ baseline scores and scores at week 8. The correlations were as follows: IBDQ total score, .70; bowel subscale, .65; emotional subscale, .65; systemic subscale, .65; and social subscale, .67. These coefficients were calculated from subjects with both stable and unstable disease activity, and were much higher than the patient and physician global reports (.09 and -.05, respectively). The authors conclude that the IBDQ is a valid and reliable measure of HRQOL.

A more recent study of the psychometric properties of the IBDQ was conducted by Han, McColl, Steen, Barton, and Welfare (1998). They randomly selected 38 patients with ulcerative colitis from a hospital outpatient database, of which 28 (74%) completed the study. The subjects were administered the IBDQ three times in a one-month time
period (each completion was separated by two weeks). On the first and third assessments, the IBDQ was given in an interview. The second administration was self-completed. The average age of the patients was 54 years, and all but two had ulcerative colitis that was in remission.

The average IBDQ score was 174, indicating that this group had relatively high HRQOL (Irvine et al., 1994). There were no score differences between subjects who were above the average age with compared those below it on any of the IBDQ subscale scores. The average item-total correlation for the IBDQ was .67. The Cronbach’s alphas for the subscales were as follows: bowel, .81; systemic, .72; emotional, .89; social, .89. An alpha coefficient was not reported for the IBDQ total score. The authors reported that the internal consistency for the subscales was similar whether the IBDQ was interviewer- or self-administered.

Intra-class correlation coefficients between the three administration times were also calculated to assess the test-retest reliability of each subscale. Correlations between the interviewer- and self-administered scores ranged from .73 to .93. Correlations between the two interview-obtained periods were slightly lower, with intra-class correlations ranging from .62 to .79. The lower correlations between the interviews may reflect actual changes in HRQOL, however, as they occurred one month apart from each other. Across all three administrations, the test-retest correlations were: bowel, .79; systemic, .71; emotional, .79; and social, .88.

To summarize, the IBDQ subscales have high internal consistency and test-retest stability. The test-retest correlation of the IBDQ total score is also high, but its internal consistency has not been reported. Although validity research is limited, the subscales
are related to disease activity and to other self-reported measurements in a theoretically consistent fashion. The IBDQ is convenient for research use, requiring a subject approximately 20 minutes to complete.

**Other Health-Related Quality of Life Scales**

Other groups have designed HRQOL instruments for IBD patients. Before describing them, however, it should be noted that they differ from the IBDQ in different respects, an example of the intra-disciplinary variance in conceptual definition that was noted above (Farquhar, 1995). Despite these differences, however, an important similarity remains: an interest in the effects of IBD on various aspects of the lives of the patient, as rated by the patient.

The first group, Farmer, Easley, and Farmer (1992), designed their questionnaire to assist physicians in their management of IBD symptoms. Four areas of daily living are investigated with this measure. The Functional/Economic category assesses the ability to function at work, school and home. Satisfaction with personal relationships and recreational activities is measured by the Social/Recreational subscale. Attitude (positive or negative) toward the future and life in general is measured by the category called Affect/Life in General. Finally, Medical/Symptoms relates to physical symptoms and health-related behaviors. The way in which these subscales were formed was not described. This scale is similar to the IBDQ in its inclusion of scales addressing physical symptoms and emotional and social functioning, but it also includes attitude toward the future. In addition the patient’s ability to function is addressed, leaving this questionnaire open to the criticism—discussed above—of confounding HRQOL and functional status.
The instrument has 18 questions, and takes 15-20 minutes to administer. Each question is rated from one to five for a maximum score of ninety, with higher scores representing better functioning.

To choose the items of this instrument, the authors administered a 47-question interview to 70 outpatients with Crohn’s disease and 94 who had ulcerative colitis. These patients were classified into two groups, surgical and nonsurgical, for a total of four patient groups. A two way (Surgery by Disease Type) ANOVA was conducted on the total scores of each patient group. F-tests of significant (p<.01), or what were referred to as marginally significant values (p=.01 to .05), were reached for 18 of the 45 questions, which were used for the final version of this instrument.

The authors assessed reliability by readministering the 45 questions to 23 patients, two weeks after the initial interview, and they reported that the Spearman correlation coefficients were between .75 and .95. The correlations for the final 18 questions, however, were not reported. The authors stated that patients with Crohn’s disease had impaired HRQOL compared to patients with ulcerative colitis. Having surgery was also related to a poorer score, and those who had surgery and Crohn’s disease had the worst scores of all. No other data concerning validity was given.

Martin, Leone, Fries and Naccarato (1995) developed a HRQOL scale similar to the IBDQ for use in the physician management of IBD, as well as an outcome measure in clinical trials. Like the IBDQ it has four scales (intestinal, systemic, emotional, and social), and like the IBDQ it can be criticized for confusing HRQOL with physical symptoms. Martin et al.’s instrument consists of 29 questions, each of which is rated from 0 (never or hardly ever) to 3 (always or nearly always). Scores range from 0-87,
with higher scores indicating worse functioning. Patients can complete the questionnaire in about 10 minutes.

To determine the questionnaire's reliability, 23 patients with IBD were given the test twice in a two-week period. The average scores and standard deviations for the two administrations were 19.6 ±13.6 and 16.8±12.6. The authors stated that the variation (15%) was not significant, but did not report the statistical test used to ascertain this. The validity of the questionnaire was determined by giving it to 72 healthy controls and to 112 patients (57 with ulcerative colitis and 55 with Crohn's disease). The Crohn's Disease Activity Index (Best, et al., 1976) and Truelove and Witt's (1955) index were used to classify the patient's disease as in remission, mild, or moderate/severe. The authors reported that patients with ulcerative colitis in remission had significantly higher scores (diminished function) than the controls. Similarly, patients with mild disease activity scored significantly higher than those who were in remission. Those with moderate/severe disease activity scored higher than those with mild disease. The same pattern was obtained for patients with Crohn's disease. Again, the authors did not report the statistical test that was used.

Finally, Drossman, Lesserman, Li, Mitchell, Zagami, and Patrick (1991) have developed the Rating Form of IBD Patient Concerns (RFIPC). It is a 25-item, self-administered questionnaire that contains concerns expressed by IBD patients that were gathered through both informal and semi-structured interviews. The RFIPC asks questions such as, "How concerned are you with the effects of your medication?" Patients respond to the questions using a visual analog scale that ranges from 0 (not at all concerned) to 100 (very concerned). In addition to scores for individual items, an
average score for all items (Sumscore) is calculated. This instrument appears especially susceptible to the criticism that it merely measures an emotional component of HRQOL, namely, worries or concerns. It differs from the HRQOL scales described above by not including separate scales that purport to address different aspects of HRQOL.

The RFIPC was administered to 62 IBD patients, and had a test-retest correlation of .87 for the Sumscore and an average correlation of .65 for the individual items. It was then administered to over 900 IBD patients (320 with ulcerative colitis, 671 with Crohn’s disease). A factor analysis on the 25 items yielded four factors with Eigen values greater than 1.0: impact of disease; sexual intimacy; complications of disease; and body stigma. The Cronbach’s alpha coefficients for these four indices ranged from .79-.91.

Evidence for the RFIPC’s construct validity was found in the differences in concerns between Crohn’s and ulcerative colitis patients. Those with Crohn’s disease worried more about pain and suffering, energy level, and being a burden on others. Ulcerative colitis patients, however, reported more concerns related to developing cancer. Drossman et al. (1991) note that these concerns relate to clinical differences between the two diseases in symptom intensity and risk of cancer.

Of the above HRQOL scales, the most work has been done concerning the IBDQ’s validity. In addition, researchers have been more concerned with showing the reliability of the IBDQ, which may be due to the IBDQ’s introduction as an outcome measure in clinical trials. Despite the popularity of the IBDQ, however, several different scales have been designed to measure an important component to the experience of IBD—health-related quality of life. It is not clear, however, that they are all measuring the same construct. Although the IBDQ and scales designed by Farmer, Easley, and
Farmer (1992) and Martin et al. (1995) have similar scales, they are not identical. In addition, the RFIPC (Drossman et al., 1991) appears to focus on the emotional impact of IBD. Thus, similar to the disease activity scales, no "gold standard" exists for HRQOL in IBD. However, the extensive work and favorable results on the IBDQ make it the best candidate for exploratory work for factors that are related to HRQOL in this area of study.

**Research Concerning HRQOL in IBD Patients**

Early studies of HRQOL in IBD patients examined how the disease affected various aspects of their lives. Joachim and Milne (1987) questioned 80 people with IBD and observed that they reported a number of illness-related perceptions that often go unnoticed by physicians. Forty percent of their subjects reported that having IBD lessened their overall satisfaction with life, and contentment in areas such as relationships, recreation, and sexuality was diminished. Although this study lacked a control group, it demonstrated that the impact of IBD extends beyond its physical symptoms.

Drossman, Patrick, Mitchell, Zagami, and Appelbaum (1989) investigated the relationship between disease activity, HRQOL, and utilization of health care. Compared to a control group, IBD patients had more trouble in the areas of work, recreation, social interaction, emotional behavior, and sleep and rest. Patients suffering from Crohn's disease reported more overall maladjustment than patients who had ulcerative colitis. A patient's HRQOL score predicted the use of health services better than did a physician rating of disease activity, which shows the impact this construct may have on behavior. The authors also reported that IBD patients have a number of worries, such as needing an
ostomy bag or surgery and developing cancer, concerns that traditional disease measures ignore.

Drossman et al. (1991) surveyed nearly 1,000 people with IBD. Compared to a control group, these patients had more dysfunction in the areas of social contact, recreation, sleep and rest, and daily work. Again, patients with Crohn's disease experienced more impairment, which the authors explained by their more severe disease activity. The authors also suggested that knowing a patient's degree of psychological distress and well-being are valuable for predicting both physician visits and hospitalization.

In what they referred to as the first quantitative study of its kind, Mitchell, Guyatt, Singer, Irvine, Goodacre, Tompkins, Williams, and Wagner (1988) attempted to ascertain the impact of IBD on a number of life functions. Their subjects reported the most problems with areas such as fatigue, feeling run down, and the emotions of frustration and depression. The subjects did not report many problems relating to social and functional impairment. However, many subjects expressed a fear of possible surgery. The authors recommend monitoring more than just physical symptoms in clinical trials. In summary, although IBD impacts a person's physical health, it also adversely affects his or her emotional and social functioning.

The Use of HRQOL Instruments as Outcome Measures in Clinical Trials

As mentioned above, health-related quality of life measures have not always been a part of evaluating interventions for IBD, evidenced by a review of surgical trials which revealed that only three of ninety-nine discussed HRQOL (O’Young & McPeek, 1986).
However, researchers have begun to include these instruments in studies that evaluate different surgical and therapeutic interventions. In their review article, Maunder, Cohen, McLeod, & Greenberg (1995) evaluated the effects of surgery, drugs, and home parenteral nutrition on HRQOL. They categorized these studies according to their methodology and the quality of the HRQOL measure used. Instruments such as the IBDQ and the RFIPC were considered more useful than those that had not demonstrated validity or reliability.

The authors found that the use of measures like the IBDQ and RFIPC has increased in recent years. Between 1981 and 1987 only two studies used such instruments, while five articles utilized them between 1988 and 1994. They also reported that a greater proportion of the studies in recent years have been prospective and controlled.

As further examples of recent interest in HRQOL, two recent drug trials for new treatments of Crohn's disease have used the IBDQ as one of the outcome measures of drug efficacy. Yacyshyn et al. (1998) tested the efficacy of ISIS 2302, an antisense phosphorothioate oligodeoxynucleotide, in 20 patients with active Crohn's disease and found that improved disease activity was associated with increased HRQOL. Infliximab, a chimeric monoclonal antibody, was approved by the FDA in 1998 for the treatment of steroid-dependent Crohn's disease. A study examining its effectiveness (Targan, Hanauer, Van Deventer, Mayer, Present, Braakman, DeWoody, Schaible, and Rutgeerts, 1997) used patients' IBDQ scores as part of the definition of a clinical response to the drug, with findings similar to that of Yacyshyn et al. (1998). The fact that the trials testing these new drugs are using the IBDQ gives evidence of the rising interest in
HRQOL among those who are studying the treatment of IBD, and they mirror the great interest in this subject in medicine in general (Bowling, 1995).

**The Relationship Between Disease Activity and HRQOL**

If HRQOL scores are too highly related to measures assessing disease activity, then the usefulness of this additional construct is doubtful. However, the relation between the two is not a perfect one. Research that provides insight into this relationship comes either from controlled drug trials or from investigations of HRQOL in IBD patients. The research that follows utilizes reliable, valid measures of disease activity. Studies that use categorical disease activity scales (e.g., good, fair, poor) are not mentioned here, due to the fact that such measures are relatively insensitive to clinical change (Irvine, 1995; Singleton, 1987).

Irvine et al. (1994) conducted a multi-center trial (described in detail above) involving over 300 patients with Crohn’s disease. To summarize, the subscales were differentially related to disease activity—from a correlation of -.71 for the bowel subscale to a correlation of -.50 for the emotional function subscale. A figure depicting the distribution of IBDQ and CDAI scores revealed that for a given CDAI score, the IBDQ scores were scattered over roughly 80 points. Irvine et al. conclude that “the IBDQ and dimensional [subscale] scores are tapping domains distinct from the activity indexes” (p. 292).

