Illness Appraisal and Symptom Dimensions in Lung Cancer

By

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ABSTRACT

TITLE: Illness Appraisal and Symptom Dimensions in Lung Cancer

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Although non-physiologic influences on symptoms are observed in clinical practice and described in theory, few investigators have empirically explored their influence in people with cancer. Self-regulation theory provided the framework for this pilot study that aimed to explore relationships between emotional representations of illness and symptom distress. A secondary aim was to examine relationships among symptom frequency, intensity and distress. A cross-sectional survey design was used in 17 participants with non-small cell lung cancer recruited from three outpatient settings and an online lung cancer support group. Seven elements of illness appraisal (consequences, cure/controllability, personal control, illness coherence, timeline, time-cyclical, and emotional representations) were measured with the Illness Perception Questionnaire – Revised (IPQ-R). Symptom frequency, intensity and distress were measured with the Memorial Symptom Assessment Scale (MSAS) and dispositional optimism was measured with the Life Orientation Test-Revised (LOT-R). Demographic and clinical data collected were age, gender, race, ethnicity, marital status, living situation, length of illness, current treatment, concurrent illnesses and self-reported smoking status.

In correlational analyses, length of illness, current chemo/radiotherapy, emotional representations, cure/controllability and personal control were related to symptom

distress. Dispositional optimism was related to the time-cyclical element of illness appraisal, with less optimistic individuals tending to view the illness as cyclical.

A regression model was constructed with length of illness, current chemo/radiotherapy, emotional representations and cure/controllability as predictors. Personal control was omitted because of its correlation with cure/controllability. Emotional representations explained 10% of the variance in symptom distress in the final model and cure/controllability explained 7%; although neither reached statistical significance. The majority of the variance was explained by current chemo/radiotherapy (adj. R sq. = .41). Symptom frequency, intensity and distress were highly intercorrelated ($p < .001$ in all cases), but also highly significantly different when subjected to paired t-tests ($p < .001$ in all cases).

The study demonstrates that while type of treatment explained most of the variance, illness appraisal appears to be related to the symptom experience, consistent with self-regulation theory. People with lung cancer seem to view frequency, intensity and distress as separate, but related, dimensions of the symptom experience. If borne out in future studies, these conclusions will support the validity of self-regulation theory and the conceptualization of symptom frequency, intensity and distress as three separate dimensions of the symptom experience. Further characterizing illness appraisal and its relationship to symptoms may suggest avenues for cognitive-behavioral treatments to influence the symptom experience in people with lung cancer.

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CHAPTER 1

Introduction

Worldwide, lung cancer is the top cause of cancer deaths in both men and women. Lung cancer is typically detected late in its progression, after it impinges on extrapulmonary tissue, causing pain, or when it impairs respiratory mechanics, causing dyspnea and fatigue. Late detection contributes to the high death-to-incidence ratio of this disease. The diagnosis of lung cancer often carries implications of suffering, pain, intractable shortness of breath and premature death. Palliative or curative treatment with radiotherapy, chemotherapy and surgery can induce or exacerbate fatigue, anemia, pain, skin breakdown and peripheral neuropathy in people with lung cancer.

In spite of the disease's prevalence and impact on well-being, lung cancer research garners less public funding than more curable cancers such as breast or prostate cancer. In 2002, for example, lung cancer research comprised slightly over 5% of the National Institute's of Health's (NIH) cancer research budget, while breast cancer garnered 13% and prostate cancer 7% (NIH, 2003). Lung cancer advocacy groups may attribute the funding disparity to blame placed upon people with lung cancer by health care professionals, scientists and the public as a result of the strong association of lung cancer with smoking (ALCASE, 2004). It is within this milieu of poor prognoses, research funding disparities, and life-disrupting symptoms that people with lung cancer cope with their disease.

The perceived stigma of lung cancer and the practice of blaming people with lung cancer for causing their disease may contribute to negative emotions regarding the illness. Emotions toward an illness are part of a cognitive scheme or image of the illness

that is hypothesized to influence coping (Johnson, 1997, Leventhal, Nerenz & Steel, 1984.) In self-regulation theory, which forms the theoretical foundation for this study, illness appraisal (the cognitive representation of an illness) is posited to influence coping responses and help inform the criteria against which coping responses are evaluated. As a contributor to the illness and symptom experience, the concept of illness appraisal suggests that altering maladaptive illness appraisals may be useful as a symptom relief measure.

Lung cancer patients experience life-altering symptoms that tend to increase in severity over time. This population thus presents significant opportunities for the development of innovative symptom relief interventions. Illness appraisal and its possible relationship to the symptom experience have not yet been investigated in people with lung cancer, and this relationship may provide a previously uninvestigated avenue for the development of useful symptom relief interventions.

Cognitive-behavioral symptom relief interventions may entail changing attitudes toward illness and treatment. A number of investigators have shown that cognitive-behavioral symptom relief interventions are effective in physical illness (Gaston-Johanson, 2000; Petrie, Cameron, Ellis, Buick, & Weinman, 2002). Such interventions are appealing because, unlike drugs, they entail negligible risks and do not adversely interact with other treatments. However, before developing interventions designed to alter illness appraisal, it must be shown that symptoms in lung cancer are associated with maladaptive illness appraisals.

Self-regulation theory states that symptom distress is related to emotional representations of illness and the other components of illness appraisal bear relationships

to symptom intensity and frequency. The major aim of the study is to explore the relationship of emotional representations to symptom distress by examining seven components of illness appraisal (consequences, timeline, time-cyclical, emotional representations, curability/controllability, personal control, and illness coherence) and symptom frequency, intensity and distress in people with non-small cell lung cancer. With respect to this aim, it is hypothesized that emotional representations contribute more to the variance in symptom distress than the other components of illness appraisal.

The study was a cross-sectional exploratory study. Study participants completed three validated research tools and a demographic questionnaire. Multiple regression was used to identify relationships between emotional representations and symptom distress and to evaluate the congruence of the regression equations thus produced with self-regulation theory.

In this study, as in self-regulation theory, symptom distress was conceptualized as a distinct, affective component of the global symptom experience, which, when combined with symptom frequency and intensity, provides a description of the symptom experience. Symptom distress is a concept often encountered in cancer literature, but it remains undefined and it has been operationalized in many different ways. To help explicate the nature of symptom distress, the secondary aim of the study was to explore relationships among symptom intensity, frequency and distress. These findings were linked to self-regulation theory and to existing literature on symptoms in people with lung cancer.

CHAPTER 2

Review of Literature and Theoretical Background

The first section of this chapter will review the literature and provide background information on the major variables under study. The characteristics of non-small cell lung cancer will be discussed as will some of the controversies surrounding the disease's screening, treatment and causation. The major concepts of the study, symptom distress, illness appraisal, and dispositional optimism will be reviewed.

Symptom distress will be discussed extensively to establish a basis for the current conceptualization and provide context for the measurement decisions made in this study. Dispositional optimism is reviewed and studies linking it, or refuting its link to, illness appraisal and symptom reports are discussed. The development of the concept of illness appraisal is discussed, and the discussion is extended to highlight the potential for cognitive and behavioral symptom management interventions to alter maladaptive illness appraisals and promote symptom control.

The second section of this chapter will describe the theoretical basis for the study, self-regulation theory. Rationale for the choice of this theory will be described and prior studies validating its usefulness reviewed.

Lung Cancer

Symptom Distress in Lung Cancer. Lung cancer is the most common cause of cancer death in both men and women in the United States. Approximately 50% of people diagnosed with lung cancer have distant metastasis at the time of diagnosis, and another 25% have regional metastasis (Jemal, Thomas, Murray & Thun, 2002). In 2004, the American Cancer Society (2004) estimates 173,770 new cases of lung or bronchus cancer

and 160,440 deaths in the United States will occur. The high death to incidence ratio (approximately .91 in 2003) associated with lung cancer is reflective of the late diagnosis and resulting poor survival associated with the disease.

Lung cancer patients experience life-altering chronic symptoms that tend to increase in severity over time. Symptoms may be more problematic in patients with lung cancer when compared to patients with other cancers (Cooley, Short, & Moriarty, 2002).

In an international sample, Vainio & Auvinen (1996) found that 51% of lung cancer patients reported moderate or severe pain, 46% reported dyspnea, and 60% reported weakness. Degner & Sloan (1995) examined symptom distress scores in 434 newly-diagnosed cancer patients at two tertiary oncology clinics in Canada. Scores were highest in lung cancer patients and lowest in males with genitourinary tract cancers. Women had significantly higher scores than men, and people with advanced stage cancers had significantly higher scores than people with early-stage cancers. Given, Given, Azzouz, Kozachik & Stommel (2001) measured pain and fatigue in 841 patients age 65 or older newly diagnosed with breast, colon, lung, or prostate cancer. They found that pain and fatigue were most prevalent in people with lung cancer. Disease stage, comorbidity and having lung cancer were predictors of pain and fatigue. McCorkle & Quint-Benoliel (1983) measured symptom distress in people with lung cancer and myocardial infarction, and found that the lung cancer patients had higher symptom distress. In another publication from this study, Donaldson, McCorkle, Georgiadou, & Benoliel (1986) reported that the lung cancer patients had both higher symptom distress and concerns on a self-report inventory than the myocardial infarction patients.

The symptomatology of lung cancer is not limited to more intense physical symptoms. With respect to psychological distress, (Zabora, BrintzenhofeSzoc, Curbow, Hooker, & Piantadosi, 2001) studied psychological distress, measured with the Brief Symptom Inventory, in a very large sample of people (N=4496) with fourteen different cancer locations. The prevalence of psychological distress was highest among those with lung cancer, at 43.4%, and lowest among those with gynecological cancers, at 29.6%. Cancer stage and prognosis were not reported in this study, so it is possible that the poorer prognosis associated with lung cancer is the cause of greater psychological distress.

The reasons for lung cancer patients' greater symptom prevalence and distress are not entirely clear. In some studies, the presence, extent and locations of metastasis and cancer stage and prognosis were not reported, so it is difficult to compare studies and to hypothesize about the reasons for higher symptom distress in lung cancer patients. Other studies did not report symptom distress scores by disease location. Certainly the fact that lung cancer is observed in clinical practice as a debilitating disease that is often diagnosed in its later stages lends credence to the observation that lung cancer patients experience more symptom distress than others. This finding needs validation in further research.

Causation. Tobacco smoking is the most prominent cause of lung cancer, implicated in 87% of cases (American Lung Association, 2001). Faller, Schilling & Lang (1995) found that 63% to 70% of lung cancer patients identified smoking as the cause of their disease. The discrepancy between these figures and those cited by the American

Lung Association may indicate a lack of concurrence between subjective illness appraisal and biomedical explanations of illness.

Although tobacco has been in use worldwide for centuries, lung cancer did not emerge as a major cause of preventable death until the 20th century. This has been attributed to addictive additives in cigarettes (Alberg & Samet, 2003), but may also be related to an elongating life span and the years it takes to develop lung cancer. Other causes of lung cancer are residential and occupational radon exposure and other occupational exposures such as asbestos and hydrocarbons.

Treatment. Resection, chemotherapy and radiotherapy are the three major treatment options for non-small cell lung cancer (NSCLC), the more common type of lung cancer. Small cell lung cancer, in contrast, is usually responsive to chemotherapy, has often metastasized at the time of diagnosis, and is rarely treated surgically. Small cell tumors grow more rapidly than non-small cell tumors in general, and primary tumors are typically larger at the time of diagnosis than non-small cell primary tumors. People with stage IIIB or IV NSCLC are not generally considered eligible for surgery, the only treatment considered curative, and their five-year survival is 5% and 1%, respectively (Mountain, 1997). Because the option for surgery creates a natural cutpoint in the staging of NSCLC, in this study stage IIIB or IV NSCLC is defined as late-stage and IIIA or earlier is defined as early-stage lung cancer.

Lung cancer screening has been examined in recent years with mixed results. There is agreement in the medical community that chest radiograph and sputum cytology are ineffective screening methods (Bach, Niewoehner, & Black, 2003), but controversy exists as to whether computed tomography (CT) screening is efficacious and cost-

effective (Henschke et al., 1986; Swensen, 2003), and whether it actually reduces deaths from lung cancer. A large randomized trial is currently being conducted in an attempt to answer these questions. The fact that 50,000 subjects will be enrolled is evidence that the expected effect size in this study is relatively small.

A diagnosis of lung cancer carries powerful implications for patients and their significant others. Even laypeople unfamiliar with the specific mortality statistics may know that the disease often carries a grave prognosis. Common knowledge of lung cancer as a serious and often fatal diagnosis may contribute to negative emotions regarding the illness, its treatment, and the likelihood of survival in patients and their significant others.

Symptom Distress

The concept of symptom distress is often used to describe the experiences of people in various states of health and illness. Multiple studies have shown that symptom distress is related to quality of life, treatment tolerance and even to survival in cancer. The importance of symptom distress in cancer as a multi-dimensional construct has been repeatedly demonstrated, and is supported by theory. Despite (or perhaps because of) its ubiquity, symptom distress has remained largely undefined, and limited concept development has occurred (McClement, Woodgate & Degner, 1997). The significance of the concept mandates the development of uniform and valid definition, conceptualization, and operationalization of symptom distress.

Definitions of Symptom Distress. The phrase symptom distress has been used in many ways in the literature, causing confusion regarding symptom distress and its measurement. Symptom distress has been equated with symptom intensity, intensity plus frequency, quality of life and health-related quality of life (McClement, Woodgate &

Degner, 1997). As noted previously, (Tishelman, Degner, & Mueller, 2000), even the meaning of the word symptom is rarely defined. Table 1 lists definitions and key components of symptom distress found in the literature.

Johnson (1973) was one of the first to explore the term symptom distress in her pioneering work on pain sensations. Johnson conceptualized pain as consisting of physiologic (sensory) and reactive components (distress), and tested the independence of these two components in a quasi-experimental design. A standard pain stimulus and repeated measures of single-item, investigator-designed sensory and distress scales were used to examine the sensory and distress components of pain. Subjects were asked to mark the sensory scale to reflect the physical intensity of the pain stimulus and the distress scale to reflect "the amount of distress the sensations caused" (Johnson, 1973, p. 263) or "how much the sensations bother[ed]" them (Johnson & Rice, 1974, p. 206). The study identified differences in sensory and distress ratings among subjects given different kinds of preparatory information prior to the painful stimulus. This research demonstrated early support for Johnson's two-factor conceptualization of pain and was the first empirical evidence that symptom distress is not synonymous with symptom intensity. The use of the words "distress" and "bother" interchangeably would be reflected in subsequent work on symptom distress.

Table 1.

Definitions and Operationalizations of Symptom Distress

Definition of symptom distress	Source
Bother equal to distress and distinct from pain intensity	Johnson, 1973; Johnson & Rice, 1974
Physical or mental upset, anguish, or suffering - distress and frequency are two fundamental symptom attributes	Rhodes & Watson, 1987; Rhodes et al., 1987; Rhodes, McDaniel, Homan, Johnson, & Madsen, 2000
Distress synonymous with discomfort; similar distress from treatment and disease	McCorkle, 1987; McCorkle & Young, 1978
Equal to bother and one of four symptom attributes with quality, timing and intensity	Lenz, Pugh, Milligan, Gift, & Suppe, 1997
Equals symptom interference with life activities and/or emotional upset	Cleeland et al., 2000
Emotional, psychological, social, or spiritual concern that may be caused by physical symptoms.	National Comprehensive Cancer Network, 2002
Distress, intensity and frequency are three symptom dimensions	Samarel, et al, 1996
Distress, intensity and frequency are three fundamental symptom attributes	Portenoy et al., 1994b

In a 1987 issue of *Seminars in Oncology Nursing* dedicated to symptoms, the word distress is defined as "pressure that is applied to produce or restrain action," (Rhodes et al., 1987, p. 243.) This definition of distress as a producer of action is reflected in more recent symptom management models, where perception and evaluation of a symptom precede and direct actions intended to relieve the symptom (Dodd, et al,

2001; Teel, Meek, McNamara & Watson, 1997). Rhodes and Watson (1987) defined symptom distress as "the degree or amount of physical or mental upset, anguish, or suffering experienced from a specific symptom," (p. 243). More recently, Rhodes, McDaniel, Homan, Johnson, & Madsen (2000) have distinguished between the frequency of occurrence of a symptom and the distress caused by it. The combination of these two dimensions was termed symptom experience and a symptom assessment tool, the Adapted Symptom Distress Scale –2 (ASDS-2), was developed using these definitions.

McCorkle (1987), in the same issue of *Seminars in Oncology Nursing*, defined symptom distress as "the person's level of distress from a specific symptom being experienced," (p.248). McCorkle was the first to point out that symptom distress need not be differentiated according to whether it resulted from the disease itself or from the treatment. Symptom distress was defined earlier as "the degree of discomfort from the specific symptom as reported by the patient" (McCorkle et al., 1978) in the development of the Symptom Distress Scale (SDS), one of the most widely used cancer symptom scales. Distress and discomfort, thus, are treated as synonymous in the SDS. Symptom distress is operationalized as the sum of responses to symptom intensity and frequency items. Not all symptoms are rated in terms of both intensity and frequency, and none are rated in terms of distress or bother. The scale, therefore, operationalizes symptom distress as a global description of the symptom experience that is described by symptom intensity and frequency.

In the Theory of Unpleasant Symptoms, (Lenz, Pugh, Milligan, Gift, & Suppe 1997), the authors refer to distress as one of four dimensions of a symptom that reflects "the degree to which the person is bothered by" the symptom (p.16). The other

dimensions of a symptom are quality, timing and intensity. The original theory (Lenz, Suppe, Gift, Pugh, Milligan, 1995) was modified to encompass the occurrence of multiple symptoms simultaneously, and the authors assert that multiple symptoms occurring simultaneously are likely to have a multiplicative, not an additive, effect. This premise, if borne out in subsequent research, casts doubt on the practice of measuring symptoms by summing several items on a scale, as is commonly done.

In the M.D. Anderson Symptom Inventory, (Cleeland et al., 2000), symptom distress is operationalized as the mean of six items asking subjects to rate how much their symptoms collectively interfere with relationships, mood, enjoyment of life, and physical activity. The first half of the tool consists of a list of thirteen symptoms where subjects rate the worst intensity of their symptoms from one to 10. In this section, one question asks subjects to rate emotional distress in terms of the intensity of "being distressed (upset)" (Cleeland et al., 2000). This tool's dual uses of the word distress illustrate the diversity in definitions of distress with respect to symptoms.

The National Comprehensive Cancer Network (2002), developed a distress thermometer consisting of a vertical scale resembling a mercury thermometer on which respondents rate their distress globally. A companion scale asks respondents to indicate which of five categories of problems (practical, family, physical, spiritual/religious, and emotional) has caused the distress. Distress is defined "a multi-determined, unpleasant experience of an emotional, psychological, social, or spiritual nature, which interferes with the ability to cope with cancer, its physical symptoms, and its treatment," (NCCN, 2002, p. MS-2.) The NCCN definition emphasizes the psychoemotional aspects of

distress. Psychoemotional distress can result from physical symptoms, but the NCCN tool and its accompanying document do not explicitly refer to symptom distress.

Samarel et al (1996) operationalized symptom experience as the sum of 24 items querying subjects' symptom intensity, frequency and distress on eight symptoms. The Symptom Experience Scale (SES), like Rhodes and colleagues' ASDS-2 (2000), began as a modification of the McCorkle SDS. In the SES, distress, frequency and intensity ratings are summed to produce a symptom experience score. Unlike the SDS, these dimensions are measured separately for each symptom in both the SES and the ASDS-2.

The Memorial Symptom Assessment Scale (MSAS) (Portenoy et al., 1994b) measures a set of symptoms in terms of frequency, intensity and distress or bother. These three attributes were described by the authors as the fundamental properties of symptoms, although the properties themselves are not explicitly defined. They offer evidence of their assertion by showing that the three subscales are moderately, but not highly, inter-correlated. Like Johnson (1973), Lenz et al (1997), Samarel and colleagues (1996) and Rhodes and Watson (1987), the authors of the MSAS considered distress one distinct aspect of the symptom experience to be examined concurrently with other symptom dimensions, not a summative description of the whole symptom experience.

