

## Revision and psychometric testing of the City of Hope Quality of Life–Ostomy Questionnaire

Marcia Grant<sup>1</sup>, Betty Ferrell<sup>1</sup>, Grace Dean<sup>1</sup>, Gwen Uman<sup>2</sup>, David Chu<sup>1</sup> & Robert Krouse<sup>3</sup>

<sup>1</sup>City of Hope National Medical Center, Duarte, California (E-mail: mgrant@coh.org); <sup>2</sup>Vital Research, LLC, Los Angeles, California; <sup>3</sup>Southern Arizona Veterans Association Health Care System (SAVAHCS), University of Arizona, Tucson, Arizona, USA

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### Abstract

*Purpose:* Ostomies may be performed for bowel or urinary diversion, and occur in both cancer and non-cancer patients. Impact on physical, psychological, social and spiritual well-being is not unexpected, but has been minimally described in the literature. The City of Hope Quality of Life (COH-QOL)-Ostomy Questionnaire is an adult patient self-report instrument designed to assess quality of life. This report focuses on the revision and psychometric testing of this questionnaire. *Patients and methods:* The revised COH-QOL-Ostomy Questionnaire involved in-depth patient interviews and expert panel review. The format consisted of a 13-item disease and demographic section, a 34-item forced-choice section, and a 41-item linear analogue scaled section. A mailed survey to California members of the United Ostomy Association resulted in a 62% response rate (n = 1513). Factor analysis was conducted to refine the instrument. Construct validity involved testing a number of hypotheses identifying contrasting groups. *Results:* Factor analysis confirmed the conceptual framework. Reliability of subscales ranged from 0.77 to 0.90. The questionnaire discriminated between subpopulations with specific concerns. *Conclusions:* Overall, the analyses provide evidence for the validity and reliability of the COH-QOL-Ostomy Questionnaire as a comprehensive, multidimensional self-report questionnaire for measuring quality of life in patients with intestinal ostomies.

**Key words:** Ostomy, Psychometric testing, Quality of life

### Introduction

Treatment involving formation of an ostomy (an intestinal stoma) for bowel or urinary diversion is accompanied by physical, functional and psychosocial changes. Thus, evaluation of quality of life of survivors of these surgical procedures can provide information valuable in supporting patients' treatment decisions and their long-term adjustment and rehabilitation [1].

The purpose of the study was to revise an older City of Hope Quality of Life – Ostomy questionnaire and establish its content validity (phase 1); then test and establish the instrument's reliability and construct, discriminant, and criterion-related

validity (phase 2). The investigators predicted significant relationships between subscale scores and an overall single-item QOL rating; significant differences between subjects with high or low sexual concerns, emotional concerns, and social support; and significantly better quality of life scores for respondents who worked or were married.

Ostomies in patients with cancer occur most commonly in the treatment of colorectal and genitourinary cancers. The incidence rates for cancer of the large bowel vary worldwide, with the highest rates in North America and Northern Europe and the lowest rates in Asia, South America, and Africa. Incidence per 100,000 is 46.5 (males) and 33.2 (females) in the US. Rates for

males range from 29 to 40 for the United Kingdom and Northern Europe and 24–30 for women [2]. Improvements in bowel surgical techniques have decreased the need for an ostomy in colorectal cancer [3]. Temporary ostomies may be necessary in some patients, due to very low anastomosis, anastomatic leaks, emergency resections where the bowel cannot be adequately prepared mechanically for surgery. Permanent ostomies may result from inadequate post operative healing or be performed when changes from chemotherapy and radiation therapy result in non-healing fistulas or other complications. Permanent colostomies are most common for very low rectal tumors.

For non-cancer patients the most common cause for creation of an ostomy is inflammatory bowel disease (IBD). The incidence of IBD varies across geographic areas with higher incidence in northern countries (United Kingdom, Norway, Sweden, and the United States) illustrated by rates of 6–12 per 100,000. Southern countries (Southern Europe, South Africa, Australia) have lower incidence rates ranging from 2 to 8 per 100,000. In Asia and South America IBD is rare [4].

Quality of life is increasingly recognized as an important outcome measure for survivors of major surgical and medical treatments. For the purpose of this paper quality of life is viewed as a multi-dimensional concept defined as the level of well-being and satisfaction with an individual's life and how this life is affected by disease, accidents and treatments [5]. The quality of life model that provides direction for the following study is a four-dimensional model created at City of Hope National Medical Center and composed of physical well-being and symptoms, psychological well-being, social well-being, and spiritual well-being [6].

Few studies of ostomy patients and quality of life assessments have been published. Earliest studies focused on the impact of surgery and drainage devices. In 1976, Ware [7] reported that closed end pouch users had significantly higher well-being and mental health scores when compared to those who had drainable pouches. Orbeck and Talent [8] studied patients with colostomies and reported that poor body image persisted 5–10 years after the surgery. Watson [9] reported positive results when testing a short term post operative counseling for cancer patients with

ostomies. More recent studies described the influence of ostomy surgery on body image [10, 11], sexual functioning [12], ability to work [13] and feelings of self-consciousness [14]. Sprangers and colleagues [15] combined results of 17 small studies to examine results related to at least one of four aspects of patient functioning: physical, psychological, social and sexual, comparing stoma and non-stoma patients. Results revealed that stoma patients had problems with gas, sleep, depression, anxiety and sexual dysfunction.

