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Reliability and Validity of the Outcome Questionnaire in a Heterogeneous Cancer Population

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Reliability and Validity of the Outcome Questionnaire in a Heterogeneous Cancer Population

by

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Each person whose signature appears below certifies that this dissertation in his/her opinion is adequate, in scope and quality, as a dissertation for the degree Doctor of Philosophy.

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ABBREVIATIONS

IOM	Institute of Medicine
NCCN	National Cancer Comprehensive Network
PRO(s)	Patient reported outcome measurement(s)
OQ	Outcome Questionnaire
DT	Distress Thermometer
QOL	Quality of life
PTSD	Posttraumatic stress disorder
GAD	Generalized anxiety disorder
SCL-90	Symptoms Check List-90
BSI	Brief Symptom Inventory
DSM	*Diagnostic and Statistical Manual of Mental Disorders*
MDD	Major depressive disorder
SES	Socioeconomic status
APA	American Psychological Association
RCT(s)	Randomized controlled trial(s)
HADS (T, A, D)	Hospital Anxiety and Depression Scale (Total score, Anxiety, Depression)
POMS	Profile of Mood States
CES-D	Center for Epidemiological Studies Depression Scale
SD	Symptom distress subscale from OQ
IR	Interpersonal relationships subscale from OQ
SR	Social role performance subscale from OQ

GSI	General Severity Index
BDI	Beck Depression Inventory
STAI	State-Trait Anxiety Inventory
ZSDS	Zung Self-Rating Depression Scale
ZSAS	Zung Self-Rating Anxiety Scale
TMAS	Taylor Manifest Anxiety Scale
IIP	Inventory of Interpersonal Problems
SAS	Social Adjustment Scale
CFA	Confirmatory factor analysis
OT	On track
NOT	Not on track
Fb	Feedback
NFb	No Feedback
IES-R	Impact of Events Scale-Revised
OSG	Online support group
LLUMC	Loma Linda University Medical Center
SE	Sensitivity
SP	Specificity
PPV	Positive predictive value
NPV	Negative predictive value
FACT-G	Functional Assessment of Cancer Therapy – General
PES	Positive Emotional Support
AES	Aversive Emotional Support

ANCOVA	Analysis of covariance
Tx	Treatment
PWB	Physical well-being

ABSTRACT OF THE DISSERTATION

Reliability and Validity of the Outcome Questionnaire
in a Heterogeneous Cancer Population

by

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Doctor of Philosophy, Graduate Program in Psychology
Loma Linda University, August 2012
Dr. Jason E. Owen, Chairperson

The Institute of Medicine (IOM) and National Cancer Comprehensive Network (NCCN) now require integration of psychosocial care into the treatment of cancer patients to identify, monitor, and treat psychosocial distress. Despite the widespread use of Patient Reported Outcomes (PRO) for these purposes, no gold standard PRO for assessing distress exists for psycho-oncology research and clinical practice. This study examined the reliability, validity, and preliminary treatment effects of the Outcome Questionnaire, a PRO never before been used or validated with heterogeneous cancer patients. Adult cancer survivors were recruited nationwide to participate in an online support group (N=187) and randomly assigned to a treatment or wait-list condition in a longitudinal randomized controlled trial. The OQ Total Score demonstrated excellent reliability ($\alpha = 0.92$). However, the subscales varied in the quality of their reliability ratings. Convergent validity was demonstrated, but divergent validity was not adequately shown. Three new significant factors were identified through exploratory factor analysis. For preliminary treatment effects in the online support group study, it was shown that those with a worse perceived health status $F\ (1, 90) = 7.48$, $p = 0.008$ and those who engaged more with the online support group improved over time $F\ (1, 59) =$

6.00, $p = 0.018$. These findings suggest mixed support for the implementation of the OQ as a PRO in a chronic disease sample. Generally, if the OQ is to be used as is within a cancer population, the Total Score may be interpreted as both reliable and valid and able to demonstrate treatment effects in a cancer population, but the subscale scores should not be interpreted.

CHAPTER ONE
INTRODUCTION

The Institute of Medicine (IOM) and National Cancer Comprehensive Network (NCCN) now require integration of psychosocial care into the treatment of cancer patients to identify, monitor, and treat psychosocial distress ("Distress Management Clinical Practice Guidelines in Oncology," 2010). Cancer patients experience significant levels of psychosocial distress related to numerous cancer and patient-related factors (Nicholas & Veach, 2000). Treatment outcome evaluation of both currently utilized and newly developed psychosocial treatments is one way to ensure that a high quality standard of care is being provided. Measuring the effectiveness and impact of an intervention or treatment via change in psychosocial distress from baseline to a follow-up timepoint is an integral part of outcome measurement. These measurements are normally assessed using patient reported outcome measurements (PROs). Despite the widespread use of PROs for this purpose, no gold standard PRO for assessing distress exists for psycho-oncology research and clinical practice. Many of the current PROs suffer from a variety of psychometric issues and it is often the case that measures employed in research settings are not widely used in clinical settings and vice versa (Luckett, et al., 2010). A potential solution is to utilize the Outcome Questionnaire (OQ: Lambert, et al., 1996), a popular clinical outcome measure that has extensive use within general psychotherapy outcome research. The OQ, despite its many potential benefits, has never before been used or validated within a chronic disease population such as with heterogeneous cancer patients. The OQ may be advantageous in this population due to its content, sound psychometric properties, sensitivity to change, successful track record

of finding treatment effects, clinically meaningful interpretation, and practical administration.

Cancer: Psychosocial Concerns

Brief History of Psychosocial Care in Cancer Patients

Cancer patient psychosocial care has not always been valued nor provided within the medical community. Neither the Patient's Bill of Rights nor the Joint Commission on Accreditation of Healthcare Organizations has mandated treatment for these concerns. Not until 1997, when the NCCN formed an interdisciplinary panel, consisting of oncologists, psychiatrists, nurses, psychologists, social workers, clergy, and patient advocates, were formal clinical practice guidelines for cancer patient psychosocial care developed. The benchmark publication in 1999 of these first guidelines for managing cancer patient distress included recommendations for identification, monitoring, and treatment of distress at all stages of cancer via screening for distress and psychosocial problems, creating and implementing a treatment plan for the identified problems, referring to appropriate psychosocial services as needed, and reevaluating the patient as necessary ("Distress Management Clinical Practice Guidelines in Oncology," 2010). Effective treatment of cancer patient psychosocial distress is the ultimate goal of these standards. These guidelines laid the groundwork for the IOM report on Cancer Care for the Whole Patient (*Cancer care for the whole patient: Meeting psychosocial health needs*, 2007) which supported the NCCN guidelines and established the necessity for psychosocial care as an integral standard for quality cancer patient care.

NCCN guidelines recommend specific psychosocial screening measurement procedures for identification of distress but have not yet standardized outcome assessment of distress treatment. Screening is a separate and distinct process from assessment of distress (Nicholas & Veach, 2000; Zabora, 1998). It is considered a quick way for professionals to identify patients with psychosocial distress and to refer them for further assessment and treatment if scores meet a critical cut-point (Zabora, Smith-Wilson, Fetting, & Enterline, 1990). The NCCN recommends screening via a one-item, visual self-report questionnaire, the Distress Thermometer (DT), and an accompanying 36-item problem checklist that the patient completes in the waiting room. The problem checklist asks patients to endorse problems in five categories: practical, family, emotional, spiritual/religious, and physical. The DT (Roth, et al., 1998), a one-item measure, reads, "How distressed have you been during the past week on a scale of 0 to 10," and depicts a visual thermometer with a 0– 10 scale that ranges from "no distress" (0) to "extreme distress" (10). Significant distress is indicated by scores four or higher. A score below four is not indicated for treatment or referral and at this level the primary oncology team typically self-manages distress via supportive care assistance. Mild distress is considered to be in the range from 4-5, moderate distress ranges from 6-7, and 8 or more is considered severe distress. If a patient scores in any of these ranges, the NCCN recommends that the nurse review the accompanying problem checklist, identify core concern areas, and refer the patient to appropriate resources for treatment, including a mental health professional, social worker, or chaplaincy service.

Assessment is a more in-depth evaluative process performed within the guidelines of the treating professionals' clinical practice. For psychological mental

health professionals, the NCCN guidelines recommend a psychological evaluation that includes an assessment of the nature of the presenting problem of psychosocial distress, psychiatric history, decision-making ability, suicidality, and symptoms and behaviors surrounding pain, fatigue, sleep, sexuality, or other relevant physical ailments ("Distress Management Clinical Practice Guidelines in Oncology," 2010). Once assessed, the health professional begins treatment. Currently, the quality of psychological treatment received is not monitored with any level of measurement. The necessity for this type of evaluation is additionally supported by the NCCN, which identified the need for clinical health outcomes measurements to incorporate assessment of the psychosocial domain ("Distress Management Clinical Practice Guidelines in Oncology," 2010). One option for monitoring the quality of treatment provided is via the use of a PRO measure, the OQ, which will be discussed in more depth later.

Importance of Distress Treatment

Early identification, assessment, and treatment of distress may benefit the patient, family, doctor, and the healthcare team. Successful treatment of distress reduces healthcare costs and can improve quality of life (QOL) (Allison, et al., 1995; Deshields, Tibbs, Fan, & Taylor, 2006; Skarstein, Aass, Fossa, Skovlund, & Dahl, 2000). Increased distress may lead to reduction of some health behaviors needed for cancer prevention (Loscalzo & Brintzenhofeszoc, 1998; Pearlin & Schooler, 1978; Schou, Ekeberg, Ruland, Sandvik, & Karesen, 2004), delay in treatment seeking (Loscalzo & Brintzenhofeszoc, 1998; Pearlin & Schooler, 1978; Schou, et al., 2004), deterioration of doctor-patient communication ("Distress Management Clinical Practice Guidelines in

Oncology," 2010), reduction of satisfaction with treatment (VonEssen, Larsson, Oberg, & Sjoden, 2002), increased treatment non-adherence (DiMatteo, Lepper, & Croghan, 2000; Kennard, et al., 2004), increased number of anxiety-related doctor visitations and contacts ("Distress Management Clinical Practice Guidelines in Oncology," 2010), and increased risk for morbidity and mortality of cancer (Antoni, et al., 2006; Giese-Davis & Spiegel, 2003; Spiegel & Giese-Davis, 2003). Additionally, distress has been highly associated with decreased aspects of QOL, including physical, psychological, social, and spiritual well-being, for cancer patients and survivors (Deshields, et al., 2006; Skarstein, et al., 2000).

The sincere risk associated with distress can be further elucidated by a metanalysis conducted by DiMatteo, Lepper, and Croghan (2000) which indicated that nonadherence was three times greater in depressed patients than those who were not depressed. These results are even more startling when placed in the context of general nonadherence to drug treatment, for even non-depressed individuals frequently do not comply with treatment. Findings have indicated that nearly half of cancer patients lacked compliance to an oral medication in the fourth year of treatment, indicating that over 25% may not gain the dosage necessary for a clinically positive outcome (Partridge, Wang, Winer, & Avorn, 2003). Sadly, many more depressed individuals may fall into this negative outcome category, increasing risk of morbidity and mortality. Evidently, improving treatment of distress is vital. An understanding of the prevalence, predictors, and nature of psychosocial distress cancer patients experience is helpful to understanding measurement of cancer patient distress that can ultimately identify efficacious and effective distress interventions.

Psychosocial Distress

Cancer patients not only have to endure physical symptoms related to their disease, but also high levels of psychosocial distress (Derogatis, Morrow, Fetting, & al., 1983; Farber, Weinerman, & Kuypers, 1984; Stefanek, Derogatis, & Shaw, 1987). Psychosocial distress is common across the trajectory of the illness as well as during survivorship, frequently arising after diagnosis, at the onset or conclusion of treatment, periodically throughout treatment, at recurrence, and when shifting into palliative care, ("Distress Management Clinical Practice Guidelines in Oncology," 2010). The NCCN guidelines define cancer patient psychosocial distress as:

> "a multifactorial unpleasant emotional experience of a psychological, social, and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms, and its treatment. Distress extends along a continuum, ranging from common normal feelings of vulnerability, sadness, and fears to problems that can become disabling, such as depression, anxiety, panic, social isolation, and existential and spiritual crisis." ("Distress Management Clinical Practice Guidelines in Oncology," 2010)

Thus, psychosocial distress encompasses issues of an emotional, psychological, spiritual, and social nature, including typical stress reactions as well as diagnosable mental disorders that may impede capability of dealing with cancer. The terminology "distress" was particularly selected by the NCCN in order to reduce stigma or embarrassment that may stem from use of the words "psychiatric" or "emotional." Because clinicians opened up dialogue regarding patient pain by using a simple self-report question, asking patients to assess their pain on a zero to ten scale, they felt that similarly it would be less offending to ask a patient to report "distress" on a zero to ten

scale. Thus, the word "distress" was chosen because it can be defined and measured with self-report instruments.

Thus, distress is both psychological and social in nature. Because of the psychosocial nature of distress, many studies use the terminology "distress" and "quality of life" somewhat interchangeably, or create additional distinctions that do not exist between them, although neither approach is entirely accurate. The definition for QOL is reportedly difficult to define (Bottomley, 2002) and has many overlapping characteristics with psychosocial distress. QOL includes a larger overarching framework of well-being in physical, social, cognitive, spiritual, emotional, and role functioning areas (for example see Carlson & Bultz, 2003). However, many studies of distress elect not to focus on any social issues of psycho*social* distress, feeling that they are impinging on the realm of QOL, despite the definition of distress including social aspects (Carlson & Bultz, 2003). Thus, many studies may not be appropriately gauging the totality of the experience of psychosocial distress. Ganz and Goodwin (2005) make the argument that the best measurement of psychosocial interventions is via examining psychosocial distress. They state that this may include measuring aspects of QOL (i.e. social aspects) without measuring the totality of QOL itself. Thus, this study will include a focus on the nature, prevalence, predictors, and outcome measurement of psychosocial distress without focusing on the totality of QOL.