Turnbull and Vallis (1995) studied the relationship between disease severity, psychological factors, and HRQOL in 16 patients with Crohn’s disease and six who had ulcerative colitis. Disease activity was measured with the Dutch Activity Index (van
Hees et al., 1980) and the St. Mark’s index (Powell-Tuck et al., 1978), respectively, and the IBDQ was used to assess HRQOL. The authors found that disease activity alone was not significantly correlated with the IBDQ overall score (r=.41). However, when disease activity was combined with other factors, such as social interaction, recreation, and work role to form a single composite score, this correlation was significant (r=.53).

Vallis and Turnbull (1996) reported the relationship between disease activity, measured by the Dutch Activity Index (van Hees et al., 1980), and the IBDQ in 39 Crohn’s patients. When 26 patients were readministered the measurements approximately four months later, the resulting correlation coefficients were significant only between disease activity and the IBDQ’s bowel and systemic subscales (r= -.46 and -.44, respectively).

The weaker correlations reported in the last two studies were probably due to the disease activity scales that were used. The instruments used by Turnbull and Vallis (1995, 1996) assessed objective parameters, such as erythrocyte sedimentation rate, albumin levels, and colonic appearance. The CDAI, by contrast, investigates several subjective factors, such as a patient’s perception of abdominal pain and general well-being. Because several of the IBDQ’s questions are also related to pain and well-being, it is not surprising that the correlations between its scales and the CDAI were higher.

These studies indicate that HRQOL and disease severity, whether defined in objective or subjective terms, are related. This finding is intuitive; a very sick person is less able to enjoy life. However, these studies also suggest that factors beyond illness alone determine the extent to which IBD affects an individual’s satisfaction with life.
The following sections summarize the theoretical and empirical articles that discuss what these factors may be.

**Theory About Factors that Influence HRQOL in IBD Patients**

Garrett and Drossman (1990) drew a distinction between disease and illness, defining disease as a physical process that does harm to the body and that can be observed or inferred without asking for the patient's perceptions (for example, by a blood test). Illness, however, is the patient's experience of disease and includes "how the symptoms are perceived, evaluated, and acted upon" (p. 95). For example, someone might have a normal sigmoidoscopy, yet experience intense abdominal pain. The authors propose that health status—the interaction of disease and illness—depends on several factors: psychological status, coping style, social support, culture, and the presence or absence of stressful life events. In their model, disease activity per se is just one contributing factor to HRQOL.

Talal and Drossman (1995) reviewed research concerned with the relationship between stress and IBD symptoms. They agreed that, in addition to disease activity, a person's response to IBD depends on the factors listed above (psychological status, coping style, social support, etc.). In addition, they claimed that the relationship between health status (HRQOL) and the factors contributing to it is bidirectional (e.g., poor health status may lead to depression, and vice versa). Given these claims, an empirical search for factors relating to HRQOL has promise for increased understanding and improved treatment. The following sections review literature investigating the influence of health...
beliefs, patient knowledge of the disease, and satisfaction with social support on HRQOL in IBD patients and in other patient groups.

**The Relationship of Health Locus of Control to HRQOL in Other Groups**

A person who believes that his or her behavior determines health has an internal health locus of control, whereas someone who attributes health to factors beyond his or her control has an external health locus of control. Much research examining the relationship between health locus of control and quality of life has been published with patients diagnosed with breast cancer (Payne, 1992), osteoarthritis (Laborde and Powers, 1985), systematic lupus erythematosus (Pfieffer and Wetstone, 1988), renal disease (Bremer, 1995), cardiac illness (Fowers, 1994), and chronic pain (Crisson and Keefe, 1988). Comparisons between these studies are difficult, however, because although many used the same measurement of health locus of control (the Multidimensional Health Locus of Control Scales; Wallston, Wallston, and DeVellis, 1978), the definition of HRQOL has varied greatly and has often been confused with adjustment to disease, as is the case with the above studies. This makes clear statements about health locus of control and HRQOL impossible, but the studies are still valuable because they demonstrate that factors such as health beliefs are related to psychological adjustment. Because psychological adjustment is often included in the operational definition of HRQOL, increased adjustment is likely to be associated with more favorable HRQOL.

The above research can be summarized as having mixed results. Although some studies report a relationship between adjustment and internal health locus of control—that is, that an internal health locus of control predicts better adjustment—other studies
have not confirmed this finding. In fact, some authors report that an internal locus of control is related to increased psychological distress (Affleck, Tennen, Pfieffer, & Fifield, 1987).

Andrykowski and Brady (1994) suggest that these inconsistencies are due to the complex relationship between health beliefs and adjustment to disease. They propose that two variables may serve as moderators in this relationship: the control realities of the situation, and the degree of threat. The control realities of the situation refer to whether or not a person actually has some influence over his or her illness. These realities may cause a person with an internal health locus of control to experience increased depression when faced with a terminal illness. In addition, health beliefs become more important to adjustment when the perceived threat of a disease is great. To summarize, the relationship between health beliefs and adjustment is complex, and it is not necessarily a direct one. One would expect to find a similar relationship between health beliefs and HRQOL.

**The Relationship of Health Locus of Control to HRQOL in IBD Patients**

Although the relationship of health locus of control to HRQOL have been investigated in many patient groups, no studies have assessed this relationship in IBD patients. Some authors have, however, examined levels of locus of control (a more general belief in one’s ability to control outcomes in life) in IBD patients. An internal locus of control indicates a belief that one’s own actions are instrumental in determining these outcomes, and an external locus of control refers to the belief that “fate” or other people control one’s life. Engstrom (1991) compared the locus of control of children...
with IBD to children with diabetes and to a control group. He reported that children with IBD had a more external locus of control than the other groups, and that increased disease activity was predictive of a more external locus of control ($r=.67$, $p<.01$). No relationship was found between locus of control and the presence of a psychiatric disorder (defined by criteria described in the Diagnostic and Statistical Manual, third edition, revised; American Psychiatric Association, 1987).

Steinhausen (1982), however, reported that children with IBD have a more internal locus of control than do healthy children. He acknowledged that this finding was contrary to findings in other illnesses, but he did not provide a clear description for the discrepancy. He also reported no relationship between locus of control score and severity of illness, which may have been due to a relatively small sample size (ten patients with Crohn’s disease and seven with ulcerative colitis). Subjects with psychiatric disturbance in this study (defined by the results of an interview) had a more external locus of control.

The above studies involved children, and did not assess health locus of control, however, two other studies have examined coping patterns in adult IBD patients. While these did not assess health locus of control directly, they provide information about what kinds of coping strategies are important to these patients. The relationship of these strategies to health locus of control will be discussed below. In the first study, Kinash, Fischer, Lukie, and Carr (1993) gathered information about coping style, personality characteristics, severity of depression, and disease activity from 88 patients with Crohn’s disease and 62 diagnosed with ulcerative colitis. Coping style was measured with the Jalowiec Coping Scale (Jalowiec, Murphy, & Powers, 1984).
Kinash et al. (1993) reported that individuals in both patient groups had similar coping patterns, regardless of their disease severity or the amount of depression they were experiencing. The three most commonly used coping strategies for coping with IBD were: (1) trying to maintain control over the situation, (2) trying to see all aspects of their situation, and (3) gathering more information about their situation. Examples of uncommonly used strategies were letting someone else handle the situation, and blaming someone else for the problem, evidence against the notion that IBD patients have a passive and dependent personality style.

Satisfaction with life in general was negatively related ($r = -.32$, $p < .05$) to the use of coping methods designed to manage the distressing emotions caused by IBD (affective-oriented coping), such as using relaxation techniques to deal with anxiety. The use of strategies for changing one's situation (problem-oriented coping; e.g., getting more information about IBD) was positively related to life satisfaction ($r = .07$), although this relationship was nonsignificant. The way in which life satisfaction was defined, however, was not specified. Similarly, those who engaged in affective- vs. problem-oriented coping strategies reported greater deterioration in relationship satisfaction with family and friends but, again, the way that this satisfaction was ascertained was not described.

In summary, the group of patients in this study appeared to benefit the most from coping methods aimed at changing one’s circumstances, behavior that may originate from a belief that their own actions largely determine their health (an internal locus of control). This interpretation is supported by Steinhausen's (1982) findings that children with IBD have a more internal locus of control than do healthy children.
Aware of these findings, Smolen and Topp (1998) predicted that IBD patients would prefer problem-focused forms of copings, those aimed at actively improving their situation, and that they would find these methods effective. These coping styles were contrasted to emotion-focused coping techniques, which are attempts to deal with the distressing emotions that a situation evokes. They also predicted that as problem-focused coping strategies increased, the patient's well-being would increase. The authors investigated these predictions by administering questionnaires to 33 patients with Crohn's disease and 13 who had ulcerative colitis, and they used the Jalowiec Coping Scale to assess the occurrence and usefulness of coping strategies. Well-being was measured by three subscales (mental health, pain, and energy/vitality) of the Health Status Questionnaire (McHorney, Ware, Lu, & Sherbourne, 1994).

The authors reported that one of the two problem-focused strategies (Supportant, which involves making use of supportive resources) was rated the most effective by the subjects. The other problem-focused method, Confrontive, which involves facing the situation, was the third most effective strategy. A finding not in accord with their predictions was that Optimism, an emotion-focused coping style characterized by a positive outlook toward the situation, was rated the second most effective strategy. When the self-reported effectiveness of Optimism was entered into a regression equation, it accounted for 39% of the variance in rated well-being. Another finding that did not support the authors' predictions was that the use of neither Confrontive nor Supportive coping methods was related to well-being ($r = -.04$ and $-.24$, respectively). The authors did not explain why these correlations were not in the predicted direction. They did point out, however, that the use of emotion-focused coping strategies such as avoiding the
problem, feeling hopeless, and responding emotionally to the problem were significantly related to decreased well-being. These studies suggest that many IBD patients use active coping strategies to deal with their illness, and that certain forms of coping strategies—those which do not attempt to change the situation—are related to lower levels of well-being. It is not clear why Confrontive and Supportive coping methods were unrelated to well-being. It is possible, however, that this was due to the definition of well-being that was used—one derived from a HRQOL measure that is not disease-specific.

Although the above studies do not directly address the relationship between health locus of control and HRQOL in IBD patients, they provide good reason for studying this relationship using a disease-specific measure of HRQOL. The fact that IBD patients use coping techniques aimed at changing their situation (e.g., gathering more information) indicates that they believe something can be done to change their situation. That is, their appraisal of the situation (something can be done to reduce the environmental stressor) may have influenced the coping technique chosen (Lazarus, 1992). Whether or not health locus of control is related to this appraisal is a part of the present study’s investigation.

Measurement of Health Locus of Control

In the present study, health locus of control was measured by Form C of the Multidimensional Health Locus of Control Scales (MHLC-C; Wallston, Stein, & Smith, 1994), an 18-item questionnaire that is a variation of an earlier instrument measuring a person’s beliefs about his or health. The reliability and validity of the original instrument (Forms A and B) were described by Wallston, Wallston, & DeVellis (1978). Wallston et
al. (1994) divided their modified instrument (by the process described below) into four belief dimensions.

The first dimension, labeled Internal, assesses the degree to which a person believes that his or her own actions determine health. The Chance scale determines whether a person believes that fate or luck primarily determines health, and beliefs regarding the control of doctors over one’s health are measured by the Doctors scale. Finally, the Other People scale asks about the perceived influence of non-health professionals on the health of the an individual. The first two scales contain six questions each, and the latter each contain three. Each item is rated on a six point Likert-type scale ranging from one (strongly disagree) to six (strongly agree). The MHLC-C was designed to yield four separate scores, as opposed to one total value, and the entire instrument can be completed in five to ten minutes.

The questions for Form C were written to apply to any particular illness, as opposed to health in general. Wallston et al. (1994) claimed that by assessing more specific beliefs about an illness, predictions about future behavior are more accurate. They also stated that a person’s beliefs about health in general may differ from those related to a specific condition. Finally, they observed that persons with specific health conditions may be unsure whether to answer a question such as, “If I do the right things I can stay healthy” as it relates to their overall health status or to their specific disease. They reasoned that a parallel question focused more on the person’s disease such as, “If I take the right actions, my condition should improve” would be less ambiguous and assess more specific health beliefs.
With these observations in mind, Wallston and colleagues (1994) wrote 24 questions, developed on the basis of their face validity, that would be comparable to the original version of the MHLC Scale (Wallston et al., 1978). These items used the word "condition" instead of "health," and fell into categories of Internal, Chance, and Powerful Others. To ascertain the reliability and validity of Form C, studies were conducted with patients of five different groups: rheumatoid arthritis, chronic pain (location unspecified), diabetes (Type I and Type II), and two cancer groups (type unspecified). All subjects completed the 24-item Form C, as well as another measure of health locus of control, and measures of pain, helplessness, and depression.

Before carrying out item and factor analyses for Form C, data from all five patient groups were combined, then the subjects were then randomly divided into two groups for cross-validation purposes (Sample 1: n=596 subjects, Sample 2: n=580 subjects). The factor analysis that was carried out on the data from Sample 1 yielded four factors: Internality (eight items), Chance (eight items), Doctors (four items), and Powerful Others (four items). To make Form C comparable to the original, 18-question MHLC, the number of items in each factor was reduced to six, six, three, and three, respectively, by eliminating the items with the weakest loadings. Wallston et al. (1994) reported reliability coefficients for the respective scales of .85, .79, .71, and .70 in Sample 2. In addition, the test-retest stability of Form C was examined in the group of chronic pain study. The corresponding correlation coefficients for the Internal, Chance, Doctors, and Powerful Others scales were .80, .72, .58, and .40, respectively (one month interval).

The validity of Form C was assessed in several ways. In the first, the group of chronic pain patients received an intervention designed to change health locus of control
beliefs (mainly by weakening beliefs in pain helplessness). After this intervention, the Internal scale was significantly higher, and the Chance, Doctors, and Other People scales decreased significantly. The authors reported this as evidence of Form C's construct validity.