Despite support for conceptualization of symptom distress as a unique dimension of the symptom experience, operational definitions of symptom distress as a simple function of intensity are not hard to find in recent literature. For example, one recent study (Mercadante et al., 2001) measured the effectiveness of methadone versus morphine for managing pain in palliative care by summing a set of symptom intensity items to produce a "distress score." This practice is at odds with even the earliest work of

nurse scientists like Johnson and McCorkle, and certainly with more recent research. To promote a more uniform usage of the term symptom distress, further concept development and validation are required.

Symptom Distress Measurement Scales. There are many cancer symptom assessment scales. Some are specific to cancer location, such as the Lung Cancer Symptom Scale (Hollen, et al, 1994); others are designed for use in specific settings. The Edmonton Symptom Assessment Scale, designed for use in palliative care, is an example of this genre (Philip, Smith, Craft & Lickiss, 1998). In this section, scales designed explicitly to measure distress associated with multiple physical and psychological cancer-related symptoms are reviewed. To be included, reports of scale development had to explicitly refer to the measurement of symptom distress. This criterion reduced the list to: the Symptom Distress Scale, the Symptom Experience Scale, the Adapted Symptom Distress Scale-2, the Memorial Symptom Assessment Scale, and the M.D. Anderson Symptom Inventory. Each of these scales will be discussed in turn.

The Symptom Distress Scale. The Symptom Distress Scale (SDS) is one of the first instruments designed to measure symptom distress in cancer patients, and perhaps the most extensively used and validated. The scale manual, originally written in 1987 and updated recently, lists 47 studies in which the scale has been used and evaluated for internal consistency reliability (McCorkle, Cooley & Shea, 2000). For this review, fifty-nine studies and abstracts were located.

The content of the SDS was based in literature and in interviews with cancer patients. The SDS is a summed scale that asks subjects to respond to items concerning the

intensity and frequency of symptoms. Distress is thus operationalized as the unweighted sum of symptom intensity (11 items) and frequency (2 items).

Earlier versions of the SDS consisted of 8 and 10 items. The 13-item version, the most recent, has a potential range of scores from 13 to 65. Responses are graded in a Likert-type format from 1 (least) to 5 (most). On the basis of interviews with cancer patients, the authors included both intensity and frequency items for nausea and pain. Other symptoms evaluated on the basis of intensity are concentration, fatigue, outlook, insomnia, bowel pattern, appetite, appearance, breathing and cough. There are verbal descriptors for each of the five response options for each item.

In many studies, SDS scores have tended to fall near the low end of the scale's range. These low scores may have many causes. Chief among these is that highly symptomatic people are often too ill to take part in symptom research. On the 13-item SDS, no studies have demonstrated a mean score as high as 39, the halfway point of the scale. When scores fall toward the lower range of the scale consistently, a positively skewed distribution of observations results, and this may distort the statistical versatility of the tool. For example, in applications such as regression, a normal distribution of the dependent variable is assumed. Despite this observation, many studies with the SDS have employed techniques such as multiple regression, although the SDS may not fit the requirements of an independent variable in complex parametric procedures such as regression. A positively skewed distribution of scores may also limit the potential range of scores, which has implications for procedures such as parametric correlation, where restriction of range can distort findings (Nunnally, 1978).

In the SDS manual (McCorkle, Cooley & Shea, 2000), mean scores from forty-seven studies where the 13-item SDS was used are listed by cancer location. The mean scale scores listed range from 16.4 for women newly diagnosed with stage I or II breast cancer (Samarel, Fawcett, & Tulman, 1993) to 33.8 for patients with various types of cancer upon admission to a palliative care unit (Degner, Henteleff, & Ringer, 1987). For this literature review, twelve additional studies where the SDS, or a modification of it, was used and descriptive statistics were provided on the SDS total or item scores were found. These studies also support the tendency of SDS scores to fall toward the low end of the scale. Table 2 in Appendix A contains a complete listing of these studies and selected characteristics. The SDS has been extensively used and validated in research with cancer patients. While not a perfect scale, the SDS has stood the test of time.

The Symptom Experience Scale. Before developing their scale, Samarel (1996) and colleagues measured symptom distress with the SDS in a study that tested a counseling intervention for women with breast cancer. The intervention, as measured by the SDS, did not appear effective, because the SDS measures only symptom intensity and frequency. However, in the qualitative portion of the study, women emphasized that their distress was reduced by the intervention, although symptom frequency and intensity were not. This observation was the impetus for development of Symptom Experience Scale (SES). The SES, designed to measure women's experience of symptoms associated with treatment for breast cancer, was developed and tested in a sample of 252 women with breast cancer.

The SES evaluates eight symptoms associated with breast and other cancers on the basis of their frequency, intensity and distress. Scores are summed to calculate a total

symptom experience score, which can range from zero (best) to 96 (worst). Factor analysis yielded six factors: nausea and appetite, fatigue and sleep, concentration, appearance, bowel pattern, and pain, which accounted for 83.2% of the variance. For each symptom, the distress, frequency and intensity dimensions loaded together. Each item loaded on a factor, so all items were retained in the tool. Subscale to subscale correlations ranged from 0.21 to 0.56, suggesting that the frequency, intensity and distress subscales measure related, but not identical, aspects of symptom distress.

Although the SES was originally designed for and has only been used in women with breast cancer, the items overlap a great deal with those on the SDS, only differing by the omission of outlook, the only psychological item, from the SES. The authors felt that outlook was not a symptom, and chose to omit it for conceptual consistency. Therefore, the SES can only be used as a measure of physical symptoms, but it may exhibit greater sensitivity than the SDS by the addition of the third dimension, distress. It may also be suitable for measuring symptom distress in many cancer types.

The Adapted Symptom Distress Scale–2. Rhodes, McDaniel, Homan, Johnson, & Madsen (2000) adapted the SDS in a different manner to measure symptom experience in oncology patients. The Adapted Symptom Distress Scale-2 (ASDS-2) is a 31-item scale measuring 14 symptoms. Subscale scores can be calculated for distress, frequency (termed symptom occurrence by the authors) and six subgroups of related symptoms (gastrointestinal, pain/discomfort, respiratory, fatigue/restlessness, concentration, and appearance.) Subjects rate the frequency and distress associated with symptoms on a 5-point Likert-type scale with verbal descriptors, the same format used in the SDS. Total

symptom experience is operationalized in the ASDS-2 as the sum of symptom frequency and distress and possesses a potential range of 0-124.

Discriminant validity was shown between adults with oncologic or medical-surgical illnesses and healthy adults on total symptom experience scores, all six symptom subscales and the distress subscale. The symptom occurrence subscale differentiated among all three groups (Rhodes et al, 2000.) Symptom subscale reliability coefficients were acceptable, ranging from .64 to .85, with the exception of the two-item appearance subscale with a coefficient of .38.

The validation study possessed certain limitations that raise questions about the scale. Mean symptom experience, symptom distress and symptom occurrence scores were not reported, and no other studies were found where the ASDS-2 was used. In totaling the reported symptom subscale means, oncology patients' mean score was 42.7, well below the potential range of the instrument. If the instrument is not sensitive to a wide range of symptom experiences, its potential for use in predictive studies and its sensitivity to change may be hindered. However, as mentioned earlier, people with multiple intense symptoms may be reluctant or unable to take part in symptom research. Achieving a wide range of scores, normally distributed, may not be a realistic goal when using symptom instruments.

In the validation study, factor analysis was not done, so it is difficult to assess the validity of the grouping of symptoms into subscales. Of particular concern is the grouping of fatigue and restlessness. Other investigators have found that fatigue is associated with insomnia or sleep problems (Degner & Sloan, 1995; Samarel et al, 1996.) The grouping of fatigue with restlessness may obscure the distress and frequency of

fatigue experienced by cancer patients. The authors do not report on the methods used to categorize symptoms in the ASDS-2; this information, and factor analysis, would support the validity of the symptom groupings.

A diverse sample of oncology patients should be tested to evaluate the ASDS-2. The oncology patient group in the validation study sample consisted of 175 patients who were receiving chemotherapy or radiation. The chemotherapy patients were all at the beginning their first cycle of antineoplastic therapy, which may help account for the low level of symptoms reported. Cancer stage and location were not reported, so it is difficult to determine how symptomatic the sample was likely to be before initiating therapy. Furthermore, subscale correlations were not reported. Analysis of the correlations among the total symptom experience score, symptom distress subscale scores and symptom occurrence subscale scores would help demonstrate the degree of interdependence of these scales and how much each contributes to the instrument.

The ASDS-2 and the SES may make a significant improvement upon the SDS by directly measuring patients' reports of distress from symptoms. The frequency of occurrence and the distress caused by all symptoms is measured, in contrast to the SDS where the frequency of only two symptoms is measured. However, in the initial report of the validation study of the ASDS-2, there is insufficient information to support the scale's validity. Further evaluation of both scales is needed in different cancer populations and analysis of the factor structure, subscale intercorrelations, and sensitivity of the ASDS-2 are needed before its use can be recommended.

Memorial Symptom Assessment Scale (MSAS). This scale was developed in the 1990's to measure "a full range of physical and psychological symptoms commonly

experienced by cancer patients" (Portenoy, et al, 1994a, p. 184). The MSAS conceptualizes distress, severity and frequency of symptoms as the "three fundamental characteristics of symptoms" (Portenoy, et al, 1994a, p.187-188.) A set of 32 symptoms is evaluated on the tool; twenty-four symptoms are evaluated on all three dimensions, eight on intensity and distress alone and there is space for the respondent to write in three other symptoms not addressed in the tool.

To rate the distress dimension, respondents are asked how much a symptom bothers or distresses them. Support for the proposed three dimensions of the tool was demonstrated by differences in the percentages of patients reporting high levels of symptom distress, frequent symptoms and high symptom severity. When individual items were analyzed, the percentage of patients reporting high symptom severity consistently exceeded the percentage reporting frequent symptom occurrence, and both exceeded the percentage reporting high symptom distress. This finding was consistent in a heterogeneous sample of 243 cancer patients. Statistical tests of these percentage differences were not reported, however, and on some symptoms, the differences between percentages of patients reporting frequent symptoms and patients reporting high distress were small. Additionally, the three dimensions were highly intercorrelated (Portenoy, et al, 1994b), raising concern about the validity of the model. Correlations of the total number of symptoms per patient with scores on other established instruments, (Rand Mental Health Inventory and Functional Living Index-Cancer) were moderate to high, but similar analyses of the three proposed dimensions with other established symptom measurement tools were not reported. Although the model is appealing, and has some

support, there is incomplete evidence of the validity of the three dimensions and the magnitude of each dimension's contribution to the global assessment of symptoms.

M.D. Anderson Symptom Inventory. The 32-item M.D. Anderson Symptom Inventory (MDASI) was validated on two samples of people with various types of cancer from outpatient and inpatient oncology settings. An 11-point numerical scale is used to rate the severity of 26 common symptoms, with zero meaning none and 10 meaning "as bad as you can imagine, "(Cleeland, et al, 2000, p. 1637.) The numerical scale was chosen in part to permit automated telephone administration of the MDASI via interactive voice response technology; the MDASI is the only scale in this review specifically designed to adapt easily for electronic administration. This property is appealing, especially in the context of the emerging field of telehealth.

The impetus for development of the tool was to devise a brief instrument for judging the burden of symptoms upon oncology patients. There are two subscales: one measures the severity of 13 symptoms and the other measures symptom distress, defined as the degree to which symptoms interfere with activity, mood, work, interpersonal relationships, walking and enjoyment of life (Cleeland, et al, 2000). Discriminant validity was supported by showing that cancer patients currently undergoing treatment experienced significantly greater symptom distress than cancer patients not being actively treated.

The MDASI possesses significant strengths. Extensive statistical validation was undertaken to reduce the number of items on the MDASI to prevent redundancy while assuring completeness. The MDASI's conceptualization of symptom distress as the degree to which symptoms interfere with functioning, relationships and mood is unique

among symptom distress scales. The inclusion of these three elements in the symptom distress portion of the scale adds face validity to the measure as a holistic measure of symptoms' impact upon patients' lives. A search of literature citations revealed no published studies using the instrument aside from the measure validation studies reported in Cleeland, et al, (2000.) Further use of the scale by other investigators is required to demonstrate its reliability, validity and suitability for use in various populations. Table 2 summarizes properties of the five scales reviewed here.

Table 2.

Properties of Symptom Distress Scales

Scale Name	Number of Items	Symptom Dimensions
Symptom Distress Scale	13	Frequency and intensity
Symptom Experience Scale	24	Distress, frequency and intensity
Adapted Symptom Distress Scale-2	31	Frequency (occurrence) and distress
Memorial Symptom Assessment Scale	32-35	Distress, frequency and intensity
M.D. Anderson Symptom Inventory	32	Distress (the sum of interference with functioning, relationships and mood) and severity

Note: Three spaces on the MSAS are allocated for respondent-generated items.

Measurement Issues

All of the scales reviewed here are constructed to allow summing of individual items to calculate a total symptom distress score, and all of the studies reviewed here used total scale scores with or without subscale scores. In all scales, equal weight is assigned to frequency items, intensity items, and distress items (if measured). Similarly, different symptoms are weighted equally in summing the scales.

There is no empirical evidence that the three dimensions should be equally weighted, nor is there conceptual or empirical support for assigning equal weight to different symptoms. There is preliminary empirical evidence, however, that patients do not weight the importance of symptoms similarly. In a pilot study of people with lung cancer, Tishelman, Degner & Mueller (2000) showed that patients do not necessarily

consider their most intense symptoms the most important symptoms. Different patients did not agree on the importance of different symptoms in this study, pointing out the subjective and personal nature of the symptom experience. The subjective and individual nature of the symptom experience is well-supported in theory. When two or more groups are to be compared, the validity of equal weighting is questionable, given that different symptoms may impose different degrees of distress on different people. The factors that encourage people to assign different weights to symptoms are not known, but may be related to meaning ascribed to symptoms by patients. Delineating these factors could help clinicians understand the importance of various symptoms to different people and help direct the development of individualized symptom management strategies that are congruent with patients' values and priorities.

Parametric statistics are typically used to compare ordinal symptom distress scores, in violation of the statistical assumption that data must be interval or ratio scale for parametric analysis. In using parametric statistics, the assumption is implicit that the difference between a score of 10 and 12 equals the difference between a score of 40 and 42, although we do not know whether or not this is the case. Perhaps as symptoms increase in number, they exert an exponential or multiplicative effect on one another, not simply an additive effect. Lenz and colleagues (1997) raise this issue, pointing out the common-sense belief that pain seems much worse when accompanied by nausea than not. Whether or not this will be supported empirically in patients with multiple symptoms is unknown. A next step in symptom measurement research is to identify ways of incorporating patients' judgments of symptom importance into symptom measurement

and management. Understanding the nature of the interactions between multiple symptoms, and their impact on the patient, is an area in dire need of clinical research.

Several scales exist that appear to be valid and reliable measures of symptom distress in adults with cancer. By far, the most widely validated of these measures is the SDS. The SDS is also the shortest instrument, and brevity has significant advantages in research with extremely ill people. All of the studies reporting on the development of the other symptom distress instruments referred to an attempt to improve upon the SDS, which is indicative of the reliance of many researchers upon the SDS as the original symptom distress tool. Scales that include distress subscales may be more sensitive to individual differences or to change over time, partly by virtue of the larger number of items that these scales employ, but this has not yet been shown.

Major Themes In Symptom Distress Studies

Fatigue. The wide prevalence of fatigue in cancer is well documented. Thirty-eight studies reviewed for this literature review addressed both fatigue and symptom distress in some manner. Thirty studies were found where either fatigue or similar symptoms, such as lack of energy, and symptom distress were systematically assessed. These studies are summarized in Table A.

Many different cancer locations, stages, demographic groups, and therapies were investigated in these thirty studies with several different instruments, and fatigue consistently appears as a significant concern. The only study in which the symptom distress instrument did not detect fatigue among the top symptoms used the ASDS-2, in a study of oncology patients who were beginning therapy (Rhodes et al., 2000), where the combination of fatigue and restlessness rated third among six subscales. Since only the

subscale scores were reported, the combination of fatigue with restlessness in the ASDS-2 may account for this finding, in addition to unreported sample characteristics, such as stage of treatment.

Global symptom distress scales may not be ideal instruments for measuring fatigue. Fatigue is not differentiated from weakness in any of the symptom distress scales discussed in this review. Notably, when a loss of strength item was added to the 10-item SDS, fatigue and loss of strength emerged as the top two highest intensity symptoms (Munkres, Oberst, & Hughes, 1992; Oberst, Hughes, Chang, & McCubbin, 1991) Research to differentiate fatigue from weakness and to determine their relationship is needed to develop meaningful interventions (Nail & Winningham, 1995). Symptom distress scales, on the whole, do appear sensitive to fatigue, but validation of symptom distress scales' ability to differentiate fatigue from weakness is needed before their usefulness in trials of interventions can be assured.

In some fatigue studies, only physical symptoms were measured (Irvine, Vincent, Graydon, & Bubela, 1998). Associations between depressive symptoms and fatigue have been shown (Pasacreta, 1997), necessitating that psychosocial variables be considered when drawing conclusions about the causes and correlates of fatigue in cancer patients. Other studies modified the SDS to rate only selected symptoms of interest. For example, Berger and Walker (2001) rated only mood, nausea and sleep disturbance in constructing an explanatory model of fatigue in women with breast cancer. Other significant symptoms, such as pain and dyspnea, were omitted. When multiple regression models are employed, omission of significant predictor variables can alter the observed significance of the measured predictor variables (Pedhazur & Schmelkin, 1991.) Strictly speaking, all

known important predictor variables should be measured and tested when constructing models, or statistical procedures such as partial regression or partial correlation should be employed (Pedhazur & Schmelkin, 1991.) For purposes of statistical power and practicality, measuring all possibly relevant variables is rarely realistic. Nonetheless, when incomplete models are tested, the limitations of the model should be acknowledged.

A relationship between fatigue and total symptom distress was supported in many studies (Irvine et al., 1998; Irvine, Vincent, Graydon, Bubela, & Thompson, 1994; Berger et al., 2001; Berger & Higginbotham, 2000; Berger, 1994; Cimprich, 1999; Graydon, 1988; Graydon, 1994; Hwang, Chang, Cogswell, Ohanian, & Kasimis, 1999). Symptom occurrence can be fatiguing in itself, and symptom management regimens themselves, such as palliative chemotherapy, entail side effects such as anemia that contribute directly to fatigue. Although treatment-induced anemia as a cause of fatigue is well documented, a relationship between treatment-induced increases in plasma cytokine levels and fatigue has also been shown (Rigas et al., 1998), shedding light on other biological contributors to fatigue. The complex and multicausal nature of cancer-related fatigue is highlighted by this relationship, and raises intriguing questions about the nature of the interactions between biological factors, fatigue and symptom distress.

Fatigue is clearly a significant yet variable element of symptom distress in cancer patients. The predictors, correlates and outcomes of cancer-related fatigue and symptom distress could be more clearly delineated if researchers consistently measured and defined symptom distress and fatigue, accounted for multiple potential predictors when constructing predictive or explanatory models, and differentiated fatigue from associated symptoms such as weakness, sleeplessness and loss of strength. Some investigators

studied cancer patients in active treatment; others studied cancer patients surviving up to several years after treatment, and still others studied newly-diagnosed cancer patients who may or may not have begun therapy. Fatigue begins, at times, before treatment, changes over time during treatment, and persists after treatment for cancer in some people. The consistent occurrence of fatigue among these samples is striking, suggesting that fatigue is both pervasive and multicausal. The impact upon cancer patients of this major symptom is worthy of the considerable attention it is now receiving.

Relationship to survival. Seventeen studies were found containing the words survival and symptom distress in the title, in the abstract or as keywords. After review of all of the abstracts, the list was reduced to 7 studies where cancer survival and multi-symptom distress were measured. Table 5 in Appendix A summarizes these studies.