Distress can be measured across a continuum, ranging from normal adjustment, to adjustment disorders, to subthreshhold mental disorders, to diagnosable mental disorders (America Psychiatric Association, 2000). Typically at the time of diagnosis most individuals experience normal adjustment, or "expected distress," symptoms.

These may consist of feelings of fear, loss, worry, anger, and uncertainty about the future and control over the world. Also, troubles with sleep, lack of appetite, trouble focusing, and preoccupation with cancer, death, and treatment/side effects may arise. The patient's oncology team often handles mild distress. More pervasive and intense symptoms are indicative of moderate to severe levels of distress that are frequently referred to be treated by a mental health professional. These symptoms include extreme worries, fears, sadness, despair, hopelessness, suicidality, family issues, and existential or spiritual problems ("Distress Management Clinical Practice Guidelines in Oncology," 2010).

More severe problems and symptoms will fall along the continuum ranging from adjustment disorders to mental disorder diagnosis ("Distress Management Clinical Practice Guidelines in Oncology," 2010). To be diagnosed, adjustment disorders must occur within three months of the onset of a stressor and represent a maladaptive reaction or an inability to cope that has some marked effects on one's ability to function at school, home, and/or work (America Psychiatric Association, 2000). If mood and anxiety symptoms become more pervasive and severe or persist beyond six months, a more severe diagnosis may be indicated.

Depressive disorders are more severe mood disorder diagnoses and also a common problem for cancer patients. Many symptoms caused by the disease and/or treatment of cancer are identical to the symptoms necessary to meet criteria for diagnosis of depression, thus, making it more difficult to distinguish the mood disorder. Psychomotor retardation, appetite suppression, sleep disturbance, fatigue, concentration difficulties, and apathy are frequent symptoms in cancer and its treatment that also

imitate the mood disorder symptoms. Distinctive symptoms for diagnosing a comorbid mood disorder include feelings of dysphoria and anhedonia, worthlessness, hopelessness, excessive or inappropriate guilt, and/or suicidal ideation (J.C. Holland & Alici, 2010). Suicidal ideation in cancer patients occurs across all stages of the disease and is thought to act as a means for an individual to gain some sense of control over the illness (J.C. Holland & Gooen-Piels, 2003). The risk of suicide is approximately two times that of the normal population (Breitbart, Lederberg, Rueda-Lara, & Alici, 2009; Chochinov, Wilson, Enns, & Lander, 1998), and an international population-based study indicated that the risk remained elevated even up to 25-years after a cancer diagnosis (Schairer, et al., 2006). Thus, untreated distress can be deadly.

In addition to depressive disorders, cancer patients commonly react with anxiety that is manifested physically as well as in thoughts and behaviors. Holland and Alici (2010) reviewed the literature that discussed the most common types of anxiety disorders existing in cancer patients and indicated the following diagnoses: acute stress disorder, posttraumatic stress disorder (PTSD), generalized anxiety disorder (GAD), panic attacks or disorder, specific phobias, anxiety disorder due to a general medical condition, and substance-induced anxiety disorder.

Prevalence of Distress

Cancer patients experience significantly more psychosocial distress than other chronic disease populations or healthy adults (Kaiser, Hartoonian, & Owen, 2010). Studies on prevalence of distress indicate that one in three cancer patients will experience levels of significant distress (Derogatis, et al., 1983; Farber, et al., 1984;

Stefanek, et al., 1987), and depending on the study, a range of 5-47% of cancer patients report significant distress levels (Carlson, et al., 2004; Derogatis, et al., 1983; "Distress Management Clinical Practice Guidelines in Oncology," 2010; Kaiser, et al., 2010). Farber and colleagues (1984), utilizing the Symptom Check List-90 (SCL-90), detected 34% of cancer patients with elevated distress. Stefanek et al. (1987) identified 28% of cancer patients with distress after assessment with the Brief Symptom Inventory (BSI). Zabora and colleagues, also using the BSI, sampled larger cancer populations in 1997 and 2001 (Zabora, et al., 1997; Zabora, BrintzenhofeSzoc, Curbow, Hooker, & Piantadosi, 2001). In 1997, these researchers measured 386 patients from 12 American cancer centers and found levels of distress at 35%. In 2001 they gathered information from 4496 participants with 35.1% reporting distress.

The prevalence of psychiatric diagnoses in cancer patients has been reported to be as high as approximately 50% ("Distress Management Clinical Practice Guidelines in Oncology," 2010; J.C. Holland & Gooen-Piels, 2003; Massie, 2004). Depending on the patient population and diagnostic criteria used, the majority of diagnoses include the following disorders and prevalence: adjustment disorders (estimates of 2/3rds of all diagnoses), depressive disorders (0-53%), and anxiety disorders (1-49%) (Derogatis, et al., 1983; Harter, et al., 2001; J.C. Holland & Gooen-Piels, 2003; Sellick & Crooks, 1999; Van'T Spijker, Trijsburg, & Duivenvoordern, 1997; Zabora, et al., 2001). Adjustment disorders with anxiety and/or depressed mood represent the most common diagnoses for cancer patients (J.C. Holland & Alici, 2010). In one of the earliest studies on psychiatric diagnosis in cancer patients, Derogatis and colleagues (1983) sampled patients from across 3 cancer programs and found that 47% were classified with a

Diagnostic and Statistical Manual of Mental Disorders (DSM) Axis I disorder based on a psychiatric interview and assessment with the SCL-90. Approximately 1/3 of individuals in his sample met criteria for adjustment disorder with anxious or depressed mood, and 7% were severe enough to be classified with major depressive disorder (MDD).

Inconsistent variations in distress across cancer patients are postulated to occur for a number of reasons. Herschbach (2004), argues for a heterogeneous picture of distress results based on cancer type, indicating that a complex picture of factors within a cancer type may be more depictive than seeking general causes of distress across the totality of cancer diagnoses. However, others argue that discrepancy in distress levels and predictors across studies may occur due to a lack of consistent nomenclature, measurement questionnaire, and different cut-off requirements for distress type and classification (Casarett & Inouye, 2001; Herschbach, et al., 2004; Luckett, et al., 2010; Massie, 2004).

Risk Factors for Distress

Correlates and predictors of distress, or risk factors for distress, may be categorized into cancer and patient-derived variables (J. C. Holland, 1998). Nicholas and Veach (2000), after reviewing the literature, describe cancer-derived variables as those that refer to illness and treatment. Patient-derived characteristics consist of demographic characteristics, past history, intrapersonal qualities, and interpersonal relationships. The authors support the position that a combination of history and demographic factors may influence the activation/perception of intrapersonal

characteristics and interpersonal relationships leading to distress. A combination of the patient-derived and cancer-derived variables can lead to either normal adjustment or to experience of psychosocial distress. The cancer and patient-derived risk factors for distress will be delineated.

Cancer-Derived Risk Factors

Holland and Alici (2010) summarized findings across the literature, and surmised that most cancer patients experience general fear and worry about disease reoccurrence, the future, current and/or potential symptoms from cancer and its treatment (i.e. pain, fatigue, death), phobias of health and hospital related treatment items (i.e. blood, needles), and anxiety induced by certain types of hormone-secreting cancers or substances used to treat the disease. Research supporting cancer-derived variables as risk factors for increased distress is prevalent, but also mixed in findings. These risk factors include variables related to the disease, including cancer type, site, stage, and prognosis; treatment, both type and phase; comorbid illness and health factors; physical symptoms; and related disability processes that can result in psychosocial stressors (Nicholas & Veach, 2000; Turner, Wooding, & Neil, 1998).

In 1999, Sellick and Crooks found that advanced stages of cancer, physical disability, and pain increased MDD. Contrary to Sellick and Crook's disease stage-MDD relationship, Zabora (1997) found no correlation between stage of cancer and distress with the exception of the terminal phase, which indicated increased levels of distress. Additionally, after sampling 4496 patients in 2001, Zabora et al. noted that distress rate varied by cancer type, with the following types reporting the most to least

distress: lung cancer (43.4)%, brain, Hodgkin's disease, pancreas, lymphoma, liver, head and neck, breast, leukemia, melanoma, colon, prostate, and gynecological (29.6%). Similarly, Carlson et al. (2004) found that certain types of cancer patients reported the highest levels of distress, specifically lung, pancreatic, head and neck, Hodgkin's disease, and brain cancer patients. However, her findings differed from both Sellick and Crooks and Zabora et al.'s results, for her study indicated that active treatment patients were currently the most distressed. Other findings demonstrated that fair or poor health status, experiencing pain, comorbid conditions (Kaiser, et al., 2010), duration of illness, and inpatient or outpatient setting (Herschbach, et al., 2004) are risk factors for distress.

Disability processes related to the disease and treatment also are risk factors for psychosocial distress. The side effects of the treatment or illness may cause disruptions in patients' daily activities and daily functioning, causing a shift for cancer patients' roles in work, play, home, and love life (Dodd, et al., 2001; Lutgendorf, et al., 2000; Morasso, et al., 2001). These shifts may lead to distress within the patient as well as the family as everyone experiences consequential shifts in their roles, structure, and needs at home and work (Hewitt, Greenfield, & Stovall, 2005). Financial burden occurs as the patient's employment status and healthcare costs may lead to depleted funds (Hewitt, et al., 2005). In addition, intimacy and sexual functioning between patient and partner is frequently decreased (Aziz & Rowland, 2003). With all of these substantial changes in functioning, survivors may struggle with indecision for how to move forward in their careers and/or intimate relationships (Hewitt, et al., 2005).

Patient-Derived Risk Factors

Findings from patient-derived demographic variables as risk factors for distress are also prevalent. Demographic risk factors commonly include age, gender, relationship status, and socioeconomic status (SES) (Nicholas & Veach, 2000). Research in this area has expanded over the past years, and a variety of studies indicate complicated findings for the significance of many of the following demographic predictors for increased distress in cancer patients: female gender, younger age, being unmarried, lower SES, lower levels of education, racial minority, higher number of children in the household, lower number of elders in the household, and lack of health insurance (Carlson, et al., 2004; Harter, et al., 2001; Herschbach, et al., 2004; Kaiser, et al., 2010; Zabora, et al., 2001).

Patient-derived factors stemming from past history compose many other risk factors for distress. Examples given of past history risk factors include prior mental disorders, substance abuse, and social history (Nicholas & Veach, 2000). Turner, Wooding, and Neil (1998) reviewed the literature on breast cancer from 1986-1996 and deduced many risk factors for distress, including history of psychological problems. Prior psychiatric history is typically associated with a diagnosis of anxiety or depression at some point during the cancer disease trajectory. One study noted a previous history of depression in 31.5% of women that were diagnosed with early breast cancer and a comorbid depressive disorder (Kissane, et al., 1998). The NCCN review provides a number of other problematic risk factors, including pre-morbid substance or alcohol abuse and previous physical or sexual abuse. Additionally, pre-existing social relationship history may be influential. Turner and colleague's (1998) review identified

recent loss of a spouse, marital problems, divorce, or widowhood, as increasing distress levels.

Intrapersonal variables, such as personality and coping styles, and interpersonal patient variables, such as social support, are also identified as risk factors. These factors individually or combined may influence the experience of distress. High trait anxiety (Love, 2004), pessimism (Pinquart, Frohlich, & Silbereisen, 2007), an avoidant coping style, and/or unwillingness to disclose emotions (Turner, et al., 1998) are demonstrated to be influential in increasing distress. Lack of social support, or perceived lack of support, is also a risk factor for psychosocial distress (Turner, et al., 1998). Cancer patients may experience loneliness and isolation (Aziz & Rowland, 2003), and those living alone and who have communication barriers are also subject to higher degrees of distress ("Distress Management Clinical Practice Guidelines in Oncology," 2010). Low perception of social support by those living alone and/or those exhibiting depressive coping behavior were associated with poorer adjustment (Sollner, et al., 1999).

Patient Reported Outcomes

Evidently, psychosocial distress is prevalent with numerous predictors related to the disease and the patient. As discussed prior, although current NCCN guidelines require treatment for psychosocial distress, they do not monitor the outcome of treatment received. Additionally, new and improved psychosocial treatments and interventions tested in epidemiological and clinical cancer studies need to be evaluated for their outcome effects. Outcome evaluation of both currently utilized and newly developed psychosocial treatments is one way to ensure that a quality standard of care is

provided. The necessity for this type of evaluation is additionally supported by the NCCN, which identified the need for clinical health outcomes measurements to incorporate assessment of the psychosocial domain ("Distress Management Clinical Practice Guidelines in Oncology," 2010). Key to this type of research is measurement of outcome of psychosocial distress, most frequently assessed with PROs.

Increasingly over the previous decades, PROs are serving as the core assessment for subjective concerns ("Distress Management Clinical Practice Guidelines in Oncology," 2010), such as anxiety, depression, distress, and QOL. These measures are used to improve understanding of the outcome of treatments in supportive care and cancer treatment (Garcia, et al., 2007). PROs are frequently being offered as paper-and-pencil-based, self-report questionnaires or electronically as ePROs (Abernethy, et al., 2010). This self-report method has developed as an alternative to resource intensive clinical diagnostic interviews, for a wide variety of continuous data can be easily measured for those experiencing a wide range of severity of symptoms, from low to high severity (Luckett, et al., 2010). Additionally, many PROs are now mandated for certain clinical trials as essential outcome assessments that contribute to clinical decision-making. For example, PROs could have contributed to clinical decision-making for a RCT comparing two leukemia treatments. One treatment significantly improved QOL compared to another (Efficace, et al., 2008). Thus, information gleaned from PROs may also provide a more complete picture of a patient and thus improve treatment (Efficace, Vignetti, & Mandelli, 2009).