Concurrent validity was investigated by comparing Form C with one of the original MHLC Scales (Form B). The correlation between the Internal scales of Form C and Form B was .59 (p<.001), and the corresponding correlation between the two Forms' Chance scales was .65 (p<.001). Finally, the Doctors and Powerful Others scales of Form C were significantly correlated with the Powerful Others scale of Form B (r=.55 and .38, respectively).

Intercorrelations between the scales of Form C in Sample 2 were also reported, and they tended to be related in a theoretically consistent way. For example, the Internal and Chance scales were inversely related (r= - .19, p<.05), but the Doctors and Other People scales were positively correlated (r=.22, p<.05). In summary, Form C has four separate scales that have high internal consistency and moderate relationships to each other. These scales responded in a theoretically consistent way to an intervention designed to change health beliefs, and they are related to an earlier version of the MHLC Scales. In addition, the test-retest coefficients are higher for the Internal and Chance scales (.80 and .72, respectively) than for the Doctors and Powerful Others scales (.58 and .40, respectively), which supports the use of the Internal scale in this study.
The Relationship of Patient Knowledge of Disease to HRQOL in Other Groups

Having knowledge about one's medical condition seems intuitively related to a person's adaptation to illness. The importance of such knowledge has been studied in conditions such as chronic pain (LeFort, Gray-Donald, Rowat, & Jeans, 1998), cancer (Ferrell, Ferrell, Ahn, & Tran, 1994; Taplin, Blanke, & Baughman, 1997), congestive heart failure (Frattini, Lindsay, Kerr, & Park, 1998), and diabetes (Glasgow, 1995). As will be shown below, HRQOL is one area impacted by increased patient knowledge.

LeFort et al. (1998) studied the effects of a psychoeducational program on pain, depression, perceived level of disability, self-efficacy, and HRQOL in a population of chronic pain patients. These subjects were randomly assigned to either the program (n=57) or to a control group (n=53). The program topics included education about the physiology of chronic pain, nutrition, coping strategies, and exercise. This intervention lasted for two hours per session and continued for six weeks. The Medical Outcomes Study Short Form-36 (SF-36; Ware & Sherboume, 1992) was used to assess HRQOL. This scale is a generic quality of life scale that assesses areas including physical function, social function, and general mental health.

The authors reported the effects of the psychoeducational program on a number of outcomes, however, its effect on HRQOL will be discussed here. The Physical role, Bodily pain, and Vitality subscales of the SF-36 changed significantly after treatment. In addition, although the mental health and social function scales did not differ significantly from pre- to post-test, they changed in the same direction. As discussed above, a disease-specific HRQOL instrument might have been more responsive to patient education (Irvine, 1997). The authors concluded that similar programs for increasing patient
knowledge provide promise for increasing HRQOL in chronic pain patients and that they deserve further research.

**The Relationship of Patient Knowledge of Disease to HRQOL in IBD Patients**

This finding suggests that increasing a patient's information about IBD can also raise his or her HRQOL. Although this relationship has not been well-studied in IBD patients, some research has been reported. Moser et al. (1995) assessed HRQOL using the Rating Patient Form of IBD Concerns (RFIPC; Drossman et al., 1991) in 72 patients with Crohn's disease and 33 ulcerative colitis patients. Disease activity was classified as severe/moderate or moderate using the CDAI (Best et al., 1976) and the Colitis Activity Index (Rachmilewitz, 1989), and patient knowledge was measured by a visual analog scale (0, totally uninformed to 100, very well informed) that subjects used to estimate their knowledge about IBD.

The authors reported that the correlation between disease activity and HRQOL was not significant. They did, however, find a significant correlation between the Sumscore of the RFIPC and estimated disease knowledge ($r = -0.20$). Thus as knowledge about IBD increased, worries about the illness decreased. A weakness of this study is the lack of an objective measure of patient knowledge, however, the results suggest that more knowledge of IBD increases adjustment to it.

Smart, Mayberry, Calcraft, Morris, & Rhodes (1986) gave 175 patients with Crohn's disease an information booklet on topics such as the symptoms, etiology and treatment of their illness. One year later, the 125 who could be reached and who had read the booklet were asked for their impressions of it. Eighty-two percent reported that the
information was valuable, and nearly as many said that they had learned more about Crohn’s disease from reading it. When asked about the effects of this material on anxiety levels, 30% said it had decreased, 13% reported an increase, and 57% reported no change. Smart et al.’s (1986) study reproduces the finding that while the majority of patients desire more information, about 20-30% do not desire more information because they find it threatening (Jones, Gallacher, Lobo, & Axon, 1993; Mansfield, Tanner, & Branble, 1997). This majority who desire more information may find this to be an effective coping style (Kinash et al., 1993). Patients who wish to know more about their illness typically ask about topics such as causal factors, new treatments, and risks in areas such as conception, pregnancy or cancer (Martin, Leone, Castagliuolo, Mario, & Naccarato, 1992).

Measurement of Patient Knowledge

In this study, a patient’s knowledge about IBD was measured using the Knowledge Questionnaire (KQ), a patient-completed form consisting of 37 true or false questions (Jones et al., 1993). The KQ was designed for both Crohn’s and ulcerative colitis patients, and can be completed in approximately 15 minutes. The topics of the test include the anatomy and function of the gastrointestinal tract, extraintestinal symptoms of the disease, medical and surgical treatments, and how patients can manage their disease.

A 44-question test was initially developed from a study that involved 64 patients with Crohn’s disease (Rees, Mayberry, & Calcraft, 1983) who listed topics that they desired more information about. The 44 questions, however, contained questions relevant to both Crohn’s disease and ulcerative colitis. This instrument was then given to
20 consecutive patients (type of disease was not specified) at a colitis clinic. An "index of difficulty" was calculated for each item by dividing the number of correct responses to an item by the total number of responses to that item. If the value of this index was greater than .75, meaning that most patients answered the question correctly, that item was either changed or eliminated.

The revised 37-question KQ was then given to a different group of 30 patients, sixteen of whom completed the questionnaire again four to six weeks later. Test-retest correlations and Cronbach's alpha were calculated from this group. In addition, a randomly selected group of 56 patients from the colitis clinic (27 had Crohn's disease and 29 had ulcerative colitis) completed the test for the reporting of normative data.

The authors reported a Cronbach's alpha of .84 and a test-retest correlation of .92 for the revised KQ. The range of test scores was 2-29, with an average score of 13.4 and a standard deviation of 6. The median score for Crohn's patients was significantly higher than the median score for ulcerative colitis patients (15 vs. 11, respectively). The KQ score was negatively correlated with age ($r = -.34$, $p < .01$), and positively correlated with the number of years spent in full-time education ($r = .49$, $p < .001$). In addition, the median score of the 13 people who were members of the National Association of Crohn's Disease and Colitis was higher than the rest of the subjects (median = 21, $p < .005$). The authors conclude that the KQ is useful for assessing patient knowledge.
The Relationship of Social Support to HRQOL in Other Groups

Social support, which is needed for a variety of challenging circumstances, has two major functions (Krol, Sanderman, and Suurmeijer, 1993). First, there is a direct effect of meeting a person’s needs for affiliation. Other people also assist an individual in marshaling cognitive and emotional resources for coping (a buffer effect). A person diagnosed with a chronic disease will presumably have an increased need for both functions of social support in order to experience an optimal satisfaction with life.

Krol et al. (1993) reviewed research on the effects of social support on quality of life in patients with rheumatoid arthritis. Although they noted that most studies were not adequately designed to establish a causal link between the two constructs, they concluded that such support is beneficial. Similarly, a review of 25 years of research on lung cancer (Montazeri, Gillis, & McEwen, 1998) ends with an exhortation for clinicians to pay closer attention to a patient’s emotional needs because this attention, the authors claim, can lead to an increased quality of life in these patients. Studies of people with diabetes (Aalto, Uutela, & Aro, 1997) and chronic pain (Trief, Carrière, & Drudge, 1995) have yielded similar results.

The Relationship of Social Support to HRQOL in IBD Patients

Since IBD is an illness without a cure—except for removal of the colon in ulcerative colitis—those who suffer from it are likely to frequently rely on emotional support from others. Several recent studies have examined the role that social support plays in helping IBD patients adapt to their illness. MacPhee, Hoffenberg, and Ferranchak (1998) administered a generic quality of life instrument to 18 ulcerative
colitis patients and 12 suffering from Crohn's disease (average age was 14 years). The subjects also completed a measurement of satisfaction with present social support, and a significant correlation between the two was reported (r=.46). The authors concluded that quality of life is better predicted by perceptions of social support than by disease activity. Although these subjects were adolescents rather than adults, and a categorical as opposed to a quantitative measure of disease activity was used, the relationship of social support to HRQOL in this study is clear.

In another study, Turnbull and Vallis (1995) administered the IBDQ and quantitative measurements of disease activity to sixteen patients with Crohn's disease and to six who had ulcerative colitis, reporting a nonsignificant correlation between disease activity and HRQOL (r=.41). Scores from measurements of psychosocial functioning, psychological distress, and coping style were then combined with disease activity into a single variable and used to predict the total and subscale scores of the IBDQ. The measure of psychosocial function (Sickness Impact Profile; Berger, Bobbitt, & Pollard, 1976) included questions about a person's social interaction and communication with others. The combined measurements were significantly related to the IBDQ total score (r=.53, p<.05); increased HRQOL was associated with higher levels of social functioning.

In a separate study, Maunder, de Rooy, Toner, Greenberg, Steinhart, McLeod, and Cohen (1997) administered the RFIPC (Drossman et al., 1991) to over 200 IBD patients. Two groups were formed: a Counseling group, composed of people who had recently sought or who were being referred for counseling, and a Noncounseling group, made up of patients who had not received counseling within the last six months. The authors reported that two RFIPC items that pertained to social support, "being alone" and "being
a burden to others," were more of a concern to those in the Counseling group. Assuming that the people seeking counseling were experiencing greater distress than those who were not, indirect evidence that difficulties with social support are related to increased distress is provided. Presumably, increasing levels of psychological distress are also related to decreased HRQOL (Drossman et al., 1991), thus showing a relationship between social support and HRQOL.

Finally, Godber and Mayberry (1988) reported on a telephone support service offered to members of an IBD support group in Nottingham, England. The phone counselors were IBD patients who had received a short course in counseling skills, and in a period of several months, 20 patients utilized these services. The most frequently discussed topics were a need to talk with someone who understands the problems of IBD, a feeling that a person's doctor was not interested in these problems, and feeling too embarrassed to discuss these problems with friends. Clearly, this group of people was composed of distressed individuals who were motivated enough to seek lay counseling, and who may not be a representative sample of IBD patients. In addition, no measurements of HRQOL or social support were taken. However, the importance of relationships with others to these people is clear, and the above studies suggest that the investigation of social support and HRQOL in IBD patients, using valid and reliable measures of these constructs, has promise for increased understanding of their relationship.
Measurement of Social Support

A subject's satisfaction with social support was measured using the six-question Social Support Questionnaire (SSQ6; Sarason, Sarason, Shearin, & Pierce, 1987). This questionnaire was designed to provide a short (it can be filled out in a few minutes) and psychometrically sound measure of social support. It was based on the 27-question Social Support Questionnaire (SSQ; Sarason, Leaven, Bash, & Sarason, 1983), which will be described first.

The SSQ (Sarason et al., 1983, Study 1) was designed from a list of 61 items concerning social support that were formed from several studies containing hundreds of college students. Items that had low correlations with other items were eliminated, reducing the SSQ to 27 items. Each question asks the subject to (a) list the people whom they rely on for support in certain circumstances and (b) report their satisfaction with these social supports, resulting in the calculation of two separate scales. The number score (N) is simply the total number of people listed. An average N score is obtained for an individual by dividing the total N score by 27. Each item also receives a satisfaction score (S), ranging from 1 (very dissatisfied) to 6 (very satisfied). The total S score is then divided by 27 to produce an average S score.

The authors administered the SSQ to 602 college students. The average N score was 4.25, and the average S score was 5.38. The Cronbach’s alphas of the N and S scales were .97 and .94, respectively. A factor analysis performed on each scale showed that a single factor accounted for 82% of the common variance in the N scale and another factor accounted for 72% of the common variance in the S scale. The correlation between the
two scales was .34, supporting their treatment as separate concepts. The test-retest correlations (four-week interval) for the N and S scales were .90 and .83, respectively.

After showing that the SSQ had good psychometric qualities, the authors investigated its validity (Sarason et al., 1983, Study 2). The subjects were 100 male and 127 female college students. All were administered the SSQ and the Multiple Affect Adjective Check List (MAACL; Zuckerman & Lubin, 1965). Four weeks later, 66 of these subjects (28 men and 38 women) were administered the Extraversion and Neuroticism scales of the Eysenck Personality Inventory (EPI; Eysenck & Eysenck, 1968).

The authors reported significant correlations ($r = -.26$ to $-.43$) between both SSQ scales and the Anxiety, Depression, and Hostility scales of the MAACL for female subjects. Similar but weaker correlations were found for men. Thus, people with higher social support (measured by the SSQ) experienced lower negative affect. For females, a significant correlation was also reported between the N score of the SSQ and the Extraversion scale of the EPI. Such a relationship was not found between the S score of the SSQ and the Extraversion scale. For men, the results were in the same direction, but were not significant. This is finding makes intuitive sense, since extraverts, by definition, are likely to have many people to turn to.