Single symptoms of cancer have been associated with prognosis, such as weight loss at the time of diagnosis of lung cancer (Sarna, Lindsey, Dean, Brecht, & McCorkle, 1994). Cancer staging is considered the "gold standard" in prognostication, yet one study found that symptom distress was a more significant predictor of survival than disease stage (McCorkle et al., 2000). This is a striking finding, and one that deserves more investigation. Both the SDS and the MSAS were used in the studies listed in Table 5, and thus, symptoms were evaluated using different dimensions of symptom distress. Which symptoms and which dimensions of symptoms best predict survival remains unknown.

There are two major possible explanations for the observed relationship between symptom distress and survival when disease severity is controlled. First, many cancer studies have shown the significance of psychoneuroimmunologic effects upon metastasis and various aspects of immune function (Kiecolt-Glaser, Page, Marucha, MacCallum, &

Glaser, 1998; Orsi, McCorkle, Tax, & Barsevick, 1996; Page & Ben-Eliyahu, 1997; Byrnes et al., 1998). Page and colleagues have demonstrated repeatedly in both human and animal studies that immune function declines in the presence of biological and psychological stressors, leading them to conclude that "pain not only results in suffering but is a pathogen itself, capable of facilitating the progression of metastatic disease (Page & Ben-Eliyahu, 1997)." The evidence of fatigue in relation to cytokine production (Rigas et al., 1998) adds further impetus to the investigation of psychoneuroimmunologic effects on cancer outcomes. Increased symptom distress may be a direct contributor to survival via biologic pathways that encourage the production of inflammatory chemical mediators, such as the cytokines, that are damaging in themselves.

The second possible explanation lies in measurement characteristics. The SDS and MSAS do not differentiate side effects of treatment from symptoms of illness. It is possible that either treatment side effects or symptoms of illness may account for differences in survival that are not differentiated by these instruments. Early post-diagnosis evidence (Kukull, McCorkle, & Driever, 1986) seems to suggest that disease symptoms, not treatment side effects, account for differences in survival. However, Molassiotis, et al, (1997) suggested that higher symptom distress after BMT may have predicted survival because patients with more intense post-transplant symptoms were responding differently to the treatment. This may be the case if allogenic transplant recipients were experiencing graft-versus-host disease. Additionally, patients with greater treatment-related symptom distress may undergo less intense therapy, limiting survival. Whether symptom or treatment side effects, or both, are responsible for these effects is an under-researched area where significant insight could be gained into the

reasons for differences in length of survival among patients with seemingly similar disease states.

Although the "gold standard" American Joint Cancer Committee (AJCC) staging criteria have been extensively evaluated, controversy remains considering their predictive validity. Suzuki and colleagues (1999) showed that conventional clinicopathological staging features possessed different prognostic validity in different stages of non-small cell lung cancer. Perhaps the addition of systematic and standardized symptom distress evaluation would improve the accuracy of prognostication based upon the AJCC staging system. Nonanatomic predictors of survival in lung cancer were systematically reviewed by AJCC (Yarbro, Page, Fielding, Partridge, & Murphy, 1999) for possible inclusion in the staging system, but only biomedical factors, such as serum tumor markers, were considered.

The finding that survival may be related to symptom distress is intriguing. As psychoneuroimmunology is incorporated into nursing science, relationships between symptom distress and survival begin to appear biologically valid as well as intuitively appealing. The nature of this relationship, the specific symptom characteristics that contribute to survival and, ultimately, whether symptom management interventions can lengthen survival must be determined. If symptom distress influences survival, appropriate interventions must be designed, tested and implemented to improve both comfort and survival.

Conclusions

A great deal of work is needed to develop the concept of symptom distress and identify its unique relationship to outcomes such as functional status and survival.

However, themes are emerging to help clinicians to understand differences in symptom distress among groups of patients and to guide further research in the role of symptom distress as a predictor or contributor to other significant health outcomes.

The basic question of what symptom distress means to people with cancer remains largely unexplored. Various approaches to measurement have been taken, and each has its advantages and disadvantages. We do not know which of these approaches best reflects patients' values and which are most suitable for detecting differences among groups, predicting significant health outcomes, or for guiding symptom management interventions.

The frequent use of the term symptom distress suggests that it is a meaningful concept to researchers and clinicians. However, significant scientific gaps persist in understanding the meaning of symptom distress to patients and in delineating the relationships between symptom distress and other health outcomes. Future research on symptom distress should identify patients' interpretations of symptom distress, define the important dimensions of symptom distress and examine the congruence among researchers', clinicians', and patients' conceptualizations of symptom distress as an initial step toward standardizing the conceptualization and measurement of symptom distress in adults with cancer.

Optimism

Dispositional optimism versus pessimism is a personality characteristic that has been linked with physical illness and longevity; (Scheier et al., 1999; Maruta, 2000; Maruta, 2002.) Pessimists tend to view adverse life events as more catastrophic than optimists and tend to use more emotion-focused coping and avoidant coping strategies

(Carver et al. 1993). These tendencies may lead pessimistic people to report greater distress from symptoms and to report greater intensity or frequency on measures of outlook, overall well-being, depression and treatment side effects (Carver et al. 1993; Walker, Nail, Larsen, Magill & Schwartz, 1996) than optimistic people. Certain coping strategies (denial, acceptance) have been shown to mediate the effects of dispositional optimism upon distress (Livneh, 2000), suggesting a possible relationship between dispositional optimism, coping and symptom reports.

Coping style has been associated with dispositional optimism and described along two dimensions: engagement versus disengagement and problem-focused versus emotion-focused (Epping-Jordan et al., 1999). Engagement coping stresses directly addressing either the problems presented by the diagnosis or the emotions associated with it. Disengagement coping consists of distraction or wishful thinking that directs one's attention away from the problems and emotions presented by the illness. Several studies have sought to describe relationships between coping style, optimism and symptom reports.

Carver and colleagues (Carver et al., 1993) found that more optimistic women with breast cancer experienced less emotional distress and this relationship was mediated by coping style. Specifically, acceptance and the use of humor (problem-focused, engagement coping strategies) predicted lesser distress while denial and disengagement (emotion-focused, disengagement coping strategies) predicted greater distress. A Japanese study appears to contradict these findings, however, in showing that avoidance as a coping style was associated with less psychological distress in ambulatory lung cancer patients (Akechi et al., 1998). Whether these apparently conflicting findings are

attributable to characteristics of the study participants, instrumentation, cultural differences, or other factors is not clear.

Relationships between dispositional optimism and coping style were also explored in a study of eighty women (Epping-Jordan et al., 1999) with Stage I-IV breast cancer who completed the Life Orientation Test-Revised (LOT-R) (Scheier, Carver, & Bridges, 1994), a commonly-used measure of dispositional optimism. Lower LOT-R scores were associated with anxiety and depression and this relationship was partially mediated by coping style, specifically emotion-focused, disengagement coping. This relationship was observed at diagnosis and six months later. Symptoms of anxiety and depression were associated with all coping styles except problem-focused engagement coping. Women with more years of formal education were observed to have higher LOT-R scores ($r=.25$, $p<.05$). Age and cancer stage were also associated with coping style, with younger and less educated women with later-stage cancer exhibiting more emotion-focused, disengagement coping.

Nail (1993) studied the frequency of use of problem-focused and emotion-focused coping and symptom severity and symptom upset at various time periods in women with gynecologic cancer undergoing radiation therapy. Emotion-focused coping was more consistently correlated with symptom severity than with symptom upset across the four time periods. The high correlations ($r = .89$-$.97$) between symptom severity and symptom upset in this study, however, make it difficult to draw separate conclusions about the two symptom dimensions.

Robinson-Whelen, Kim, MacCallum, and Kiecolt-Glaser (1997) explored the factor structure of the earlier version of the LOT-R to determine whether optimism and

pessimism are opposite extremes of a single construct or two separate constructs. A sample of caregiving and non-caregiving middle-aged and older adults (N=224) was administered the LOT on two occasions two years apart as part of a larger longitudinal study. Pessimism, but not optimism, predicted physical and psychological health in the year following the second administration of the LOT. Optimism scores in year 1 on the LOT accounted for 62% and 69% of the variance in year 3 LOT optimism scores in caregivers and non-caregivers, respectively. LOT pessimism scores in year 1 accounted for 70% and 79% of the variance in year 3 LOT pessimism scores in caregivers and non-caregivers, respectively. These findings lend weight to the assertion that the original LOT, at least, consists of two separate factors, optimism and pessimism, although not all authors agree with this hypothesis (Scheier et al., 1994).

The developers of the original LOT (Scheier, Carver, & Bridges, 1994) report that the tool was somewhat confounded with negative affectivity, particularly in measurement of associations between symptom reports and dispositional optimism. Optimism, as measured by the LOT, was also correlated with self-mastery, self-esteem, trait anxiety and neuroticism, (Scheier, Carver, & Bridges, 1994.) In a study of over 1000 college undergraduates who filled out a battery of tests, including the LOT, optimism had somewhat low but significant correlations with the reported number of physical symptoms (r=.21) and intensity of physical symptoms (r=.25) However, when self-mastery, self-esteem, trait anxiety and neuroticism were controlled, the partial correlation with number of symptoms became non-significant. The partial correlation with intensity was reduced to r=.12 when self-mastery and self-esteem were controlled singly and became non-significant when controlling for neuroticism and trait anxiety. Both the

number and intensity of reported physical symptoms became non-significant when all four potential mediators were controlled, suggesting that the four mediators suggested by the authors of the original version of the LOT do confound relationships between optimism and physical symptom reports. This study led to the current revision of the tool, the LOT-R, which consists of the same scale with two of the original scored items deleted. Associations between optimism and coping by positive reinterpretation and growth remained significant with the new version of the tool, leading the authors to conclude that a tendency toward the use of certain coping styles remains an important mediator of the effects of optimism on physical symptom reports.

Illness Appraisal

Theoretical Roots. Illness appraisal, also called illness representation, is a fundamental concept in self-regulation theory, the theory that provides the conceptual basis for this study. Illness appraisal consists of an implicit model of an illness constructed by the individual to help plan actions and direct responses to the illness. Nerenz & Leventhal defined illness representation as "the reception and interpretation of information for the definition of the potential or actual health threat" (1983, p. 15)

The influence of symbolic interactionism (Benzies & Allen, 2001) on self-regulation theory is evident in the underlying assumption that human beings are meaning-seeking organisms whose thoughts and actions are influenced by the meanings ascribed to life events. Systems theory (von Bertalanffy, 1968) is reflected in the feedback loop in self-regulation theory that shows how individuals modify responses to health threats in response to an internal evaluation of their coping responses.

Conceptualization of illness as a phenomenon that extends beyond physiological derangement and compels human beings to seek meaning has become incorporated into nursing symptom management theory. The Symptom Interpretation Model (Teel, Meek, McNamara & Watson, 1997) states that people use a process of appraisal and interpretation to impart meaning to symptoms, relying upon and refining knowledge structures that are analogous to the illness representations described by Leventhal. The University of California San Francisco School of Nursing Symptom Management model postulates that illness appraisal bears an effect upon coping and, ultimately, upon well-being (Dodd, et al, 2001).

Figure 1 depicts Leventhal's self-regulation model and shows the centrality of illness representation in the model. In the model, appraisal refers to appraisal of the effectiveness of coping procedures, not illness appraisal. Arrows between the upper concrete-objective pathway and the lower subjective pathway indicate feedback between the two pathways that occurs continuously. Appraisal of the success of coping procedures is fed back into the system as well and used to modify or reinforce coping procedures. The model is discussed in greater detail in the next section of Chapter 2.

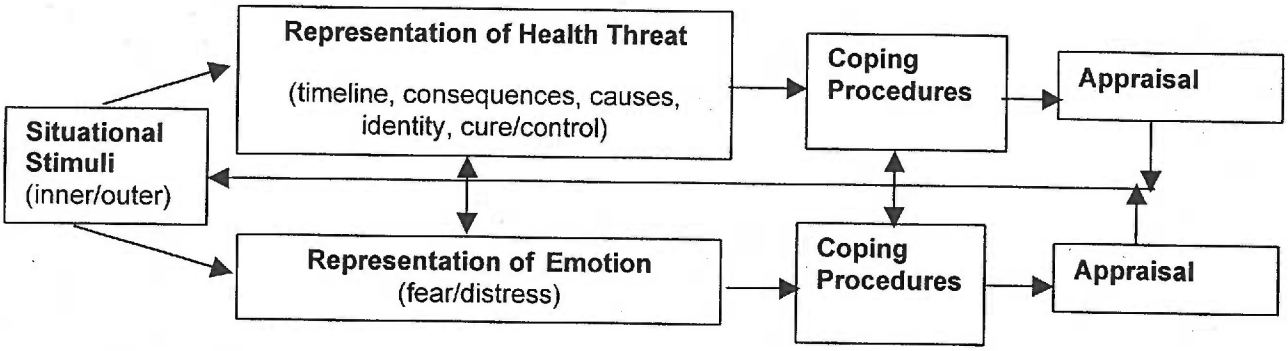


Figure 1. Self-Regulation Model in Leventhal, Diefenbach, & Leventhal (1992)

Relationship to Non-Lung Cancer Disease States. Meaning ascribed to treatment side effects or symptoms of illness has been equated with illness appraisal (Bova, 2001; Dunbar, Jenkins, Hawthorne & Porter, 1996). Bova, (2001) found associations between illness appraisal, measured by the Meaning of Illness Questionnaire (MIQ) (Browne et al, 1988), and adjustment to illness and symptom intensity in women with HIV. Appraisal of specific symptoms and illnesses has been investigated by various methods in men and women with a variety of medical diagnoses, including coronary heart disease (Rosenfeld & Gilkeson, 2000), breast cancer (Luker, Beaver, Leinster & Owens, 1996), colon, breast, lung, prostate, testicular and lymphatic cancer (Fife, 1995), musculoskeletal pain (Johansson, Hamberg, Westman & Lindgren, 1999) and fibromyalgia, (Hellstrom, Bullington, Karlsson, Lindqvist, & Mattsson, 1999).

Martin and Lemos (2002) describe the "stress-illness rule" as the lay perception that symptoms are less important when they occur under stressful conditions and that women are more likely than men to experience stress-induced symptoms. The authors cite evidence from the literature and describe two studies supporting the assertion that both men and women tend to discount women's symptoms. In the studies they describe, healthy male and female undergraduate students were exposed to patient vignettes that varied by symptom presentation, stress level, and gender. Symptom presentations in the vignettes were consistent with heart attack, gallstones, and melanoma; although no diagnostic labels were used. Both male and female study participants attributed symptoms to disease and recommended medical treatment less often for women than for men in otherwise identical vignettes.

Nesbitt and Heidrich (2000) studied older women's physical health, quality of life, illness appraisal and sense of coherence. In this study, symptom bother and functional health were mediated by illness appraisal and sense of coherence in predicting quality of life. These findings are consistent with self-regulation theory, where illness appraisal mediates relationships between symptom experiences and outcomes, such as coping strategies, that may be closely linked to quality of life.

In one study, (Luker, Beaver, Leinster, & Owens, 1996) women with breast cancer were shown a series of cards, each with a different meaning written on it, and the women were asked to select the card that most exemplified the meaning of their illness. From the possible meanings challenge, enemy, value, loss, punishment, weakness, strategy and relief, women most often chose challenge. This study demonstrates that when faced with cancer, people do not uniformly draw negative cognitive schemata.

Relationship to Lung Cancer. Although illness appraisal's contribution to the symptom experience in lung cancer is not yet known, there exists some empirical and clinical support for the relationship. One study (Brown, Carrieri, Janson-Bjerklie, & Dodd, 1986) showed that some lung cancer patients attributed dyspnea to tumor progression and powerlessness over cancer. Clinically, cancer patients are observed to interpret changes in symptoms as evidence of disease progression, reflecting appraisals that may influence symptoms through negative cognitive schemata.

The strong association of lung cancer with smoking and the rise of anti-smoking campaigns in recent years may contribute to self-blame in lung cancer patients. This assertion is supported by evidence in the lay literature and from lung cancer Internet bulletin boards and websites. According to the Alliance for Lung Cancer Advocacy,

Support and Education (ALCASE), "a prevailing attitude of fear and blame surrounds lung cancer," (ALCASE, 2003).

Self-blame may be amenable to change through cognitive-behavioral interventions, but it should be noted that whether taking personal responsibility for an illness is adaptive or maladaptive is not yet known (Faller, Schilling, & Lang, 1995). Identifying whether self-blame enhances belief in a controllable and comprehensible illness, increasing illness coherence, or whether it leads to feelings of guilt and low self-esteem (Faller, Schilling, & Lang, 1995) is an example of research needed to help differentiate adaptive from maladaptive illness appraisals.

There is some evidence that positive expectations, even if biomedically unrealistic, may contribute to healthy behaviors. A study in a sample of mostly males having their first myocardial infarction (MI) showed that return to work was predicted by the belief that the illness would last a short time and have less serious consequences, despite the chronic nature of coronary artery disease and the lay perception of MI as a life-threatening condition (Petrie, Weinman, Sharpe, & Buckley, 1996). In this study, however, the relationships were confounded by peak creatine kinase (CK) levels, which were used as a proxy for illness severity. Those with higher CK levels accurately perceived their illness as more serious and tended to return to work later. It is not clear, therefore, whether illness severity was a direct determinant of later return to work or whether the relationship was mediated by illness appraisal.

Cognitive-Behavioral Symptom Relief Strategies. Cognitive-behavioral therapy assumes that thoughts, assumptions and beliefs direct behavior, and that altering underlying cognitive processes facilitates desired behavior change. Behavioral change is

viewed as a product of both cognitive change, or restructuring, and practice. Typical elements of cognitive-behavioral treatment are education, practicing of new behaviors between sessions or "homework", and attitudinal change.

Cognitive-behavioral intervention has its roots in psychology, where cognitive-behavioral therapy has been shown effective for treating a range of disorders, such as anxiety and panic disorders, depression, phobias and eating disorders (Chambless, et al, 1996). More recently, cognitive-behavioral interventions have been expanded to apply to the treatment of physical disorders such as chronic pain (McCracken& Turk, 2002) and myocardial infarction (Petrie et al., 2002).

A recent review of behavioral (BT) and cognitive-behavioral (CBT) intervention for chronic pain (McCracken& Turk, 2002) demonstrated that BT-CBT for chronic pain reduces pain, distress, and pain behavior, and improves daily functioning.

Petrie and colleagues (Petrie et al., 2002) randomized post-myocardial infarction patients to usual care or an intervention designed to alter illness perceptions. The intervention, offered in-hospital, was delivered by cardiac rehabilitation nurses. Patients in the intervention group believed the illness would last a shorter time and had higher levels of belief that the illness could be cured or controlled relative to the control group. Intervention group patients also felt better prepared to leave the hospital, returned to work earlier and reported fewer episodes of angina at the 3–month follow-up.

Many studies have investigated cognitive-behavioral treatment in cancer. Bottomley (1998) used group cognitive-behavioral therapy in a small qualitative study of women newly diagnosed with cancer, showing that coping skills and adaptation to illness could be enhanced this way. The treatment consisted of relaxation training, activity

scheduling skills, assigning and reviewing homework, challenging dysfunctional thinking and learning coping skills.

Among people with lung cancer, research suggests that distressed mood may be a suitable target for cognitive-behavioral intervention. Maliski, Sarna, Evangelista & Padilla (2003) found that long-term survivors of lung cancer with distressed moods expressed more negativity with respect to existential issues, health and self-care, physical ability, adjustment, and support than survivors with non-distressed moods. Sarna, Padilla, Holmes, Tashkin, Brecht & Evangelista (2002) showed that distressed mood among lung cancer survivors contributed to poorer physical and mental health scores.