Despite the increasing reliance on PROs in psycho-oncology research, no gold-standard PRO currently exists to measure anxiety, depression, distress, and QOL across

cancer patients (Luckett, et al., 2010). Flynn et al. (2006) summarized the concerns from qualitative interviews from 42 primary authors of clinical trials, including 11 oncology researchers, published in top-tier journals. They stated that the first problem is that clinical trials use different PROs to address identical constructs, making it difficult to compare findings across studies. Second, many PROs suffer from problematic psychometrics. Many have not been validated within cancer populations, are not sensitive to change, and suffer from floor or ceiling effects that minimize effect of a treatment intervention. Third, many PROs are a burden for patients and administrators to complete or score.

Additionally, many PROs measuring distress do not meet American Psychological Association (APA) standards for outcome measurement decided by the 1994 APA-sponsored conference on developing outcome batteries (Horowitz, Lambert, & Strupp, 1994). The group of 20 noted experts determined that the patient's subjective distress, psychological symptoms, and impairment in social functioning (i.e., work, interpersonal relationships, etc.) were all necessary for appropriately measuring each patient's unique problems. Most PROS either assess psychological symptom distress or social distress, but not both processes (Jong, et al., 2007).

Luckett and colleagues (2010) performed the first comprehensive oncology measurement outcome review. These authors delineated guidelines for optimal PROs utilized within psycho-oncology research. First, PROs need to have appropriate content and be shown to be suitable for a heterogeneous cancer population with people in varying types and stages of treatment. Second, optimal PROs need to demonstrate sound psychometric properties including reliability and validity in English-speaking

cancer patients. Most importantly, the measure needs to be sensitive to change. Third, the track record of the measure is key. The measure needs to have a history of finding treatment effects in randomized controlled trials (RCTs) of psychosocial interventions. Fourth, the measure needs to be interpretable. Scores need to be clinically meaningful and comparison data needs to be available from both cancer and general populations. Finally, practical issues are key to a PRO being optimal. A brief, low-cost measure available in many languages is ideal. The PRO needs to be efficient in its length—minimizing item number and maximizing constructs assessed, thus having minimal patient burden. Next, the measure needs to have minimal administration and scoring burden.

With these guidelines in mind, Luckett et al. (2010) evaluated publications between 1999 and May 2009 for numerous distress outcome questionnaires currently used to measure anxiety, depression, and distress. These assessments have all been applied during psychosocial intervention RCTs within English-speaking, heterogeneous cancer populations. They chose to exclude PROs that solely measured the psychological constructs of coping, adjustment, self-esteem, PTSD, and QOL. Also excluded were measures that had one-third or greater of its items designated to measure somatic concerns or health preoccupation. However, they included measurements that assessed a combination of anxiety, depression, and distress. A total of 30 PROs were compared. The top three ranked scales in order of suggestion included the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983), the brief Profile of Mood States (POMS), the POMS-37 (Shachem, 1983), and the original POMS-65 (McNair & Heuchert, 2003) and the Center for Epidemiological Studies Depression Scale (CES-D)

(Radloff, 1977) tied for third. However, none of these measures are commonly utilized within clinical practice settings. Also, even after promoting these as the most optimal assessments, Luckett and colleagues still had reservations about these measurements. These measures and reservations based on the Luckett et al. findings will be outlined.

The HADS (Zigmond & Snaith, 1983) is a 14-item measure rated on a four-point Likert scale asking patients to recall symptoms for the past seven days. It takes approximately two to five minutes to complete. The cost is approximately $40 for the manual and 90 cents per patient form. Subscale anxiety and depression scores are available, and the total score is seen as an "unofficial" score. Although it ranked well in terms of its psychometric reliability and validity as well as its efficiency at measuring numerous constructs with only 14-items, there are problems involving the HADS overall score (HADS-T), content, and appropriate cut-offs. Each problem within the HADS will be briefly discussed.

Despite the HADS manual advising against utilizing the HADS total (HADS-T) score as an overall measure of distress (Snaith & Zigmond, 1994), many researchers continue to do so. Content analysis of the HADS anxiety (HADS-A) and depression (HADS-D) scale indicate that only three items assess emotional experiences other than criteria necessary for GAD and MDD. Therefore, positive findings for the HADS-T as an overall measure of distress are mixed, with some results indicating its superiority over the HADS-A and HADS-D in detecting clinically significant distress (Chaturvedi, 1991; Katz, Kopek, Waldron, Devins, & Tomlinson, 2004; Le Fevre, Devereux, Smith, Lawrie, & Cornbleet, 1999; Lloyd-Williams, Friedman, & Rudd, 2001; Smith, et al., 2006). However, factor analyses demonstrated mixed results (Johnston, Pollard, &

Hennessey, 2000; Moorey, et al., 1991; Rodgers, Martin, Morse, Kendell, & Verill, 2005; Smith, et al., 2002). Additionally, RCTs were not utilized enough in the study to indicate the sensitivity to change of the HADS-T over time. Luckett (2010) advised that further psychometric assessment of the HADS-T is needed.

The content of the HADS also has several problems. First, somatic content is completely omitted in hopes of reducing confounding disease and mood symptoms; however, this creates an overemphasis on symptoms of anhedonia. Thus, the measure was not as valid within late-stage cancer as well as depressive disorders, for it may lack sensitivity to mild depression or adjustment disorder with depressed mood (Lloyd-Williams, et al., 2001; Love, 2004). Thus, the measure may not be the most sensitive to changes that occur post-intervention, and it may not demonstrate true treatment outcomes for some of these individuals.

Lastly, the recommended cut-off scores by the HADS creators do not always perform well across studies, and optimal cut-off scores have differed (OHall, A-Hern, & Fallowfield, 1999). Additionally, reporting of outcomes of the HADS sometimes takes different forms, such as means and standard deviations, and only sometimes with reference to cut-off scores. Also, more research is necessary to determine an optimal cut-score for the HADS-T. These cut-off score problems make clinically meaningful interpretation of the HADS very difficult. It also becomes problematic to compare treatment effects across studies.

The POMS-37 is a 37-item measure rated on a five-point Likert scale, asking participants to recall symptoms over the past seven days. It takes approximately five minutes to complete and is free for non-commercial use. It includes measures of

tension-anxiety, depression-dejection, anger-hostility, vigor, fatigue-inertia, and confusion-bewilderment. A total mood disturbance score and individual subscale scores are available. However, in the Luckett et al. (2010) study the total mood disturbance score was not counted as a distress measure because the score is calculated via addition of numerous subscales that included too many confounding somatic variables. Luckett and colleagues noted the POMS-37 has a few significant problems including content and track record. First, the measure was not created to screen for psychological disorders, but only to assess for mood. Although it eases administrator cost and performs well for anxiety and mixed affective disorders, it does not offer a suitable index of general distress nor is it a good measure of depression for it also overemphasizes anhedonia. Second, it has only been utilized in one RCT of psychosocial interventions to assess for anxiety, depression, or distress since 1999 (Shachem, 1983). This limits the track record for this instrument in finding significant psychosocial treatment effects.

The original POMS-65 is a 65-item measure rated on a five-point Likert scale that asks participants to recall symptoms over the past seven days. It takes approximately 10 minutes to complete. The manual costs $27 dollars and each measure is $1.32. It includes measures of tension-anxiety, depression-dejection, anger-hostility, vigor, fatigue-inertia, and confusion-bewilderment. A total mood disturbance score and individual subscale scores are available. Like the Poms-37 in the Luckett et al. (2010) study, the total mood disturbance score was not counted as a distress measure because the score is calculated via addition of numerous subscales that included too many confounding somatic variables. The POMS-65 is also less appealing due to its cost and its length, and it is not perceived to be a very good measure of overall distress.

Finally, the CES-D (Radloff, 1977) is a 20-item measures rated on a five-point Likert scale based on the previous seven days. It takes approximately five minutes to complete and is free for non-commercial use. It provides a total score of depression. This measure is problematic for several reasons noted by Luckett et al. (2010). First, its criterion validity has only been evaluated in two studies, and in one of these studies it was outperformed by the HADS-T, which has psychometric issues that have already been discussed. Furthermore, the cognitive burden of the CES-D was ranked in the mid-range due to its questions assessing symptom frequency rather than severity. Finally, the CES-D is not a good measure for anxiety and distress, and it is a lengthy measure that examines only one construct.

Solution: Alternative PRO, the Outcome Questionnaire

Their conclusions demonstrate that an overall gold-standard measure for measuring anxiety, depression, and distress in cancer patients does not currently exist in the literature. Many problems inherent in prior PROs may be resolved by incorporating the consistent use of a standardized psychological disturbance outcome measure in psycho-oncology cancer research. One measure with laudable strength is the OQ (Lambert, et al., 1996). The OQ is one of the top ten measures utilized in the United States for clinically measuring outcome of general psychosocial distress and functioning (Hatfield & Ogles, 2004). As discussed prior, Luckett and colleagues (2010) made many recommendations for evaluating and appraising PROs as optimal. Content, psychometric properties, track record, interpretability, and practical issues of the OQ are all key to classifying it as an optimal PRO. These gold-standard PRO requirements will

be further discussed in terms of how the OQ already meets many of these guidelines and/or how the current study plans to fulfill any gaps in these standards.

OQ Content

Content of optimal PROs attempting to measure psychological distress should be suitable for a heterogeneous cancer population (Luckett, et al., 2010). The OQ was specifically designed to measure key constructs and components of outcomes in global psychological distress and functioning. Despite never being utilized within a cancer population, the OQ has been prominently used to measure general functioning and distress in patient-focused psychotherapy outcome research (for examples see: Harmon, et al., 2007; Lambert, Hansen, & Finch, 2001; Lambert, Harmon, Slade, Whipple, & Hawkins, 2005; Okiishi, et al., 2006; Slade, Lambert, Harmon, Smart, & Bailey, 2008; Whipple, et al., 2003). A brief description of the OQ and a discussion of the rationale behind the measure's item and domain selection may support its suitability for use as a measure of psychosocial distress within cancer patients.

Description of the OQ

The OQ (Lambert, et al., 1996) measures the global functioning and psychological disturbance of a client. The assessment is a 45-question, five-point Likert scale self-report measure ranging from zero (never) to four (almost always), resulting in scores that range from 0 to 180. Higher scores indicate a higher endorsement of disturbance. Composed of three subscales, the OQ measures symptom distress (SD), interpersonal relationships (IR), and social role performance (SR). Major symptoms of

psychiatric disorders, especially anxiety and depression, are assessed in the first subscale, Symptom Distress. The second subscale, Interpersonal Relationships, measures satisfaction and problem areas of relationships. Satisfaction and ability to function in primary roles such as in school, work, or home, are measured in the third subscale, Social Role. The authors of the OQ argue that all three subscales contribute to a total score that captures global functioning and distress.

Rationale Behind Item and Construct Selection

All items and construct domains utilized in the OQ were selected rationally and empirically (Lambert, et al., 1996). The content of the OQ has extensive clinical use and relevance, for the items and constructs were selected to examine three key domains: psychological symptom distress, interpersonal relationship problems, and social role functioning (Lambert, et al., 1996; Mueller, Lambert, & Burlingame, 1998; Umphress, Lambert, Smart, Barlow, & Clouse, 1997). Mueller and colleagues (1998) noted how these three domains were designed to conceptually capture the definition of "mental disorder" given in the DSM (4th Edition):

> Each of the mental disorders is conceptualized as a clinically significant behavioral or psychological syndrome or pattern that occurs in an individual and that is associated with present distress (e.g., a painful symptom) or disability (i.e., impairment in one or more important areas of functioning). (American Psychiatric Association, 1994, p. xxi)

Thus, these domains of outcome meet the standards for outcome measurement decided by the 1994 APA-sponsored conference on developing outcome batteries: patient's subjective distress, psychological symptoms, and impairment in social functioning (i.e.,

work, interpersonal relationships, etc.) (Horowitz, et al., 1994). These concerns were all considered necessary for appropriately measuring each patient's unique problems. Most outcome measures pale in comparison by either assessing symptom distress or functioning but not both processes (Jong, et al., 2007).

OQ researchers selected items to include in the Symptom Distress subscale based on reviewing survey data regarding psychological symptom and diagnosis prevalence in the U.S. population (Lambert, et al., 1996). Analysis of the 1988 National Institute of Mental Health epidemiological questionnaire informed researchers that the most consistent symptoms and diagnoses included anxiety and depressive disorders closely followed by substance abuse problems (Regier, et al., 1988). Thus, the OQ was heavily loaded with items that measure these symptoms. Item selection was based on fit of items to current DSM criteria for these disorders, additional symptoms supported by the literature, and statistical analysis (Lambert, et al., 1996). One limitation of the OQ is that a few items that were selected to best represent common symptoms of depression and anxiety may overlap with common physical problems due to cancer treatment side effects (e.g., fatigue, concentration). However, without the inclusion of these items it may overestimate the symptoms of anhedonia and suffer from floor or ceiling effects of the score.

Lambert and colleagues (1996) argue that the Interpersonal Relationships subscale domain was also founded upon research that indicates that, a) people consider relationship satisfaction key to personal happiness (Andrews & Withey, 1974; Beiser, 1973 ; Blau, 1977; Diener, 1984; Veit & Ware, 1983) and, b) that interpersonal problems are the most prominently addressed issues in therapy (Horowitz, 1979;

Horowitz, Rosenberg, Baer, Ureno, & Villasenor, 1988). Individual items were created based on marriage and family literature and research on patient-reported interpersonal problems for those in therapy (Horowitz, et al., 1991). Items were thus selected in order to assess relationship conflict, loneliness, inadequacy, and withdrawal.