Studying non-cancer patients, Drossman and colleagues [16] compared concerns of persons with ulcerative colitis (UC) and those with Crohn's disease (CD) and revealed that having an ostomy bag was among the top highest concerns for both UC persons, and CD persons. Love and colleagues [17] compared quality of life in 182 persons with IBD to 48-age and sex matched control patients and demonstrated consistently lower QOL scores (global, systemic symptoms, bowel symptoms, functional impairment, social impairment and emotional function) in persons with IBD. These studies reveal that the presence of an intestinal stoma is an important QOL concern for both cancer and non-cancer patients.

In summary, earlier studies focused on ostomy products and their usefulness. Later studies have begun to identify physical and psychological concerns. Missing in studies to date is the use of a valid and reliable multidimensional QOL instrument focusing on the effects of an intestinal stoma. With such a questionnaire, areas of concern across a large number of cancer and non-cancer patients with intestinal stomas can be identified. Results could provide health professionals with valuable information to be used for patient counseling and teaching cancer and non-cancer patients.

#### **Development of the City of Hope QOL-Colostomy Index**

The current study builds on the authors' previous initial work on developing quality of life instruments for cancer patients [18–24]. Content for a colostomy-specific QOL index was identified from the literature and included 23 items, four of which focused on looking at the stoma, worrying about it, adjustment, and concerns about odor and

leakage. This instrument was given to 70 subjects, 35 above and 35 below the age of 62 and included 33 males and 37 females. Diagnoses included 37 with colorectal cancer, 4 gynecologic cancer, 7 with diverticulitis and 22 with a variety of other diagnoses. Factor analysis revealed four factors: psychological well-being, social concerns, physical well-being, and colostomy concerns. An overall quality of life mean score was calculated and compared to similar scores for non-patients, diabetics, chemotherapy and radiation outpatients and chemotherapy inpatients. Results revealed that colostomy patients' QOL was low (overall mean of 57 on a 100 point scale) with only chemotherapy in-patients scoring lower ( $n = 52$ ). The instrument was subsequently used in a quality assurance program for care of colostomy patients [25] and used in developing educational materials for staff nurses.

### **Expanding the COH-QOL Colostomy Questionnaire**

The purpose of the current study was to revise and update the original COH-QOL Colostomy Questionnaire expanding it to focus on all ostomy patients – whether for urinary or fecal diversion, cancer or non-cancer. The conceptual framework used for revisions was the City of Hope Quality of Life framework involving four dimensions, psychological, social, spiritual, and physical well-being. Revisions started with in-depth individual interviews of patients, and then focus groups using these data to revise the tool. The conceptual model was used to define and categorize aspects of ostomy care expressed by ostomy patients during in-depth qualitative interviews and focus groups transcriptions. Publications of the interview data are in process. This report focuses on two phases: (1) steps in developing the revised instrument and (2) subsequent testing in a large mailed survey to ostomy patients.

#### **Phase one**

The aims of this phase were to (1) Revise the original City of Hope Quality of Life Ostomy Tool using data derived from in depth patient interviews

and focus groups. (2) Establish content validity of the revised tool using professional experts.

#### **Methods**

Revising the original instrument involved examination of the content analysis from 26 individual interviews and three focus groups. Content or face validity was established by an expert panel and a group of outside reviewers. The expert panel was assembled that included one enterostomal therapist, two general surgeons, one urologist and four nursing researchers. Each was provided with a copy of the themes from the qualitative interviews and a table that identified the items in the original City of Hope Quality of Life Colostomy Questionnaire. Each expert identified items to retain, new items, items to revise and items to eliminate. Experts were asked to recommend whether items should be formatted on a 0–10 scale or a forced-choice yes/no with comments. For example, items like fatigue and constipation were appropriate for a 0–10 scale and items like 'Are you sexually active?' were more suited to a yes/no scale. The panel met to discuss the differences and resolve issues.

The questionnaire was next mailed to three enterostomal therapists and one additional nursing researcher. Directions to these outside reviewers included deciding whether to keep, revise or delete each item; classifying each item within one of the four QOL dimensions, and providing comments about format and content.

#### **Results**

The resulting instrument contained 90 items divided into three sections. 'Introduction' had 13 items focused on disease and demographic characteristics. 'Section 2: Life Style Impact' included 34 the forced-choice yes/no questions organized into several themes: work related items, health insurance, sexual activity, psychological concerns, clothing, diet, daily care of ostomy, and nutritional implications. These sections included space for comments. 'Section 3: QOL Impact' had 41 items rated on a scale of 0–10 and was organized into physical, psychological, social and spiritual well-being dimensions.

## Phase two

The aim for phase two was to psychometrically test the revised quality of life ostomy questionnaire. Analysis included reliability testing and examination of construct, discriminant, and criterion-related validity via specific hypotheses. A mailed survey approach involved obtaining a list of members of the United Ostomy Association for the state of California. Prior to mailing, the study was approved by the institution's scientific and ethical review boards. The mailing included the COH-QOL Ostomy questionnaire and a consent form.