Finally, there was a significant negative correlation among female subjects between the S scale of the SSQ and the Neuroticism scale of the EPI, but a nonsignificant relationship between the N scale of the SSQ and the Neuroticism scale; that is, women who were not satisfied with their social support reported more emotional disturbance. Again, the results were similar, but not significant, in the group of men. These results are
consistent with the findings—described above—that emotional distress is related to difficulties with one’s social support system (Maunder et al., 1997). In summary, the N and S scales of the SSQ are internally consistent and stable, and are related in a theoretically consistent way to measures of negative affect and sociability.

The SSQ6 (Sarason et al., 1987) was designed to be a short measure of social support that would correlate highly with the SSQ. It is composed of six questions from the SSQ, and takes less than 10 minutes to complete. These questions were selected using data from two studies (Sarason et al., 1987) in which the subjects were several hundred adults who had completed the SSQ and other measures of social support. The six items of the SSQ6 were chosen on the basis of their high average loadings following a factor analysis of the SSQ.

A third sample of subjects was used for cross-validation. An SSQ-6 score was computed for each subject, and compared to his or her SSQ score. The correlation between the SSQ-6 and the SSQ Number scales was .97. The correlation between the SSQ-6 and SSQ Satisfaction scales was .96. The internal reliabilities for these the SSQ-6 scales were greater than .90. The authors also computed correlations between the SSQ-6 and several measures of social support, which did not differ from the corresponding correlations involving the SSQ. The authors concluded that the SSQ-6 is a satisfactory measurement of social support.

**Purpose and Hypotheses**

A great deal of research has been done concerning the treatment of the physical symptoms of IBD. Only recently, however, has attention been focused on the other areas
of functioning that it impacts—a person’s health-related quality of life. This attention has also increased in areas such as cancer, asthma, epilepsy, rheumatoid arthritis, angina, diabetes and AIDS (Bowling, 1995). Despite the increased attention to this area in IBD, few studies have used valid and reliable measurements to study the factors that are related to HRQOL in this patient group. The purpose of this study is to attempt to identify some of these factors. If strong relationships are observed between these constructs and HRQOL, future research could examine these variables in a manner that permits causal inferences about them. A review of research leads to the following hypotheses:

1) A person’s disease activity, health locus of control beliefs, knowledge of his or her illness, and satisfaction with social support will predict his or her health-related quality of life better than will disease activity alone;

2) Believing that one’s behavior is able to effect positive health outcomes will be positively related to increased knowledge about inflammatory bowel disease;

3) Scores on a subject’s Social subscale of the IBDQ will be strongly and positively related to his or her scores on the Satisfaction scale of the SSQ6;

4) The IBDQ will have reliable subscale scores and a reliable composite score, and;

5) The four subscale scores of the IBDQ will be only moderately correlated to each other.
Participants

Participants were recruited from rural outpatient treatment facilities in Michigan and Montana by gastroenterologists with whom the experimenter was acquainted. In addition, subjects who responded to a posting on an Internet chat group and in an IBD newsletter also participated. All were patients 18 or older who had a diagnosis of either Crohn's disease or ulcerative colitis that was potentially confirmable by medical records (although to protect anonymity, this was not done). Patients who had an ostomy bag were excluded from the study. Based on related research, a medium effect size was likely for this study; thus, to obtain a power of .80 with an alpha level of .05, 84 subjects would be needed (Cohen, 1992). Sixty-two subjects were actually recruited.

Materials

Demographic Questionnaire. Each subject completed a questionnaire that gathered information about gender, age, and type and duration of disease. It requires approximately one minute to complete. See Appendix A for the Demographic Questionnaire.

Health-Related Quality of Life. The Inflammatory Bowel Disease Questionnaire (IBDQ) was used to quantify health-related quality of life (Guyatt et al., 1989). This measure has 32 items, and it takes approximately 20 minutes to complete. The
development of this instrument, as well as data on its validity and reliability, were described above. See Appendix B for the IBDQ.

**Disease Activity.** The Chapel Hill Index (CHI) was used to measure disease activity (Sandler et al., 1988). The development and characteristics of this instrument were described above. This questionnaire contains three questions and it can be completed in less than five minutes. See Appendix C for the CHI.

**Health Locus of Control.** The 18-item Multidimensional Health Locus of Control Scale, Form C (MHLC-C) was used to measure health locus of control (Wallston et al., 1994). This measurement was described in detail above, and it requires approximately 10 minutes to complete. See Appendix D for the MHLC-C.

**Patient Knowledge.** The amount of information that a patient knows about his or her disease was assessed by a modified form of the Patient Knowledge Questionnaire (KQ; Jones et al., 1993). Information about this measurement's development, validity, reliability, and modification was given above. It has 37 items and takes about 15 minutes to complete. The correct responses to the KQ were not indicated in the original article, but were obtained by having the gastroenterologist from Montana complete it. See Appendix E for the KQ.

**Social Support.** The six-item Social Support Questionnaire (SSQ-6) was used to measure each patient's satisfaction with social support (Sarason et al., 1987). Its development and validity and reliability information were described above. This instrument can be completed in approximately 10 minutes. See Appendix F for the SSQ-6.
**Procedure**

Approval by the Institutional Review Board was obtained before this study began (Appendix G). Many of the participants were recruited by a gastroenterologist or nurse who briefly explained the study to consecutive patients at an outpatient clinic in either Marquette, Michigan or Missoula, Montana during regularly scheduled visits. A packet containing the questionnaires was then distributed to those who both wished to participate and who met the exclusion criteria. Those who declined were not asked again. To minimize the amount of time spent explaining the study, detailed instructions were included with each packet (Appendix H), and they were also printed at the top each instrument.

Participants who wished to participate completed the questionnaires at home, with a total time to read and complete the packet of approximately one hour. To ensure complete anonymity, the instructions stated that subjects were not to write their names on any of the questionnaires. Each packet contained a postage-paid, addressed envelope, which was mailed to the principal investigator at the University of Montana. When the questionnaires were received, a number code was assigned to all questionnaires in a packet to prevent any possibility that they would be confused with each other. In order to minimize the time demands on the gastroenterologist, the campus phone number of the principal investigator was included in the instructions. Thus, subjects had the opportunity to leave their first names and a number where they could be reached if they had any questions.

In order to increase the sample size of this study, subjects were recruited from two additional sources. First, a brief description of the study was posted on an Internet
message board, asking any interested people to respond to the e-mail address of the experimenter. Those who responded were then sent a more detailed message that emphasized the anonymity of the study, explained the exclusion criteria, and asked—if they were eligible and still interested—for an address to which the study could be mailed via the U.S. Postal Service. When an address was received, a questionnaire pack was sent and the address was deleted from the computer. In addition, a brief description of the study was placed in an IBD newsletter (Appendix K). Interested persons responded with an address by either e-mail or traditional mail, and a questionnaire packet was sent to them. All of these packets and the instructions were identical to the ones distributed in the doctor's office.
Chapter 3
Results

Sample Characteristics

All data were scored and entered into a computer equipped with SPSS, then double-checked for accuracy in both scoring and entering. A total of 113 questionnaires were distributed either directly or by mail, of which 62 (55%) were received and used for this study. Breaking this down according to source, thirty were received from Michigan, two were received from Missoula, seven came from Internet subjects, and twenty-three came from responders to the IBD newsletter.

Table 1 displays the sample’s demographic characteristics. Seventy-three percent of the subjects were diagnosed with Crohn’s disease, and of the 59 subjects who indicated their gender, 43 (73%) were female. All but one were Caucasian, and the mean age and years since diagnosis of the sample were similar to those reported in a recent study (Slonim, Bulone, Damore, Goldberg, Wingertzahn, and McKinley, 2000).

In Table 2 are the range, mean and standard deviation of the scales and subscales. Most of the scales did not appear normally distributed; however, the SSQ-6 and the IBDQ Social subscale were particularly skewed in a positive direction. The average Chapel Hill Index score was 187.8, a value equivalent to a moderate level of disease activity (Best et al. 1976; Sandler, Jordan, and Kupper, 1988). This score was slightly lower than the baseline score of subjects in a recent trial of growth hormone therapy for Crohn’s disease (Slonim et al., 2000). In two other studies the pretreatment means were approximately 300 (Targan, Hanauer, van Deventer, Mayer, Present, Braakman,
DeWoody, Schaible, and Rutgeerts, 1997; Yacyshyn et al., 1998). The average IBDQ Total score was 152.4, slightly lower than the “in remission” group (that is, people with a low level of disease activity) means of 169.0 and 174.0 reported by Irvine (1997) and Han et al. (1998), respectively.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crohn’s disease</td>
<td>45*</td>
</tr>
<tr>
<td>Male</td>
<td>10</td>
</tr>
<tr>
<td>Female</td>
<td>32</td>
</tr>
<tr>
<td>Ulcerative colitis</td>
<td>17</td>
</tr>
<tr>
<td>Male</td>
<td>6</td>
</tr>
<tr>
<td>Female</td>
<td>11</td>
</tr>
<tr>
<td>Age in years</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>46 (17)</td>
</tr>
<tr>
<td>Range</td>
<td>20-80</td>
</tr>
<tr>
<td>Years since diagnosis</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>15 (12)</td>
</tr>
<tr>
<td>Range</td>
<td>1-48</td>
</tr>
<tr>
<td>Source</td>
<td>Number (% who responded** )</td>
</tr>
<tr>
<td>Michigan</td>
<td>30 (50%)</td>
</tr>
<tr>
<td>Missoula</td>
<td>2 (18%)</td>
</tr>
<tr>
<td>Internet</td>
<td>7 (54%)</td>
</tr>
<tr>
<td>Newsletter</td>
<td>23 (79%)</td>
</tr>
</tbody>
</table>

* Three subjects with Crohn’s disease did not report gender
** This is the percentage of subjects from each source who mailed back a questionnaire, not the percentage each source contributes to the sample

The average Multidimensional Health Locus of Control-Internal score was slightly higher (20.2 vs. 17.7) than it was in a sample of arthritis patients (Wallston et al, 1994). The average Knowledge Questionnaire score was 19.0, higher than the 13.4 reported during the test’s development (Jones et al, 1993). Finally, the mean score of 5.2
for this sample's SSQ-6 Satisfaction score was only slightly lower than that reported for the original SSQ6 (5.4; Sarason et al., 1983). The most common sources of social support reported by subjects were friends (60%), parents (50%), spouses (44%), siblings (39%), and children (35%). Other responses were employer (8%), doctor (6%), and God (3%).

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
<th>Total Possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHI*</td>
<td>187.8</td>
<td>131.2</td>
<td>0-513</td>
<td>650</td>
</tr>
<tr>
<td>MHLC-I</td>
<td>20.2</td>
<td>6.7</td>
<td>6-36</td>
<td>36</td>
</tr>
<tr>
<td>KQ</td>
<td>19.0</td>
<td>5.9</td>
<td>9-30</td>
<td>37</td>
</tr>
<tr>
<td>SSQ-6</td>
<td>5.2</td>
<td>1.2</td>
<td>1.2-6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>IBDQ Bowel**</td>
<td>49.0</td>
<td>12.1</td>
<td>17-69</td>
<td>70</td>
</tr>
<tr>
<td>IBDQ Systemic</td>
<td>20.9</td>
<td>7.5</td>
<td>7-35</td>
<td>35</td>
</tr>
<tr>
<td>IBDQ Emotion</td>
<td>55.8</td>
<td>16.6</td>
<td>22-82</td>
<td>84</td>
</tr>
<tr>
<td>IBDQ Social</td>
<td>26.7</td>
<td>8.0</td>
<td>8-35</td>
<td>35</td>
</tr>
<tr>
<td>IBDQ Total</td>
<td>152.4</td>
<td>40.9</td>
<td>59-220</td>
<td>224</td>
</tr>
</tbody>
</table>

*Higher scores indicate greater disease activity; ** For IBDQ, higher scores indicate better functioning; CHI = Chapel Hill Index; MHLC = Multidimensional Health Locus of Control-Internal Scale; KQ = Knowledge Questionnaire; SSQ-6 = Social Support Questionnaire (Satisfaction Scale)

**Hypothesis One**

The first and major hypothesis of this study was that disease activity, health locus of control beliefs, knowledge of illness, and satisfaction with social support would predict a person's HRQOL better than will disease activity alone. This was tested by first forcing disease activity (the Chapel Hill Index) into a regression equation in a hierarchical fashion (Step 1). The remaining predictors (the Multidimensional Health Locus of Control-Internal scale, the Knowledge Questionnaire score, and the Satisfaction...
scale of the SSQ-6) were then entered together as a group, and the computer was
instructed to proceed in a stepwise fashion (Step 2). The dependent variables in the five
resulting regression equations were the IBDQ Total score and each of the IBDQ subscale
scores (Bowel, Systemic, Emotional, and Social).

Table 3 shows the results of the five regression analyses. As expected, the Chapel
Hill Index accounted for a significant amount of variance in all of the IBDQ subscale
scores and in the IBDQ Total score, with R-squared in Step 1 ranging from .43-.67. The
only other significant predictor was the SSQ-6 Satisfaction scale for the Emotion
subscale, accounting for an additional eight percent of the subscale variance.

**Hypothesis Two**

The second hypothesis was that believing one’s behavior is able to effect positive
health outcomes will be positively related to increased knowledge about IBD. This was
tested by calculating a Pearson’s correlation coefficient between the Internal scale of
Multidimensional Health Locus of Control questionnaire and the Knowledge
Questionnaire. The correlation coefficient (one-tailed) was not significant ($r = -.16,$
$p>.05$).

**Hypothesis Three**

The third hypothesis was that the Social subscale of the IBDQ would be strongly
and positively related to the Satisfaction scale of the SSQ-6. This was tested by
calculating a Pearson’s correlation coefficient between the Social subscale of the IBDQ
and the Satisfaction scale of the SSQ-6. The correlation coefficient (one-tailed) was significant \( r = .33, p < .05 \), and the value of \( r^2 \) was .11.