Cognitive-behavioral therapies for symptom management focusing on modifying interpretations of the cause and meaning of symptoms have been shown effective for cancer patients (Kwekkeboom, 1999; Gaston-Johansson et al., 2000). These interventions suggest that the effectiveness of cognitive-behavioral symptom interventions in cancer may be related to the malleability of illness appraisal.

One model (Kwekkeboom, 1999) of cognitive-behavioral symptom relief interventions for cancer patients posits that outcome expectancies, or beliefs about an intervention's likely effectiveness, help determine an intervention's success. The model was tested in a pilot study of a guided imagery pain intervention, (Kwekkeboom, 2001). Outcome expectancies were hypothesized as determined by experience with guided imagery, coping style and perceived credibility of the provider, variables that may be subject to the influence of illness appraisal and dispositional optimism. Pain outcomes were mean intensity, pain-related distress, affect and perceived control over pain. In this study, outcome expectancies were not shown to be significant predictors of pain

outcomes. Experience with guided imagery did predict outcome expectancies, but credibility of the provider and coping style did not. The degree of variance in pain outcomes predicted by the model varied widely among pain outcomes, from 3 to 48%, suggesting that the intervention influenced some outcomes considerably more than others.

Donovan & Ward (Donovan & Ward, 2001) developed a cancer pain intervention based upon self-regulation theory designed to induce conceptual change in persons living with cancer and their significant others. A standard pain educational program was administered to control subjects. Misconceptions about pain and analgesic use, operationalized as barriers to pain relief, were the target of conceptual change in the representational intervention group. Barriers to pain relief and pain severity were significantly lower in the representational intervention group after two months.

Health care providers typically assume that possessing biomedically accurate knowledge of disease causation and other disease facts enhances adaptation. However, biomedically inaccurate illness appraisals may promote coping by permitting patients to focus their energies on functional outcomes (Johnson, 1996), and "correcting" these illness appraisals may be counterproductive. It is therefore useful to describe adaptive and maladaptive illness appraisals, whether or not biomedically accurate, before embarking on interventions that alter illness appraisal.

Modifying illness appraisals requires preliminary research to identify specific targets of cognitive-behavioral treatment in the cancer population. One study (Hjerl et al., 2003) identified medically diagnosed depression as an independent risk factor for mortality from breast cancer. Meek (2003) identified anxiety as a consistent factor in

breathing distress among people with chronic lung disease. Ward (2003) targeted barriers to effective pain management in modifying beliefs about analgesia and pain in people with cancer and their spouses. These three studies are examples of three different targets of cognitive-behavioral intervention that may help produce symptom relief for people with lung cancer and their significant others. Explicating the relationship of illness appraisal to symptom distress in people with lung cancer will help identify potential targets of cognitive-behavioral symptom relief interventions.

Literature Summary

Lung cancer is a highly symptomatic disease that frequently carries a poor prognosis. The causes and effects of physical and psychological symptoms, and the distress associated with them, have been incompletely elucidated. Indeed, the words used to describe symptoms and their conceptualization and measurement remain loosely defined. Evidence is emerging, however, that symptom distress encompasses physical and psychological symptoms and is but one aspect of the complete symptom experience. The degree of distress associated with symptoms is individual and subject to influences that are, as yet, unknown.

Illness appraisal has not been studied in people with lung cancer, despite evidence of its impact upon health-related quality of life (Padilla, Mishel, & Grant, 1992; Hendriks, van Olffen, & Vingerhoets, 2000), health behaviors (Petrie & Weinman, 1997) and similar health outcomes. Lung cancer, especially those subtypes linked strongly to smoking, may be a special case of illness appraisal because of public and professional perceptions of lung cancer. A sense of personal responsibility for the disease may fuel shame or guilt in people with the disease, or it may contribute to improved illness

coherence. Knowledge of the characteristics of lung cancer patients' illness appraisals will help clarify these questions.

Nurse scientists are building a body of intervention research supporting the usefulness of altering illness appraisal for symptom relief. However, before furthering this work in people with lung cancer, an appreciation of the role of illness appraisal in influencing symptoms is needed. Understanding the influence of illness appraisal on symptom distress, as predicted by self-regulation theory, will help establish a theoretical base for the development of cognitive and behavioral symptom relief interventions in this population.

Theoretical Basis

Self-regulation theory is the theoretical basis for the study. Developed in the 1970's in the fields of psychology and nursing, self-regulation theory helps explain human behavior in the context of the illness or symptom experience. The theory has been applied in numerous clinical studies that have validated its usefulness in various populations. Its applicability to the present study lies in its linking the meaning of illness (illness perception or illness appraisal) to symptoms. For this reason, self-regulation theory may form a useful theoretical basis for the development of symptom relief interventions designed to alter illness perception using cognitive-behavioral methods. This section will describe the theory, review studies where it has been used, and provide the rationale for its use as the theoretical basis of the present study.

Description of the Theory. Leventhal and others (Leventhal, Nerenz, & Steele, 1984) described a common-sense illness model constructed by individuals experiencing symptoms ascribed to illness. Self-regulation theory posits that illness appraisal, or the

common-sense model of illness, directs individual responses to illness through cognitive representations that help direct coping responses. Subjective illness appraisal occurs in an iterative process of interpretation and evaluation, and is reflected in cognitive representations that drive responses to an illness or its symptoms. In self-regulation theory, Johnson (1999) states that interpretations and representations of symptoms are incorporated into cognitive schemata that are used to regulate illness behaviors. Goals and expectations are part of these schemata. Discrepancies between goals and expectations and actual illness experiences motivate people to take action to resolve the discrepancy.

The process by which this occurs is composed of dual cognitive pathways, the concrete-objective and the subjective, in which individuals attend to certain features of the experience, interpret the experience, and develop ways of coping in parallel processes that interact and modify each other. Concrete-objective features include physical sensations and symptoms, their causes, temporal characteristics and environmental features (Johnson, 1999). Minimizing disruption of usual activities is the goal of this pathway. The subjective features of an illness include emotions elicited and subjective evaluations of illness-related distress. Emotional comfort is the goal of the subjective pathway.

The self-regulation model as applied in this study is depicted in Figure 2. Symptom distress is part of the subjective pathway, influenced by emotional representations of illness. The other components of illness appraisal are conceptualized as part of the concrete-objective pathway (Moss-Morris et al., 2002; Cameron, Leventhal, & Leventhal, 1993). In the theoretical model, emotional representations and symptom

distress contribute to emotion-focused coping in the subjective pathway. The effectiveness of coping is evaluated against emotional goals, and fed back into the pathway if goals are not met. Symptom frequency and intensity are processed in the concrete-objective pathway. The two pathways interact and feed back into one another to modify coping responses.

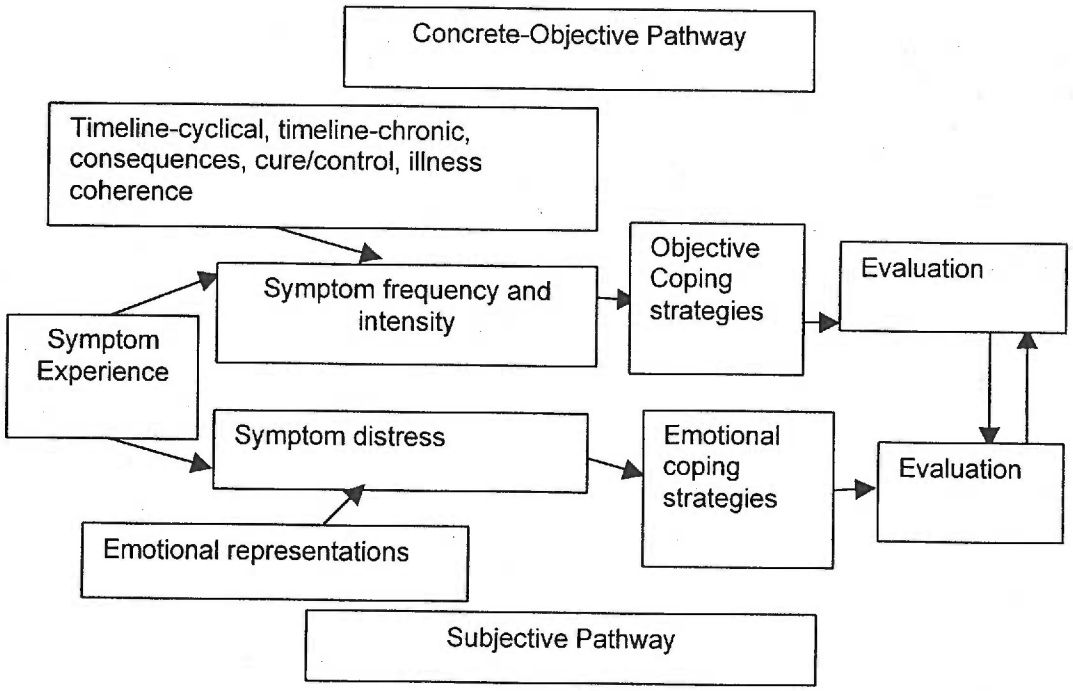


Figure. 2. Self-Regulation Model Adapted From Leventhal, Nerenz & Steele, (1984)

Research Using Self-Regulation Theory. Clinical studies validating the importance of providing concrete preparatory information to people facing a new health care experience have been conducted in many populations (Johnson, Fieler, Jones, Wlasowicz, & Mitchell, 1997). These studies included children undergoing cast removal, cancer patients preparing for radiotherapy, women undergoing a pelvic exam, people undergoing gastroendoscopy, and patients preparing for surgery.

In patients undergoing radiation therapy for cancer and people undergoing gastroendoscopy, Johnson showed that providing concrete-objective preparatory information enhanced functional outcomes and decreased the amount of sedation required among certain patients (Johnson, 1996; Johnson et al., 1997; Johnson, Morrissey, & Leventhal, 1973). This effect is explained by the intervention's effectiveness in helping patients reduce attention to subjective emotional responses and focus on functional outcomes of the concrete-objective pathway (Johnson, 1999), enhancing problem-focused coping. Consistent with this explanation, pessimistic people, who tend to focus on the emotional features of an experience, benefited more from concrete-objective preparatory information than optimists, who tend to focus on the concrete features of a new experience. Greater attention to the emotional features of an illness has been associated with negative mood (Suls & Fletcher, 1985), and Johnson's work suggests that interventions that guide patients to attend to the non-emotional features of a new health care experience improve functional outcomes. It is important to acknowledge, however, that the specific nature of the emotional representation of illness is not In a sample of Taiwanese NSCLC patients, (Kuo & Ma, 2002) participants with greater physical symptom distress had greater psychological distress and more use of emotion-focused

coping strategies. The Symptom Distress Scale and the Coping Strategies Scale were used to measure the major variables. Physical symptom distress and the frequent use of emotion-focused coping strategies explained 48.8% of the variance in psychological symptom distress. Although causal relationships cannot be inferred from this study, the relationships demonstrated are congruent with self-regulation theory and provide a link to the use of emotion-focused coping commonly associated with less optimistic dispositions. This study is the one in the literature that is most similar to the present study, although the operationalization of symptom distress and the measurement of coping strategies versus dispositional optimism make the two studies somewhat difficult to compare.

Rationale for the Use of Self-Regulation Theory in the Present Study. Cognitive-behavioral interventions for the treatment of symptoms in cancer and other patients were described in the preceding section. Randomized controlled trials of these interventions, and other supporting studies, provide evidence that altering illness appraisal can ameliorate symptoms, even if biological factors are not directly influenced by the intervention.

Johnson conducted the first nursing studies of these interventions. Johnson's research supports interventions aimed at enhancing coping in the concrete-objective pathway. However, less research has been conducted on the subjective pathway, where symptom distress is processed. This pathway is the focus of the present study.

If the relationships posited in self-regulation theory are not completely mediated by other intervening variables, it should be possible to show relationships among aspects

of illness appraisal and the three theorized components of the symptom experience. That is the overriding objective of this study.

CHAPTER 3

Design and Methods

The study uses a cross-sectional exploratory survey design with a set of four questionnaires to elicit information and perceptions from participants. The overall objective is to identify relationships hypothesized in self-regulation theory in people with NSCLC. The cross-sectional, exploratory design was chosen over a more complex prospective, longitudinal design for several reasons. First, the illness appraisals of people with NSCLC have not been examined previously. As such, there were no pilot data on this major predictor variable on which to base hypotheses and statistical power estimates for a prospective, longitudinal, predictive research design. Second, no studies have been published where the subscales of the IPQ-R were used as predictors in multiple regression. Third, no studies were found documenting correlations among the IPQ-R subscales, so it was not possible to confirm the independence of the elements of illness appraisal.

Theory suggests that certain subscales, such as personal control and curability/controllability may well be intercorrelated. Because of the risk of multicollinearity among the subscale scores, the characteristics of the IPQ-R subscales in multiple regression had to be understood before embarking upon attempts at prospective, predictive uses of the IPQ-R, such as in an attempt to predict coping effectiveness or adaptation to illness. In this sense, this study acts as a pilot study of the use of the IPQ-R subscales not only in this population but with regard to certain inferential procedures such as multiple regression. Third, more complex statistical procedures such as canonical correlation or path analysis might have been employed to strengthen and clarify the study

conclusions, but the limited availability of potential participants with NSCLC would have required a much longer period of recruitment to gain the necessary sample size to achieve adequate statistical power. The various recruitment methods employed in the study are fully addressed in Chapter 4. Fourth, the MSAS was scored in a novel way for the study in an attempt to differentiate symptom distress from intensity and frequency, as proposed by self-regulation theory. This study, therefore, piloted a novel method of scoring an established symptom instrument, and the feasibility of this scoring method had to be established before subjecting scores to more complex statistical procedures. For these reasons, an exploratory, cross-sectional pilot study was most suitable to begin answering the research questions.

Instruments

The study variables and measures are summarized in Table 3.

Table 3.

Study Variables and Measures

Variable	Measure
Symptom frequency, intensity, & distress	MSAS
Illness appraisal dimensions	IPQ-R
Dispositional optimism	LOT-R
Age, gender, race, ethnicity, marital status. living situation, stage of illness, concurrent illnesses, current treatment & length of Illness	Demographic Data Sheet

Demographics. A demographic data form created by the PI was completed by subjects, and any missing information was garnered from the paper or electronic medical chart. Information that subjects did not know and that required seeking out the medical chart typically consisted only of stage of cancer and concurrent illnesses, although all subjects recruited through the Internet and many of the others knew this information. Race, age, gender, ethnicity, living situation, marital status, current treatment, smoking status, and length of illness were typically completed by the subject without difficulty. The demographic data sheet and all other instruments used in the study are in Appendix B.

Symptom Dimensions. In the Memorial Symptom Assessment Scale (MSAS) (Portenoy et al., 1994a), a set of symptoms is evaluated in terms of intensity, frequency and/or distress. To rate the distress dimension, respondents are asked how much a symptom bothers or distresses them. In this way, distress is directly measured in a manner that incorporates the meaning of distress to the respondent, permitting valid comparison of subjective distress ratings with symptom intensity and frequency ratings.

The MSAS includes 35 symptoms. Of these, 24 are rated in terms of frequency, intensity and distress, and 8 are rated in terms of intensity and distress only. The eight symptoms that are not rated in terms of frequency are mouth sores, change in food taste, weight loss, hair loss, constipation, swelling of arms or legs, "I don't look like myself," and skin changes. There are three spaces for the respondent to add symptoms not covered elsewhere in the questionnaire, and these three are rated in terms of distress or bother only.

The MSAS was chosen for this study because it was the only symptom assessment instrument found in the literature search that evaluated many symptoms on all three dimensions (frequency, intensity and distress.) The fact that all thirty-five items queried distress or bother was an important strength for this study's purposes. The MSAS has prior use in people with cancer, although it has not been used extensively in people with lung cancer.

The factor structure of the MSAS divides the scale into psychological, high-prevalence physical and low-prevalence physical subscales. In the initial tool validation study, Cronbach's alpha internal consistency coefficients in the high-prevalence physical and psychological factors were 0.88 and 0.83, respectively, and in the low-prevalence physical factor was 0.58 (Portenoy et al., 1994b). Mean symptom scores may be computed by simply adding the responses to each dimension for a symptom and dividing by the number of dimensions. The scale's author recommends scoring the MSAS using its three summary scales: a psychological subscale, a physical subscale and a global distress index (GDI), comprised of a set of most frequently occurring symptoms. The GDI uses either intensity or distress items from the group of high-prevalence symptoms identified in the factor analysis. The psychoemotional and physical subscales are comprised of a set of summed mean symptom scores.

The MSAS has been repeatedly validated in samples of people with life-threatening illness. The MSAS has been used to measure physical and psychological symptom distress in people with AIDS (Vogl et al., 1999) recurrent cancer (Kennelly, 1994), various cancers (Hwang, et al, 1999), and chronic obstructive pulmonary disease (Gift & Shepard, 1999).

Cronbach's alpha coefficients for the previously validated subscales of the MSAS, (the physical, psychoemotional and global distress indexes) and the frequency, intensity and distress dimensions calculated for this study are presented in Table 4. Nine symptoms were endorsed by at least 9 (53%) of the respondents. To remove inflation of the reliability coefficients of the symptom dimensions caused by multiple zero values on infrequently-endorsed symptoms, symptoms endorsed by 9 more respondents were grouped into three high-frequency symptom dimensions. These high-frequency symptom dimensions consisted of responses to nine items: pain, lack of energy, cough, feeling nervous, drowsiness, difficulty sleeping, shortness of breath, worrying and lack of appetite. Three 7-item high-frequency physical symptom dimensions were constructed, consisting of only physical symptoms experienced by more than nine respondents, omitting the items feeling nervous and worrying.

Table 4.

Reliability Coefficients of Measures

Scale	Cronbach's alpha	Number of items
LOT-R	.71	6
IPQ-R Timeline	.84	6
IPQ-R Time-Cyclical	.72	4
IPQ-R Illness Coherence	.83	5
IPQ-R Personal Control	.87	6
IPQ-R Cure/Controllability	.89	5
IPQ-R Consequences	.10	6
IPQ-R Emotional Representations	.70	6
MSAS GDI	.78	10
MSAS Psych	.89	6
MSAS Phys	.85	12
MSAS frequency item mean of all items	.83	24
MSAS intensity item mean of all items	.89	32
MSAS distress item mean of all items	.85	32
MSAS HF symptom frequency	.66	9
MSAS HF symptom intensity	.68	9
MSAS HF symptom distress	.74	9
MSAS HF physical symptom frequency	.66	7
MSAS HF physical symptom intensity	.74	7
MSAS HF physical symptom distress	.72	7

Note: LOT-R = Life Orientation Test – Revised, IPQ-R = Illness Perception Questionnaire - Revised, MSAS = Memorial Symptom Assessment Scale, MSAS GDI = MSAS Global Distress Index, MSAS Psych = MSAS psychoemotional subscale, MSAS Phys = MSAS Physical subscale, HF= high frequency

Illness Appraisal. Illness appraisal was evaluated with the Illness Perception Questionnaire-Revised (IPQ-R) (Weinman, Petrie, Moss-Morris, & Horne, 1996; Moss-Morris et al., 2002). The IPQ-R measures the cognitive appraisal of illness on seven subscales: illness identity, timeline (acute, chronic or cyclical), consequences, control-cure, illness coherence, emotional representations and causes. The original version of the IPQ-R evaluated the five dimensions identified by Leventhal and colleagues in the development of the self-regulation model: causes, identity, timeline, control-cure and consequences. The revised version added two subscales, emotional representations and illness coherence, to enhance consistency with self-regulation theory and psychometric qualities (Moss-Morris et al., 2002). In the illness identity subscale, fourteen symptoms are rated yes or no, according to whether the respondent has experienced the symptom and whether the respondent believes the symptom is related to the illness. The illness identity subscale is not suitable for parametric analysis. The next five subscales are rated in a series of questions where the respondent indicates agreement or disagreement on a Likert-type five-point scale. Examples are: "My illness will last a short time," (timeline scale) and "My illness makes me feel afraid," (emotional representations scale.) The final subscale, causes, differentiates groups of respondents according to their causal beliefs about the illness. Potential causes are listed, e.g. "pollution in the environment", "my own behavior", and subjects rate the extent to which they endorse the causes on a 5-point Likert scale. Subjects also are asked to write in the three most important causes of their illness, in their opinion. This subscale is useful for differentiating subjects who attribute their illness to personal behaviors and those who do not.