## Methods

A total of 2455 surveys were mailed and resulted in a return of 1513 (62% response rate). All returned questionnaires were coded by standard procedures. Items were coded so that '0' equals poorest quality of life and '10' equals the best quality of life. Codes were verified and entered into the SPSS software.

The conceptual framework was evaluated for 'Section 3: QOL Impact' of the questionnaire using exploratory factor analysis with principal axis factoring and oblique rotation. Criteria for simple structure were used to determine the best factor structure, with a liberal cut off for factor loadings of 0.30 or above. Based on these criteria, 41 items were retained in the factor solution, accounting for 51% of the variance.

Each of the factors derived from the analysis was tested for internal consistency reliability using coefficient  $\alpha$  and a scale score was computed for each factor using the weighted mean of factor items. Similarly, a composite QOL score was computed using all 41 items.

Hypothesis 1 (convergent validity) was tested by correlating each scale score with the single overall QOL item, using the Pearson product moment correlation. Construct validity based on ability of the scores to differentiate between known groups was tested using:

(1) For Hypothesis 2, a two way ( $2 \times 2$ ) factorial multivariate analysis of variance (MANOVA) of scale scores by sexual concerns (yes or no) and gender. Hotelling's  $T^2$  was the statistic used to determine multivariate significance. The composite

QOL score was tested using a two way factorial ANOVA. Simple main effects analysis was used to further test any significant interactions.

(2) For Hypothesis 3, 5 and 6, a one-way MANOVA with Hotelling's  $T^2$  to examine differences in the six scale scores by emotional concerns (yes or no), employment (yes or no), and marital status (married or not). The composite QOL score was tested using an independent  $t$ -test.

(3) For Hypothesis 4, a one-way MANOVA to examine differences in the six scale scores by four levels of social support. Pillai's Trace was the statistic used to determine multivariate significance, and a Bonferroni *post hoc* analysis was used to further test the significance of any individual scale score. A one-way ANOVA with a Scheffe *post hoc* test was used to test the significance of the composite QOL score.

## Results

### *Demographics*

Table 1 presents the demographic data of the sample. There were approximately equal numbers of men and women, and the median age was 72 years. The majority of the sample was Caucasian, with approximately equal numbers of Asian, African Americans and Hispanics. Marital status changed from before the ostomy to the time of the survey, with 72% married before the ostomy and 64% married at the time of survey; 9% were widowed at the time of ostomy and 19% at the time of the survey. Distribution of ostomy across types revealed approximately equal numbers of ileostomies and colostomies, with somewhat fewer urinary diversions and a small number of respondents with more than one ostomy. Cancer was the cause for the ostomy in 54% of the respondents. The length of time since the ostomy was created varied, ranging from <1 to 76 years.

### *Conceptual framework evaluation*

The four dimensions of the conceptual framework (Physical Well-Being, Psychological Well-Being, Social Well-Being, and Spiritual Well-Being) were used to organize the items in 'Section 3: QOL Impact' of the questionnaire. Factor analysis was

**Table 1.** Demographics

<b>Gender</b>		
Male	n = 717	(47%)
Female	n = 795	(53%)
<b>Age</b>		
Mean = 69.5 years		
Standard deviation = 12.77		
Range = 11–95		
<b>Height</b>		
Mean = 66 in.		
Standard deviation = 4.1 in.		
Range = 48–80		
<b>Weight</b>		
Mean = 160 pounds		
Standard deviation = 37.3 pounds		
Range = 50–360 pounds		
<b>Ethnicity</b>		
Caucasian	n = 1407	(94.4%)
Asian	n = 32	(2.1%)
Hispanic	n = 24	(1.6%)
African American	n = 14	(0.9%)
American Indian	n = 3	(0.27%)
Other	n = 11	(0.7%)
<b>Marital status</b>		
	Before ostomy	Now
Married	n = 1093 (72.2%)	n = 966 (64.2%)
Single	n = 193 (12.8%)	n = 126 (8.4%)
Widowed	n = 132 (8.8%)	n = 294 (19.5%)
Divorced	n = 79 (5.2%)	n = 105 (7.0%)
Separated	n = 11 (0.7%)	n = 13 (0.9%)
<b>Ostomy</b>		
Colostomy	n = 658 (43.5%)	
Ileostomy	n = 629 (41.6%)	
Urinary diversion	n = 257 (17.0%)	
Multiple ostomies	n = 31 (2%)	
<b>Diagnosis</b>		
Cancer	n = 816 (54%)	
Non-cancer	n = 634 (42%)	
Missing	n = 63 (4%)	
<b>Years since ostomy</b>		
	Mean	Range
Ileostomy	19	<1–76
Colostomy	11	<1–54
Urinary diversion	10	<1–66

used to identify the distinctiveness of these dimensions, and identify whether or not they should be considered subscales of the questionnaire. Six factors, revealed using principal axis factoring, accounted for 58% of the total variance