<table>
<thead>
<tr>
<th>Table 3: Regression Analyses for IBDQ Subscales and Total Score.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bowel Subscale</strong></td>
</tr>
<tr>
<td>Step* Variable Entered</td>
</tr>
<tr>
<td>1 CHI</td>
</tr>
<tr>
<td>Constant</td>
</tr>
</tbody>
</table>

| **Systemic Subscale**                                         |
| Step* Variable Entered | B  | T   | p   | \( p^2 \) | \( s^2 \) | Total \( R^2 \) |
| 1 CHI               | -.038 | -6.8  | .00 | .44*           | .44*           | .44*           |
| Constant            | 28.2  | 22.1  | .00 |                 |                 |                 |

| **Emotion Subscale**                                          |
| Step* Variable Entered | B  | T   | p   | \( p^2 \) | \( s^2 \) | Total \( R^2 \) |
| 1 CHI               | -.008 | -6.7  | .00 | .43*           | .43*           | .43*           |
| 2 CHI SSQ-6         | -.007 | -5.8  | .00 | .37*           | .29*           | .37*           |
| Constant            | 4.0   | 3.0   | .00 |                 |                 |                 |

| **Social Subscale**                                           |
| Step* Variable Entered | B  | T   | p   | \( p^2 \) | \( s^2 \) | Total \( R^2 \) |
| 1 CHI               | -.004 | -7.9  | .00 | .52*           | .52*           | .52*           |
| Constant            | 34.8  | 28.2  | .00 |                 |                 |                 |

| **Total Score**                                               |
| Step* Variable Entered | B  | T   | p   | \( p^2 \) | \( s^2 \) | Total \( R^2 \) |
| 1 CHI               | -.24  | -9.2  | .00 | .59*           | .59*           | .59*           |
| Constant            | 197.9 | 33.9  | .00 |                 |                 |                 |

* significant at .05 level; \( p^2 \) = squared partial correlation; \( s^2 \) = squared semipartial correlation

*In Step 1 and Step 2 the CHI was entered hierarchically, and in Step 2 the SSQ-6 was entered in a stepwise fashion; CHI = Chapel Hill Index; SSQ-6 = Social Support Questionnaire (Satisfaction Scale)

**Hypothesis Four**

The fourth hypothesis was that the IBDQ would have reliable subscale scores and a reliable composite score. This was tested by calculating Crohnbach’s alphas for each of
the four subscales and for the composite score of the IBDQ. These values were as follows: Bowel (.86), Systemic (.85), Emotion (.95), Social Function (.90), and Total score (.97). These results were higher than those reported by Han et al. (1998) for the IBDQ subscales. They reported the following alphas: Bowel (.81), Systemic (.72), Emotion (.89), and Social (.89). The alpha for Total score was not given. Appendix I displays the items of the IBDQ categorized according to subscale.

_Hypothesis Five_

The fifth hypothesis was that the four subscale scores of the IBDQ will be only moderately correlated to each other. This was tested by calculating the Pearson’s correlations between each of the four subscales, and between each subscale and the composite score. Table 4 displays these correlations, which ranged from .77 between the Bowel and Systemic subscales to .96 between the Emotion subscale and the Total Score. All of the correlations were significant. To date, no other studies have reported the scale intercorrelations of the IBDQ, although Han et al. (1998) reported an average item-total correlation of .67.

<table>
<thead>
<tr>
<th></th>
<th>Bowel</th>
<th>Systemic</th>
<th>Emotion</th>
<th>Social</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowel</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Systemic</td>
<td>.77</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Emotion</td>
<td>.80</td>
<td>.87</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Social</td>
<td>.76</td>
<td>.76</td>
<td>.82</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Total</td>
<td>.91</td>
<td>.91</td>
<td>.96</td>
<td>.89</td>
<td>--</td>
</tr>
</tbody>
</table>

* All correlations were significant (two-tailed)
Back to Hypothesis One: Nonsignificant Predictors

In an effort to find possible reasons why most of the additional predictors were not significant in the regression equations for the first hypothesis, several other analyses were carried out. First, a close look was given to the probability values of the t-tests for each of the excluded variables in the regression analyses. This was done to determine if the study had low power, and to ascertain whether any of the variables were approaching significance, as well as what their partial correlation coefficients were. Table 5 displays the probabilities and partial correlation coefficients of the excluded variables in each of the five regression equations. The probabilities ranged from .08-.89, with an average value of .49, and the squared partial correlation coefficients ranged from .00-.05.

After this, the years since diagnosis, sex and age of the subjects were entered hierarchically into five separate regression equations (IBDQ subscale scores and the Total Score), with sex coded as a dummy variable (0=female, 1=male). None of these three predictors accounted for significant variance in any of the IBDQ subscales or in the Total score.

In the next post-hoc analysis, the Chapel Hill Index and the SSQ-6 were entered together into a regression equation to determine the amount of variance in IBDQ scores they accounted for together. The Chapel Hill Index score and the SSQ-6 score were then multiplied to create an interaction score for each subject. Finally, the interaction score was entered into the equation to establish whether it accounted for any significant additional variance. This was done to determine whether the SSQ-6 was a better predictor of HRQOL at, for example, lower versus higher levels of disease activity. The
Table 5: Probabilities and Partial Correlation Coefficients of Excluded Variables in the Five Regression Equations.

<table>
<thead>
<tr>
<th>Dependent Variable</th>
<th>Excluded Variable</th>
<th>$t^*$</th>
<th>$p$</th>
<th>$pr^{**}$</th>
<th>$pr^2$</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBDQ Bowel</td>
<td>KQ</td>
<td>.14</td>
<td>.89</td>
<td>.02</td>
<td>.00</td>
</tr>
<tr>
<td></td>
<td>SSQ-6</td>
<td>-.39</td>
<td>.70</td>
<td>-.05</td>
<td>.00</td>
</tr>
<tr>
<td></td>
<td>MHLC</td>
<td>.76</td>
<td>.45</td>
<td>.10</td>
<td>.01</td>
</tr>
<tr>
<td>IBDQ Systemic</td>
<td>KQ</td>
<td>-.69</td>
<td>.50</td>
<td>-.09</td>
<td>.01</td>
</tr>
<tr>
<td></td>
<td>MHLC</td>
<td>.95</td>
<td>.35</td>
<td>.13</td>
<td>.02</td>
</tr>
<tr>
<td></td>
<td>SSQ-6</td>
<td>1.2</td>
<td>.23</td>
<td>.16</td>
<td>.03</td>
</tr>
<tr>
<td>IBDQ Emotion</td>
<td>KQ</td>
<td>.19</td>
<td>.85</td>
<td>.03</td>
<td>.00</td>
</tr>
<tr>
<td></td>
<td>MHLC</td>
<td>.50</td>
<td>.62</td>
<td>.07</td>
<td>.00</td>
</tr>
<tr>
<td>IBDQ Social</td>
<td>KQ</td>
<td>.40</td>
<td>.70</td>
<td>.05</td>
<td>.00</td>
</tr>
<tr>
<td></td>
<td>SSQ-6</td>
<td>1.3</td>
<td>.20</td>
<td>.17</td>
<td>.03</td>
</tr>
<tr>
<td></td>
<td>MHLC</td>
<td>1.5</td>
<td>.13</td>
<td>.20</td>
<td>.04</td>
</tr>
<tr>
<td>IBDQ Total</td>
<td>KQ</td>
<td>.23</td>
<td>.82</td>
<td>.03</td>
<td>.00</td>
</tr>
<tr>
<td></td>
<td>MHLC</td>
<td>.97</td>
<td>.34</td>
<td>.13</td>
<td>.02</td>
</tr>
<tr>
<td></td>
<td>SSQ-6</td>
<td>1.8</td>
<td>.08</td>
<td>.23</td>
<td>.05</td>
</tr>
</tbody>
</table>

* $t^*$ = t-test, ** $pr^*$ = partial correlation coefficient
KQ = Knowledge Questionnaire; MHLC = Multidimensional Health Locus of Control Scale-Internal; SSQ-6 = Social Support Questionnaire (Satisfaction Scale)

The same procedure was repeated for each IBDQ subscale and for the Total score. Table 6 displays the results of the five regression equations. The Interaction score significantly increased the R-squared value only for the Emotion subscale (4%), and it accounted for approximately eight percent of unique variance (not shown in table).
Table 6: Interaction Between Disease Activity and Social Support.

<table>
<thead>
<tr>
<th>IBDQ Subscale</th>
<th>Step 1 (R²)</th>
<th>Step 2 (R²)</th>
<th>R² increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowel</td>
<td>.67*</td>
<td>.67*</td>
<td>.00</td>
</tr>
<tr>
<td>Systemic</td>
<td>.46*</td>
<td>.48*</td>
<td>.02</td>
</tr>
<tr>
<td>Emotion</td>
<td>.51*</td>
<td>.55*</td>
<td>.04*</td>
</tr>
<tr>
<td>Social</td>
<td>.53*</td>
<td>.53*</td>
<td>.00</td>
</tr>
<tr>
<td>Total</td>
<td>.61*</td>
<td>.63*</td>
<td>.02</td>
</tr>
</tbody>
</table>

* significant at .05 level

Step 1 = Chapel Hill Index and SSQ-6 Entered; Step 2 = Interaction Score Entered

Finally, the subjects were divided into two groups based on diagnosis to address the possibility that the regression predictions would be supported for people with either Crohn's disease or ulcerative colitis, but not in a mixed sample. To examine this possibility, the regression analysis was repeated separately on the 17 subjects diagnosed with ulcerative colitis and on the 45 diagnosed with Crohn's disease (Table 7). The Chapel Hill Index accounted for more variance in all of the IBDQ scales for the subjects with ulcerative colitis. The SSQ-6 also accounted for a greater portion of unique Emotion subscale variance in the ulcerative colitis subjects (.07 vs. .27). Finally, the SSQ-6 accounted for 30% of unique Total score variance in the ulcerative colitis patients, compared to a nonsignificant amount in the Crohn's disease subjects. Appendix J displays the means and standard deviations for the scales for each group.

To determine whether the Multidimensional Health Locus of Control-Internal Scale (MHLC) or the Knowledge Questionnaire were approaching significance in any of the regression equations for the ulcerative colitis patients, the probability values and partial correlation coefficients for each of these excluded variables were examined (Table 8). If a more liberal p-value of .10 was adopted, the SSQ-6 and the MHLC would
become additional significant predictors in three of the subscales. For the Bowel subscale, the SSQ-6 accounted for 18% of unique variance. In addition, the MHLC accounted for 20% and 21% of unique variance in the Social and Total scales, respectively.

| Table 7: Regression Analyses for Crohn's Disease vs. Ulcerative Colitis |
|-------------------------------------------------|-----------------|-----------------|-----------------|
| **Bowel Subscale**                               | **Crohn's disease** | **Total R²** | **Ulcerative colitis** | **Total R²** |
| Step 1 Variable Entered*                         | pr² | sr² | Total R² | pr² | sr² | Total R² |
| 1 CHI                                            | .59* | .59* | .59*     | .76* | .76* | .76*     |
| **Systemic Subscale**                            | **Crohn's disease** | **Total R²** | **Ulcerative colitis** | **Total R²** |
| Step 1 Variable Entered                          | pr² | sr² | Total R² | pr² | sr² | Total R² |
| 1 CHI                                            | .34* | .34* | .34*     | .62* | .62* | .62*     |
| **Emotion Subscale**                             | **Crohn's disease** | **Total R²** | **Ulcerative colitis** | **Total R²** |
| Step 1 Variable Entered                          | pr² | sr² | Total R² | pr² | sr² | Total R² |
| 1 CHI                                            | .37* | .37* | .37*     | .49* | .49* | .49*     |
| 2 SSQ-6                                          | .11* | .07* | .44*     | .53* | .27* | .76*     |
| **Social Subscale**                              | **Crohn's disease** | **Total R²** | **Ulcerative colitis** | **Total R²** |
| Step 1 Variable Entered                          | pr² | sr² | Total R² | pr² | sr² | Total R² |
| 1 CHI                                            | .45* | .45* | .45*     | .64* | .64* | .64*     |
| **Total Score**                                  | **Crohn's disease** | **Total R²** | **Ulcerative colitis** | **Total R²** |
| Step 1 Variable Entered                          | pr² | sr² | Total R² | pr² | sr² | Total R² |
| 1 CHI                                            | .51* | .51* | .51*     | .72* | .72* | .72*     |
| 2 SSQ-6                                          | .03† | ‡    | .51*     | .30* | .08* | .80*     |

* significant at .05 level; † not significant; ‡ not in printout; pr² = squared partial correlation; sr² = squared semipartial correlation; CHI = Chapel Hill Index; SSQ-6 = Social Support Questionnaire (Satisfaction Scale); *In Step 1 and Step 2 the CHI was entered hierarchically, and in Step 2 the SSQ-6 was entered in a stepwise fashion