Lastly, the social role performance domain was also included based on prior research. Previous QOL research asserts that patient symptoms may influence their ability to perform at work, at home, and in relationships. Satisfaction in personal and professional roles is correlated strongly with QOL (Beiser, 1973 ; Blau, 1977; Veit & Ware, 1983). Thus, items were created to assess patients' degree of distress within tasks associated with their play, work, and relationship roles.

Overall, the content of the OQ is supported by the prior effort that went into developing the items and domains for assessing psychological distress and functioning. In order to determine if it is fully suitable for a heterogeneous cancer population, the psychometric properties will need to be closely examined within a sampling of these patients.

OQ Psychometric Properties

Gold-standard PROs need to be shown to be reliable and valid within the population that they purport to measure (Luckett, et al., 2010). Prior psychometric studies have been conducted with the OQ in both normal and psychiatric patient populations. Despite these prior studies, this measure has never before been validated in any cancer population or other chronic disease sample. Examination of the previous reliability and validity studies may, a) support the psychometric properties of this

instrument and thus support its implementation within a cancer population, and b) give some indication for how the OQ may function in a cancer population. These previous reliability and validity studies will be described, with a highlight of the findings noted. Based on these research findings, predictions will later be postulated regarding the reliability and validity of the OQ in a cancer population.

Reliability

Lambert and colleagues (1996) conducted the cornerstone study of the reliability of the OQ. Undergraduate (N=157) and psychotherapy patient populations (N=289) were sampled to determine internal consistency of the OQ. Excellent internal consistency was demonstrated for students and patients' OQ total score (student/patient $\alpha = .93$) as well as the Symptom Distress scale score (student $\alpha = .92$; patient $\alpha = .91$). The Interpersonal Relationships and Social Role scales, having greater variation in the functioning assessed in their measurements, demonstrated poorer reliability (Interpersonal Relationships: student/patient $\alpha = .74$; Social Role: student $\alpha = .70$; patient $\alpha = .71$). Undergraduate students (N=157) who received no therapeutic treatment were tested a second time at three weeks post-baseline assessment to examine test-retest reliability. Pearson product-moment correlation coefficients indicated temporal-stability of the OQ over this time frame for the OQ total score (r=.84), Symptom Distress (r=.78), Interpersonal Relationships (r=.80), Social Role (r=.82).

Validity

Concurrent validity of the OQ has been examined in two key studies, Lambert et al. (1996), which utilized an undergraduate population (N=238), and Umphress, Lambert, Smart, Barlow, and Clouse (1997), which sampled counseling center clients (n=53), community clinic patients (n=106), and an inpatient psychiatric population (n=24). Both studies measured concurrent validity by computing Pearson product-moment correlations between the OQ total and subscale scores and the criterion measures. Both studies indicated similar validity patterns within their results.

High levels of convergent validity were demonstrated across each study, for the OQ total and subscale scores had significant validity coefficients ($p < 0.05$) with all criterion measures. The studies used the same criterion measures, although the Lambert et al. (1996) study utilized additional measures. Within the Lambert et al. (1996) study, the General Severity Index (GSI) from the SCL-90-R, Beck Depression Inventory (BDI), State-Trait Anxiety Inventory (STAI), Zung Self-Rating Depression Scale (ZSDS), Zung Self-Rating Anxiety Scale (ZSAS), Taylor Manifest Anxiety Scale (TMAS), Inventory of Interpersonal Problems (IIP), and Social Adjustment Scale (SAS) were utilized as the criterion measures. As hypothesized, the OQ total score and Symptom Distress subscale maintained moderate to high validity coefficients with all criterion measures (Total OQ: $r = .60$-$.88$, Symptom Distress: $r = .50$-$.89$), with depression (ZSDS, BDI), anxiety (TMAS, STAI, and ZSAS), and global distress (GSI) demonstrating the strongest relationships. Despite subscale-criterion measure hypotheses, the Interpersonal Relationships and Social Role subscales did not correlate highest with their predicted respective measures, yet still correlated significantly with all

applicable measures (Interpersonal Relationships: *r* =.44-.67; Social Role: *r* =.41-.71). Umphress and colleagues (1997) criterion measures included only the GSI, IIP, and SAS-revised. Again, although the OQ total and Symptom Distress subscale scores correlated as predicted with the respective criterion measures (Total OQ: *r* = .66-.88, Symptom Distress: *r* = .65-.92), the Interpersonal Relationships and Social Role subscales did not, despite their significant validity coefficient scores across measures (Interpersonal Relationships: *r* =.45-.69; Social Role: *r* =.53-.73).

Lambert et al. (1996), Umphress et al. (1997), Vermeersch, Lambert, and Burlingame (2000) and Mueller, Lambert, and Burlingame (1998) each conducted research relevant to the construct validity of the OQ. Multiple means of assessing construct validity were utilized in these studies, including examination of the following: the OQ's sensitivity to change, a confirmatory factor analysis (CFA) of the subscales of the OQ, and the OQ's ability to discriminate between psychiatric patient and non-patient populations.

OQ total and individual item score sensitivity to change were examined by Lambert et al. (1996) and Vermeersch, Lambert, and Burlingame (2000) respectively. Lambert and colleagues (1996) make the argument that the validity of a psychotherapy outcome measure like the OQ rests on its ability to demonstrate change in the desired direction following a therapeutic intervention. Thus, scores of those not receiving psychotherapy would be expected to remain the same, however scores of those receiving psychotherapy would be expected to change in the direction of improvement. Lambert et al. (1996) demonstrated support for total and subscale score sensitivity to change after examining data from 40 psychotherapy patients at baseline and after seven sessions of

outpatient psychotherapy treatment. T-test comparison of pre and post-scores demonstrated significant improvement for patients across the total score and subscales. Expounding upon this idea, Vermeersch, Lambert, and Burlingame (2000) examined item-level sensitivity to change in a control group of undergraduate students (n=284) and an experimental group of individuals from four outpatient mental health groups (n=1176). Results from hierarchical linear modeling indicated that the majority of items were sensitive to change in the optimal direction following treatment.

Despite favorable results for the OQ's sensitivity to change, outcome of the CFA for the three subscales of the measure were not as preferable. Three factor analysis models were assessed using a split-sample and cross-validating design (Mueller, et al., 1998). Model 1 tested a three-factor solution using the original three subscales of the OQ (Symptom Distress, Interpersonal Relationships, Social Role) as three oblique factors. Model 2 analyzed a two-factor solution by examining two oblique factors—the original Symptom Distress and a new second factor that combined the Interpersonal Relationships and Social Role scales. Lastly, Model 3 assessed a single-factor solution of all three original subscales. Findings indicated that all models had a relatively poor fit. However, chi-square analysis of the models indicated that Model 1, the three-factor solution, had a significantly better fit than the other models. Other researchers have noted that the OQ may be examining one global distress factor, for the correlations between the subscales are significant (Umphress, et al., 1997). Mueller and colleagues (1998) recommended that exploratory factor analysis should be performed in other patient populations. Thus, this will be a focus for the current study.

Discriminant validity findings regarding the ability of the OQ to discriminate patient and non-patient sample mean scores, examined by Lambert et al. (1996) and Umphress et al. (1997), supported the construct validity for this measure. These studies compared a normal community sample with patient populations sampled from several types of mental health services centers. In both studies, patient populations scored significantly higher on the OQ ($\bar{x}$ = 67.6-99.9) than non-patient populations ($\bar{x}$ = 42.3-48.16), with the most severe patient populations (outpatient, inpatient) scoring the highest on the measure. Umphress et al. (1997) further discriminated within the patient populations and noted a significant difference in pre-treatment total OQ scores for those diagnosed with a coded DSM disorder (x = 85.3) compared to those with a V-code score (x = 66.2). Additionally, the Symptom Distress and Social Role subscales were significantly higher in those with a DSM disorder. Lambert and colleagues (1996) determined sensitivity (SE) and specificity (SP) by comparing classification accuracy for patient and nonpatient populations via the previously described 64-cutoff score. The sensitivity index was .85, meaning that 85 out of 100 patients were correctly classified. The specificity index was .74, indicating that 74 out of 100 nonpatients were correctly classified.

OQ Track Record

In addition to content and psychometric properties suggesting suitability for a cancer population, optimal PROs should have a history of finding treatment effects in RCTs of psychosocial interventions. Although never before examined in a cancer population, previous OQ research supports its ability to find treatment effects in RCTs.

Utilized within patient-focused outcome research, the OQ has repeatedly demonstrated significant treatment effects for this type of research. The patient-focused research paradigm will be discussed as well as some of the significant findings demonstrated by the OQ. Showing treatment effects of the OQ in a cancer population will be a focus for the current study.

Theoretical Development of Patient-Focused Paradigm and Utilization of the Outcome Questionnaire

Stemming partly from pressures of managed care third-party payers, consumers, and mental health workers to quantitatively demonstrate the benefit of psychological service, psychological outcome research originated. The patient-focused research paradigm developed in response to limitations by various types of outcome research. This paradigm, dominated by the use of OQ-data, directly answers the question of whether the current client is being helped by the current treatment. Clinicians receive current and consistent feedback on clients' progress in therapy at every session (via the OQ scores) so that clinicians may alter treatments and prescribed therapeutic attendance as necessitated by the clients' progress or lack thereof (Howard, Moras, Brill, Martinovich, & Lutz, 1996).

The patient-focused research paradigm was partially founded on two rationales or theories. First, this paradigm declares that patient progress is often predictable, and positive or negative therapeutic outcome may be revealed in the first few sessions of therapy (Lambert & Bergin, 1994). Thus, knowledge of patients' level of distress and progress from session to session may increase therapists' abilities to predict those who

may have a negative outcome. Second, this research method was also in part developed using the rationale from the dose-response theory of therapy effectiveness. The dose-response theory indicates a linear relationship between the log of session numbers and the probability of patients' positive progress. Thus, the higher the dosage (number of therapy sessions), the better the response (patient progress) (Howard, Kopta, Krause, & Orlinsky, 1986). Utilizing support from these theories, patient-focused researchers assert that feedback given to therapists on patient progress may increase/decrease the dose of therapy sessions or treatment, and thus better the outcome response (Lambert et al., 2001; Lambert et al., 2002; Whipple et al., 2003; Hawkins et al., 2004).

The dose-response theory was also influential in developing a mathematical equation to assist in giving accurate patient-progress feedback. Many patient-focused researchers are using an algorithm computed by Finch, Lambert, and Schaajli (2001) to identify clients at risk for having a negative outcome to therapy, or those clients who may drop out before receiving therapeutic benefits. These algorithms use the clients' intake level of distress (OQ-score) along with the change in OQ-score of client's level of distress at the indicated session. Next the client is classified on a range of functionality in either a "functional" or "dysfunctional" range based on Jacobson and Truax's (1992) clinical significance definitions. The feedback provided by the algorithm informs therapists if a client is making the expected amount of progress at a point in time to receive a clinically significant outcome. Thus, patients may be labeled as on track (OT), if they are progressing normally, or not on track (NOT), if their progress is poor.

Significant Treatment Effects Found in RCTs via the OQ

Many patient-focused research studies have examined the development and implementation of OQ-feedback systems that incorporate the use of the previously mentioned algorithm that assesses progress and change (e.g., Hawkins, Lambert, Vermeersch, Slade, & Tuttle, 2004; Lambert, Whipple, et al., 2001; Lambert, et al., 2002 ; Whipple, et al., 2003). These studies use an assigned experimental condition consisting of therapists that receive patient progress OQ-feedback (Fb), while the control condition did not receive patient OQ-feedback (NFb). Each of these two conditions has clients that are represented by two status classifications based on the algorithm—NOT or OT. The combination of the treatment levels and status conditions creates the following groups: NOT-NFb (client is not progressing as expected and therapist is not receiving feedback), NOT-Fb (client is not making appropriate progress and therapist is receiving feedback), OT-NFb (client is making expected progress and therapist is not receiving feedback), OT-Fb (client is making expected progress and therapist is receiving feedback). This is the basic crux for these RCTs, although many of the patient-focused paradigm studies add enhanced types of feedback (e.g.,Hawkins, et al., 2004; Whipple, et al., 2003).

The previous research conducted using the patient-focused paradigm indicates some important clinical trends as well as demonstrates support for the OQ's ability to detect significant effect sizes. First, consistent feedback of patient's level of functioning and progress significantly improved overall patient functioning (measured by change in OQ-score from baseline to last session) and therapeutic outcome and attendance. Second, greater degrees of feedback and support contributed to more clinically

significant changes in overall patient functioning and therapeutic outcome (measured by change in OQ-score from baseline to last session). Thus, the OQ has consistently demonstrated significant treatment effects in patient-focused outcome research.

OQ Interpretability

A gold-standard PRO needs to be easily interpretable, having both clinically meaningful scores and comparison data available from both the desired population as well as the general population (Luckett, et al., 2010). Prior research on the OQ has demonstrated clinically meaningful interpretation of the OQ scores as well as comparison data available for general and distressed populations.