The IPQ-R and its parent tool, the IPQ, have been used in chronic obstructive pulmonary disease (Scharloo, Kaptein, Weinman, Willems, & Rooijmans, 2000), myocardial infarction (Cherrington, 2001), HIV (Moss-Morris et al., 2002), chronic fatigue syndrome (Moss-Morris, 1997; Moss-Morris, Petrie, & Weinman, 1996), and other illnesses. There are no published studies where the IPQ or IPQ-R were used in lung cancer. Subscale internal consistency reliability alphas ranging from .79 to .89 were demonstrated in patients with rheumatoid arthritis and renal failure (Moss-Morris et al., 2002). Test-retest reliability for the subscale dimensions ranged from .35 (timeline-cyclical) to .80 (illness identity.) Discriminant, known group and predictive validity were demonstrated for the IPQ-R in the same study.

Internal consistency reliability of the subscales was calculated using Cronbach's alpha. Table 6 shows these values. Internal consistency reliability coefficients were acceptable (>.70) except for the consequences subscale of the IPQ-R ($\alpha = .10$). Item analysis revealed responses to items IP7 (my illness has major consequences on my life), and IP10 (my illness has serious financial consequences) were the most inconsistent. Removal of IP10 alone only increased the reliability coefficient to .22. Removal of IP7 alone changed the reliability coefficient to -.36. Income data were not collected in this study, but possibly the insurance status and income made financial consequences of little concern to the study participants. The consequences subscale was excluded from further analyses because of very low internal consistency reliability that was not remedied by excluding the most problematic items.

Dispositional Optimism. The Life Orientation Test –Revised (LOT-R) was used to measure subjects' tendency toward optimism versus pessimism. The LOT consists of

ten items, six scored and four filler questions that are marked by subjects in a five-point Likert-type format. The range of scores is 6 to 30, with higher scores indicating greater optimism. The scale has been used in cancer patients and showed acceptable internal consistency reliability previously (Carver & Scheier, 1994; Johnson, 1996) and in the current sample.

Sample

A convenience sample of outpatients with a medical diagnosis of non-small cell lung cancer was recruited from three hospitals in Portland, Oregon, and from an Internet lung cancer support group website. The *a priori* power analysis revealed that, if alpha = .10, approximately 50 subjects would yield a power of .78 to detect a change in R squared of .06 upon entering a thirteenth variable into the model (Hintze, 2000). The initial recruitment goal was 60, chosen to compensate for incomplete or uninterpretable questionnaires and enrollees who were unable or unwilling to complete all the study forms.

Four outpatient facilities in three hospitals in the Pacific Northwest were used as study sites. Attempts to gain permission to enroll participants at two other locations were unsuccessful.

All consenting people with non-small cell lung cancer at the three participating hospitals were eligible. The inclusion criteria were: 1) medically diagnosed non-small cell lung cancer and 2) cognitive ability to provide informed consent. Exclusion criteria were: 1) non-English speaking and 2) thoracotomy within the past month.

Non-small cell lung cancer was chosen because it is the more prevalent type of lung cancer and it is treated with chemotherapy, radiotherapy and/or surgery. In contrast,

small cell lung cancer is less common and is rarely treated surgically. Participants with various disease stages and various treatment regimens were desired to maximize variability on the illness appraisal and symptom measures, so NSCLC was selected. Lung cancer was of interest because of its often poor prognosis and the "blame the victim" mentality cited by lung cancer advocates. The PI hoped that these factors might increase variability on the IPQ-R emotional representations subscale to enhance generalizability of the findings.

People who were not cognitively able to provide informed consent were excluded for the protection of these vulnerable individuals and because they would likely be unable to complete the study instruments. None of the study instruments has been translated into languages other than English, so the study was limited to English-speaking participants. Additionally, in this pilot study, the cultural differences that accompany language differences might have added variability in perceptions of illness that was not desirable in this limited study.

Individuals who had undergone a thoracotomy in the past month were excluded to eliminate the effects of short-term immediate post-thoracotomy symptoms such as incisional pain and decreased functional status. The long-term persistence of post-thoracotomy symptoms was viewed as a potential cause of symptoms and a potential influence on illness appraisal, but not likely to mediate or moderate the relationships of interest in this study, so remote thoracotomy did not exclude participation.

Recruitment. Despite the use of several different recruitment strategies, the initially desired sample size of 60 was not achieved. The inability to achieve the desired N may be explained in two ways. First, Spring, 2003, saw the beginning of enforcement

of the privacy provisions of the 1997 Health Information Portability and Accountability Act (HIPAA.) These portions of the act put into place stricter enforcement of privacy of personal information, called protected health information (PHI), and allowed for substantial fines to institutions if the privacy of PHI was breached. At Hospital 1, where data collection began, HIPAA required no explicit changes with respect to the divulging of PHI, because the privacy protection elements of the law were already written into institutional policies. Nonetheless, the law did create a need for consistent documentation of permission to divulge. What was previously a three-sentence form, created by the principal investigator (PI) in large type at a 6th grade reading level, became a formal consent to discuss research that required the subject's signature, date, details of what information would be divulged and to whom, the purpose of the disclosure, when the disclosure would end, and the PIs name and address. The new form was in small type and written at the 12th grade level, as analyzed by the Flesch-Kincaid reading grade level method in the word processing program Microsoft Word for Windows 2000 ®.

The new form may have presented a barrier to recruitment because health care workers were required to make the initial request of the subject, explain the form, obtain the potential participant's signature and file the form in the medical record. Additionally, the extensive training preceding implementation of the HIPAA privacy rules may have confused some staff regarding their role in the protection of PHI, and they may have been reluctant, therefore, to share information with the PI, who was not an employed at the facility.

An example of reluctance to assist with recruitment occurred in two radiation oncology departments where physicians were unwilling to offer lung cancer patients

written information regarding the study, and the departments' managers were unwilling to ask the staff to provide lung cancer patients with the necessary form. One radiation oncology department did allow the PI to place a recruitment flyer and the PIs contact information on business cards in the patient waiting area.

This experience is echoed in a recent report on the effects of the HIPAA privacy rule on research that was issued by a subcommittee of the National Cancer Advisory Board. The report states, "Uncertainty about the requirements of the rule, and excessive fear of sanctions…are having wide-ranging repercussions," (Anonymous, 2003, p.11). Varying interpretations of the HIPAA privacy rule, the level of language in consent and authorization forms and adverse effects on study recruitment and generalizability are cited as among the problems associated with the privacy rule (Oncology News International, 2003).

The other major reason for the failure to recruit sixty subjects was that this study, unlike a treatment study, involved only information collection from subjects, without a clear benefit to them for taking part (aside from altruistic reasons.) In a study of palliative care patients, (Crowley & Casarett, 2003), willingness to participate in a non-treatment study was shown to be lower than in a study offering hope of modifying the disease process.

In the context of lung cancer, a preference by patients to restrict expenditures of their limited time and energy to pursuits that offer hope of curing or controlling the disease process is understandable. Many people with lung cancer are highly symptomatic at the time of diagnosis or soon after and are faced with a short life span, complex treatment decisions, and end-of-life decisions that dominate their attention. A percentage

of potential study participants enter hospice programs and have little contact with the health care system after diagnosis. Recruiting these individuals could be accomplished through home visits in partnership with a hospice organization, and it may be necessary to alter the study design to reduce the length and number of instruments to accommodate these individuals.

Procedures

Institutional Review Board (IRB) approval was obtained from each participating hospital. Permission to post a recruitment message on the online lung cancer support group website was sought from the site administrator. After IRB approval, the PI registered as a member of the online support group and occasionally posted lung cancer-related information and supportive messages on the Internet bulletin board. No mention was made in these posts regarding participants in the study, progress of recruitment efforts or study results. The IRB-approved recruitment message was the only information about the study posted by the PI on the online support group. The same recruitment message was posted at the Oregon Health & Science University research recruitment website found at http://www.ohsu.edu/research/rda/so/#7589. Participants were offered a summary of their own survey results. The text of the website recruitment message, a sample participant feedback letter, the recruitment flyer and all IRB approvals are found in Appendix C.

Recruitment flyers coupled with take-away business cards containing the PI's contact information were placed at three locations at PSVMC. Potential participants were identified with the assistance of staff nurses, physicians, receptionists, and medical

assistants at all three participating hospitals. Individual institutional policies were followed for recruitment and enrollment.

Table 5 shows the recruitment methods employed to enroll the final seventeen participants in the study.

Table 5.

Recruitment Methods, Locations And Number Recruited

Location and Method of Initial Contact	Number Recruited
Hospital 1 physician office staff requests	N/A
Cardiothoracic surgeon	3
Pulmonologist 1	2
Pulmonologist 2	0
Pulmonologist 3	1
Hospital 1 Outpatient Infusion RN requests	2
Hospital 1 Recruitment flyers	0
Hospital 2 research website advertisement	0
Hospital 2 thoracic surgery clinic PI requests	2
Message on private lung cancer advocacy website	2
Hospital 3 Outpatient Chemotherapy staff requests	5

Human Subjects Protections. This study entailed little risk to participants. There was a risk that completing the study may have fatigued subjects or brought to mind distressing thoughts and memories of unpleasant experiences. The PI assured participants of their right to leave the study tools incomplete, and the PI was available to discuss the results with subjects after the study tools were completed. The PI shared the email address especially set up for this study and her cell phone number with all participants.

None of the participants indicated that taking part induced fatigue or upset. Eight potential participants who agreed to consider taking part were given the study forms but did not return any of them. Their reasons for not taking part are not known.

Limitations

The cross-sectional exploratory design of this study is well-suited for identifying potentially important relationships that have not been previously studied. However, this design does not establish these relationships as reliable and valid, it merely suggests that they are worthy of further study. With alpha set at .10, the probability of identifying as significant a non-significant relationship, i.e., making a Type I error, is twice the customary probability of .05. It is likely that further studies with larger samples will establish that some of the relationships discovered in this study are spurious.

A related issue is that many comparisons will be made in exploring all the demographic and illness appraisal variables for relationships to symptom distress. In multiple comparisons, the risk of Type I error rises as more comparisons are made. Because of the exploratory nature of this study, no adjustments are made for the "alpha inflation" that will occur in the exploratory analysis, increasing the Type I error rate.

A final limitation of the study is that the population of the geographic area in which it is conducted is primarily Caucasian, with small percentages of African-American, Native American, Asian, Hispanic, Pacific Islander and other racial and ethnic groups. This is particularly problematic with respect to African-Americans whose rate of lung cancer incidence exceeds that of Caucasian Americans. Cultural differences between racial and ethnic groups may severely limit the generalizability of findings with respect to the relationship between illness appraisal and symptom distress.

CHAPTER 4

Results

Sample Characteristics

Participants from four states (Massachusetts, Ohio, Oregon, and Washington) were recruited, consented and completed the study forms over ten months between February and December, 2003. Of thirty-five potential participants approached for study participation, thirty-three agreed to consider taking part in the study. Nineteen (57.5%) actually returned usable sets of questionnaires. One participant was excluded because it was found that the lung cancer was considered cured, and another was excluded because the consent form was not returned with the study forms and the subject could not be contacted again to gain consent, leaving a final sample of 17.

The median age of the final sample (N=17) was 66 years, ranging from 46 to 79 years. The median length of time since lung cancer diagnosis was 10 weeks, ranging from 1 to 114 weeks. Table 6 shows the number, percentages, mean values and ranges of the characteristics of the sample. There were no Native American, Alaskan Native, Pacific Islander, Hawaiian, Caucasian Hispanic, or Asian participants.

Table 6.

Demographic Characteristics of the Sample

Characteristic	Number	(Percent) [Mean] {Range}
Male gender	11	(64.7)
Age in years	n/a	[64.7] {33}
Smoking Status		
Current	5	(29.4)
Past	10	(58.8)
Never	2	(11.8)
Race		
Caucasian, non-Hispanic	16	(94.1)
African-American	1	(5.9)
Marital Status		
Married	14	(82.4)
Unmarried	3	(17.7)
Living Situation		
Alone	1	(5.9)
With non-spouse	1	(5.9)
With spouse	15	(88.2)
Current Treatment Regimen		
Chemotherapy	9	(52.9)
Radiation	4	(23.5)
Stage		
I, II or IIIA (early)	8	(47.1)
IIIB or IV (late)	9	(52.9)
Length of illness in weeks	n/a	[28.1] {113}

Table 7 shows the concurrent illnesses experienced by subjects. The median number of concurrent illness was 1, ranging from zero to three. In the participants recruited from the online support group, access to medical records was not possible, so these data were strictly self-reported.

Table 7.

Concurrent Illnesses Experienced By Participants

Illness	Number of Participants
Hypertension	4
Chronic Obstructive Pulmonary Disease or emphysema, atherosclerosis	3 each
Prior thoracotomy, diabetes mellitus, chronic back pain, congestive heart failure, thromboembolic disease	2 each
Other cancer, Reiter's syndrome, radiation pneumonitis, rheumatoid arthritis	1 each
None	4

Descriptive Analysis

Descriptive statistics were used to depict the means and range of responses to the IPQ-R, LOT-R, and MSAS. The Kolmogorov-Smirnov test was used to test the normality of the distributions. None of the demographic variables were normally distributed. Of the

illness appraisal dimensions, all but illness coherence were normally distributed. Normality tests of the various MSAS subscales that were explored in this study are described with their results.

Illness Perception Questionnaire - Revised. The IPQ-R means for the illness coherence, emotional representations, cure/controllability, timeline, time-cyclical and personal control subscales of the IPQ-R are displayed in Table 8.

Table 8.

Descriptive Statistics of IPQ-R Subscales

IPQ-R Subscale	Mean [Minimum, Maximum] (Standard Deviation)	Number (Percent) Missing
Illness Coherence	3.82 [2.00, 5.00] (.71)	0
Emotional Representations	3.25 [1.67, 5.00] (.89)	0
Timeline	3.25 [1.67, 5.00] (.89)	1 (5.9%)
Time-cyclical	2.24 [1.00, 3.25] (.65)	0
Cure/Controllability	3.72 [1.40, 5.00] (.89)	1 (5.9%)
Personal Control	3.61 [1.00, 5.00] (.95)	1 (5.9%)

The causal dimension subscale ends with three blank spaces and instructs the participant to list the most important causes of the illness in his or her opinion. Of thirty-seven responses, smoking was by far the most frequently endorsed (N=17). Of these seventeen, six responses were from two participants who listed smoking three times as the top three causes of their lung cancer. Overall, twelve of seventeen subjects (70.6%) listed smoking as among the top three causes of their illness. Fifteen of seventeen (88%)

were current or former smokers. Aging, environmental pollution and heredity or family history were each written in three times. All other responses were single incidences. The complete results of the causal dimension Likert-type scale of the IPQ-R are represented in Table A4 in Appendix A. The causes written in by the study participants in the open-ended portion of the causal subscale are shown in Table 9.

Table 9.

Participants' Listed Top Three Causes Of Lung Cancer

Cause	Frequency
Smoking	17
Aging, environmental pollution, heredity or family history	3 each
Altered immunity, the U.S. Army, Vietnam, bad luck, drug use, secondhand smoke, changing societal attitudes, germ or virus, stress, diet, overwork	1 each

Memorial Symptom Assessment Scale. Descriptive statistics for the two high-frequency symptom subscales are presented in Table 10.

Table 10.

Descriptive Statistics: MSAS High-Frequency Symptom Subscales

Subscale	Mean (S.D.)
HF symptom frequency	1.7 (.71)
HF symptom intensity	1.4 (.63)
HF symptom distress	1.1 (.73)
HF physical symptom frequency	1.8 (.85)
HF physical symptom intensity	1.5 (.74)
HF physical symptom distress	1.1 (.83)

Note: HF = high frequency

All symptoms were endorsed by at least two respondents. The number of symptoms per respondent ranged from 1 to 33. Mean symptom scores were fairly low overall, with none exceeding 2.5. Lack of energy, cough and shortness of breath were the three symptoms with the highest individual symptom scores, calculated as the mean of the frequency, intensity and distress dimensions. Figure 3 shows all the symptoms in decreasing order of mean score.

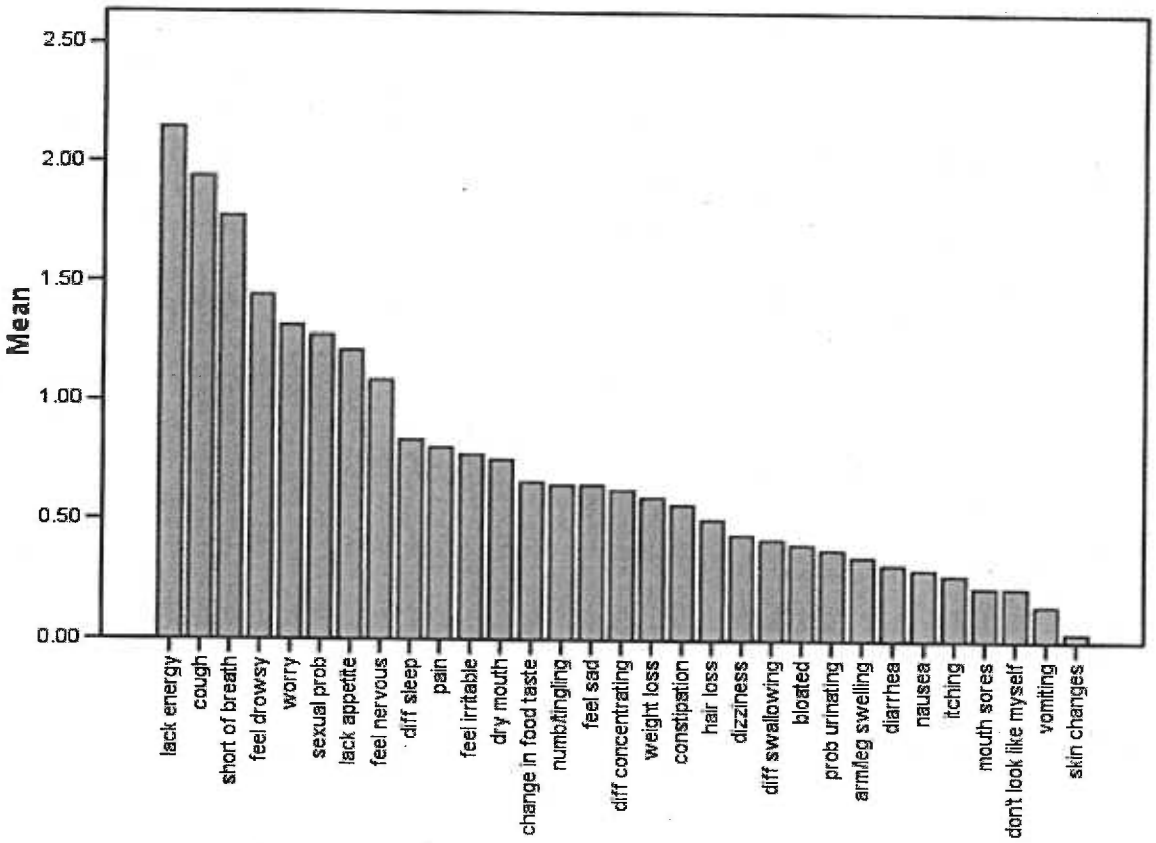


Figure 3. Mean Symptom Scores for all Items on the MSAS

The MSAS was designed to provide information about individual symptoms and the dimensions identified in the original factor analysis (Portenoy. et al, 1994a). The MSAS was first scored in the manner recommended by the authors using the subscales derived in the original factor analysis in a study of people with various types of cancer (Portenoy, et al, 1994a.) This procedure produced scores for each symptom and for psychoemotional, physical and global distress index subscales. Mean scores on these three subscales are shown in Table 11.

Table 11.