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.
<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>Excluded variable</th>
<th>t*</th>
<th>p</th>
<th>pr**</th>
<th>pr^2</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBDQ Bowel</td>
<td>KQ</td>
<td>-.90</td>
<td>.38</td>
<td>-.23</td>
<td>.05</td>
</tr>
<tr>
<td></td>
<td>MHLHC</td>
<td>1.7</td>
<td>.11</td>
<td>.42</td>
<td>.18</td>
</tr>
<tr>
<td></td>
<td>SSQ-6</td>
<td>1.8</td>
<td>.10</td>
<td>.43</td>
<td>.18</td>
</tr>
<tr>
<td>IBDQ Systemic</td>
<td>SSQ-6</td>
<td>.36</td>
<td>.72</td>
<td>.10</td>
<td>.01</td>
</tr>
<tr>
<td></td>
<td>KQ</td>
<td>-1.6</td>
<td>.14</td>
<td>-.38</td>
<td>.14</td>
</tr>
<tr>
<td></td>
<td>MHLHC</td>
<td>1.7</td>
<td>.12</td>
<td>.41</td>
<td>.17</td>
</tr>
<tr>
<td>IBDQ Emotion</td>
<td>KQ</td>
<td>-.80</td>
<td>.44</td>
<td>-.22</td>
<td>.05</td>
</tr>
<tr>
<td></td>
<td>MHLHC</td>
<td>1.0</td>
<td>.32</td>
<td>.27</td>
<td>.07</td>
</tr>
<tr>
<td>IBDQ Social</td>
<td>KQ</td>
<td>-.68</td>
<td>.51</td>
<td>-.18</td>
<td>.03</td>
</tr>
<tr>
<td></td>
<td>SSQ-6</td>
<td>.83</td>
<td>.42</td>
<td>.22</td>
<td>.05</td>
</tr>
<tr>
<td></td>
<td>MHLHC</td>
<td>1.9</td>
<td>.08</td>
<td>.45</td>
<td>.20</td>
</tr>
<tr>
<td>IBDQ Total</td>
<td>KQ</td>
<td>-1.2</td>
<td>.23</td>
<td>-.33</td>
<td>.11</td>
</tr>
<tr>
<td></td>
<td>MHLHC</td>
<td>1.8</td>
<td>.10</td>
<td>.46</td>
<td>.21</td>
</tr>
</tbody>
</table>

* t = t-test; ** pr = partial correlation coefficient
CHI = Chapel Hill Index; KQ = Knowledge Questionnaire; MHLHC = Multidimensional Health Locus of Control Scale-Internal; SSQ-6 = Social Support Questionnaire (Satisfaction Scale)
Chapter 4
Discussion

Hypothesis One

Social support. This study confirms that disease activity is related to HRQOL, a finding that is consistent with previous research (Irvine et al., 1994; Vallis and Turnbull, 1996). The major hypothesis of this study, however, was that a person’s disease activity, health beliefs, knowledge of illness, and satisfaction with social support would predict his or her HRQOL better than would disease activity alone. Possible reasons for the nonsignificance of health beliefs and knowledge of illness will be discussed below, but first the relationship of social support to HRQOL will be discussed.

The SSQ-6 was a significant predictor for the Emotion subscale of the IBDQ (Table 3). This finding is consistent with research in areas such as lung cancer (Montazeri et al., 1998) and diabetes (Aalto et al., 1997), and it also supports findings with IBD patients (MacPhee et al., 1998; Maunder et al., 1997). The present study has refined the understanding gained by previous research in IBD, however, by overcoming two methodological limitations.

First, a quantitative rather than a categorical measure of disease activity was used, and a disease specific rather than a generic HRQOL instrument was employed, allowing for a more precise description of the relationship between social support, disease activity, and HRQOL. Second, satisfaction with social support was measured with a well-validated and reliable instrument, rather than a composite score based on psychosocial functioning, psychological distress and coping style (Turnbull and Vallis, 1995).
Specifically, the present study suggests that satisfaction with social support is related to the emotional aspect of HRQOL in IBD (Table 3). In addition to depression, the Emotion scale asks about anxiety, worries related to having IBD, embarrassment, anger, and feeling misunderstood by others (Appendix J). This relationship suggests that having people to talk to about the feelings associated with IBD is important, because many of the symptoms—abdominal pain and rectal bleeding for example—are embarrassing and could isolate a person in his or her suffering.

Based on this finding, several interventions may be helpful. Some people may benefit from learning communication skills specifically aimed at proper disclosure of symptoms. For example, a person would describe their discomfort differently to a spouse than to an employer. In addition, certain individuals may receive encouragement from a support group, which could be either face-to-face or through an online chat room. Advantages to an online group include easy accessibility (to those with computers) and anonymity. Doctors who deal regularly with IBD patients would do well by being aware of and referring to both types of support groups in their cities.

Health locus of control. Health locus of control (HLOC) and patient knowledge were not significant predictors of any aspect of HRQOL (Table 3). In chronic illnesses such as osteoarthritis and chronic pain, a relationship between HLOC and psychological adjustment has been demonstrated (e.g., Crisson and Keefe, 1988; Laborde and Powers, 1985). It was assumed for this study both that psychological adjustment was an aspect of HRQOL (Farquhar, 1995), and that the active coping methods used by some IBD patients (Kinash et al., 1993) are prompted by the belief that one's actions to a large extent determine health.
The negative findings of this study in regards to HLOC, however, are similar to the research by Smolen and Topp (1998), who did not find a strong relationship between problem-focused coping styles and well-being, a concept related to HRQOL (Farquhar, 1995). Andrykowski and Brady (1994) have suggested that health beliefs become more important to adjustment when the perceived threat of the disease is great. It may be that sufferers of IBD view their illness more as a nuisance than a great threat to their health. It may also be the case that psychological adjustment—a vague term to be certain—is not an important aspect of HRQOL as defined by the IBDQ. Future research on HRQOL should clearly define the construct, and it should not interchange terms such as well-being or health status for HRQOL (Anderson and Burckhardt, 1999).

Knowledge of illness. A patient’s knowledge of his or her illness is related to HRQOL in conditions such as chronic pain (Lefort et al., 1998) and diabetes (Glasgow, 1995), and studies with IBD patients have suggested a similar link (Moser et al., 1995; Smart et al, 1986). The present study, however, did not offer support for the relationship between knowledge and HRQOL over and above the effects of the Chapel Hill Index (Table 3). There are at least two possible reasons for this discrepancy.

First, the symptoms of IBD are qualitatively different than conditions like chronic pain. Education programs for chronic pain often teach coping techniques such as relaxation (LeFort et al., 1998) and present information about the physiology of pain. These programs are successful at addressing the physical symptoms of chronic pain, and have a corresponding effect on HRQOL (LeFort et al., 1998). Because of the nature of Crohn’s disease and ulcerative colitis, however, similar programs for IBD have not been successful at addressing physical symptoms (Schwartz and Blanchard, 1991). Thus,
although knowledge may help reduce the suffering involved in chronic pain, it apparently has little effect on the symptoms of IBD.

The second possibility for the discrepancy between this study and previous research concerning patient knowledge is that past studies with IBD patients have used less rigorous methodologies. Moser et al. (1995) and Smart et al (1986) reported a relationship between disease knowledge and HRQOL, however, they had subjects estimate their knowledge rather than complete an objective measure. It may be that what a person thinks (s)he knows and what (s)he actually knows are different. Further, Jones et al. (1993) reported that about 20-30% of people do not want more information about IBD. Future research could examine the role of disease knowledge on HRQOL in the subgroup of patients who strongly desire more information.

**Hypothesis One: Additional Analyses Concerning the Nonsignificant Predictors**

Although the modest contribution of social support and the nonsignificant contributions of HLOC and patient knowledge to HRQOL may have occurred for the reasons mentioned above, additional analyses were done to determine if future research should investigate a modified version of the first prediction. An analysis of the sample (Table 2) reveals that subjects had, on the average, moderate disease activity and a correspondingly diminished HRQOL. On these variables, as well as for age and years since diagnosis (Table 1), the sample was similar to other groups reported in the literature. Thus, this sample appears to be fairly representative of the population of IBD patients, at least of those who are Caucasian. In addition, although most of this group
was female, sex accounted for a nonsignificant proportion of variance in the IBDQ subscales and the Total score, as did the years since diagnosis and age of the subjects.

Despite the fact that, with a larger sample, health beliefs and disease knowledge may have been significant predictors, the actual amount of variance they would account for would likely have been quite small compared to disease activity and, to a lesser degree, satisfaction with social support. Whereas the values of $R^2$ for the Chapel Hill Index ranged from .43-.67 (Table 3), the squared partial correlations for health beliefs or disease knowledge were very small ($pr^2$ ranged from .00-.04; Table 5), and the corresponding values for the SSQ-6 ranged from .00-.05. It does not appear, therefore, that the failure to confirm the major hypothesis was merely due to insufficient statistical power.

Similarly, level of disease activity did not play a major role in prediction of HRQOL. With the exception of the Emotion subscale, the interaction variable (disease activity X social support) did not add significantly to $R^2$, and it added only 4% to the Emotion subscale (Table 6). Thus it was not the case that the major hypothesis was confirmed at only certain (e.g., lower) levels of disease activity.

The choice of disease activity scale could have contributed to the lack of support for the major hypothesis. Previous research (Irvine et al., 1994) has shown that the Crohn's Disease Activity Index (and thus the Chapel Hill Index) and the IBDQ Total score are highly correlated, most likely because both ask for subjective symptoms of IBD (Appendices B and C). The use of an objective disease activity scale may have produced results that supported the major hypothesis.
Beside the possibility that the null hypothesis is true, however, the most likely explanation for the lack of support for the major hypothesis is that grouping both Crohn's disease and ulcerative colitis patients together obscured the results. Disease activity was a better predictor for every aspect of HRQOL for subjects with ulcerative colitis and, similarly, social support was a better predictor for the Emotion and Total scales (Table 7). In addition, health beliefs approached significance in both the Social and Total scales (Table 8). The fact that these variables were significant or close to significant in a sample of only 17 subjects strongly suggests that more research be done to examine the relationship of these variables to HRQOL in ulcerative colitis patients.

This analysis, although post-hoc, is consistent with research showing that Crohn's patients have diminished HRQOL compared to ulcerative colitis patients (Drossman et al., 1989; Farmer, Easley, and Farmer, 1992), and that the two groups have different disease-related concerns (Drossman et al., 1991). Although Drossman et al. (1991) explained the impairment in Crohn's disease in terms of greater disease activity, this study did not support that interpretation. Before concluding, however, that the lack of support for the major hypothesis is due to a "Crohn's personality style," that is, a passive or dependent manner of relating to others, it should be noted that such speculation has not been consistently supported (North and Alpers, 1994). It may be that people with ulcerative colitis experience symptoms that are slightly different than those of Crohn's sufferers (e.g., weight loss vs. fatigue), and that they are better able to manage the impact that their illness has on their lives. A better understanding of this process could lead to interventions that would increase the HRQOL of people with Crohn's disease and ulcerative colitis alike.
**Hypothesis Two**

The second hypothesis—believing that one’s behavior is able to effect positive health outcomes will be positively related to increased knowledge about IBD—was not confirmed. The original rationale for this hypothesis was that an internal HLOC may prompt people to learn more about their illness, or, alternatively, having a lot of knowledge about IBD may cause one to feel more in control of the illness. Both interpretations were based on Kinash et al.’s (1993) research showing that maintaining control and gathering information were commonly used coping strategies in IBD patients.

The fact that these two constructs were not related to each other is consistent with the finding by Smolen and Topp (1998) that a positive outlook (optimism), not more active strategies, is related to well-being. It may be that an interaction between optimism, HLOC, and knowledge of illness exists, a possibility that future research could investigate. The data in this study, however, suggest that health beliefs and knowledge of illness are not related.

**Hypotheses Three, Four and Five**

**Hypothesis Three.** The last three hypotheses deal with certain psychometric properties of the IBDQ and, therefore, will be treated together. The third hypothesis was that the Social subscale of the IBDQ will be strongly and positively related to the Satisfaction scale of the SSQ-6. Such an association would help to establish the concurrent validity of the IBDQ’s subscale, which is important, because the validity of this scale has not yet been firmly established.
In this study, the relationship between the two scales was a significant but moderate ($r = .33$) correlation; thus there is some support for the concurrent validity of the Social subscale of the IBDQ. Although a higher correlation was anticipated, a close look at the content of the items in the two measures reveals some differences between them. The SSQ-6 (Appendix F) asks for a list of people who are, for example, dependable when help is needed, and how satisfied they are with their support. The IBDQ Social subscale (Appendix I), however, asks about how having IBD has limited one’s ability to attend social events such as school, work, or leisure activities. It is possible for a person with IBD to have a severely restricted social life (and a correspondingly low Social subscale score), yet still be relatively satisfied with his or her social support. This satisfaction could occur by means of an accommodating support system; for example, the healthy husband could stay home with his wife who is too ill with IBD to attend, thus preserving social satisfaction in spite of social limitations.

It is a mistake, therefore, to assume that, because a person with IBD is restricted in their ability to engage in activities outside the home, they are also dissatisfied with their social support. Acknowledging this point can lead to creative ways of increasing social support to individuals with severe disease activity, and it also highlights the importance of educating friends and family members about IBD, so that they can help the person with IBD compensate for their illness. Thus, the Social subscale of the IBDQ appears to have utility as a way to quantify how impacted a person’s social life is by IBD, although it may not give a clear indication of satisfaction with social support.

**Hypothesis Four.** Although previous research has shown that the individual subscales have sufficiently high Cronbach’s alphas, the total score has not received this
attention. In this study, the alpha coefficient for the total score was .97, supporting the use of the composite score as a way of providing an overall picture of a person's HRQOL.