(Table 2) with the first factor accounting for the greatest proportion of variance. Factor loadings are shown in Table 2. The resulting adapted conceptual framework consists of disease-specific dimensions: (Social Adjustment to Ostomy, Disease-Specific Effects on Physical Well-Being, Disease-Specific Effects on Psychological Well-Being) and General Quality of Well-Being dimensions (General Quality of Psychological Well-Being, General Quality of Spiritual Well-Being, and General Quality of Physical Well-Being). The six factors were distributed for simplicity across the four dimensions of the QOL Model, combining factors 3 (Quality of Physical Well-Being) and factor 4 (Disease-Specific Effects on Physical Well-Being) under Physical Well-Being, and factor 2 (Quality of Psychological Well-Being) and factor 6 (Disease-Specific Effects on Psychological Well-Being) under Psychological Well-Being (Figure 1).

### Reliability

Reliability of ‘Section 3: QOL Impact’ of the revised questionnaire was computed for internal consistency using Cronbach’s coefficient  $\alpha$  measuring agreement between items and six factors of the revised model (Figure 1). Analysis revealed an overall questionnaire  $\alpha$  of 0.95 with the six dimension factors ranging from 0.77 to 0.90. Descriptive factor scores and  $\alpha$  coefficients are found in Table 3. Item to total correlations are also shown in Table 3 and provide strong evidence for consistency.

### Validity

Content-related validity was established initially with the in-depth interviews of patients with ostomies, review of the questionnaire by a panel of experts and a review of the literature. Construct validity involved a number of analyses. Each of these was organized around a specific hypothesis. Evidence for convergent validity used a one-item QOL score and factor scores.

Hypothesis 1: Factor scores will be significantly correlated with a single-item overall quality of life rating given by subjects. As shown in Table 3, results showed that the correlations are all positive, ranging from  $r = 0.24$  to  $0.76$ . The most highly correlated factor score is General Quality of

**Table 2.** Factor loadings (structure matrix)<sup>a</sup>

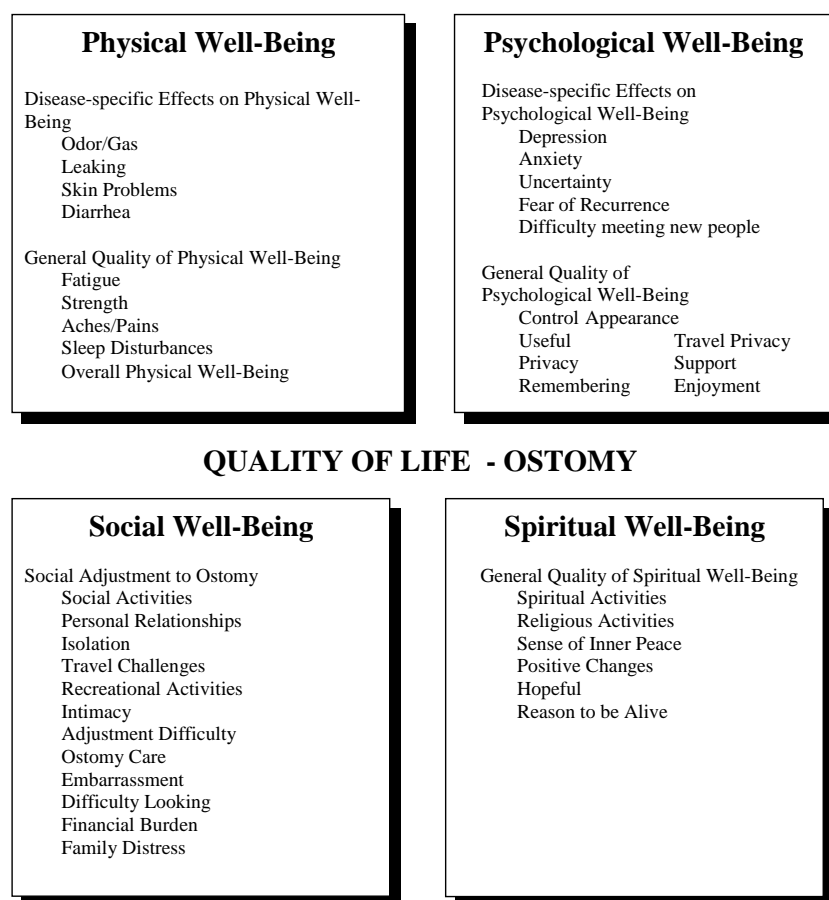
Item	Factor					
	1. Social Adjustment to Ostomy	2. General Quality of Psychological Well-Being	3. General Quality of Physical Well-Being	4. Disease-Specific Effects on Physical Well-Being	5. General Quality of Spiritual Well-Being	6. Disease-specific Effects on Psychological Well-Being
Social – Has ostomy interfered with social activities?	0.822	0.333	0.523	0.408	-0.343	-0.370
Isolation – How much isolation is caused by your ostomy?	0.817	0.390	0.400	0.429	-0.399	-0.449
Relation – Has ostomy interfered with personal relationships?	0.754	–	–	0.378	-0.348	-0.349
Travel – How much does ostomy interfere with travel?	0.727	0.334	0.509	0.376	-0.333	–
Difadj – Difficult to adjust to ostomy?	0.727	–	0.478	0.446	-0.366	-0.499
Recreat – Has ostomy interfered with rec-sports activities?	0.675	–	0.571	0.390	–	–
Intimate – Has ostomy interfered with ability to be intimate?	0.657	–	0.332	–	–	–
Care – How difficult is it to care for ostomy?	0.642	–	0.388	0.423	-0.332	-0.411
Embarrass – How much are you embarrassed by ostomy?	0.603	–	–	0.510	–	-0.416
Look – How difficult is it to look at your ostomy?	0.569	–	–	0.367	–	-0.483
Finburd – How much financial burden results from illness/treatment?	0.484	–	0.400	0.390	–	–
Family – How distressing has your illness been for your family?	0.476	–	0.343	0.369	–	–
Enjoy – How much satisfaction/enjoyment in life?	0.458	0.811	–	–	-0.483	–
Useful – How useful do you feel?	0.420	0.754	–	–	-0.395	–
Control – Do you feel like you are in control of things?	0.470	0.737	0.350	–	-0.471	–
Appear – How satisfied are you with your appearance?	0.440	0.643	0.384	–	-0.443	–
Support – Is support from friends/family sufficient?	–	0.603	–	–	-0.427	–
Privacy – Do you have enough privacy at home for ostomy care?	–	0.589	–	–	-0.349	–
Remember – How is your ability to remember things?	–	0.509	–	–	–	–
Travpriv – Do you have enough privacy when traveling for ostomy care?	0.365	0.490	–	–	-0.376	–
Fatigue – How much fatigue do you have?	0.496	–	0.864	0.384	–	–
Strength – How much physical strength do you have?	0.512	–	0.830	0.376	–	–
Ovrphys – How is your overall physical well-being?	0.514	–	0.809	0.459	–	–
Aches – Do you have aches or pains?	0.429	–	0.679	0.479	–	–