MSAS Subscale Means and Standard Deviations

Subscale	Mean (S.D.)
Global Distress Index (GDI)	9.9 (1.7)
Psychoemotional	5.9 (1.4)
Physical	10.1 (1.8)

The literature search and a personal communication with the author of the MSAS (R. Portenoy, 2003) revealed no instances where the three symptom dimensions measured with the instrument were analyzed separately. Therefore, several methods of scoring the MSAS to derive subscale scores for each of the three symptom dimensions were devised and evaluated. Table 12 summarizes the results of these methods.

Table 12.

Scores Produced by Various MSAS Symptom Dimensions Scoring Methods - Sample Mean, [Minimum, Maximum], (S.D.)

Method	Frequency (24 items)	Intensity (32 items)	Distress (32 items)
Sum across all items	27.0 [2,48] (13.2)	27.0 [2,57] (15.8)	18.5 [2.0, 39.0] (12.7)
Mean of all items	1.1 [.08,2.0] (.55)	0.8 [.06,1.78] (.49)	0.6 [.06,1.22] (.40)
Endorsed item mean	2.1 [1.44, 2.81] (.424)	2.0 [1.44, 2.52] (.37)	1.4 [.3, 2.33] (.63)

The simplest method of summarizing each symptom dimension separately is to sum the responses to the frequency, intensity and distress items across items. This scoring method treats increasing symptoms in an additive fashion, as do many symptom assessment scales, accounting for the added impact of additional symptoms. A drawback of simple sums, however, is that they do not differentiate the impact of many low-level symptoms from that of a few symptoms of high frequency, intensity and distress. Additionally, eight fewer items are rated in terms of frequency than in terms of intensity and distress on the MSAS, so simple sums do not permit comparisons across all symptom dimensions.

A second alternative explored was to sum each of the three symptom dimensions and divide by the total number of items in the dimension subscale. This produced mean frequency, intensity and distress indexes that were referenced to a potential maximum

number of symptoms. Symptoms not experienced by the respondent, or not associated with any distress, reduced the respondents' mean score. The three mean scores thus produced were entitled frequency mean of all items, intensity mean of all items, and distress mean of all items. This method did not solve the problem of failing to distinguish between a few, high-scoring symptoms and many, low-scoring symptoms, but it did return the scores to the original scale for ease of interpretation, allowing for comparisons between symptom dimensions.

Totaling all the items in a single symptom dimension and dividing by the total number of symptoms endorsed by the respondent yielded a mean undistorted by zero values on the symptoms not experienced. These means provided an index of the average frequency, intensity and distress of only the symptoms experienced by the participant. It may be useful to calculate mean scores this way as an indicator of the symptom experience if it is assumed that the effect of additional symptoms is not additive, or if other methods are incorporated to account for the effects of differing numbers of symptom among participants, such as statistical weighting. However, assuming that the effect of more symptoms is not additive seems to contradict observations from practice as well as theory (Lenz, Pugh, Milligan, Gift, & Suppe, 1997).

Naturally, the endorsed item means were higher than the item means of all items because most participants did not endorse all the symptoms. Calculating endorsed item means altered the distributions of the scores, which may be helpful in normalizing skewed distributions, but conceptual issues surround the validity of a score reflective of the mean frequency, intensity and distress of only the symptoms experienced by the respondent. Adding more symptoms at or below the mean of the pre-existing symptoms

does not produce a higher score with this method, so endorsed item means may blunt the contribution to the global symptom experience made by the co-existence of multiple symptoms.

Comparisons between symptoms with the highest intensity ratings and symptoms with the highest distress ratings were made to evaluate whether some symptoms are more distressing than others. These results are shown in Table 13.

Table 13.

Mean Intensity and Distress Ratings of Ten Highest Intensity Symptoms

Symptom	Mean (S.D.) Intensity	Mean (S.D.) Distress
Lack of energy	1.7 (1.5)	2.1 (1.3)
Cough	1.5 (1.5)	2.0 (1.2)
Shortness of breath	1.4 (1.1)	1.6 (1.0)
Worrying	1.3 (1.6)	1.5 (1.5)
Sexual problems	1.2 (1.7)	1.5 (1.7)
Drowsiness	1.2 (1.3)	1.5 (1.2)
Feeling nervous	.82 (1.2)	1.1 (1.2)
Difficulty sleeping	.82 (1.2)	1.1 (1.2)
Feeling irritable	.76 (1.2)	.62 (1.1)
Feeling sad	.71 (.98)	.56 (.81)

Life Orientation Test - Revised. The mean LOT-R score was 15.6 (S.D. 4.20) on a 6 to 30 scale where 6 indicates minimal optimism and 30 indicates maximum optimism.

Scores in this sample ranged from 9 to 24. Prior investigators (Robinson-Whelen, et al, 1997) have suggested that the positively-worded and negatively-worded items may comprise separate optimism and pessimism subscales, respectively, with potential scores ranging from 3 to 15. However, this scoring method has not been widely adopted, and the scores obtained in this manner were uninterpretable. The original scoring method was therefore retained to facilitate interpretation in relation to prior published work and the relationship between LOT-R scores and symptom reports.

Exploratory Analysis

Demographic and clinical variables were subjected to bivariate correlations. Spearman's rho, a nonparametric statistic, was used because not all variables were normally distributed and Spearman's rho is less subject to the effects of outlying values than Pearson's r, a parametric correlation coefficient. Categorical variables were coded for this part of the analysis as shown in Table 14.

Table 14.

Coding Of Categorical Variables

Variable	Coding
Marital status	0 = unmarried 1 = married
Living situation	0 = with significant other 1 = alone
Smoking status	0 = current 1 = past 2 = never
Stage category	0 = early 1 = late
Gender	0 = male 1 = female
Current chemotherapy	0 = no 1 = yes
Current radiotherapy	0 = no 1 = yes

Race and ethnicity were excluded from the correlational analysis because of lack of variability. Spearman's rho correlations showed that fewer women than men were receiving current chemotherapy ($r_s = -0.5$, $p = .05$), more participants with early stage cancer were married ($r_s = 0.4$, $p = .08$), and participants with longer duration of illness were more likely to be receiving current chemotherapy ($r_s = 0.5$, $p = .03$), and less likely to be undergoing current radiotherapy ($r_s = -0.5$, $p = .06$). Table 15 shows all the

correlations among demographic and clinical variables. Significant correlations are boldfaced.

IPQ-R. Table 16 depicts the zero-order correlations of demographic and clinical variables with illness appraisal dimensions. Significant correlations are boldfaced. The only demographic or clinical variable significantly correlated with emotional representations was age. None of the other illness appraisal dimensions were intercorrelated with emotional representations. Current chemotherapy was associated with longer illness duration in weeks and current radiation was associated with shorter illness duration. This finding is consistent with lung cancer treatment practices where maximal radiation doses are administered early in the course of treatment, making people with longer illness duration eligible only for chemotherapy. Similarly, the timeline dimension of illness appraisal was associated with chemotherapy and with longer illness duration, but not with radiation.

The cure/control and personal control dimensions of illness appraisal were associated with current chemotherapy, current radiation and illness duration. The positive correlations of personal control and cure/control with current radiation suggest that participants undergoing radiation had confidence in their treatment regimens. Negative correlations of personal control and cure/control with chemotherapy may be reflective of the longer duration of illness among people receiving chemotherapy.

Table 15.

Spearman's rho Correlations of Demographic and Clinical Variables

		1	2	3	4	5	6	7	8
1 Age	r_s	1.000							
	significance	.							
2 Gender	r_s	-.025	1.000						
	significance	.924	.						
3 Marital status	r_s	-.016	-.304	1.000					
	significance	.952	.236	.					
4 Living situation	r_s	.281	.339	**-.540**	1.000				
	significance	.275	.184	.025	.				
5 Current chemotherapy	r_s	-.277	**-.477**	-.040	-.161	1.000			
	significance	.282	.053	.879	.536	.			
6 Current radiation	r_s	-.354	.171	-.107	-.139	-.358	1.000		
	significance	.163	.512	.683	.596	.158	.		
7 Stage category	r_s	-.169	.203	**-.436**	.236	.350	.245	1.000	
	significance	.518	.434	.080	.362	.169	.343	.	
8 Weeks since diagnosis	r_s	-.159	-.050	-.221	.256	**.529**	**-.469**	.338	1.000
	significance	.543	.848	.393	.321	.029	.058	.184	.
9 Smoking status	r_s	-.034	-.172	.376	-.348	-.270	.193	-.082	-.149
	significance	.898	.510	.136	.170	.295	.457	.754	.568

Note: Statistically significant correlation coefficients are shown in boldfaced font.

Table 16.

Spearman's rho Correlations of Demographic and Clinical Variables with Illness Appraisal Dimensions

		Timeline	Time-cyclical	Consequences	Personal control	Cure/control	Illness coherence	Emotional representations
Age	r_s	-.19	.16	**-.61**	-.05	.01	-.34	**-.43**
	significance	.47	.53	**.01**	.86	.98	.19	**.08**
Gender	r_s	-.19	-.10	.01	.26	.28	.24	.23
	significance	.48	.69	.96	.32	.31	.35	.38
Marital status	r_s	-.02	.11	-.23	.07	.18	.11	-.36
	significance	.95	.67	.40	.80	.53	.67	.15
Living situation	r_s	-.08	.31	-.11	.08	-.03	-.34	.23
	significance	.76	.22	.68	.76	.91	.19	.37
Current chemotherapy	r_s	**.45**	-.01	.08	**-.57**	**-.65**	-.03	-.05
	significance	**.08**	.96	.77	**.02**	**.01**	.92	.84
Current radiation	r_s	-.19	-.28	.28	**.42**	**.44**	-.04	.14
	significance	.49	.28	.29	**.10**	**.10**	.87	.59
Stage category	r_s	.37	-.35	**.45**	-.22	-.16	-.10	-.06
	significance	.16	.17	**.08**	.41	.58	.71	.82
Weeks since diagnosis	r_s	**.63**	.26	-.09	**-.74**	**-.70**	.11	.06
	significance	**.01**	.31	.74	**.00**	**.00**	.68	.83
Smoking status	r_s	.01	.02	.02	.05	.29	.11	-.20
	significance	.97	.95	.93	.84	.29	.69	.45

Note: Statistically significant correlation coefficients are shown in boldfaced font.

Bivariate correlations were computed to explore interrelationships among the IPQ-R dimensions of illness appraisal. The illness identity and causal dimensions were excluded from this section of the analysis because they were not suitable for correlational analysis. The identity subscale is a nominal scale that measures the presence or absence of a set of symptoms and whether the respondent believes the symptom is related to the current illness. There is no subscale score for the identity subscale, so it was unsuitable for inclusion in further analysis. The ordinal causal subscale items were analyzed individually to depict causal perceptions of the respondents. Like the identity subscale, the causal dimension does not produce a summed score suitable for inclusion in further analysis. Of the illness appraisal dimensions suitable for analysis, timeline, cure/control and personal control were intercorrelated. Table 17 shows the Spearman's r_s correlations among the illness appraisal dimensions. Significant correlations are boldfaced.

Table 17.

Spearman's rho Correlations Among IPQ-R Dimensions

		1	2	3	4	5	6
1 Timeline	r_s	1.000					
	significance	.					
2 Time-cyclical	r_s	.268	1.000				
	significance	.316	.				
3 Personal control	r_s	**-.760**	-.234	1.000			
	significance	.001	.383	.			
4 Cure/control	r_s	**-.550**	-.004	**.822**	1.000		
	significance	.040	.990	.000	.		
5 Illness coherence	r_s	.291	-.013	-.189	.003	1.000	
	significance	.274	.961	.483	.992	.	
6 Emotional representations	r_s	-.027	.224	.003	-.113	.341	1.000
	significance	.922	.388	.991	.689	.181	.

Note: Statistically significant correlation coefficients are shown in boldfaced font.

LOT-R. LOT-R scores were examined for relationships to MSAS symptom means and IPQ-R subscales. These results are presented in Table 17. In this analysis, the only significant relationship was observed between LOT-R scores and the IPQ-R time-cyclical subscale (r_s = -.53, p=.03). This relationship suggests that less optimistic people are more inclined to see the illness as coming and going in cycles. The limited variability on the timeline-cyclical subscale of the IPQ-R may have decreased the magnitude of the correlation coefficient due to restriction of range (Nunnally & Bernstein, 1994).

Table 18.

Correlations of LOT-R with IPQ-R and MSAS Subscales

	LOT-R Score	
	r_s	Significance
Timeline	.02	.93
Time-cyclical	**-.53**	**.03**
Consequences	.02	.95
Personal control	-.03	.92
Cure/control	.09	.75
Illness coherence	.34	.18
Emotional representations	-.22	.41
MSAS intensity item mean of all items	.12	.66
MSAS frequency item mean of all items	.00	.99
MSAS distress item mean of all items	-.07	.79
MSAS HF symptom distress	.03	.90
MSAS HF physical symptom distress	-.02	.93

Note: MSAS = Memorial Symptom Assessment Scale, HF = high frequency

MSAS. All of the symptom dimension scores were normally distributed (Kolmogorov-Smirnoff test statistic > .119, p >.20 in all cases), so there was no need in this sample to transform scores for parametric analysis. Strong intercorrelations were observed among the three symptom dimensions regardless of scoring method. Item means of all items were chosen for analysis because they returned the scores to the original scale, unlike sums, and because dividing the scores by the total number of symptoms experienced was conceptually untenable as discussed above. Table 19 shows the correlations among the item means of all items.

Table 19.

Pearson r Correlations Among MSAS Item Means of All Items

	Frequency	Intensity
Intensity	.94 ***	
Distress	.91 ***	.92 ***

Note: *** p <.001

Although there was a very strong tendency among the three symptom dimensions to vary similarly, systematic differences in scores are not revealed in correlational analysis. In repeated measures analysis of variance (ANOVA), a linear relationship among the three dimensions, entered in the order distress, intensity and frequency, was strongly supported ($F = 72.8$, $p < .001$). Paired t-tests were used as post-hoc tests to examine which item means of all items were significantly different among the three dimensions, and revealed that all three means were highly significantly different, as shown in Table 19.

Table 20.

Paired T-Statistics of Comparisons Among Item Means of All Items

Pair	t
Frequency-distress	-9.0
Distress-intensity	- 4.7
Intensity-frequency	-6.4

Note: All p <.001

Further analysis revealed that the emotional representations subscale was correlated with the intended dependent variable in the regression analysis, distress item mean of all items (r_s = .421, p = .092.) This finding is probably explained, at least in part, by similarity between some of the items on the two scales. The IPQ-R emotional representations subscale contains three items that refer to feeling depressed, worried, and anxious in regard to the illness. Three similar items on the MSAS that comprise part of the psychoemotional subscale refer to feeling sad, worrying and feeling nervous. In order to eliminate distortion of the regression analysis attributable to collinearity between the independent and dependent variables, a 29-item physical symptom distress subscale of the MSAS was calculated. This subscale was comprised of the distress item mean of all items with the three overlapping items eliminated. The mean of the physical symptom distress subscale was .50, S.D. .39.

Correlations between the MSAS physical symptom distress subscale and the IPQ-R emotional representations subscale were not significant (r=.094, p=.719.) The very low correlation coefficient signifies that low statistical power due to the small sample size is not likely to be the sole cause of the lack of significance. None of the other illness appraisal dimensions were correlated with physical symptom distress. However, the large number of

zero values on the symptoms endorsed by few respondents may have distorted these correlations. To eliminate this potential problem, correlations were computed with the illness appraisal dimensions and the 9-item high frequency symptom distress subscale and the 7-item high frequency physical symptom distress subscale. Both the 9-item and 7-item scales were used in this analysis to show differences in the correlation coefficients when psychoemotional items were excluded.

The 9-item high frequency symptom distress subscale was correlated with the illness appraisal dimensions cure/control, personal control, and emotional representations. All of the correlations among the illness appraisal dimensions and the 7 and 9-item high frequency scales are shown in Table 21.

Table 21.

Correlations Among IPQ-R Illness Appraisal Dimensions and MSAS High-Frequency Symptom Distress Subscales

		HF symptom distress	HF physical symptom distress
Timeline	r_s	-.211	-.205
	significance	.433	.445
Time-cyclical	r_s	.032	.006
	significance	.904	.981
Personal control	r_s	**.451**	**.452**
	significance	.080	.079
Cure/control	r_s	**.470**	**.518**
	significance	.077	.048
illness coherence	r_s	-.067	.010
	significance	.798	.970
Emotional representations	r_s	**.421**	**.402**
	significance	.093	.109

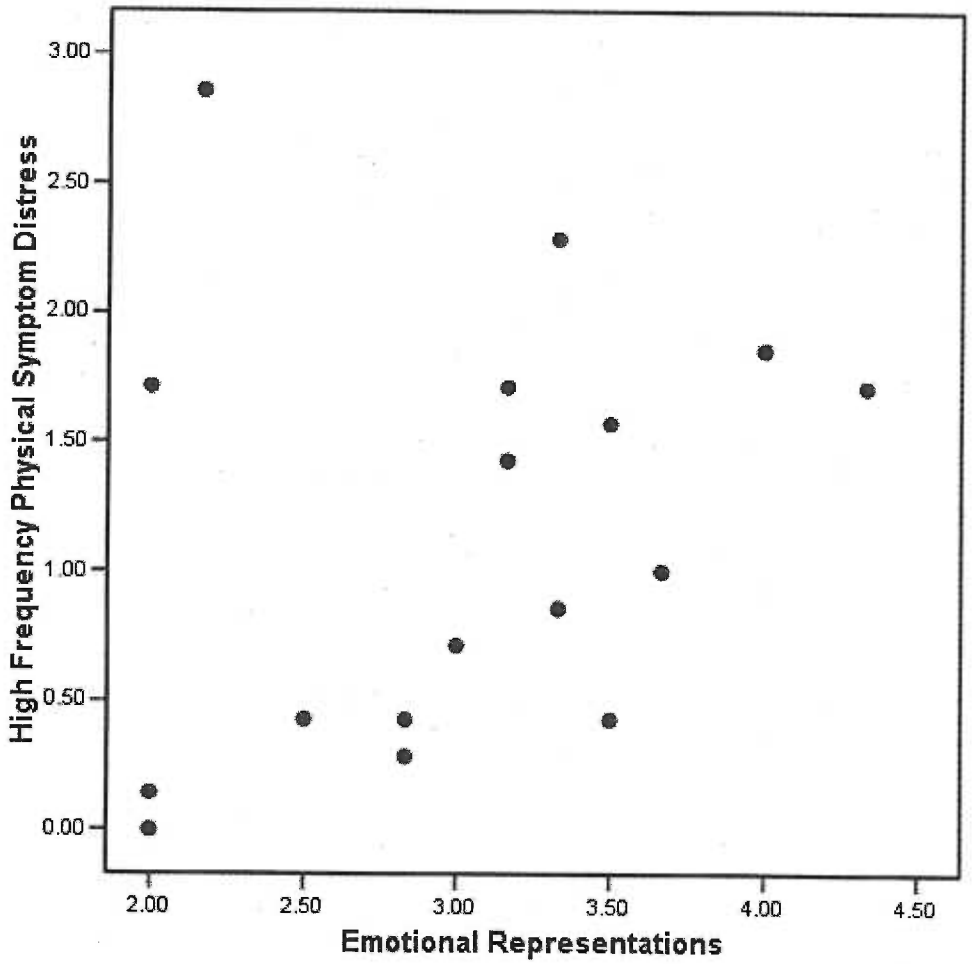
Note: Statistically significant correlation coefficients are shown in boldfaced font. HF = high frequency.

When high frequency physical symptom distress scores were used, omitting worrying and feeling nervous from the subscale, the correlation with emotional representations became nonsignificant (r_s = .40, p=.11), although a trend remained evident in the near-significant p value. Personal control and cure/control were significantly correlated with both the 7-item and the 9-item scales. Power analysis revealed that the power to detect a significant Pearson r of .40 with alpha = .10 in this sample of seventeen subjects was .48. Thirty-eight participants

would be needed to demonstrate a significant Pearson r correlation of .40 between emotional representations and high-frequency physical symptom distress if alpha = .10 and power=.80 (University of California at Los Angeles Statistics Department, 2002.)