The OQ was designed to assess distress/functioning of individuals suffering from a broad array of V-Code, Axis-I, and Axis-II disorders, meaning that one can compare patients across vastly different diagnoses (Jong, et al., 2007). Lambert et al. (1996) examined the OQ to determine the scores for clinically significant change and for the Reliable Change Index. People with scores that increase or decrease by 14 points are seen as making "reliable change." The cut-off score from functional to dysfunctional is 64 points, with higher scores being indicative of higher dysfunction. To be considered "recovered," one's OQ score must decrease by at least 14 points and pass below the 64 cut-off score. "Improved" individuals have an OQ score that decreases by a minimum of 14 points but does not fall below the 64 cut-off score. "No change" individuals' score does not fluctuate by more than 14 points. "Deteriorated" individuals must have an increase in score by 14 or more points. Additionally, the OQ has been found to function

similarly across age and gender for both the total score as well as the subscales (Lambert, et al., 1996).

OQ Practical Issues

In addition to each of the aforementioned qualities of a potential gold-standard PRO, practical issues of the measure such as ease of patient and administrator burden are key. The OQ was designed as a low-cost measure with ease of administration and scoring (Lambert, et al., 1996). The OQ can be given as a paper and pencil questionnaire or on a computer/PDA. The creators of the OQ have developed a program so that the OQ can be easily scored electronically. However, at 45-items, even the time to score it by hand is minimal for an administrator. Thus, this measure is practical for use in outcome research.

Current Study Aims and Hypotheses

The current study plans to further evaluate the properties of the OQ in order to fulfill appropriate standards recommended for a gold-standard PRO utilized in a cancer population.

Aim One

The first aim of the current study is to demonstrate the reliability of the OQ in a cancer population. It is hypothesized that the OQ Total score and three subscales of the OQ will demonstrate reliability using Cronbach's alpha.

Aim Two

The second aim of the current study is to demonstrate the concurrent and construct validity of the OQ in a cancer population.

It is hypothesized that concurrent validity will be demonstrated by showing convergent validity of the OQ total score and DT and the Functional Assessment of Cancer Treatment-General (FACT-G); the Symptom Distress subscale and the CES-D and Brief POMS; the Interpersonal Relationships subscale and the Social Support Scale and the FACT-G; and the Social Role subscale with the Social Constraint Scale and FACT-G. Additionally, the current study hypothesizes that concurrent validity will be supported by divergent validity of the OQ Total score and the Impact of Events Scale-Revised (IES-R); the Symptom Distress subscale and Social Constraint Scale; the Interpersonal Relationships subscale and the CES-D; and the Social Role subscale with the Brief POMS. It is hypothesized that construct validity of the three domains of the OQ will be demonstrated via an exploratory factor analysis.

Aim Three

The final purpose of the current study is to show preliminary treatment effects of using the OQ in a cancer population. This will be examined in two ways. First it is hypothesized that individuals who receive 12-weeks of treatment in an online support group (OSG) will show a significant decrease in their scores from baseline to post-test. However, it is postulated that individuals in a 12-week wait list for OSGs will show no difference in their scores from a baseline testing of their OQ distress and their start time in an OSG after a 12-week waiting interval. Second, it is hypothesized that all

participants (treatment and control) will show a decrease in scores from the beginning of treatment to post-treatment.

CHAPTER TWO

METHODS

Participants

Participants were recruited primarily from the cancer registry at a cancer treatment facility, Loma Linda University Medical Center (LLUMC). Additionally, efforts were made to recruit nationally using a variety of methods, including informative letters to health-care providers, flyers, newspaper advertisements, public service announcements, and Internet-based advertising. Patients were considered eligible if they met the following criteria: adult (age 18 and over), cancer diagnosis, distress > 3 (based on DT's 0-10 scale), English-language literate, and daily access to Internet.

Design and Procedures

LLUMC

Cancer patients' contact information was compiled based on the listings in the LLUMC cancer registry from July 2008 to July 2010. Individuals on the registry are either diagnosed or treated for cancer at LLU during these years. Recruitment via a cancer registry has been noted for raising some concerns as well as having obvious benefits for researchers and patients (Beskow, Sandler, & Weinberger, 2006). While allowing access to a particular population, privacy regulation has been a noted issue for registry members. However, the information gained via studies that utilize the registry recruitment methods has the potential to benefit registry members. Rules, requirements, methods, and strategies for using a cancer registry have varied by registry and state. The most common approach allows researchers to notify physicians regarding their

study, receive contact information of participants via the cancer registry, and finally invite registry participants to participate in the study with an opt-out approach (Beskow, et al., 2006). Other registries allow direct contact with registry members under the *autonomy* principle of human subjects protections (i.e., patients themselves are better judges of whether a study is of interest to them than would be their physician). This approach was most similar to what was utilized in the current study as patients were directly contacted and invited to participate.

Cancer registry members were mailed an informational letter inviting them to join an OSG for cancer patients and survivors. Included was information regarding their ability to sign up or opt-out at anytime of future contact. One week following the mailing of the letter, research assistants attempted to verbally recruit cancer registry patients by phone. Participants who were reached within three to five phone calls were invited to participate in the study. During the phone call, participants first were briefly informed about the nature of the study and screened based on the eligibility criteria. Those who passed screening were informed of the basic features of the website, how to make the most of their experience, and questionnaire and participation expectations. Patients who verbally consented were signed-up for the online support group, allowed to select a username and password, and automatically emailed an informational letter with a link to access the support group. Lastly, they were instructed to read the informed consent page that would appear upon logging into the website and told that they could opt-out of further contact, and that consenting or declining would have no impact on their medical treatment or relationship with their physicians.

Nationwide Recruitment

Cancer patients were recruited nationwide via a number of different methods. Physicians, social workers, and marriage and family therapists were mailed informative packets that included advertisement flyers that could be posted in offices. Additionally, flyers, newspaper advertisements, public service announcements, and Internet-based advertising were used to recruit patients. These advertisements directed patients to the website where they could learn more information and automatically enroll themselves in the OSG.

All Participants

Once patients logged into the confidential OSG, they are automatically directed through a series of screens. First, the consent form appears and patients have the option to agree or decline. Second, a baseline questionnaire appears and must be completed before a participant receives information regarding their randomization status. After questionnaire completion, participants are informed whether they are randomized into the immediate treatment group or 12-week wait-list, control group. The treatment group is asked to complete a questionnaire two weeks later, and at three and six months post-baseline. The control group is asked to complete a second survey at the end of their 12-week wait, a questionnaire two weeks later, and then at three and six months post-baseline. Participants are reminded to complete questionnaires by email prompts, phone calls, and were mailed questionnaires with a stamped return envelope if a questionnaire had not been completed at four weeks post-due date. Each participant was mailed a $10 reimbursement and thank you note for each questionnaire completed.

Measures

OQ

Psychological disturbance will be measured using the OQ-45 (Lambert, et al., 2004). The OQ-45 measures the global functioning of a client and is composed of three subscales that measure subjective discomfort (intrapsychic functioning), interpersonal relationships, and social role performance. The OQ-45 has adequate internal consistency (α = .93) and test-retest reliability (r = .84) (Lambert, et al., 2004). A number of studies have examined the validity of the OQ. It has also been found to be sensitive to change over brief periods of time in treatment populations, while remaining the same in untreated people (Vermeersch, et al., 2000). Umphress and colleagues (1997) concurrent validity criterion measures included the GSI, IIP, and SAS-revised. While the OQ total and Symptom Distress subscale scores correlated as predicted with the respective criterion measures (Total OQ: r = .66-.88, Symptom Distress: r = .65-.92), the Interpersonal Relationships and Social Role subscales did not have the strongest magnitude with their predicted measure, despite their significant validity coefficient scores across measures (Interpersonal Relationships: r =.45-.69; Social Role: r =.53-.73).

Distress Thermometer

The DT (Roth, et al., 1998), a one-item measure, reads, "How distressed have you been during the past week on a scale of 0 to 10," and depicts a visual thermometer with a 0–10 scale that ranges from "no distress" (0) to "extreme distress" (10). Significant distress is indicated by scores of four or higher. Mild distress ranges from

four to five, moderate distress ranges from six to seven, and eight or more is considered severe distress. A comprehensive review of the SE, SP, positive predictive value (PPV), and negative predictive value (NPV) supported its performance when examining distress but not anxiety or depression (Mitchell, 2007). Specifically, for distress the study found an SE of 77.1%, SP of 66.1%, PPV of 55.6%, and NPV of 84.0%. However, for anxiety the SE was 77.3%, SP 56.6%, PPV of 55.2%, and an NPV of 80.25%. When measuring depression, the SE was 80.9%, SP of 60.2%, PPV of 32.8% and NPV of 92.9%.

Fact-G

The FACT-G scale (Cella, et al., 1993) is a 28-item general cancer QOL measure that results in a total score as well as subscales for physical, functional, social, and emotional well-being along with satisfaction with treatment relationship. Test-retest reliability for the scales is the following: physical well-being (.88), functional well-being (.84), social well being (.82), emotional well-being (.82), satisfaction with physician relationship (.83), and total score (.92). Validity was supported by hypothesized convergent and divergent validity scores with criterion measures. Convergent validity was demonstrated by the total score correlation with the Functional Living Index-Cancer (r =.79), Brief Poms (r = -.65), and Taylor Mass Anxiety Scale (r = -.58). However, correlation with social desirability, as measured by the brief M-CSDS, was low (r = .22).

CES-D

The CES-D (Radloff, 1977) utilizes 20 items on a four-point Likert scale to examine depressive symptoms in individuals. Previous research has validated it for widespread use in cancer populations (Hann, Winter, & Jacobsen, 1999). Validity studies have found good levels of relationship between the CES-D and other depression rating scales including the following: the Hamilton rating scale (r = .50s to .80s), the Raskin rating scale (r = .30s to .80s), the Lubin Depression Adjective Checklist (r = .40s to .50s) (Locke & Putnam, Unknown). A previous lung cancer study has found it to have good reliability with this population (α = .79; Sanders, et al., 2009).

Brief POMS

The brief POMS is a 37-item shortened version of the original 65-item scale that attempts to identify mood states. By utilizing a five-point-Likert-scale to endorse mood adjectives from "not at all" to "extremely," participants are classifying moods across six-factors: tension-anxiety, depression-dejection, anger-hostility, and confusion-bewilderment. Total mood score is determined by subtracting vigor-activity from the sum of the other five scales. Cronbach's alpha ranges from .78 to .91 for each of the six subscales and for the total score. Convergent and divergent validity were demonstrated by hypothesized correlations between the following: the POMS depression subscale and total score and the CES-D (both .63); the POMS fatigue and vigor subscales with the Self-Rated Karnofsky (-.40. to .39); the POMS fatigue and vigor subscales with the MOS SF-20 Physical Functioning (both -.42); the POMS-vigor scale and the Bradburn Positive Affect Scales (.53); the POMS total score and the Bradburn Negative Affect

Scales (.60); and low correlations between the POMS anger, confusion, depression, and tension subscales with the MOS SF-20 Physical Functioning and the Self-Rated Karnofsky (-.08 to -.20). Additionally a CFA supported the six-factor structure of the POMS (Baker, Denniston, Zabora, Polland, & Dudley, 2002).

Social Support Scale

The six-item social support scale is a combination of two, 3-item subscales drawn from the 29-item Yale Social Support Index. The Positive Emotional Support (PES) subscale and Aversive Emotional Support (AES) scale assess the quantity and quality of social support and interaction on a four-point Likert scale. Construction of items on these subscales was standardized per item in order to allow items to be aggregated onto the appropriate scale. A prior study conducted by Butler, Koopman, Classen, and Spiegal (1999) has utilized these subscales and found Cronbach alpha at .71 for the PES, and .68 for the AES. Although the validity coefficients could not be found, these subscales have also been utilized in Koopman et al. (1998).

Social Constraint Scale

The Social Constraint Scale (S.J. Lepore & Ituarte, 1999) is a 15-item measure that assesses social constraints, specifically with "friends and family" in this version, on disclosure of distressing feelings and thoughts related to cancer. On a four-point Likert scale participants rate a variety of social constraint experiences in the prior four weeks. The coefficient alpha has ranged from .89 to .92. This measure has been found to have good convergent validity with the Mental Health scale from the MOS-SF36, as well as

the Negative Affect scale from the PANAS. Additionally, divergent validity is supported, for the scale was generally not significantly associated with the amount of social support received as measured by the UCLA social support scale (S.J. Lepore, 2001).

IES-R

The IES-R (Weiss & Marmar, 1996) assessed the post-traumatic emotional reactions of patients dealing with their cancer diagnosis and symptoms. The measure includes 22 items, three subscales (intrusiveness, avoidance, and hyperarousal scale), and a five-point, Likert-scale format. Good reliability was found in a previous lung cancer research study (α = .89; Sanders, et al., 2009). The IES-R has been utilized in a variety of cancer-related studies (Lindberg & Wellisch, 2004; Mehnert & Koch, 2007; Sanders, et al., 2009) and has been found to be highly valid. The PTSD Checklist and IES-R correlate at high levels (r = .84) demonstrating convergent validity (Creamer, Bell, & Failla, 2003).

Data Analysis

Aim One

The first aim of the current study was to demonstrate the reliability of the OQ in a cancer population. This was examined by a Cronbach's alpha analysis for the OQ Total score and 3 subscale totals of the OQ. Cronbach's alpha was ranked according to guidelines supplied by George and Mallery (2003): > .9 excellent, > .8 good, > .7 acceptable, > .6 questionable, > .5 poor, and < .5 unacceptable (p. 231).

Aim Two

The second aim of the current study was to demonstrate the concurrent and construct validity of the OQ in a cancer population (see Figure 1).