**Hypothesis Five.** All of the scale intercorrelations were very high, and because the lowest correlation was .76 (Table 4), there is some question concerning the treatment of the scales as measuring separate constructs. It may be that all of the scales measure a common aspect of having IBD such as depression, an emotion frequently reported by IBD patients (Mitchell et al., 1988). As discussed above, the Emotion subscale asks about depressive symptoms, such as discouragement, tearfulness and life dissatisfaction (Appendix I), and the Systemic subscale inquires into symptoms such as fatigue and sleep and appetite disturbances. In addition, the Social subscale describes diminished social interactions, which some researchers (Bellack, Hersen, and Himmelhoch, 1981; Hoberman, 1990) have linked to depression. It is at least plausible that depression could account for a sizeable portion of variance in all of the subscales. Future research using the IBDQ should include a measure of depression such as the Beck Depression Inventory (Beck, Ward, Mendelson, Mock, and Erbaugh, 1961) to address this question. Until that is done, the utility of using the IBDQ to discuss distinct components of HRQOL is uncertain.

**Final Conclusion**

Although this study provided some insights into HRQOL in IBD patients, it also raised many questions, a fact reflecting the relatively small amount of research that has been done in this area. (Maunder et al., 1995). Future research should begin with a clear
definition of HRQOL as a construct distinct from terms such as well-being and health status, and the use of disease activity measures that covers both the objective and subjective physical symptoms of IBD should be considered. In addition, it may be wise to reconsider the utility of grouping both Crohn's disease and ulcerative colitis subjects together for HRQOL research, because the two groups appear to be impacted differently by the illnesses. Although the IBDQ is currently the best instrument for this type of research, its ability to define discrete areas of HRQOL has not been sufficiently demonstrated. More definite answers in this area are essential for assisting people in adapting to the life-changing experience of IBD.
References


APPENDIX A

DEMOGRAPHIC QUESTIONNAIRE

Gender:

Age:

Ethnicity (circle one): Caucasian Hispanic African-American
Native American Other

Type of illness (circle one): Crohn’s disease Ulcerative colitis

Duration of illness (how many years or months you have had it): ______________________

Have you ever had surgery because of your Crohn’s disease or ulcerative colitis? ____
If yes, list dates: ________________________________________________

Current medications and dosages (please list ALL that you are taking, even if they are not
for Crohn’s disease or ulcerative colitis):

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX B

THE INFLAMMATORY BOWEL DISEASE QUESTIONNAIRE (IBDQ)

This questionnaire asks questions concerning the impact of Crohn's disease or ulcerative colitis on various areas of your life. There are no right or wrong answers, so just answer as honestly as you can.

Please indicate how you feel about each item by circling a number from 1 to 7 in the space provided. A 1 indicates that the area of your life is a current difficulty. A 7 means that the area of your life is not a current difficulty. (NOTE: The actual IBDQ has a card for each question that explains in detail what each number means).

1. How frequent have your bowel movements been during the last two weeks?
   (Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

2. How often has the feeling of fatigue or of being tired and worn out been a problem for you during the last two weeks?
   (Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

3. How often during the last two weeks have you felt frustrated, impatient, or restless?
   (Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

4. How often during the last two weeks have you been unable to attend school or work because of your bowel problem?
   (Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

5. How much of your time during the last two weeks have your bowel movements been loose?
   (Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

6. How much energy have you had during the last two weeks?
   (Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

7. How often during the last two weeks did you feel worried about the possibility of needing to have surgery because of your bowel problem?
   (Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

8. How often during the last two weeks have you had to delay or cancel a social engagement because of your bowel problem?
   (Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

9. How often during the last two weeks have you been troubled by cramps in your abdomen?
   (Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)
10. How often during the last two weeks have you felt generally unwell?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)

11. How often during the last two weeks have you been troubled because of fear of not finding a washroom?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)

12. How much difficulty have you had, as a result of your bowel problems, doing leisure or sports activities you would have liked to have done during the last two weeks?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)

13. How often during the last two weeks have you been troubled by pain in the abdomen?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)

14. How often during the last two weeks have you had problems getting a good night’s sleep, or been troubled by waking up during the night?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)

15. How often during the last two weeks have you felt depressed or discouraged?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)

16. How often during the last two weeks have you had to avoid attending events where there was no washroom close at hand?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)

17. Overall, in the last two weeks, how much of a problem have you had with passing large amounts of gas?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)

18. Overall, in the last two weeks, how much of a problem have you had maintaining, or getting to, the weight you would like to be at?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)

19. Many patients with bowel problems often have worries and anxieties related to their illness. These include worries about getting cancer, worries about never feeling any better, and worries about having a relapse. In general, how often during the last two weeks have you felt worried or anxious?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)

20. How much of the time during the last two weeks have you been troubled by a feeling of abdominal bloating?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)

21. How often during the last two weeks have you felt relaxed and free of tension?
(Current difficulty)  1  2  3  4  5  6  7 (Not a difficulty)
22. How much of the time during the last two weeks have you had a problem with rectal bleeding with your bowel movements?
(Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

23. How much of the time during the last two weeks have you felt embarrassed as a result of your bowel problem?
(Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

24. How much of the time during the last two weeks have you been troubled by a feeling of having to go to the bathroom even though your bowels are empty?
(Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

25. How much of the time during the last two weeks have you felt tearful or upset?
(Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

26. How much of the time during the last two weeks have you been troubled by accidental soiling of your underpants?
(Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

27. How much of the time during the last two weeks have you felt angry as a result of your bowel problem?
(Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

28. To what extent has your bowel problem limited sexual activity during the last two weeks?
(Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

29. How much of the time during the last two weeks have you been troubled by feeling sick to your stomach?
(Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

30. How much of the time during the last two weeks have you felt irritable?
(Current difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

31. How often during the last two weeks have you felt lack of understanding from others?
(CURRENT difficulty) 1 2 3 4 5 6 7 (Not a difficulty)

32. How satisfied, happy, or pleased have you been with your personal life during the last two weeks?
(CURRENT difficulty) 1 2 3 4 5 6 7 (Not a difficulty)
The following questions relate to problems caused by your Crohn’s disease or ulcerative colitis. Please answer the questions to the best of your knowledge. If you cannot remember exactly, an estimate is fine.

Answer the questions as they relate to your Crohn’s disease or ulcerative colitis, not to other situations in your life. For example, if your Crohn’s disease was not active, but you had abdominal pain due to food poisoning, you would circle “None” for Question 2.

1. In the past seven days, how many liquid or very loose stools have you had per day?

2. In the past seven days, how much abdominal pain have you had each day? (Please circle one of the following):
   None  Mild  Moderate  Severe

3. In the past seven days, how would you rate your general well-being? (Please circle one of the following):
   Well  Slightly below par  Poor  Very poor  Terrible
APPENDIX D

MHLC-C

Instructions: Each item below is a belief statement about your medical condition with which you may agree or disagree. Beside each statement is a scale which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to circle the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you circle. The more you disagree with a statement, the lower will be the number you circle. Please make sure that you answer EVERY ITEM and that you circle ONLY ONE number per item. This is a measure of your personal beliefs; obviously, there are no right or wrong answers.

<table>
<thead>
<tr>
<th>Item</th>
<th>Belief Statement</th>
<th>SD</th>
<th>MD</th>
<th>D</th>
<th>A</th>
<th>MA</th>
<th>SA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>As to my condition, what will be will be</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>I am directly responsible for my condition getting better or worse</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Other people play a big role in whether my condition improves, stays the same, or gets worse</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Whatever goes wrong with my condition is my own fault</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>In order for my condition to improve, it is up to other people to see that the right things happen</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Whatever improvement occurs with my condition is largely a matter of good fortune</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>The main thing which affects my condition is what I myself do</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>I deserve the credit when my condition improves and the blame when it gets worse</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Following doctor's orders to the letter is the best way to keep my condition from getting any worse</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>If my condition worsens, it's a matter of fate</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>If I am lucky, my condition will get better</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>The type of help I receive from other people determines how soon my condition improves</td>
<td>1 2 3 4 5 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX E

PATIENT KNOWLEDGE QUESTIONNAIRE

The following questions relate to different topics about Crohn's disease and ulcerative colitis. Read each statement and circle the response you believe is correct—T if the item is true, and F if the item is false. If you do not know the answer to an item, please do not guess; instead, circle DK (don't know).

1. The following things may be caused by Crohn's disease or ulcerative colitis:
   a. Red eyes. T F DK
   b. Dry mouth. T F DK
   c. High blood pressure. T F DK
   d. Painful joints. T F DK
   e. Anemia. T F DK

2. Concerning your bowel:
   a. The large bowel connects the outlet of the stomach to the back passage. T F DK
   b. Crohn's disease affects the small bowel only. T F DK
   c. Ulcerative colitis may affect any part of the bowel. T F DK
   d. The small bowel absorbs protein from food into the bloodstream. T F DK
   e. The bowel absorbs water from drinks into the bloodstream. T F DK

3. The chances of your children inheriting Crohn's disease/ulcerative colitis are:
   a. Very small. T F DK
   b. Greater than if you did not have the disease. T F DK
   c. Children of the same sex as you will probably inherit the disease. T F DK

4. Blood tests are often performed in the colitis clinic for the following purposes:
   a. To check your cholesterol level. T F DK
   b. To find out your blood group. T F DK
   c. To help assess whether your bowel is inflamed. T F DK
   d. To check whether you are short of vitamins. T F DK

5. Steroid tablets used in treating Crohn's disease or ulcerative colitis:
   a. May build up muscles. T F DK
   b. May cause thinning of bones. T F DK
   c. May cause nosebleeds. T F DK

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.
6. When you are well, the following tablets are used in the long-term to prevent Crohn’s disease/ulcerative colitis from becoming active again:
   a. Loperamide (Imodium)  T  F  DK
   b. Azathioprine (Azamune, Imuran)  T  F  DK
   c. Prednisolone (steroid)  T  F  DK
   d. Ranitidine (Zantac)  T  F  DK
   e. Sulfasalazine (Salazopyrine)  T  F  DK
   f. Mesalazine (Asacol)  T  F  DK

7. Regarding surgical operations in Crohn’s disease and ulcerative colitis:
   a. Most people with Crohn’s disease will require an operation at some point during the course of their illness.  T  F  DK
   b. Most people with ulcerative colitis will require an operation at some point during the course of their illness.  T  F  DK
   c. Following an operation, Crohn’s disease may occur again elsewhere in the bowel.  T  F  DK
   d. Following an operation to remove the large bowel, ulcerative colitis may occur again elsewhere in the bowel.  T  F  DK
   e. Removing part of the bowel can cause more frequent bowel movements.  T  F  DK

8. Regarding diet in Crohn’s disease and ulcerative colitis:
   a. Most people with Crohn’s disease and ulcerative colitis do not need to be restricted to a low residue (low fiber) diet.  T  F  DK
   b. You should avoid sugary foods.  T  F  DK
   c. You need not restrict your alcohol intake because you have Crohn’s disease/ulcerative colitis.  T  F  DK
   d. You should avoid milk.  T  F  DK

9. If you should start with an episode of diarrhea you should:
   a. Continue to eat as you normally would.  T  F  DK
   b. Wait a while but see your doctor if it persists for more than three weeks.  T  F  DK

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.
APPENDIX F

SOCIAL SUPPORT QUESTIONNAIRE (SHORT FORM)

SSQ6

The following questions ask about people in your environment who provide you with help or support. Each question has two parts. For the first part, list all of the people that you know, excluding yourself, whom you can count on for help or support in the manner described. Give the persons' initials and their relationship to you (see example). Do not list more than one person next to each of the numbers beneath the question.

For the second part, circle how satisfied you are with the overall support you have. If you have had no support for a question, check the words “No one,” but still rate your level of satisfaction. Do not list more than nine persons per question.

Please answer all of the questions as best as you can. All of your responses will be kept confidential.

EXAMPLE:
Who do you know whom you can trust with information that could get you in trouble?

<table>
<thead>
<tr>
<th>No one</th>
<th>1) T.N. (brother)</th>
<th>2) L.M. (friend)</th>
<th>3) R.S. (friend)</th>
<th>4) T.N. (father)</th>
<th>5) L.M. (employer)</th>
<th>6)</th>
<th>7)</th>
</tr>
</thead>
</table>

How satisfied?

<table>
<thead>
<tr>
<th>6-very satisfied</th>
<th>5-fairly satisfied</th>
<th>4-a little satisfied</th>
<th>3-a little dissatisfied</th>
<th>2-fairly dissatisfied</th>
<th>1-very dissatisfied</th>
</tr>
</thead>
</table>

1. Whom can you really count on to be dependable when you need help?

<table>
<thead>
<tr>
<th>No one</th>
<th>1)</th>
<th>4)</th>
<th>7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2)</td>
<td>5)</td>
<td>8)</td>
<td></td>
</tr>
<tr>
<td>3)</td>
<td>6)</td>
<td>9)</td>
<td></td>
</tr>
</tbody>
</table>

2. How satisfied?

<table>
<thead>
<tr>
<th>6-very satisfied</th>
<th>5-fairly satisfied</th>
<th>4-a little satisfied</th>
<th>3-a little dissatisfied</th>
<th>2-fairly dissatisfied</th>
<th>1-very dissatisfied</th>
</tr>
</thead>
</table>

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.
3. Whom can you really count on to help you feel more relaxed when you are under pressure or tense?

No one \( \Rightarrow \) 1) 4) 7)
2) 5) 8)
3) 6) 9)

4. How satisfied?

6-very satisfied 5-fairly satisfied 4-a little satisfied 3-a little dissatisfied 2-fairly dissatisfied 1-very dissatisfied

5. Who accepts you totally, including your worst and your best points?

No one \( \Rightarrow \) 1) 4) 7)
2) 5) 8)
3) 6) 9)

6. How satisfied?

6-very satisfied 5-fairly satisfied 4-a little satisfied 3-a little dissatisfied 2-fairly dissatisfied 1-very dissatisfied

7. Whom can you really count on to care about you, regardless of what is happening to you?

No one \( \Rightarrow \) 1) 4) 7)
2) 5) 8)
3) 6) 9)

8. How satisfied?

6-very satisfied 5-fairly satisfied 4-a little satisfied 3-a little dissatisfied 2-fairly dissatisfied 1-very dissatisfied

9. Whom can you really count on to help you feel better when you are feeling generally down-in-the-dumps?

No one \( \Rightarrow \) 1) 4) 7)
2) 5) 8)
3) 6) 9)
10. How satisfied?