In fifteen of seventeen subjects, there was a strong relationship between emotional representations and physical symptom distress. However, two subjects were outliers in this regard, exhibiting high physical symptom distress, but low emotional representations scores. This finding is illustrated in Figure 4. These two participants' scores on the other instruments and their demographic characteristics did not reveal any distinct features that might account for their outlying scores. Both were married males, one with very early stage disease (Stage 0) and the other with late stage disease. Their LOT-R scores were in the middle of the range. Other factors that could influence the relationship between emotional representations and physical symptom distress, such as carryover from non-illness sources of distress, were not addressed in this study.

Figure 4. Scatterplot of Physical Symptom Distress Item Mean of all Items and IPQ-R Emotional Representations Scores



Regression Analysis

Strictly interpreted, the original plan for analysis using multiple regression was not indicated, given the lack of significance of the correlation between emotional representations and high-frequency physical symptom distress. An alternative plan, to compare the relative contributions of the IPQ-R dimensions to symptom intensity and frequency, was not feasible because cure/control was the only IPQ-R dimension correlated with the 7-item high-frequency physical symptom intensity subscale ($r_s = .473$, $p = .09$).

Nonetheless, the near-significant correlation between emotional representations and high-frequency physical symptom distress may indicate a trend worthy of further study. For this reason, an exploratory multiple regression analysis was completed in an attempt to identify the amount of variance in high-frequency physical symptom distress explained by emotional representations of illness when accounting for cure/control, current radiation therapy and weeks since diagnosis, the other variables with significant relationships to high-frequency physical symptom distress. Because the cure/control and personal control dimensions of the IPQ-R were correlated, only the cure/control dimension was chosen for regression analysis. The summary of the resulting model is shown in Table 22. All four predictor variables were forced to enter the model. When emotional representations was entered into the model, the change in R squared was not significant ($F=1.6$, $p = .24$). Current radiation was the only significant predictor in the model, yielding an adjusted R squared of .41. Part (semi-partial) correlations revealed that emotional representations explained 7% of the unique variance in high-frequency physical symptom distress and cure/control explained 10%.

Table 22.

Summary of Multiple Linear Regression Model Predicting High-Frequency Physical Symptom Distress

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F	df1	df2	Sig. F Change
a	.352[a]	.124	.056	.8001	.124	1.838	1	13	.198
b	.474[b]	.224	.095	.7835	.101	1.556	1	12	.236
c	.539[c]	.291	.097	.7827	.066	1.025	1	11	.333
d	.762[d]	.581	.413	.6309	.290	6.930	1	10	.025

Note: a. Predictors: (Constant), weeks since diagnosis

b. Predictors: (Constant), weeks since diagnosis, subscale-emotional representations

c. Predictors: (Constant), weeks since diagnosis, subscale-emotional representations, subscale - cure/control

d. Predictors: (Constant), weeks since diagnosis, subscale-emotional representations, subscale - cure/control, current rx-radiation

e. Dependent Variable: high frequency physical symptom distress

CHAPTER 5

Discussion, Summary and Implications

Discussion

Major Aim. There was partial support for the hypothesized relationship between emotional representations and symptom distress. Although the small sample size surely reduced the magnitude of the observed relationship, emotional representations accounted for approximately 10% of the variance in high-frequency physical symptom distress, more than any other element of illness appraisal. However, the variance accounted for did not reach statistical significance.

Not unexpectedly, biophysiologic elements of the lung cancer experience, measured here as current treatment and stage of disease, bore a stronger influence on symptom distress than did illness appraisal. Other biophysiologic elements not measured in this study include anatomic location of the tumor(s) and the existence of paraneoplastic syndromes. These physical causes of symptoms may be much stronger factors in determining symptom frequency, intensity and distress than illness appraisal, even when objective illness severity is accounted for by a system such as the AJCC staging system.

Self-regulation theory is more a heuristic than a practical model because it is limited in scope. While the model provides a framework for conceptualizing relationships between illness appraisal and symptoms, the model does not account for biophysiological factors or other variables that may bear a greater effect on symptom distress than emotional representations. Aside from biophysiological aspects, these intervening variables may include existential meaning and aspects of health and illness such as quality of social support and coping strategies that were not measured in the study.

Elements of illness appraisal that are not measured by the IPQ-R, such as existential meaning, may help account for attitudes that minimize or exacerbate negative feelings such as distress. Anecdotal evidence of this possibility is found in one interaction with a study participant who scored low on all the distress items, stating that only pain distressed him, and his pain was controlled. However, his emotional representations score was 3.17, somewhat higher than the mean of 3.02. This anecdote raises the question of whether intervening variables may influence the relationship between emotional representations and symptom distress.

The study was not able to demonstrate that emotional representations contributed more to symptom distress than to symptom frequency and intensity. Collinearity among symptom frequency, intensity and distress made it impossible to distinguish the effects of the dimensions of illness appraisal on the three symptom dimensions, although the difference in mean scores on these three dimensions suggests that people with lung cancer may evaluate the three dimensions somewhat differently.

Secondary Aim. This study provides some support for the multidimensional nature of the symptom experience advocated by previous investigators. It should be noted, however, that the observed differences among means on the three dimensions may be partially explained by instrumentation. The MSAS is scored such that if a respondent does not have a given symptom, all three dimensions are coded as zero. If a respondent endorses a given symptom, the minimum distress response option is zero, but the minimum frequency and intensity options are one. Differing response options for the dimensions created the possibility of a response set where a study participant might systematically choose the minimum option for symptoms experienced, creating a

spurious significant difference between distress item mean of all items and those of the other symptom dimensions. This possibility, however, does not explain the highly significant differences between frequency and intensity item means of all items.

In addition, the differing response options on the MSAS are conceptually consistent with self-regulation theory: symptoms may be associated with zero subjective distress, but the fact of symptom recognition guarantees an association with the concrete-objective features of symptoms, frequency and intensity. In this regard, the highly significant differences among the item means of all items, particularly differences between distress and the other two dimensions, supports the independence of these three symptom dimensions in the perceptions of people with lung cancer.

Comparing the intensity and distress ratings of the symptoms with the highest intensity ratings revealed evidence that symptom intensity and symptom distress may have distinct meanings. Five of the ten most distressing symptoms comprise the MSAS psychoemotional subscale, whereas only three psychoemotional symptoms were among those rated highest in intensity. This finding may indicate that symptom distress is more strongly associated with emotional well-being than is symptom intensity in this sample of generally poor-prognosis individuals with lung cancer. This supports a conceptualization of the symptom experience as comprised of three dimensions (frequency, intensity and distress) that is the basis of the MSAS and self-regulation theory.

This finding has implications for the measurement of symptom distress. If distress is the affective component of the symptom experience, the basis for cognitive-behavioral symptom management interventions in this population may be strengthened. Just as Johnson and colleagues (1978) showed that providing concrete preparatory information

improved functional outcomes along the concrete-objective pathway, perhaps it will be possible to demonstrate decreased symptom distress as an outcome of the subjective pathway in self-regulation theory by promoting adaptive emotional representations of illness. If emotional representations may be modified to improve symptom distress, then the clear next step is to demonstrate that decreased subjective symptom distress improves outcomes. Measures of adaptation, depression, mood, or quality of life may be suitable to answer this question. Furthermore, it may be important to measure symptom distress in attempting to capture the whole symptom experience, not merely intensity and frequency, as is more commonly done in research and clinical settings.

The MSAS was chosen for symptom measurement in this study primarily because it queries all symptoms in terms of distress or bother, the major symptom attribute of interest in the study. Although this tool exhibited significant strengths, it also possessed its drawbacks. One of these was length. The tool as administered to subjects was three pages, although all pages were only partially filled. The length of the tool, coupled with the other instruments in the study, may have deterred some respondents who initially expressed interest in the study from following through with completing the study forms. This may represent a threat to external validity if potential respondents with more symptoms, later stage of illness, or other shared characteristics were deterred from taking part in greater numbers than other people with lung cancer.

Type size and orientation may have presented a threat to validity. Even after enlarging, the instructions on the MSAS remained small and may have been difficult for some respondents to read. A significant drawback of the tool is that some of the text is vertically aligned, and this may have made reading the response options difficult for

some people. Notably, two respondents seemed to not notice the vertically written "did not have" option, and chose the lowest level of symptom frequency, leaving the other two dimensions blank, for many symptoms. In clarifying their responses with them, both respondents said they had overlooked the "did not have" option. The MSAS was first published in the *European Journal of Cancer Care*, and this is evident in its British spelling of the word diarrhea (diarrhoea.) This fact did not appear to present a problem for study participants as there were no missing data on this item.

In future use, it would be wise to re-format the MSAS to re-orient the vertical script and further increase the font size. Despite these drawbacks, there were very little missing data on the MSAS. Following up with subjects to clarify their responses and completing missing responses in person or by telephone with the participant was effective. The only piece of missing data on the MSAS was from a subject who could not choose a single answer to the pain intensity question because of the widely varying nature of his pain.

Although internal consistency reliabilities of the symptom dimension subscales were acceptable for purposes of this pilot study, higher coefficients alpha than those derived here are desirable in future research. Nunnally & Bernstein (1994) consider .70 a "modest" (p. 265) coefficient alpha, and the values in this study ranged from .66 to .74 on the seven-item high-frequency physical symptom dimension subscales. In order to improve internal consistency reliability, Nunnally & Bernstein (1994) recommend adding items to short scales to increase the coefficient alpha. The equation in Formula 1 is used to estimate the number of times the original number of items on the instrument would have to be duplicated to produce a given reliability.

$$k = \frac{r_{kk}(1 - r_{11})}{r_{11}(1 - r_{kk})}$$

Formula 1. Estimated Number Of Times A Scale Must Be Lengthened To Produce A Desired Coefficient Alpha Where K =Number Of Times, R_{kk}=Desired Reliability And R_{11}= Reliability Of The Existing Scale, (Nunnally & Bernstein, 1994, p. 264.)

In the case of the high-frequency physical symptom distress subscale, with an original coefficient alpha of .72, doubling the length of the scale (k=2) would yield an improved coefficient alpha of .84. Traditionally, this higher reliability coefficient is considered more acceptable for research attempting to predict outcomes such as depression and for making clinical decisions. However, high internal consistency should not be regarded as mandatory in tools where multiple symptoms are measured. A valid symptom measurement tool should discriminate among multiple symptoms experienced at differing degrees of frequency, intensity and distress. This property would preclude similarity in ratings across symptoms, reducing internal consistency reliability.

Optimism. No association was found between dispositional optimism and emotional representations or any of the symptom distress subscales. Less optimistic participants were more likely to perceive the illness as cyclical, but no other associations were observed in this sample.

This finding seems to contradict associations found in earlier studies (Johnson et al., 1997) where more pessimistic individuals undergoing radiation therapy began with lower mood scores and showed more improvement than more optimistic individuals

when provided with concrete preparatory information. Johnson and colleagues used a median split to classify the sample into more pessimistic and more optimistic groups, so it was possible for individuals with similar scores to be classified differently.

The instrument used in that study, the Profile of Mood States, measures a broader range of emotion than the emotional representations scale of the IPQ-R, which may explain this incongruence. As Luker and colleagues (1996) showed, cognitive schemata associated with cancer are not always negative. Importantly, individuals with lower LOT-R scores (pessimists) tend to express more negative affectivity than optimists, but this may not be the case universally. Individuals who possess positive general outcome expectancies may not possess the same expectancies with respect to individual situations (Smith, Pope, Rhodewalt & Poulton, 1989), so a measure of dispositional optimism may not correlate with situation-specific affectivity. This possibility is supported by comparing the mean LOT-R scores in the current study with the higher mean scores found by Walker and colleagues (1996) in a study of people with localized breast and prostate cancer.

Summary and Implications

This pilot study examined the relationship of emotional representations of illness to symptom distress in a sample of individuals with various stages of NSCLC. The sample was well-distributed with respect to gender, age and stage of disease, but possessed little variability with respect to race, ethnicity, marital status, and living situation.

Self-regulation theory proposes that emotional representations exert influence on the subjective, affective element of the symptom experience, symptom distress, and that the other elements of illness appraisal influence the concrete-objective elements of the symptom experience, symptom frequency and intensity. Even in this small sample, zero-order correlations of emotional representations of illness and high-frequency physical symptom distress approached statistical significance. It should be noted, however, that zero-order correlations of cure-control and personal control with physical symptom distress were larger. In regression analysis, when adding concurrent radiotherapy into the model, the effect of emotional representations on physical symptom distress became insignificant.

Self-regulation theory provided a useful framework for conceptualizing the relationships of interest in this study. Limited support for the theory was demonstrated in the relationships found between the elements of illness appraisal and the symptom dimensions. The three-dimensional conceptualization of symptoms was also partially supported in the highly significant differences among mean scores on the three symptom dimensions and in the incidence of selection of the zero response option on the distress dimension for endorsed symptoms. The selection of the zero distress option on endorsed

symptoms indicates that the concrete-objective features of a symptom, intensity and frequency, were not always accompanied by distress, the subjective feature, consistent with self-regulation theory.

Research Implications. The study showed, not unexpectedly, that biophysiological factors contribute much more to symptom distress, a variable highly correlated with symptom frequency and intensity, than does illness appraisal. However, this conclusion is limited by the small sample size, and the somewhat limited range of scores in this sample on the emotional representations subscale may have decreased the magnitude of the small observed relationship. A larger sample with greater diversity on the demographic factors noted above may produce more variable emotional representations.

The small effect of illness appraisal on the three symptom dimensions of interest will likely require a much larger study to evaluate the degree of variance in symptom distress explained by the various dimensions of illness appraisal. Examining these relationships in a longitudinal within-subjects study may be a useful way to control variability and examine relationships over time as illness appraisal and symptoms change.

It may not be possible to fully distinguish symptom distress from symptom frequency and intensity when using standardized measures. Nonetheless, the study was successful in piloting the use of the IPQ-R in multiple linear regression and in exploring a novel method of evaluating symptom distress with the MSAS to identify the elements of illness appraisal that contribute to the global symptom experience.

If it is not feasible to distinguish symptom distress from intensity and frequency with quantitative measures, symptom measurements may not need to incorporate all three dimensions. Briefer instruments than the MSAS could conceivably be used without losing information about the global symptom experience. This limited study is not sufficiently powerful or generalizable to conclude that the three symptom dimensions will be strongly intercorrelated in larger samples or in other populations, so this finding will have to be explored in larger studies.

Perceptions of symptom distress among people with lung cancer have not been defined, and are operationalized in different ways in the literature. Differences in subscale means of symptom frequency, intensity and distress suggest that participants evaluated these three dimensions differently, although the subjective meaning of symptom distress remains poorly understood. Distress ratings were higher in symptoms associated with psychoemotional responses to illness. Further research should seek to determine what symptom distress means to people with lung cancer. It may also be fruitful to further explore which symptoms are commonly associated with greater distress in this population and others to better understand the nature of symptom distress.

It is possible that cognitive-behavioral therapies aimed at altering illness appraisal may diminish distress in people with lung cancer. This study did not attempt to measure distress from non-symptom sources, such as fear of dying or worry for the well-being of one's loved ones, that may also be amenable to this type of intervention. The study did not measure factors that may potentially ameliorate distress, such as specific coping strategies and religious beliefs. Notably, in two participants, the observed relationship between reported symptom distress and emotional representations of illness appeared

opposite of that seen in the other study participants. Perhaps this observation was the result of intervening variables, such as ineffective coping or non-illness sources of distress that increased distress in spite of largely positive emotional representations of illness. In future studies, this could be explored with the addition of a coping measure to the study and a qualitative component to broadly examine sources of distress.

Clinical Implications. Oncology practitioners may wish to use the findings of this study in considering how people with lung cancer prioritize their needs. Treatment decisions may be better informed by considering individual reports of symptom distress rather than intensity or frequency when prioritizing treatment. Clearly, this recommendation will require further study.

Personal control and cure-controllability were more highly correlated with symptom distress than was emotional representations. If this finding remains stable in future studies, clinicians may use this information to support the use of interventions to enhance confidence in treatment, self-efficacy and a sense of mastery over the illness. The biomedical accuracy of perceptions of cure-controllability was not explicitly evaluated in this study, but given the poor survival rates and high symptomatology in this disease, perceptions of personal control seem a more suitable target for cognitive-behavioral intervention. Empowering people with lung cancer in making their treatment decisions and teaching the use of specific self-initiated symptom relief measures, such as breathing techniques, may be effective in enhancing a sense of personal control and decreasing distress.

The importance of improved symptom control for people with lung cancer is undisputed. This study piloted alternative ways of using the MSAS to measure the global

symptom experience and explored its relationship to illness appraisal, as posed by self-regulation theory. Future work should extend the preliminary findings of this study to explore whether altering elements of illness appraisal may help ameliorate symptom distress in people with lung cancer.

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APPENDIX A

Tables and Figures

Table A1.

The Symptom Distress Scale: Descriptive Statistics

Source	Version of SDS	Sample (N)	SDS Scores: Mean (M), Standard Deviation (SD)
Cimprich, 1999	10-item SDS (scale range 10-50)	Women newly diagnosed with breast cancer (74)	Scale M 19.35
Coward, 1991	10-item SDS (scale range 10-50)	Women with advanced breast cancer (107)	Item M 3.41 Item SD 1.33
Lev, Paul, & Owen, 1999	13-item SDS	Cancer patients receiving chemotherapy or radiotherapy (307)	Scale M 21.4 (patients > 57 years) Scale M 24.1 (patients < 57 years)
Lindley, Vasa, Sawyer, & Winer, 1998	Modified 13-item SDS, reversed scoring and added five symptoms (food aversion, smell aversion, numbness, pain, and swelling of the surgical area). Minimum potential score = 66.	Breast cancer patients who had completed systemic adjuvant therapy and were considered disease-free (86)	Scale M 58.2 Scale SD 5.1
Morasso et al., 1999	Italian version of 13-item SDS	Cancer patients receiving palliative care at an Italian cancer center (324)	Scale M 31 Scale SD 8.0
Munkres et al., 1992	Modified 11-item SDS using 100 mm visual analog scale (item range 0-100)	Patients receiving chemotherapy in an ambulatory setting (60)	Item M 36.65 Item SD 16.89
Passik, Kirsh, Rosenfeld, McDonald & Theobald, 2001	13-item SDS	Solid tumor, leukemia and lymphoma patients beginning chemotherapy (255)	Scale M 23.5 Scale SD 8.1

Source	Version of SDS	Sample (N)	SDS Scores: Mean (M), Standard Deviation (SD)
Peruselli, Paci, Franceschi, Legori, & Mannucci, 1997	Italian version of 13-item SDS administered at three intervals	Cancer patients receiving home palliative care (73)	Scale M 29.2 - 33.1
Porock, Kristjanson, Tinnelly, Duke, & Blight, 2000	13-item SDS administered at five intervals	Subjects aged 51-77 years with advanced cancer receiving hospice care (9)	Scale M 22-27
Samarel, Fawcett, & Tulman, 1997	Modified SDS – 10 items, scale range 10 (lowest distress) - 50 (highest distress)	Women with early stage breast cancer taking part in a trial of a coaching support group intervention (181)	Scale M 15.5 – 18.0 Scale SD 4.2-5.9
Sarna, 2001	13-item SDS administered at four intervals	Adults cancer patients receiving radiotherapy (7)	Scale M 15.0 – 15.71 Scale SD 2.34-3.32
Whelan et al., 1997	13-item SDS	Newly diagnosed cancer patients (134)	Scale M 23.6 Scale SD 4.3

Table A2.