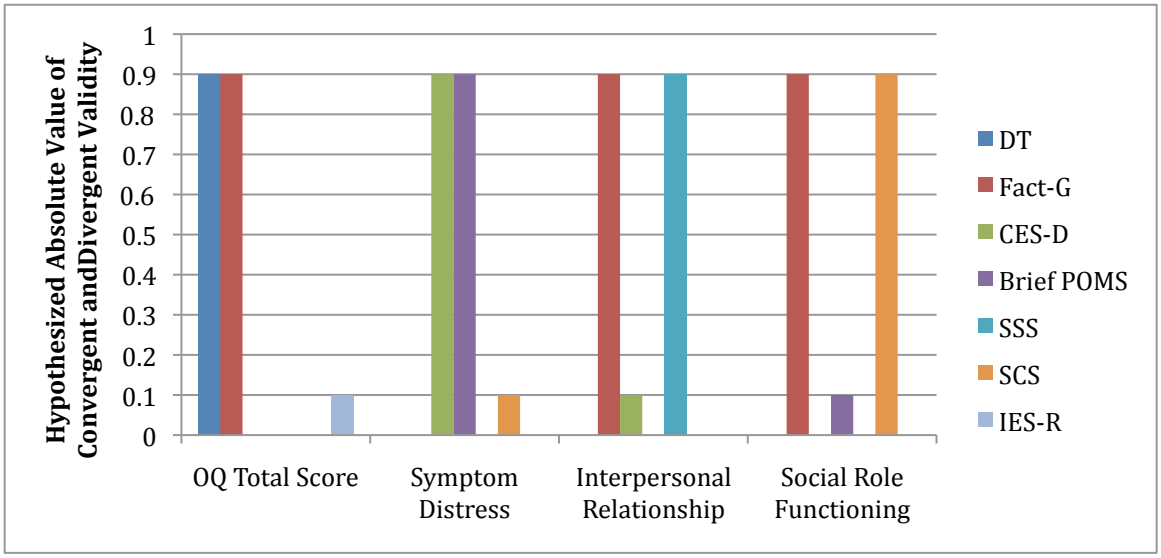

Figure 1. Hypothesized absolute values of convergent and divergent validity for the OQ Total Score, Symptom Distress, Interpersonal Relationships, and Social Role scales. DT= Distress Thermometer; FACT-G= Functional Assessment of Cancer Therapy – General; CES-D= Center for Epidemiologic Studies Depression Scale; POMS= Profile of Mood States; SSS= Social Support Scale; SCS= Social Constraint Scale; IES-R= Impact of Event Scale-Revised.

Concurrent validity was examined via significant correlations ($p < .05$) between the OQ total score and DT and FACT-G; the Symptom Distress subscale and the CES-D and Brief POMS; the Interpersonal Relationships subscale and the Social Support Scale and the FACT-G; and the Social Role subscale with the Social Constraint Scale and FACT-G. Divergent validity will be supported by insignificant correlations ($p > .05$) between the OQ Total score and the Impact of Events Scale; the Symptom Distress subscale and

Social Constraint Scale; the Interpersonal Relationships subscale and the CES-D; and the Social Role subscale with the Brief POMS. Power was calculated via G*Power for bivariate normal correlations with ∝= .05, two-tailed test, power = .80, correlation p (Ho) =0.00. The sample size required 84 participants in order to be adequately powered for $r \geq .30$.

Further construct validity of the three domains of the OQ was examined by conducting an exploratory factor analysis. Parallel analysis determined the number of factors extracted as five (Hayton, Allen, & Scarpello, 2004). When the items were re-factored, the principle axes method was used, with five factors extracted, Varimax rotation, and loadings sorted by size while suppressing loadings that were less than .15. A significant factor must have at least three items that load on or above .30, or it has a minimum of two variables that load at .50 or greater. If any of these salient items cross-load closer than .13 with another item than they are no longer considered salient. If there are any non-significant factors, the factor number will be reduced by one and the process will be repeated until there are no trivial factors. If Cronbach's Alpha is smaller than .60 for any factor's set of salient items, the number of factors should will be decreased by one and then re-factored.

Aim Three

The final purpose of the current study was to show preliminary treatment effects of using the OQ in a cancer population. This aim was evaluated in two ways. First, all participants were examined for treatment effects by conducting a repeated measures, within factors analysis of covariance (ANCOVA) examining the appropriate measures

from the beginning and completion of treatment (i.e. OSG = Time 1 to Time 2; Wait = Time 2 to Time 3). Significant measure differences in the direction of improvement after an OSG intervention were indicated by $p < .05$. Second, an interaction of treatment group by time was examined by conducting a repeated measures, between-within factors ANCOVA examining differences between the treatment group (Time 1 to Time 2) and control group (Time 1 to Time 2). It was expected that there would be a significant interaction, indicated by $p < .05$. Also, the treatment group should have significantly lower Time 2 scores than the control group. Power was identical for both ANCOVAS, and was examined for repeated measures, within-between interaction as well as a within-interaction. Using G*Power, the following were used for the a-priori power analysis: *F* test family, effect size $(f)^2 = .25$, alpha error probability = .05, power = .80, with two groups, two times of measurement, and a correlation among repeated measures of .50. In order to meet critical $F = 4.15$, the sample size would need to be 34. Our current sample size exceeds this requirement.

CHAPTER THREE

RESULTS

Characteristics of Participants

Characteristics of participants are presented in Table 1. A majority of participants identified themselves as White (86.3%), female (69.8%), and married (68.1%). Participants averaged a mean age of 52.7 years with 15.4 years of education, and had a 5% trimmed median household income of $62,500. The highest number of participants reported not knowing their cancer stage (25.3%), followed by Stage II (20.9%); suffered from breast (28%) or prostate (17%) cancer; and received surgery as treatment (67%). Moderate to significant distress (DT: $\bar{x}$ =6; OQ: $\bar{x}$ = 69) was average.

Table 1

Characteristics of Participants

Participant Characteristics *(N = 182)*	$\bar{x}$ (sd)	%
Age (years)	52.7 (11.8)	
Gender (% Female)		69.8
Education (In Years)	15.4 (2.5)	
Ethnicity		
White		86.3
Other		4.9
Latino		4.4
African American		3.3
Asian		1.1
Income (Median)	$62,500 ($57,313)	
Marital Status		
Married		68.1
Single		14.8
Divorced		13.2

Table 1. *Continued.*

Widowed		3.8
Cancer Stage		
I		16.5
II		20.9
III		18.1
IV		14.3
Insitu		4.9
Unsure		25.3
Cancer Type		
Breast		28.6
Prostate		17.2
Thyroid		7
Female Reproductive (ovarian)		6.6
Melanoma		2.6
Blood/Leukemia/Lymphoma		5
Bladder/Kidney		1.5
Colon/Rectum		3.0
Lung		2.5
Multiple		3.0
Other		23
Cancer Treatment		
Bio (?)		3.3
Chemotherapy		42.9
Hormone Therapy		17
Immunotherapy		4.4
Surgery		67
Xrt		47.8
Outcome Questionnaire (0-180, >63 distress)		
Total Time 1	69.3 (21.8)	
Symptom Distress	41.4 (14.3)	
Interpersonal Relationships	16.3 (6.6)	
Social/Role Functioning	11.6 (4.3)	
Distress (1-10; > 4 = distress)	6 (2.2)	
FACT-G Total (0-108; lower = lower QOL)	64.8 (18.4)	
CESD Total (>16 cutoff for depression)	22.5 (11.9)	
POMS Total (0-124; higher = higher	37.7 (28.8)	
SSS Total (6-24; higher = higher support)	17.9 (3.2)	
SCS Total (15-60; higher = more constraint)	29.5 (11.5)	
IES-R Total (0-88; higher = more neg)	26.2 (15.8)	

Note. XRT= External Beam Radiation Therapy; FACT-G= Functional Assessment of Cancer Therapy – General; CES-D = Center for Epidemiologic Studies Depression Scale; POMS= Profile of Mood States; SS= Social Support Scale; SCS= Social Constraint Scale; IES-R = Impact of Event Scale-Revised.

Aim One: Reliability of the OQ

The OQ Total Score demonstrated excellent reliability (α = .92). However, the subscales varied in the quality of their reliability ratings. Whereas the Symptom Distress scale exemplified excellent reliability (α = .91), the Interpersonal Relationships only showed good/acceptable reliability (α = .80), and the Social Role displayed poor reliability (α = .59).

Aim Two: Concurrent and Construct Validity of the OQ

Concurrent Validity

Validity coefficients for the OQ Total Score, Symptom Distress, Interpersonal Relationships, and Social Role subscales with the DT, Fact-G, CES-D, Brief POMS, SSS, SCS, and IES-R, may be viewed in Table 2. All criterion measures were significantly correlated with the OQ Total, Symptom Distress, Interpersonal Relationships, and Social Role scores. The OQ Total (r = .836) and Symptom Distress (r = .836) subscale scores were most highly associated with depression (CES-D), whereas Interpersonal Relationships correlated most strongly with social support (SSS: r = -.643) and the Social Role with negative moods (Brief POMS: r = .525).

Table 2

Intercorrelations for OQ Scores and Patient Reported Outcome Measures

V	1	2	3	4	5	6	7	8	9	10	11
1	1										
2	.947	1									
3	.792	.605	1								
4	.690	.538	.457	1							
5	.592	.581	.481	.348	1						
6	-.795	-.778	-.639	-.464	-.568	1					
7	.836	.836	.633	.510	.611	-.835	1				
8	.831	.831	.606	.525	.603	-.821	.889	1			
9	-.586	-.467	-.643	-.452	-.289	.554	-.466	-.439	1		
10	.637	.632	.508	.366	.338	-.637	.630	.594	-.578	1	
11	.664	.700	.414	.419	.524	-.657	.714	.696	-.312	.572	1

Note. V= Variable; 1= OQ Total; 2=OQ SD; 3=OQ IR; 4=OQ SR; 5=DT; 6=Fact-G; 7=CES-D; 8=Brief POMS; 9=SSS; 10=SCS; 11=IES-R. All correlations = $p < .001$.

A graphic representation of the outcome of the convergent and divergent validity of particular hypothesized measures may be seen in Figure 2. Convergent validity was demonstrated across all measures for the OQ Total, Symptom Distress, Interpersonal Relationships, and Social Role scores; however, divergent validity was not demonstrated.

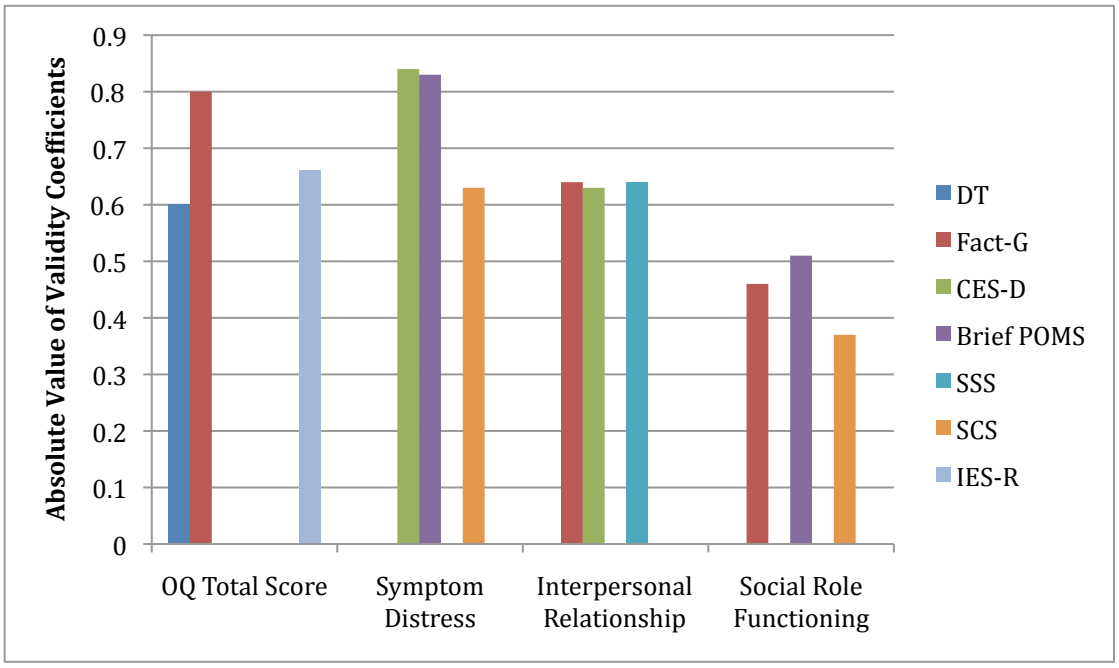

Figure 2. Absolute values of validity coefficients for the OQ Total Score, Symptom Distress, Interpersonal Relationships, and Social Role scales. DT=Distress Thermometer; FACT-G= Functional Assessment of Cancer Therapy – General; CES-D = Center for Epidemiologic Studies Depression Scale; POMS= Profile of Mood States; SSS= Social Support Scale; SCS= Social Constraint Scale; IES-R = Impact of Event Scale-Revised.

Construct Validity

Parallel analysis determined the number of factors extracted as five (Hayton, Allen, & Scarpello, 2004). When the items were re-factored, the principle axes method was used, with five factors extracted, Varimax rotation, and loadings sorted by size while suppressing loadings that were less than .15. Varimax rotation was selected because it forces items to be uncorrelated and thus most clearly defines the structure of a factor conceptually. The loadings were ordered by size for ease of viewing, and loadings under .15 were suppressed because they were the most insignificant. Significant factors were required to have at least three items that load on or above .30 or

have a minimum of two variables that load at .50 or greater. If any salient items cross-loaded closer than .13 with another item than they were no longer considered salient. For factors that did not meet the minimal significance criteria, the factor number was reduced by one and the process was repeated until there were no trivial factors. If Cronbach's Alpha was smaller than .60 for any factor's set of salient items, the number of factors was decreased by one and then re-factored. Through this process five factors were reduced to three significant factors (see Table 3). The three factors differed from the original three factor subscales and were renamed the following: Factor 1, Sense of Well-being; Factor 2, Symptom Distress; Factor 3, Externalizing Behaviors.