<table>
<thead>
<tr>
<th>6-very satisfied</th>
<th>5-fairly satisfied</th>
<th>4-a little satisfied</th>
<th>3-a little dissatisfied</th>
<th>2-fairly dissatisfied</th>
<th>1-very dissatisfied</th>
</tr>
</thead>
</table>

11. Whom can you count on to console you when you are very upset?

<table>
<thead>
<tr>
<th>No one</th>
<th>1)</th>
<th>4)</th>
<th>7)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2)</td>
<td>5)</td>
<td>8)</td>
</tr>
<tr>
<td></td>
<td>3)</td>
<td>6)</td>
<td>9)</td>
</tr>
</tbody>
</table>

12. How satisfied?

<table>
<thead>
<tr>
<th>6-very satisfied</th>
<th>5-fairly satisfied</th>
<th>4-a little satisfied</th>
<th>3-a little dissatisfied</th>
<th>2-fairly dissatisfied</th>
<th>1-very dissatisfied</th>
</tr>
</thead>
</table>
APPENDIX G

Institutional Review Board Proposal

The Relationship of Health Beliefs, Knowledge of Disease, and Social Support to Health-Related Quality of Life in Patients with Inflammatory Bowel Disease

Principal Investigator: Michael T. Bach
Under the direction of D. Balfour Jeffrey, Ph.D.

1. Purpose of the Research Project

The purpose of this study is to examine the relationship of several factors—health beliefs, patient knowledge, and satisfaction with social support—to health-related quality of life in patients with inflammatory bowel disease (IBD). Despite the attention given to pharmaceutical and surgical treatments of the physical symptoms of IBD, less research has been devoted to studying the other areas that this illness effects, such as emotional and social functioning (areas subsumed under the heading, health-related quality of life).

The major hypothesis of this study is that the above factors will predict health-related quality of life better than will disease activity alone. If this prediction occurs, interventions based on this finding will be discussed. These include increasing a person’s belief in his or her ability to effect positive health outcomes, providing information about IBD to interested patients, and providing interested people with listings of local IBD support groups.

2. The Subjects

The subjects will be 100-150 persons from Michigan who are 18 or older and who have a diagnosis of inflammatory bowel disease.
3. Recruiting or Selecting Subjects

Potential subjects will have the study briefly explained to them by a gastroenterologist from Michigan during a regularly scheduled appointment. Those who wish to participate will be given a packet containing questionnaires measuring the above constructs.

4. Where the Study Will Take Place

Subjects will complete the questionnaires at their homes in Michigan. The information gathered from the questionnaires will then be analyzed in Montana.

5. The Activities the Subjects Will Perform

The subjects will complete five questionnaires: a Demographic Questionnaire (Appendix A) that asks about gender, age, and type of disease; the Inflammatory Bowel Disease Questionnaire (Appendix B), which will measure health-related quality of life; the Chapel Hill Index (Appendix C), which will measure disease activity; the Multidimensional Health Locus of Control Scale, Form C (Appendix D), which will measure a person's beliefs about how his or her behavior affects health outcomes; the Patient Knowledge Questionnaire (Appendix E), which will assess a patient's knowledge about IBD; and the six-item Social Support Questionnaire (Appendix F), which will measure a patient's satisfaction with the social support he or she is receiving. These questionnaires are brief, with a total completion time of approximately one hour. When the subject have completed the questionnaires, they will place them in a stamped envelope with prepaid postage that is addressed to the principal investigator.

6. Benefits of the Research

If the predicted results occur, several possible interventions designed to improve the
health-related quality of life of IBD patients become promising. These include increasing a person’s belief in his or her ability to effect positive health outcomes, providing information about IBD to interested patients, and providing interested people with listings of local IBD support groups.

7. Risks and Discomforts to Subjects

The potential risks and discomforts to the subjects in this study are minimal because they will fill out the questionnaires only once, and will need only one hour to complete them. Although some of the questions that they will respond to require revealing slightly embarrassing information (such as the frequency of bowel movements in the past two weeks), none of the forms ask for the person’s name. In fact, the Subject Instructions (see Appendix H) explicitly state that subjects are not to put their names on any of the questionnaires.

8. Minimizing Deleterious Effects

Questionnaire packets will be distributed only to those subjects who express an interest in the study. Those who do not wish to participate will not be pressured in any way to do so. Once at home, subjects can choose not to complete the forms if they find them objectionable for any reason. For such subjects, no negative consequences will follow, because the gastroenterologist will not follow-up on their agreement to participate.

9. How the Subject’s Privacy is to be Protected

Instead of requiring subjects to write their names, each questionnaire in a packet will have an identification number on it. This will eliminate the possibility of personal information being attached to any of the subjects.
10. Request for a Waiver of the Written Consent Form

Because of the sensitive nature of some of the information gathered, it is essential to preserve the anonymity of the participants in this study. For this reason, a waiver of informed consent is requested, as it will ensure total anonymity for the participants. In lieu of a consent form, participants are told in the instructions that mailing back the questionnaires is tantamount to giving their consent to participate in this study. In addition, every effort has been made to state the voluntary nature of their participation.
APPENDIX H

PARTICIPANT INSTRUCTIONS

Thank you very much for agreeing to participate in this study. I am interested in how certain factors influence health-related quality of life (HRQOL) in persons like both you and myself, who suffer from inflammatory bowel disease (IBD). I was diagnosed with Crohn's disease about six years ago, and was a patient of Dr. Noren's when I lived in Marquette. As you know, having IBD affects many areas of your life in addition to physical comfort, like your emotions and your ability to enjoy social activities. These areas that are impacted by IBD affect your current satisfaction with life, or HRQOL.

The questionnaires in this packet are designed to measure disease activity (of either Crohn's disease or ulcerative colitis), HRQOL, beliefs about how your behavior influences your condition, your knowledge about IBD, and your satisfaction with the social support that you are receiving. Hopefully, this study will provide ideas for increasing HRQOL in the areas mentioned above. Your participation will help make this possible.

Please fill out the questionnaires carefully after reading the instructions on each of them, but do not put your name on any of the forms. By not putting your name on the forms you can be assured that the information you record will be kept absolutely anonymous. If you have any questions while completing these measurements, feel free to call me at (406) 243-4523. If you find that filling out these questionnaires is burdensome, you may dispose of them. I hope, however, that you will complete them, because your participation will add to our knowledge about how to improve the treatment of IBD. This project should take only about an hour of your time. Please try to finish these as soon as possible and, when you are done, simply seal them up and drop the envelope in the mail. Because you will not be signing your name to any of the forms, by mailing back the questionnaires you are giving your consent to participate in this study.

If you would like to know more about this research, feel free to call, e-mail, or write me at the numbers below; I would be glad to answer any questions. I would also be happy to send you a summary of the results when the study is finished. Thanks so much for your time, and I wish you well.

Sincerely,

Michael Bach

Professor D. Balfour Jeffrey, Ph.D.
Study Supervisor

For more information contact:
Michael Bach
Clinical Psychology Center
1444 Mansfield Avenue
Missoula, MT 59812
e-mail: mbach@bigsky.net
(406) 243-4523
APPENDIX I

IBDQ ITEMS ACCORDING TO SUBSCALE

**Bowel Subscale**
- How frequent have your bowel movements been during the last two weeks?
- How much of your time during the last two weeks have your bowel movements been loose?
- How often during the last two weeks have you been troubled by cramps in your abdomen?
- How often during the last two weeks have you been troubled by pain in the abdomen?
  - Overall, in the last two weeks, how much of a problem have you had with passing large amounts of gas?
  - How much of the time during the last two weeks have you been troubled by a feeling of abdominal bloating?
  - How much of the time during the last two weeks have you had a problem with rectal bleeding with your bowel movements?
  - How much of the time during the last two weeks have you been troubled by a feeling of having to go to the bathroom even though your bowels are empty?
  - How much of the time during the last two weeks have you been troubled by accidental soiling of your underpants?
  - How much of the time during the last two weeks have you been troubled by feeling sick to your stomach?

**Systemic Subscale**
- How often has the feeling of fatigue or of being tired and worn out been a problem for you during the last two weeks?
- How much energy have you had during the last two weeks?
- How often during the last two weeks have you felt generally unwell?
- How often during the last two weeks have you had problems getting a good night’s sleep, or been troubled by waking up during the night?
  - Overall, in the last two weeks, how much of a problem have you had maintaining, or getting to, the weight you would like to be at?

**Emotion Subscale**
- How often during the last two weeks have you felt frustrated, impatient, or restless?
- How often during the last two weeks did you feel worried about the possibility of needing to have surgery because of your bowel problem?
- How often during the last two weeks have you been troubled because of fear of not finding a washroom?
- How often during the last two weeks have you felt depressed or discouraged?
  - Many patients with bowel problems often have worries and anxieties related to their illness. These include worries about getting cancer, worries about never feeling any
better, and worries about having a relapse. In general, how often during the last two weeks have you felt worried or anxious?
   How often during the last two weeks have you felt relaxed and free of tension?
   How much of the time during the last two weeks have you felt embarrassed as a result of your bowel problem?
   How much of the time during the last two weeks have you felt tearful or upset?
   How much of the time during the last two weeks have you felt angry as a result of your bowel problem?
   How much of the time during the last two weeks have you felt irritable?
   How often during the last two weeks have you felt lack of understanding from others?
   How satisfied, happy, or pleased have you been with your personal life during the last two weeks?

Social Subscale
   How often during the last two weeks have you been unable to attend school or work because of your bowel problem?
   How often during the last two weeks have you had to delay or cancel a social engagement because of your bowel problem?
   How much difficulty have you had, as a result of your bowel problems, doing leisure or sports activities you would have liked to have done during the last two weeks?
   How often during the last two weeks have you had to avoid attending events where there was no washroom close at hand?
   To what extent has your bowel problem limited sexual activity during the last two weeks?
APPENDIX J

MEANS AND STANDARD DEVIATIONS FOR SCALES IN THE CROHN’S DISEASE AND ULCERATIVE COLITIS GROUPS

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Crohn’s disease*</th>
<th>Ulcerative colitis**</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHI</td>
<td>211.8 125.8</td>
<td>125.7 127.7</td>
</tr>
<tr>
<td>MHLC</td>
<td>20.4 6.7</td>
<td>19.8 7.0</td>
</tr>
<tr>
<td>KQ</td>
<td>18.5 6.1</td>
<td>20.3 5.2</td>
</tr>
<tr>
<td>SSQ-6</td>
<td>5.1 1.3</td>
<td>5.4 .9</td>
</tr>
<tr>
<td>IBDQ Bowel</td>
<td>46.9 11.5</td>
<td>54.5 12.2</td>
</tr>
<tr>
<td>IBDQ Systemic</td>
<td>19.7 7.4</td>
<td>24.0 7.2</td>
</tr>
<tr>
<td>IBDQ Emotion</td>
<td>52.7 16.9</td>
<td>64.1 12.9</td>
</tr>
<tr>
<td>IBDQ Social</td>
<td>25.6 8.1</td>
<td>29.6 7.2</td>
</tr>
<tr>
<td>IBDQ Total</td>
<td>144.9 40.3</td>
<td>172.2 36.6</td>
</tr>
<tr>
<td>Age</td>
<td>44.6 17.4</td>
<td>48.1 15.5</td>
</tr>
<tr>
<td>Length of illness</td>
<td>14.0 11.6</td>
<td>16.9 14.6</td>
</tr>
</tbody>
</table>

* n = 45; ** n = 17

CHI = Chapel Hill Index (higher scores = more severe symptoms); MHLC = Multidimensional Health Locus of Control-Internal; KQ = Knowledge Questionnaire; SSQ-6 = Social Support Questionnaire (Satisfaction Scale); IBDQ = Inflammatory Bowel Disease Questionnaire (higher scores = improved HRQOL)
ANNOUNCEMENT OF STUDY IN IBD NEWSLETTER

**A Study of Health-Related Quality of Life in Patients with Crohn’s Disease or Ulcerative Colitis**

Greetings all! My name is Mike Bach, and I am currently working on my Master’s thesis at the University of Montana with my supervisor, Balfour Jeffrey, Ph.D. I am asking readers to consider participating in this study of how certain factors are related to health-related quality of life in Crohn’s disease and ulcerative colitis. A lot of fantastic research is currently aimed at treating the physical symptoms of inflammatory bowel disease (IBD). I am interested, however, in how health beliefs, knowledge about IBD, and satisfaction with social support are related to living with this illness. You can help shed light on these relationships by filling out an anonymous questionnaire packet that can be completed in less than 45 minutes. If you have IBD, are 18 years of age or older, and do not have an ostomy bag, please consider e-mailing or sending me an address where you can receive the questionnaire packet. It will contain instructions and a postage-paid return envelope. Remember, your responses are TOTALLY ANONYMOUS. Your time can help provide ideas to help people who—like both you and myself—live each day with IBD. I plan to finish this study this fall and will write a summary of results from the questionnaires I receive. The Northwest Chapter of the CCFA will publish that summary in the Winter 2001 newsletter. Thanks for your help!!!

Mike Bach, Clinical Psychology Center  
1444 Mansfield Avenue, Missoula, MT 59812  
e-mail: mbach@bigsky.net