Sleep – Do you have sleep disturbances?	0.463	–	0.585	0.554	–	–
Odor – Problem with odor?	0.361	–	–	0.730	–	–
Gas – Problem with gas?	0.365	–	0.358	0.640	–	–
Skin – Problem with skin surrounding ostomy?	0.394	–	0.448	0.611	–	–
Leaking – Problem with leaking from pouch or around appliance?	0.372	–	0.364	0.611	–	–
Diarrhea – Problem with diarrhea?	0.394	–	0.460	0.516	–	–
Spiritac – Support from personal spiritual activities sufficient?	–	0.405	–	–	–0.856	–
Religact – Support from religious activities sufficient?	–	–	–	–	–0.739	–
Inpeace – Do you have a sense of inner peace?	0.373	0.633	–	–	–0.735	–0.400
Hopeful – How hopeful do you feel?	0.459	0.676	–	–	–0.714	–0.415
Reason – Do you sense a reason for being alive?	–	0.595	–	–	–0.599	–
Positive – Has having an ostomy made positive changes in your life?	–	–	–	–	–0.331	–
Depression – How much depression do you have?	0.592	–	0.461	0.424	–0.431	–0.691
Uncertainty – How much uncertainty do you feel about your future?	0.584	–	0.455	0.365	–	–0.622
Anxiety – How much anxiety do you have?	0.549	–	0.465	0.445	–0.338	–0.617
Fearful – Are you fearful that your disease will come back?	0.445	–	–	–	–	–0.483
Meeting – Do you have difficulty meeting new people?	0.477	–	–	0.386	–	–0.483

Eigenvalues and cumulative variance for the factors 1, 2, 3, 4, 5, and 6 are 14.3 and 34.7, 3.8 and 43.7, 1.9 and 48.3, 1.5 and 51.9, 1.3 and 55.1, and 1.2 and 58.1, respectively.

Extraction method: principal axis factoring.

Rotation method: Oblimin with Kaiser normalization.



**Figure 1.** Revised city of hope quality of life model for ostomy patients.

**Table 3.** Subscale scores,  $\alpha$ , and correlations and overall scale  $\alpha$

Factor	Mean score	SD	Coefficient $\alpha$	Correlation to single QOL item	Range of item correlations
(1) Social Adjustment to Ostomy	7.64	2.03	0.90	0.44*	0.47–0.79
(2) General Quality of Psychological Well-Being	7.50	2.03	0.83	0.76*	0.50–0.76
(3) General Quality of Physical Well-Being	7.81	2.10	0.88	0.39*	0.55–0.81
(4) Disease-Specific Effects on Physical Well-Being	7.58	1.89	0.77	0.24*	0.24–0.59
(5) General Quality of Spiritual Well-Being	7.22	2.34	0.81	0.51*	0.28–0.70
(6) Disease-Specific Effects on Psychological Well-Being	7.80	2.08	0.82	0.38*	0.51–0.69
Overall total scale	7.65	1.57	0.95	0.62*	

\* $p > 0.001$ .

Psychological Well-Being, suggesting that first and foremost, QOL is a psychological construct. Disease-Specific Effects on Physical Well-Being has the lowest correlation with the single-item QOL

rating. These findings parallel those of other quality of life questionnaires developed in our previous studies where psychological well-being is the strongest subscale [21–23, 25].