Table 3

Means, Standard Deviations, Rotated Factor Loadings, and Communalities for OQ Items

				Factor Loadings		
Item (Prior Factor Subscale)	$\bar{x}$	**SD**	h^2	**1**	**2**	**3**
31 (SD): I am satisfied with my life	1.85	1.053	.770	**.782**	.252	
13 (SD): I am a happy person	1.44	.902	.682	**.724**		
20 (IR): I feel loved and wanted	1.47	1.041	.668	**.719**		
43 (IR): I am satisfied with my relationships with others	1.45	.951	.644	**.696**		.162
37 (IR): I feel my love relationships are full and complete	1.91	1.359	.629	**.670**		
24 (SD): I like myself	1.48	.975	.676	**.651**	.187	
21 (SR): I enjoy my spare time	1.63	1.044	.594	**.647**		
12 (SR): I find my work/school satisfying	1.78	1.203	.636	**.563**	.162	-.186
15 (SD): I feel worthless	1.41	1.033	.639	**.509**	.440	
1 (IR): I get along well with others	.63	.824	.523	**.505**		.203

Table 3. *Continued.*

7 (IR): I feel unhappy in my marriage/significant relationship	1.56	1.257	.544	**.447**	.218	
30 (IR): I have trouble getting along with friends and close acquaintances	1.00	.789	.531	**.421**	.247	.257
8 (SD): I have thoughts of ending my life	.57	.864	.450	**.397**	.190	
17 (IR): I have an unfulfilling sex life	2.43	1.338	.435	**.348**		
19 (IR): I have frequent arguments	1.31	.903	.458	**.313**	.226	.210
42 (SD): I feel blue	1.98	.986	.707	.345	**.698**	
9 (SD): I feel weak	2.04	1.132	.707	.192	**.655**	-.158
36 (SD): I feel nervous	1.78	1.082	.566	.185	**.603**	.222
10 (SD): I feel fearful	1.90	1.028	.603		**.599**	
22 (SD): I have difficulty concentrating	2.27	1.047	.630	.261	**.597**	.196
23 (SD): I feel hopeless about the future	1.86	1.096	.676	.479	**.566**	
41 (SD): I have trouble falling asleep or staying asleep	2.30	1.317	.478		**.562**	
2 (SD): I tire quickly	2.50	.911	.664		**.554**	-.263
33 (SD): I feel that something bad is going to happen	1.73	1.089	.635	.252	**.548**	
6 (SD): I feel irritated	2.23	.857	.635	.351	**.535**	.293
34 (SD): I have sore muscles	2.15	1.093	.519		**.525**	
40 (SD): I feel something is wrong with my mind	1.47	1.133	.589	.367	**.501**	.152
5 (SD): I blame myself for things	2.07	1.031	.588	.356	**.494**	
29 (SD): My heart pounds too much	1.24	1.067	.407		**.491**	.153
3 (SD): I feel no interest in things	1.90	.943	.615	.431	**.490**	
18 (IR): I feel lonely	2.06	1.079	.630	.420	**.462**	
16 (IR): I am concerned about family troubles	2.30	1.111	.435	.244	**.437**	
27 (SD): I have an upset stomach	1.54	1.103	.424		**.420**	
25 (SD): Distrubing thoughts come into my mind that I can't get rid of	1.59	1.085	.539	.220	**.401**	
45 (SD): I have headaches	1.40	1.094	.437		**.339**	

Table 3. *Continued.*

28 (SR): I am not working/studying as well as I used to	2.03	1.140	.530		**.310**	.164
35 (SD): I feel afraid of open spaces, or driving, or being on buses, subways, and so forth	.50	.860	.363		**.261**	.249
11 (SD): After heavy drinking, I need a drink the next morning to get going	.15	.457	.614			**.653**
32 (SR): I have trouble at work/school because of drinking or drug use	.08	.324	.622			**.637**
26 (IR): I feel annoyed by people who criticize my drinking (or drug use)	.20	.621	.550			**.549**
39 (SR): I have too may disagreements at work/school	.62	.740	.541	.242		**.525**
44 (SR): I feel angry enough at work/school to do something I may regret	.36	.715	.524	.280		**.516**
4 (SR): I feel stressed at work/school	2.05	1.112	.618		.378	**.435**
38 (SR): I feel that I am not doing well at work/school	1.38	1.086	.586	.157	.201	**.389**
14 (SR): I work/study too much	1.69	1.180	.428	-.211		**.315**

Note. Boldface indicates highest factor loadings. Factor 1 = Sense of Well-Being; Factor 2 = Symptom Distress; Factor 3 = Externalizing Behaviors; OQ = Outcome Questionnaire; h^2= Communality.

Aim Three: Preliminary Treatment Effects

Finally, a series of repeated measure ANCOVAs were conducted in order to examine whether the OQ can indicate preliminary treatment effects of an OSG in a cancer population. This aim was evaluated in two ways. First, to discern if the OQ can detect a difference over time, all participants, regardless of level of engagement in the support groups, were evaluated for improvement from baseline to post-treatment while controlling for health status. Secondly, analyses were conducted to determine if the OQ

could distinguish the difference between a treatment and control group when controlling for health status.

Improvement Post-Treatment

First, all participants, regardless of treatment condition or level of engagement in OSG, were examined for treatment effects over time by conducting a repeated measures ANCOVA. The repeated measures ANCOVA examined the participant scores from baseline to post-treatment with perceived physical well-being, as measured by the FACT-G physical well-being subscale, used as a covariate. Table 4 can be consulted for baseline and post-treatment OQ means and standard deviations for all participants. Greenhouse-Geisser was used as a significance level due to Mauchly's Test of Sphericity not being valid. As seen in Table 5 and Figure 3, there was a significant decrease in distress as measured by the OQ from Time 1 to Time 2, F (1, 60) = 5.78, p = .019.

Table 4

Means and Standard Deviations for Two Treatment (Tx) Groups and Repeated Testing Times of the OQ

	Pre-Tx		**Baseline: OQ Total Time 1**		**Post-tx: OQ Total Time 2**	
Tx Group (n)	$\bar{x}$	***SD***	$\bar{x}$	***SD***	$\bar{x}$	***SD***
All Participants (63)	NA	NA	66.92	25.56	59.89	23.43
Experimental (46)	NA	NA	72.09	24.30	62.61	23.52
Control (Pre-tx and T1 = 48; T2 = 17)	62.63	19.10	52.94	24.23	52.53	22.21

Table 5

Effect of Time on OQ Scores While Controlling for FACT-G Physical Well-Being (PWB)

Source	*df*	*Type III SS*	*MS*	*F*
Within Subjects				
Time	1	573.69	573.69	5.78*
Time x FACT-G PWB	1	189.90	189.90	1.91
Error	61	6059.07	99.33	
Between Subjects				
FACT-G PWB	1	114226.94	114226.94	153.00***
Error	61	45542.35	746.60	

Note. *$p < .05$, ** $p < .01$, ***$p < .001$. Time= Baseline (1) and Post (2) Treatment.

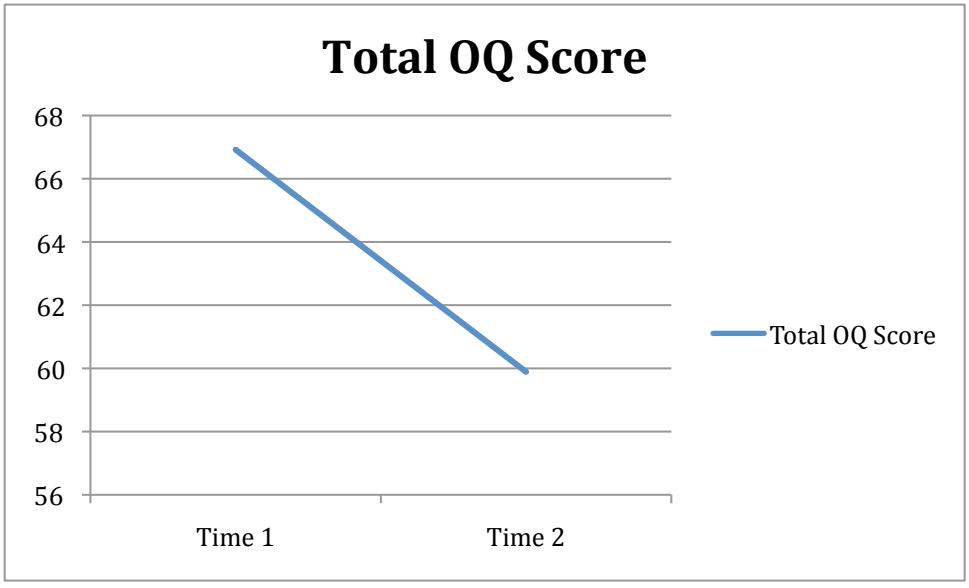

Figure 3. All participants Total Mean OQ scores from Time 1 to Time 2 while controlling for Fact-G physical well-being ($\bar{x}$ = 19.12).

Interaction of Treatment Group by Time

Next, the data was analyzed in order to discern if the OQ can detect not only a difference over time, but also to distinguish significance of the experimental group that received treatment when compared to a control group over time. An interaction of treatment group by time was examined by conducting a repeated measures, between-within factors ANCOVA examining differences between the treatment group (baseline to post-treatment) and control group (pre-treatment to baseline) while covarying for self-perceived level of physical well-being as measured by the FACT-G physical well-being subscale.

Some assumptions of a repeated measure ANCOVA were examined before results were interpreted. First, homogeneity of variance across levels of treatment groups was assessed using Box's M Test. Since Box's M was significant ($p = .002$), indicating that the variance across levels of treatment may not be the same, Levene's tests were examined for significant inequality across the dependent variables. Since neither Levene's test was significant for either univariate analysis for OQ Time 1 ($p = .59$) or 2 ($p = .40$), it was decided that equality could be assumed and that likely hypersentivity of Box's M lead to its flagged significance. Thus, the model results were still examined. Greenhouse-Geisser was used as a significance level due to Mauchly's Test of Sphericity not being valid. Table 6 records the findings. Again, there was as a significant decrease in distress over time, regardless of level of treatment group F (1, 90) = 14.99, $p < .001$. Additionally, those with worse health status showed a significant change over time F (1, 90) = 7.48, $p = .008$. However, no interaction between treatment condition and time was indicated by these results (see Table 6 and Figure 4).

Table 6

Effect of Treatment Condition Over Time on OQ Scores While Controlling for FACT-G Physical Well-Being (PWB)

Source	*df*	*Type IV SS*	*MS*	*F*
Within Subjects				
Time	1	2059.79	2059.79	14.99***
Time x FACT-G PWB	1	1027.47	1027.47	7.48*
Time x Tx Condition	1	37.96	37.96	.60
Error	91	12508.77	137.46	
Between Subjects				
FACT-G PWB	1	127747.19	127747.19	201.68***
Tx Condition	1	1163.08	1163.08	1.84
Error	91	57640.53	633.41	

Note. *$p < .05$, ** $p < .01$, ***$p < .001$.

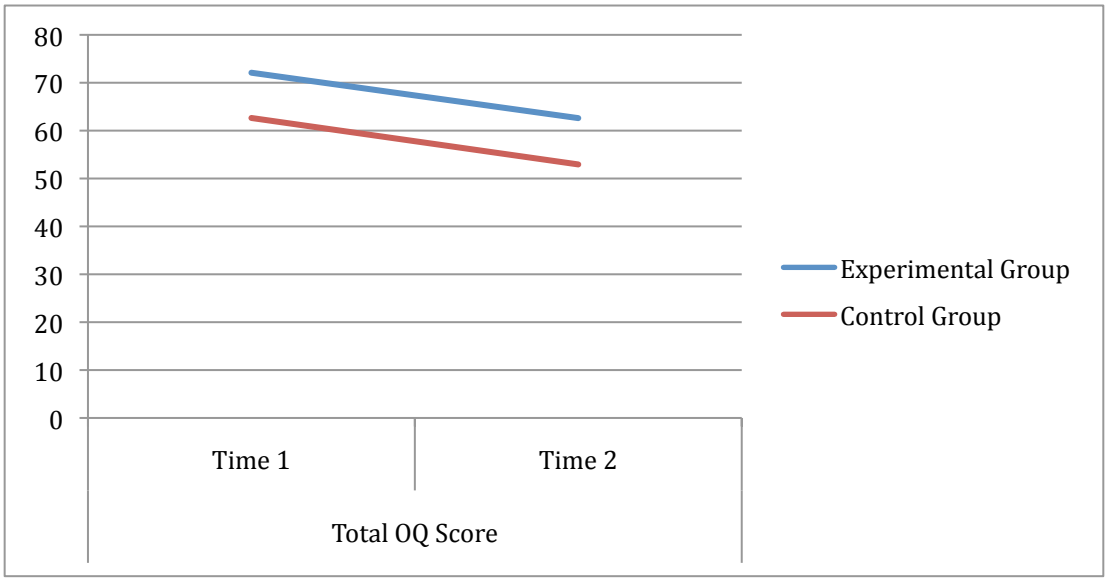

Figure 4. Effect of time on treatment level for Total Mean OQ scores while controlling for Fact-G physical well-being ($\bar{x}$ = 19.12).