Discriminant or known-groups validity was calculated by dividing respondents into groups based in responses to forced-choice questions found in Part 2 of the questionnaire. Three hypotheses were developed and related to sexual concerns, emotional concerns and participation in individual or group support.

Hypothesis 2: Respondents reporting sexual concerns will have lower quality of life scores than those who did not report sexual concerns. For this analysis three variables for males and two for females from the forced choice section of the questionnaire were used: resumption of sexual activity, sexual satisfaction, and, for males, ability to maintain an erection. Because there was a significant association among the three variables, they were transformed into a composite score, equalizing males and females, so that the score ranged from 0 to 3 for both genders. Subjects with no or only one sexual concern were classified as having low sexual concern ( $n = 532$ ), and those with a score of more than 1 were classified as having high sexual concern ( $n = 691$ ). One exception was made. Males whose only sexual concern of the three items was not being able to maintain an erection were reclassified as having high sexual concerns. Overall 1200 subjects (79%) answered at least one of the sexual concerns questions, and could be classified in one of the categories described above. There was a significant association between the new sexual concerns variable and gender ( $\chi^2_{(df=1)} = 108.17$ ), such that males were more likely to have sexual concerns than females.

Results revealed a significant main effect for gender and for sexual concerns for each factor. For each factor, subjects with low sexual concerns had a significantly higher quality of life score than did those who had high sexual concerns (see Table 4). In addition, there was a significant interaction between gender and sexual concerns for social adjustment, general physical QOL, specific physical QOL and specific psychological QOL. Interactions analysis revealed that (1) of those with sexual concerns, females have significantly lower quality of life scores and (2) there is a significantly lower quality of life score for both males and females who have sexual concerns compared to those who do not have sexual concerns, except in the general quality of physical well-being factor, in which males with and without concerns do not differ significantly. Total QOL findings were similar, with significant main effects and interaction, and the pattern of the interaction being the same as for the general physical factor (see Table 4).

Hypothesis 3: Respondents with emotional concerns will have lower quality of life scores than those that did not report emotional concerns. Items from the forced choice section of the questionnaire were used: were you depressed after your ostomy surgery, and have you considered or attempted suicide. Because the two items were significantly associated, a composite variable was created so that subjects were grouped into those with no depression or suicidal ideation, and those who had either or both emotional concerns.

**Table 4.** QOL factors by sexual concerns

QOL factor	No sexual concerns N = 528		Sexual concerns N = 673		Total N = 1200 <sup>a</sup>		F
	<i>X</i>	SD	<i>X</i>	SD	<i>X</i>	SD	
(1) Social Adjustment to Ostomy	8.30	1.54	7.18	2.21	7.67	2.02	104.61*
(2) General Quality of Psychological Well-Being	8.10	1.82	7.21	2.09	7.60	2.03	66.73*
(3) General Quality of Physical Well-Being	8.33	1.77	7.55	2.23	7.89	2.08	57.00*
(4) Disease-Specific Effects on Physical Well-Being	7.83	1.70	7.43	1.99	7.61	1.88	22.41*
(5) General Quality of Spiritual Well-Being	7.76	2.11	6.82	2.41	7.24	2.33	36.06*
(6) Disease-Specific Effects on Psychological Well-Being	8.20	1.71	7.62	2.20	7.88	2.02	39.90*
Total QOL	8.13	1.26	7.29	1.68	7.65	1.57	101.83*

\* $p \sim 0.001$ .

<sup>a</sup> 1200 subjects answered at least one sexual concern question and had a score on all 6 factors.

**Table 5.** QOL factors by emotional concerns

QOL factor	No emotional concerns N = 818		Emotional concerns N = 649		Total N = 1491 <sup>a</sup>		F
	<i>X</i>	SD	<i>X</i>	SD	<i>X</i>	SD	
(1) Social Adjustment to Ostomy	8.40	1.40	6.66	2.26	7.63	2.03	325.66*
(2) General Quality of Psychological Well-Being	7.95	1.88	6.97	2.06	7.51	2.02	89.96*
(3) General Quality of Physical Well-Being	8.37	1.65	7.12	2.38	7.82	2.10	141.03*
(4) Disease-Specific Effects on Physical Well-Being	8.00	1.62	7.06	2.06	7.58	1.89	96.17*
(5) General Quality of Spiritual Well-Being	7.72	2.12	6.61	2.44	7.23	2.33	87.73*
(6) Disease-Specific Effects on Psychological Well-Being	8.52	1.53	6.87	2.31	7.79	2.08	266.88*
Total QOL	8.19	1.15	6.85	1.73	7.60	1.58	289.34 <sup>b</sup>

\*  $p \sim 0.001$ .

<sup>a</sup> 1491 subjects had a total QOL score and responded to emotional concern questions.

<sup>b</sup> Squared  $t$  value.

Those with no emotional concerns had significantly higher quality of life scores than did those who had emotional concerns (Table 5).

Hypothesis 4: Respondents who report individual and/or group social support will have higher quality life scores than those that did not report this support. Items from the forced choice section of the questionnaire were used: Do you belong to a ostomy support group, another support group, or have talked with other ostomates? A tally of the number of 'Yes' responses to the support questions resulted in a variable ranging from 0 (no support groups or contacts) to 3, which was tested on the six factors using a one-way MANOVA. The multivariate  $F$ , and the main effect for univariate tests of each of the six factors were significant, as shown in Table 6.

The Bonferroni *post hoc* analysis revealed that having a score of 2 or 3 for support resulted in significantly higher social adjustment to ostomy general quality of spiritual well-being, disease-specific effects on psychological well-being, and total QOL scores. Having a support score of 2 resulted in significantly higher disease-specific effects on physical well-being QOL scores than scores of less than 2. Having a support score of 1 or higher resulted in significantly higher spiritual well-being scores. For general quality of physical well-being, having a support score of 2 resulted in significantly higher QOL than a support score of 0.

Criterion-related validity was calculated by dividing respondents into groups based on responses to two forced choice items on Part 1 of

**Table 6.** QOL factors by support

QOL Factor	Support					F
	0 N = 153 <i>X</i> (SD)	1 N = 452 <i>X</i> (SD)	2 N = 754 <i>X</i> (SD)	3 N = 107 <i>X</i> (SD)	Total N = 1490 <sup>a</sup> <i>X</i> (SD)	
(1) Social Adjustment to Ostomy	7.12 (2.43)	6.43 (2.11)	7.83 (1.88)	7.82 (1.88)	7.63 (2.03)	7.56*
(2) General Quality of Psychological Well-Being	7.12 (2.04)	7.34 (2.08)	7.67 (1.99)	7.64 (1.89)	7.51 (2.02)	4.84**
(3) General Quality of Physical Well-Being	7.33 (2.46)	7.72 (2.19)	8.00 (1.95)	7.59 (2.11)	7.82 (2.10)	5.51*
(4) Disease-Specific Effects on Physical Well-Being	7.13 (2.13)	7.49 (2.03)	7.71 (1.75)	7.64 (1.70)	7.58 (1.89)	4.55**
(5) General Quality of Spiritual Well-Being	6.33 (2.51)	7.04 (2.36)	7.41 (2.28)	7.97 (1.80)	7.23 (2.33)	14.11*
(6) Disease-Specific Effects on Psychological Well-Being	7.21 (2.34)	7.58 (2.24)	8.01 (1.92)	7.94 (1.86)	7.79 (2.08)	8.60*
Total QOL	7.09 (1.80)	7.42 (1.66)	7.78 (1.47)	7.77 (1.38)	7.60 (1.58)	11.44*

\*  $p \sim 0.001$ ; \*\*  $p < 0.01$ .

<sup>a</sup> 1490 subjects had a total QOL score and responded to support items.

the questionnaire. Two hypotheses were developed and related to working status and marital status.

Hypothesis 5: Respondents who are working full time or part time will have higher quality of life scores than those who do not work full or part time. Information on working was derived from the demographic section of the questionnaire. A single variable representing working or not working was created. Many subjects who were not working classified themselves as retired, but it was not possible to tell if their retirement was a result of their illness or ostomy. The multivariate  $F$ , as well as the univariate tests for the general quality of psychological well-being, general quality physical well-being, and disease-specific physical well-being scores were all significant. As shown in Table 7, subjects who worked had significantly higher QOL scores on those general quality of psychological well-being and general quality of physical well-being factors, than did subjects who were not working. However, working subjects had lower QOL scores on the factor, disease effects on specific physical well-being. This might be explained by the working people being more aware of gas, odor, leaks, skin problems and diarrhea while being in the work setting.

Hypothesis 6: Respondents who were married at the time of the survey will have better quality of life than those who are divorced, widowed, or separated or single. Information on marital status was obtained from the demographic section of the questionnaire. The multivariate  $F$  and main effects for each of the six factors (and the  $t$  value for total

QOL) were all significant, as shown in Table 8. Married subjects had significantly higher QOL scores than did those who were not currently married, however, from a clinical standpoint the scores were less than one point apart and it might be difficult to detect differences in quality of life by marital status when assessing patients.

### Discussion and conclusions

The current study reports on the development, revision and psychometric testing of the City of Hope Quality of Life Ostomy Questionnaire. The instrument was based on previous work done on measuring quality of life in colostomy patients conducted by the investigators in the 1980s [18, 25–26]. The questionnaire has established reliability and validity and consists of three sections, the demographic section, forced choice responses and a group of linear analogue scales for specific quality of life items. The questionnaire was constructed with data from in-depth interviews of 26 cancer and non-cancer patients who represented colostomies, ileostomies, and urinary diversions. Focus groups were employed: two focus groups with patients and one focus group with immediate family members. The content validity was established by a panel of professional experts. Following mail out, 1513 completed questionnaires were returned for a 62% response rate. Reliability was computed with Cronbach's  $\alpha$ , with overall reliability of the tool being 0.95 and factors ranging from 0.77 to 0.90. Validity analysis included content, construct, discriminant, and criterion-related