Post-Hoc Analyses

Although it was not demonstrated that treatment condition impacted outcome, it was believed this may have been due to an additional variable, engagement. Participant engagement in the treatment varied greatly due to self-selection. Specifically, engagement in the experimental group was measured in the following ways: time in seconds on support group website, number of discussion board posts, number of emails sent, number of blogs posted, number of live support group chats attended, time in seconds in live support group chat, and total chat word count (please see Table 7). Because these variables were highly positively skewed (range= 2.82 to 5.53) with a great degree of kurtosis (range= 7.70 to 42.00), the variables were computed for the log of their original score and transformed. This procedure created more normally distributed variables that were used in all later analyses (skew range = -.63 to .72; kurtosis range= -1.48 to -.31).

Table 7

Characteristics of Participant Engagement (Log)

Engagement *(N = 182)*	$\bar{x}$	**M**	**% > 0**
Time on Website (Seconds)	11722.60	1752.50	100%
Discussion Board Posts	1.82	0	29.1%
Emails sent	2.53	0	33%
Blogs Posted	1.42	0	22.4%
Live Support Group Chats Attended	0.82	0	20.3%
Time in Live Support Group Chat (Seconds)	11024.82	0	29.1%
Total Chat Word Count	466.68	0	25.3%

To determine which engagement variables specifically correlated the greatest with improvement in OQ distress scores (from baseline to post-treatment), a correlation was conducted (See Table 8). Based on these findings, it appears that change in OQ score, or positive improvement in distress, is most positively associated with the total time spent engaging with the intervention ($r = .313$, $p < .01$).

Table 8

Correlations Between Change in OQ Score and (Log of) Engagement (N = 182)

Variable	1	2	3	4	5	6	7	8
1. OQ Change	1							
2. Total Time	.313**	1						
3. DB Posts	.057	.688***	1					
4. Emails	.039	.737***	.627**	1				
5. Blogs Posted	-.014	.452**	.407*	.397*	1			
6. # Chats	.153	.724***	.502**	.458**	.184	1		
7. Chat Time	-.031	.668***	.350*	.397**	.237	.625***	1	
8. # Chat Words	-.185	.667***	.343*	.501**	.305	.644***	.876***	1

Note. *$p < .01$; ** $p < .001$; *** $p < .0001$.

Thus, another repeated measures ANCOVA was conducted. The repeated measures ANCOVA examined the participant scores from baseline to post-treatment with perceived physical well-being, as measured by the FACT-G physical well-being subscale, and engagement, as measured by total time spent utilizing the intervention, used as covariates. Because Mauchly's test of sphericity was invalid, Greenhouse-Geisser significance levels were noted in Table 9 below. This time it was shown that those who engaged more with the OSG improved over time F (1, 59) = 6.00, p = 0.018.

Table 9

Effect of Time on OQ Scores While Controlling for FACT-G Physical Well-Being (PWB) and Engagement

Source	*df*	*Type IV SS*	*MS*	*F*
Within Subjects				
Time	1	35.44	35.44	.386
Time x FACT-G PWB	1	128.471	128.471	1.40
Time x Engagement	1	550.97	550.97	6.00*
Error	60	5508.10	91.80	
Between Subjects				
FACT-G PWB	1	20628.53	20628.53	29.88***
Engagement	1	4120.29	4120.29	5.97*
Error	60	41422.06	690.37	

Note. *p < .05, ** p < .01, ***p < .001.

OQ Interpretability

Based on the previously discussed standards the OQ was interpreted in four major categories. The greatest number of patients were categorized as no change (56.5%), followed by recovered (21%), improved (14.5%), and deteriorated (8.1%). Of those in the treatment group, the majority were categorized as no change (56.5%, n=6), followed by recovered (23.9%, n=11), improved (8.9%, n=8), and lastly deteriorated (2.2%, n=1). Of those in the control group, the majority were also considered to be in the no change category (56.3%, n=9), followed by deteriorated (25%, n=4), then recovered (12.5%, n=2), and finally improved (6.3%, n=1).

CHAPTER FOUR

DISCUSSION

This study examined the suitability of the use of the OQ as a PRO in a heterogeneous cancer population. As noted previously, Luckett and colleagues (2010) suggested the following categories for the evaluation of instrument quality: examination of the content, psychometric properties, track record, interpretability, and practical issues. These issues will be elucidated and summarized. Overall, the results show mixed support for the implementation of the OQ as a PRO in a chronic disease sample. Generally, if the OQ is to be used as is within a cancer population, the Total Score may be interpreted as both reliable and valid and able to demonstrate treatment effects in a cancer population, but the subscale scores should not be interpreted.

OQ Content and Psychometric Properties

Content

The OQ item content was considered suitable (face valid) for a heterogeneous cancer population. More so than other PROs, this scale's content can determine both psychological distress and global functioning. Thus, this measure has a high level of face validity for its items.

Reliability

Consistent with the previous research in general psychiatric populations and the

present study's hypotheses, the OQ Total Score and Symptom Distress subscale demonstrated excellent reliability and the Interpersonal Relationships revealed good/acceptable reliability. However, in this study's sample, the Social Role's reliability was rated as poor although it had measured more highly as acceptable/questionable in prior findings. Consistently between present and previous findings the Social Role scale is the least reliable of the three subscales.

Present results may indicate that either there is a problem with the items that construct the Social Role scale or that these results indicate that the social role questions were likely not answered as reliably by cancer patients. It is noted by the researcher that some patients verbally commented or transcribed on their PRO that they were confused at how to best answer questions regarding their functioning at work or school (despite the instructions clarifying this issue) because they were unemployed or taking a leave of absence due to health status but also had co-occurring mental health issues. However, perhaps a more clearly defined set of items would clarify this issue and increase the reliability of these items.

Validity

Concurrent Validity

Concurrent validity findings were mixed for the OQ within this mixed cancer population. As hypothesized, convergent validity was demonstrated across the OQ Total Score and subscales. Although the OQ Total Score did indeed correlate with its criterion measures (DT and Fact-G), it was associated the most strongly with the CES-

D. Upon examination, the OQ Total score is highly correlated with the Symptom Distress subscale. The Symptom Distress scale, as predicted, was associated most strongly with the CES-D as well as the Brief POMS. Likewise, the Interpersonal Relationships subscale also correlated the most strongly with its predicted measures, the Fact-G and the SSS. Unlike the other subscales, the Social Role subscale did not correlate strongly with its predicted criterion measures. While it was significantly associated with the Fact-G and SCS, it correlated the most strongly with the Brief POMS.

There are several potential explanations for why the OQ Total Score and Social Role subscale may not have correlated strongly with their criterion measures. The OQ Total score may attempt to measure general distress and well-being using three subscales, but the total score is so highly associated with the Symptom Distress subscale in this population that it is driven by scores on this subscale which highly correlate with the CES-D. Additionally, the Social Role subscale was more strongly associated with mood states (Brief POMS) instead of physiological difficulties in completing tasks, which the Social Role subscale items also measure.

Despite hypothesized divergent validity, the OQ Total Score and subscales were significantly correlated with each measure selected. This is likely due to the researcher's poor selection of divergent measures due to underestimation of how highly correlated the domains of symptom distress, interpersonal relationships, and social roles can be. Support for this rationale is indicated by the significant correlations between the DT, FACT-G, CES-D, Brief Poms, SSS, SCS, and IES-R with all measures as well. The researcher selected divergent criterion measures based on the assumption that the

subscales of the OQ would represent separate factors and thus not be highly correlated. These findings suggest that the current factor structure of the OQ, which is widely used in general outpatient psychotherapy settings, may not generalize well to use in cancer survivors.

Construct Validity

As hypothesized, the current factor structure of the OQ was not supported by this study, and a differing three-factor model was identified via exploratory factor analysis. However, a larger sample size is needed to confirm the new factors identified in this study. This new three-factor model has the following labels: Sense of Well-Being, Symptom Distress, and Externalizing Behaviors. The 15-item Sense of Well-Being factor included items that were generally positively worded, i.e. "I am satisfied with my life, " and included items mainly from the prior Symptom Distress and Interpersonal Relationships subscales (13 of 15-items). The 22-item Symptom Distress subscale included items that generally reflected symptoms or negative life events such as "I feel blue" and generally reflected the previous Symptom Distress subscale items (19 of 22 items). The eight-item externalizing behaviors subscale included substance abuse items and anger and is mainly composed of the previous scale's Social Role items (six of eight items). These newly created factors demonstrated at minimum acceptable reliability and were forcibly uncorrelated due to the Varimax rotation.

Prior literature reflects the likelihood that a new factor structure would be necessary, for the pervious articles cited that the current three-factor model was poorly-fitting and requested exploratory factor analysis to be conducted to further elucidate the

domains and subscales exemplified in the OQ. It is likely that the highly correlated nature of the OQ's subscale domains lead to trouble with these original three factors. This makes subscale interpretation of scores difficult. If the OQ is to be used in a cancer population, only the Total Score should be interpreted as valid. Further research should attempt to confirm the factor structure identified here in other populations, both cancer and psychiatric, before being generalized.

OQ Track Record

As hypothesized, the current study indicated that the OQ was able to demonstrate preliminary treatment effects in a RCT of cancer patients engaging in an OSG. Many previous studies that demonstrated the OQ's track record implemented a more complex OQ-feedback system that incorporated the use of the previously mentioned algorithm that assesses progress and change and flags cases that may not be on track for improvement (e.g., Hawkins, Lambert, Vermeersch, Slade, & Tuttle, 2004; Lambert, Whipple, et al., 2001; Lambert, et al., 2002 ; Whipple, et al., 2003). In these studies, part of the intervention included receiving feedback from the OQ itself. However, the current study did not focus on a complex flagging system for the OQ-feedback. In this study, the total OQ scores were viewable by the OSG clinicians, although no effort was made to emphasize or track whether clinicians noted this score. The primary intervention was via the online support group.

When all results were taken into account, the OQ was able to demonstrate an improvement in distress over time for those individuals with a worse perception of their physical well-being as well as for those who spent more time utilizing the online

intervention. Interestingly, perception of physical well-being was not related to the amount of time spent engaging in the intervention (r=-0.015, p= 8.47.)

OQ Interpretability

It is also easy to interpret results based on the reliable change index of four. In this study it was found that the majority of individuals (56.5%) made no reliable change in their status. However, 35.5% made a reliable change to recovery or improved by a clinically significant amount. Importantly, a few participants deteriorated (8.1%). These numbers are comparable to those found in a meta-analysis of previous OQ studies (M. J. Lambert, et al., 2003). When a multitude of feedback OQ studies were analyzed for treatment effects, it was noted that 54.8% made no reliable change, 38.7% made reliable change of recovery or improvement, and 6.5% of the sample deteriorated.

OQ Practical Issues

This study had less administrator and patient burden than previous studies. The OQ was easily distributed via an email link. Internet-based point and click answers were possible on the Likert-type scale. The scale was computer-scored and accessible via a database as well as linked to support group participants' profiles. These profiles were viewable by clinicians treating those in the OSG.

Study Limitations and Strengths

There were many strengths associated with this study as well as some challenges and areas that could be improved upon. First, this study represented the first attempt to

examine the reliability and validity of this outcome measure within a cancer population. Second, this study used a randomized controlled longitudinal design to assess outcomes in an online support group. However the OQ is a face-valid self-report form, which is susceptible to all the inherent flaws within this reporting procedure—accuracy, response bias, etc.

Because participants were required to use the internet for treatment, it is likely that this study captured data from those who may otherwise not have been able to participate (the extremely ill or those with difficult work schedules) but may also have excluded some who would otherwise have participated (those without internet access or computer literacy). Also, many potential participants were eliminated due to an English-literacy requirement. Additionally, there may have been a response bias for those who chose to respond to the questionnaire when compared with non-responders.

However, because the trial occurred over the internet we were able to capture behavioral data that may be missed in face-to-face groups, i.e. number of conversations had with other participants, time spent reading homework, number of words said in support group, etc. However, the drawback to an online group format was potentially a lower dose of intervention because individuals could self-select their levels of engagement within the treatment group. Thus, the dose of intervention was self-determined regardless of treatment status. Whereas some participant's engaged frequently and often, other participants struggled with attrition and completion of follow-up questionnaires. This problem significantly and dramatically decreased the sample size and resulting power for our analyses that included post-test measures and was a significant challenge throughout the course of the study.

Future Directions

Ultimately, there are several areas for future directions of this study. First, the reliability and validity of the OQ should be examined in other cancer populations in order to demonstrate support for the findings noted here. Specifically, a confirmatory factor analysis should be utilized within a cancer population to give further evidence to the three different factors that were identified in this study. Next, other face-to-face or online studies should examine whether the OQ can demonstrate significance for outcomes in other cancer support groups.

Another area of interest from this study may be that of the format of the online support group itself. Further studies should examine ways to improve engagement and decrease attrition within online support groups. Some questions that may be asked: what is an essential dose of treatment within an online study for participants to clinically benefit from it? What types of interventions are the most effective online? What do people want out of an online support group? What keeps them returning? These are questions that the future of psychology may quickly need to answer.

Particularly, one way to increase engagement may be feedback of the OQ itself to online participants. This study did not utilize feedback of the OQ as part of the intervention. Future studies may attempt to improve treatment effects as well as engagement by implementing some of the strategies utilized in prior OQ research. This may include flagging participants who are at risk for not being on track, providing OQ scores to participants, and helping both clinician and participant visibly see a graph over time of OQ-change with qualitative understanding of the meaning of the change.

Summary

This study identified the suitability of the use of the OQ Total Score as a PRO in a heterogeneous cancer population based on the examination of the content, psychometric properties, track record, interpretability, and practical issues. Despite some study limitations, this was the first study of its kind to examine the use of this measure in a chronic disease population. Future studies may shed some more light on not only the reliability and validity of this measure, but also ways to improve engagement and treatment outcomes for cancer populations.

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