**Table 7.** QOL factors by work status

QOL factor	Not working N = 1050		Working N = 414		Total N = 1489 <sup>a</sup>		F
	X	SD	X	SD	X	SD	
(1) Social Adjustment to Ostomy	7.61	2.07	7.67	1.92	7.63	2.03	0.24
(2) General Quality of Psychological Well-Being	7.34	2.12	7.93	1.69	7.51	2.92	25.64*
(3) General Quality of Physical Well-Being	7.71	2.15	8.03	1.98	7.80	2.11	6.77**
(4) Disease-Specific Effects on Physical Well-Being	7.68	1.87	7.29	1.93	7.57	1.90	12.90*
(5) General Quality of Spiritual Well-Being	7.18	2.42	7.33	2.12	7.22	2.34	1.28
(6) Disease-Specific Effects on Psychological Well-Being	7.79	2.14	7.80	1.93	7.79	2.98	0.00
Total QOL	7.56	1.61	7.69	1.48	7.61	1.55	2.20 <sup>b</sup>

\*  $p \sim 0.001$ ; \*\*  $p < 0.01$ .

<sup>a</sup> 1489 subjects had a total QOL score and responded to the work status item.

<sup>b</sup> Squared  $t$  value.

**Table 8.** QOL factors by marital status

QOL factor	Not married N = 532		Married N = 948		Total N = 1480		<i>F</i>
	<i>X</i>	SD	<i>X</i>	SD	<i>X</i>	SD	
(1) Social Adjustment to Ostomy	7.33	2.22	7.79	1.90	7.63	2.03	18.29*
(2) General Quality of Psychological Well-Being	7.25	2.10	7.64	1.97	7.50	2.03	13.25*
(3) General Quality of Physical Well-Being	7.64	2.26	7.91	2.01	7.81	2.10	5.84**
(4) Disease-Specific Effects on Physical Well-Being	7.43	2.05	7.66	1.79	7.58	1.89	5.03**
(5) General Quality of Spiritual Well-Being	7.04	2.49	7.31	2.25	7.21	2.34	4.39**
(6) Disease-Specific Effects on Psychological Well-Being	7.56	2.20	7.92	2.01	7.79	2.08	9.82***
Total QOL	7.37	1.68	7.72	1.50	7.50	1.61	17.34 <sup>a</sup>

1505 subjects had a total QOL score and responded to the work status item.

\* $p < 0.001$ ; \*\* $p < 0.05$ ; \*\*\* $p < 0.01$ .

<sup>b</sup>Squared  $t$  value.

approaches. Factor analysis, correlations, ANOVAs,  $\chi^2$  and  $t$ -tests were used to test hypotheses and establish validity. The resulting COH-QOL Ostomy Questionnaire has established initial reliability and validity and can be used to describe adjustment to either a colostomy, ileostomy or urinary diversion in adults. It is designed for self-administration. The results indicate support for many of the attributes and review criteria used by the Medical Outcomes Trust [26].

The COH QOL-Ostomy questionnaire was based on the same four-dimensional conceptual model used with previous instruments [20, 22–24]. These dimensions are physical, psychological, spiritual and social well-being. Factor analysis revealed six factors that fit easily into the four-dimension model. General factors were related to psychological well-being, spiritual well-being and physical well-being. In addition to those three factors, specific ostomy adjustment factors included social adjustment, disease effects on physical well-being, and disease effects on psychological well-being. Thus the instrument includes both general QOL assessment as well as assessment of concerns specific to ostomy patients. Comparative analyses using items found in the forced choice section establishes the ability of the questionnaire to predict lower QOL scores for those who have more problems. That is, QOL in patients who have sexual concerns, emotional concerns, limited social support, are not married or partnered, and/or are not working will be reflected in lower QOL score. Patients defined by these characteristics can be

targeted by clinicians for increased teaching and counseling to help in adapting to their ostomies. An open-ended question asking for additional comments on stories allows for identification of concerns not included in the questionnaire. Including additional comments is an aspect of QOL questionnaires recommended by Gill and Feinstein [27].

As with most mailed surveys, some limitations are present. Our response rate of 62% exceeded our expectations. However, we do not have any information on those who did not respond. The restrictions imposed by the United Ostomy Association included assuring anonymity of their members. Thus we did not identify who did and did not respond from our original mailing list. Future studies of other populations will assist in verifying whether or not our population was typical of most ostomy patients. In addition, the survey is moderately long, although most responses require simply checking or circling responses. Responses were received predominantly from Caucasians. This is typical of the older population of California. Testing in other populations is planned in current and future studies.

The investigators plan to continue analysis of this large database and will use results obtained to conduct comparisons between cancer and non-cancer patients and between types of stomas. We are also planning to study other populations of ostomy patients to verify the current results. These findings will help investigators interested in using the questionnaire to apply it to various clinical

trials. The psychometric analysis of this instrument continues to support the need for a multi-dimensional approach to measuring quality of life.

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*Address for correspondence:* Marcia Grant, Nursing Research and Education, City of Hope National Medical Center, 1500 East Duarte Road, Duarte, CA 91010, USA  
Phone: +1-626/301-8346; Fax: +1-626/301-8941  
E-mail: mgrant@coh.org

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