Studies of Symptom Distress and Fatigue

Source	SD Instrument	Population (N)	Major Findings
Berger, 1994	Modified SDS; modifications not reported.	Women beginning adjuvant chemotherapy for breast cancer (60)	Fatigue at cycle mid-points was predicted by symptom distress at the time of treatment.
Berger et al., 2000	SES	Women with Stage I or II breast cancer breast cancer receiving chemotherapy with doxorubicin and cyclophosphamide (14)	Correlates of fatigue were greater symptom distress, lower activity, and poorer physical and social health status.
Berger et al., 2001	Modified SDS: excluded all items except mood, nausea and sleep disturbance.	Women who received chemotherapy after surgery for Stage I or II breast cancer (60)	Symptom distress directly influenced fatigue during treatments and at cycle midpoints.
Chang, Hwang, Feuerman, & Kasimis, 2000	MSAS	Medical oncology patients at a Veterans Administration medical center (240)	The most prevalent symptoms were lack of energy, pain, dry mouth, shortness of breath and difficulty sleeping.
Cimprich, 1999	SDS	Women ages 25 to 79 years and newly diagnosed with breast cancer (74)	Higher levels of symptom distress were related to insomnia, fatigue, and loss of concentration.
Cleeland et al., 2000	MDASI	Cancer outpatients (527) and blood and bone marrow transplant inpatients (30)	Patients rated fatigue-related symptoms as the most severe.
Dean et al., 1995	SDS used to evaluate concurrent validity of the Piper Fatigue Scale (PFS)	Patients with malignant melanoma actively being treated with interferon alpha (30)	The pattern of fatigue was consistent over time, with the highest fatigue scores in the affective domain, followed by the sensory, temporal, total fatigue, and fatigue severity scores of the Piper Fatigue Scale. Positive correlation between SDS and PFS.
Degner & Sloan, 1995	SDS	Newly diagnosed cancer patients (434)	40% of patients reported fatigue and 30% reported insomnia to a moderate or high degree.

Source	SD Instrument	Population (N)	Major Findings
Dutcher et al., 2000	SDS	Metastatic renal cell cancer patients receiving recombinant interleukin 2 (50)	The most common toxicities were fatigue, nausea/vomiting, and anorexia.
Graydon, 1994	SDS	Women who had a lumpectomy or other breast-conserving surgery for breast cancer followed by radiation therapy (53)	Subjects experienced few changes in usual activities, were not distressed emotionally, and were experiencing very few symptoms, but they reported fatigue. Those with the most fatigue had the most symptoms and poorest functioning.
Hwang et al., 1999	MSAS- Short Form	Male cancer inpatients and outpatients (180)	Patients with moderate and severe fatigue demonstrated lower quality of life, greater depression and symptom distress and shorter survival.
Irvine et al., 1998	Associated Symptom Subscale of the Piper Fatigue Scale	Patients with breast cancer receiving external radiation therapy (76)	Fatigue significantly increased over the course of treatment, was highest at the last week of treatment, and returned to pretreatment levels by 3 months after treatment. Fatigue was significantly related to symptom distress.
Irvine, Vincent, Graydon, Bubela, & Thompson, 1994	Modified version of the 13-item SDS; added difficulty sleeping and decrease in appetite.	Patients receiving treatment with radiotherapy (54) and chemotherapy (47)	Symptom distress and mood disturbance predicted fatigue. Symptom distress and fatigue predicted functional impairment.
Knobf, 1986	SDS	Subjects with Stage II breast cancer (78)	Fatigue was the most distressful physical symptom.
Lawrence, Gilbert & Peters, 1996	SDS	Women with breast cancer in an outpatient autologous bone marrow transplant program (28)	Anorexia, nausea, fatigue, insomnia, and bowel problems were the most distressing symptoms.

Source	SD Instrument	Population (N)	Major Findings
Lindley, Vasa, Sawyer, & Winer, 1998	Modified SDS by adding five symptoms: food aversion, smell aversion, numbness, pain and swelling in the surgical area	Patients who had begun systemic adjuvant therapy for early-stage breast cancer 2 to 5 years prior (86)	Fatigue was reported by 31.4% of patients.
McCorkle, Hughes, Robinson, Levine, & Nuamah, 1998	SDS	Surgical cancer patients aged 60-92 years (37)	Over 50% of subjects reported significant impairment secondary to pain and fatigue.
McCorkle & Quint-Benoliel, 1983	SDS	Lung cancer patients (56) and myocardial infarction patients (65)	Both groups of patient identified fatigue their most distressing symptom on both occasions.
Munkres, et al., 1992	Modified 10-item SDS – added two items: "loss of strength" and "bodily discomfort"	Patients with first-time (28) or recurrent (32) cancer.	Fatigue and loss of strength were the two highest-rated symptoms.
Oberst, Hughes, Chang, & McCubbin 1991	Modified 10-item SDS – added two items: "loss of strength" and "bodily discomfort"	Radiation outpatients (72)	Fatigue was the most distressing symptom.
Passik, Kirsh, Rosenfeld, McDonald & Theobald, 2001	SDS	Solid tumor, leukemia and lymphoma patients beginning chemotherapy (255)	Forty percent of patients endorsed frequent or intense fatigue before chemotherapy and 3-6 months later.
Porock, Kristjanson, Tinnelly, Duke, & Blight, 1994	SDS	Subjects aged 51-77 years with advanced cancer (9)	Subjects experienced moderate to high levels of fatigue and symptom distress that was low to moderate.
Rhodes, McDaniel, Homan, Johnson, & Madsen, 2000	ASDS-2	Oncology patients receiving radiotherapy or first-time chemotherapy (175)	Fatigue/restlessness was third highest of the six symptom subscales.

Source	SD Instrument	Population (N)	Major Findings
Sarna, 1993a	SDS	Women with lung cancer (69)	The most prevalent and distressing symptoms were fatigue, frequent pain, and insomnia. 41% of subjects with fatigue concurrently experienced frequent pain, and 31% had insomnia.
Sarna, 1993b	Modified SDS	Women with lung cancer (69)	Prevalent serious disruptions were fatigue, difficulty with household chores, worry about ability to care for self, and worry about cancer progression.
Sarna, 1998	SDS	Men and women newly diagnosed with advanced lung cancer	Fatigue was the most common severely distressing symptom.
Sarna & Brecht, 1997	SDS	Women with advanced lung cancer (60)	Fatigue, disruptions in outlook, frequent pain, and difficulties in sleeping were rated the most distressing and were the most prevalent serious disruptions.
Sarna & Conde, 2001	SDS	Adults with cancer who received a six-week course of external beam radiation therapy to the trunk.	Physical activity increased during treatment and fatigue decreased. SDS showed minimal change in symptom distress.
Tishelman et al., 2000	SDS	Primary lung cancer patients	Fatigue received the highest intensity score, but ranked second lowest in importance.
Whelan et al., 1997	SDS	Newly diagnosed breast, colorectal, head and neck, lung, prostate and skin cancer patients (134)	129 patients (96%) reported symptoms that included fatigue (66%), worried outlook (61%), difficulty sleeping (48%), and pain (42%).
Winer et al., 1999	SDS	Breast cancer patients surviving one year after high dose chemotherapy with autologous bone marrow transplant	The most commonly reported symptoms were insomnia, fatigue, and pain.

Table A3.

Studies Investigating Symptom Distress as a Predictor of Survival

Source	SD Instrument	Population (N)	Major Findings
Chang et al., 1998	MSAS	Inpatients (122) and outpatients (96) with colon, breast, ovary, or prostate cancer	Extent of disease, inpatient vs. outpatient status, higher physical symptom subscale score and lower performance status independently predicted decreased survival.
Chang, Hwang, Kasimis, & Thaler, 2001	Condensed MSAS (C MSAS)	Various cancer patients (479), most with metastatic disease (341)	C-MSAS physical symptom subscale was the single strongest predictor of survival.
Degner & Sloan, 1995	SDS	Lung cancer patients in early (13%) and advanced (72%) stages of disease (82)	Age of the subject and stage of illness were not significant covariates when symptom distress scores were entered into a survival analysis model.
McCorkle et al., 2000	SDS	Patients aged 60 to 92, with solid cancers taking part in a randomized controlled trial of home care nursing intervention by advanced practice nurses (375)	Relative hazard of death in the usual care group was 2.04 (CI: 1.33 to 3.12; P = .001) after adjusting for stage of disease and surgical hospitalization length of stay.
Kukull, McCorkle, & Driever, 1986	SDS	Patients (mean age 62 yrs) with inoperable lung cancer (53)	Post diagnosis symptom distress was the most important predictor of survival after adjusting for age, functional status, and personality traits.
Frederickson, Jackson, Strauman, & Strauman, 1991	SDS	Patients with various cancer types taking part in an interleukin-2 clinical trial (45)	Perception of symptoms (SDS) and psychosocial adaptation were correlated with survival at six months and not with actual physiological status.

Source	SD Instrument	Population (N)	Major Findings
Molassiotis, Van Den Akker, Milligan, & Goldman, 1997	SDS	Adults 1-2 years post-bone marrow transplantation (BMT) (31)	Shorter survival associated with mismatched marrow grafts, prior chemo/radiotherapy, disease stage, higher symptom distress during BMT, less hopefulness, and more acceptance of the situation.

Table A4.

Number and Percents (in Parentheses) of Subjects Endorsing Each Item on the Causal Dimension Subscale of the IPQ-R

Cause	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree	Missing Data
Heredity	**7 (41.2)**	3 (17.6)	2 (11.8)	3 (17.6)	2 (11.8)	0
Stress or worry	**5 (29.4)**	4 (23.5)	4 (23.5)	2 (11.8)	2 (11.8)	0
Germ or Virus	4 (23.5)	**7 (41.2)**	4 (23.5)	0	1 (5.9)	1 (5.9)
Diet or Eating Habits	**6 (35.3)**	**7 (41.2)**	5 (29.4)	2 (11.8)	1 (5.9)	0
Chance or Bad Luck	4 (23.5)	**6 (35.3)**	4 (23.5)	2 (11.8)	1 (5.9)	0
Poor Medical Care	4 (23.5)	**8 (47.1)**	4 (23.5)	0	1 (5.9)	0
Environmental Pollution	1 (5.9)	2 (11.8)	**9 (52.9)**	4 (23.5)	1 (5.9)	0
My Own Behavior	1 (5.9)	2 (11.8)	**6 (35.3)**	4 (23.5)	4 (23.5)	0
My Mental Attitude	**8 (47.1)**	5 (29.4)	3 (17.6)	1 (5.9)	0	0
Family Problems or Worries	**7 (41.2)**	**7 (41.2)**	1 (5.9)	1 (5.9)	1 (5.9)	0
Overwork	6 (35.3)	**7 (41.2)**	3 (17.6)	1 (5.9)	0	0

Cause	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree	Missing Data
My Emotional State	**7 (41.2)**	**7 (41.2)**	2 (11.8)	0	0	1 (5.9)
Aging	2 (11.8)	3 (17.6)	4 (23.5)	**6 (35.3)**	1 (5.9)	1 (5.9)
Alcohol	**7 (41.2)**	**9 (52.9)**	1 (5.9)	0	0	0
Smoking	1 (5.9)	1 (5.9)	2 (11.8)	4 (23.5)	**9 (52.9)**	0
Accident or Injury	**7 (41.2)**	**7 (41.2)**	1 (5.9)	0	2 (11.8)	0
My Personality	7	**8 (47.1)**	2	0	0	0
Altered Immunity	2	**9 (52.9)**	5	0	1	0

Note: Boldfaced cells indicate modal responses.

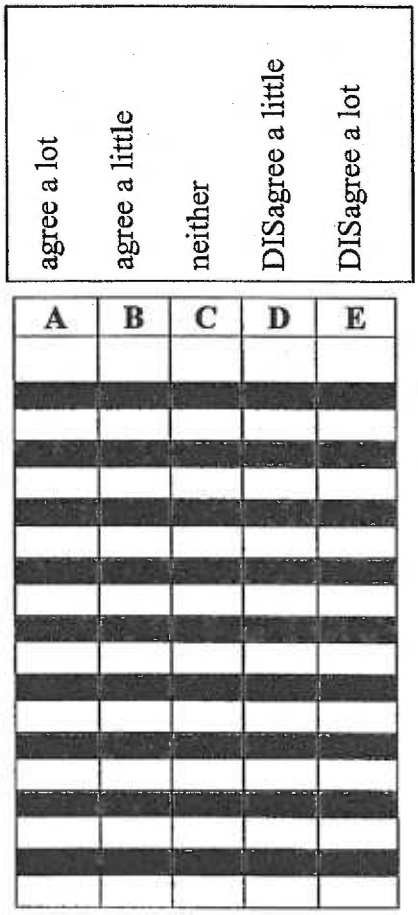
APPENDIX B

Instruments

LOT-R

Please be as honest and accurate as you can throughout. Try not to let your response to one statement influence your responses to other statements. There are no "correct" or "incorrect" answers. Answer according to your **own** feelings, rather than how you think most people would answer.

A = I agree a lot
B = I agree a little
C = I neither agree nor disagree
D = I DISagree a little
E = I DISagree a lot



1. In uncertain times, I usually expect the best.
2. It's easy for me to relax.
3. If something can go wrong for me, it will.
4. I'm always optimistic about my future.
5. I enjoy my friends a lot.
6. It's important for me to keep busy.
7. I hardly ever expect things to go my way.
8. I don't get upset too easily.
9. I rarely count on good things happening to me.
10. Overall, I expect more good things to happen to me than bad.

MEMORIAL SYMPTOM ASSESSMENT SCALE

ubject Code _____ DATE:

CTION 1:

NSTRUCTIONS: We have listed 24 symptoms below. Read each one carefully. If you have had the symptom during this past eek, let us know how OFTEN you had it, how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by ircling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

DURING THE PAST WEEK. Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How OFTEN did you have it?				IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost constantly	Slight	Moderate	Severe	Very severe	Not at all	A little bit	Somewhat	Quite a bit	Very much
Difficulty concentrating		1	2	3	4	1	2	3	4	0	1	2	3	4
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Cough		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Dry mouth		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4
Numbness/ tingling in hands/feet		1	2	3	4	1	2	3	4	0	1	2	3	4
Difficulty sleeping		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling bloated		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with urination		1	2	3	4	1	2	3	4	0	1	2	3	4

Subject Code _____

(b)

DURING THE PAST WEEK. Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How OFTEN did you have it?				IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost constantly	Slight	Moderate	Severe	Very severe	Not at all	A little bit	Somewhat	Quite a bit	Very much
Vomiting		1	2	3	4	1	2	3	4	0	1	2	3	4
Shortness of breath		1	2	3	4	1	2	3	4	0	1	2	3	4
Diarrhoea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling sad		1	2	3	4	1	2	3	4	0	1	2	3	4
Sweats		1	2	3	4	1	2	3	4	0	1	2	3	4
Worrying		1	2	3	4	1	2	3	4	0	1	2	3	4
Problems with sexual interest or activity		1	2	3	4	1	2	3	4	0	1	2	3	4
Itching		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of appetite		1	2	3	4	1	2	3	4	0	1	2	3	4
Dizziness		1	2	3	4	1	2	3	4	0	1	2	3	4
Difficulty swallowing		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling irritable		1	2	3	4	1	2	3	4	0	1	2	3	4

Subject Code _____

(c)

SECTION 2:

INSTRUCTIONS: We have listed 8 symptoms below. Read each one carefully. If you have had the symptom during this past week, let us know how SEVERE it was usually and how much it DISTRESSED OR BOTHERED you by circling the appropriate number. If you DID NOT HAVE the symptom, make an "X" in the box marked "DID NOT HAVE".

DURING THE PAST WEEK. Did you have any of the following symptoms?	DID NOT HAVE	IF YES, How SEVERE was it usually?				IF YES, How much did it DISTRESS or BOTHER you?				
		Slight	Moderate	Severe	Very severe	Not at all	A little bit	Somewhat	Quite a bit	Very much
Mouth sores		1	2	3	4	0	1	2	3	4
Change in the way food tastes		1	2	3	4	0	1	2	3	4
Weight loss		1	2	3	4	0	1	2	3	4
Hair loss		1	2	3	4	0	1	2	3	4
Constipation		1	2	3	4	0	1	2	3	4
Swelling of arms or legs		1	2	3	4	0	1	2	3	4
"I don't look like myself"		1	2	3	4	0	1	2	3	4
Changes in skin		1	2	3	4	0	1	2	3	4

****IF YOU HAD ANY OTHER SYMPTOMS DURING THE PAST WEEK, PLEASE LIST BELOW AND INDICATE HOW MUCH THE SYMPTOM HAS DISTRESSED OR BOTHERED YOU.**

Other:	0	1	2	3	4
Other:	0	1	2	3	4
Other:	0	1	2	3	4

APPENDIX

SCORING OF THE MEMORIAL SYMPTOM ASSESSMENT SCALE

The revised MSAS questions patients about their experiences of 32 symptoms during the previous week. Twenty-four symptoms are evaluated in terms of severity, frequency and distress, and eight symptoms are evaluated in terms of severity and distress. A patient may indicate that a symptom was not experienced by checking a column labelled 'did not have'. If a symptom was experienced, the patient describes its severity on a 4-point categorical scale; its frequency, if appropriate, on a 4-point categorical scale; and its associated distress on a 5-point categorical scale.

The values for the severity and frequency measurements are scales 1 to 4, where 1 is 'slight' on the severity scale and 'rarely' on the frequency scales, and 4 is 'very severe' on the severity scale and 'almost constantly' on the frequency scale. For ease of calculation, the values on the distress scale are set to a range that is roughly similar to the other dimensions: 'not at all' is scored as 0.8, 'a little bit' is 1.6, 'somewhat' is 2.4, 'quite a bit' is 3.2, and 'very much' is 4.

The initial step calculates a score for each symptom. If a symptom is not experienced, each dimension is scored as 0, and the score for that symptom is 0. If a symptom is experienced, the score for that symptom is determined as the average of the scores on the severity, frequency and distress scales, or if appropriate, on the severity and distress scales only. Items that are missing are simply not included in the calculation of this symptom score. If a symptom that is supposed to have all three dimensions completed by the patient actually has two dimensions completed, the score for that symptom is the average of the two items rather than the three items. Only a selected amount of missing data should be allowed before a patient is excluded from the calculation of MSAS scores; in the present study, this was arbitrarily established at *13% of the items.*

In calculating the Global Distress Index, only one dimension is used for each symptom, and the score on the single dimension is considered the symptom score. As discussed in the text, a short form of the MSAS can be developed that similarly used a score on a single dimension as the overall symptom score.

The symptom scores are combined into various subscale scores:

(1) The PSYCH subscale score is the average of the symptom scores for six symptoms: feeling sad, worrying, feeling irritable, feeling nervous, difficulty sleeping and difficulty concentrating.

(2) The PHYS subscale score is the average of the symptom scores for the 12 symptoms identified in the present study as high prevalence physical symptoms: lack of appetite, lack of energy, pain, feeling drowsy, constipation, dry mouth, nausea, vomiting, change in taste, weight loss, feeling bloated and dizziness.

(3) The Global Distress Index is the average of the single dimension scores for 10 symptoms: the frequency scores for feeling sad, worrying, feeling irritable and feeling nervous, and the distress scores for lack of appetite, lack of energy, pain, feeling drowsy, constipation and dry mouth.

(4) The total MSAS score is the average of the symptom scores for all 32 symptoms. If the original MSAS is used, each symptom score is an average of the dimensions; if the short form is used, each symptom score is the score on the single dimension used to assess the symptom. As discussed in the text, the total MSAS score can provide valid information about symptom distress, but is less meaningful from the clinical perspective than the Global Distress Index.

ILLNESS PERCEPTION QUESTIONNAIRE (IPQ-R)

Name..... *Date*.....

YOUR VIEWS ABOUT YOUR ILLNESS

Listed below are a number of symptoms that you may or may not have experienced since your illness. Please indicate by circling *Yes* or *No*, whether you have experienced any of these symptoms since your illness, and whether you believe that these symptoms are related to your illness.

	I have experienced this symptom *since my illness*			This symptom is *related to my illness*	
Pain	**Yes**	**No**	_____	**Yes**	**No**
Sore Throat	**Yes**	**No**	_____	**Yes**	**No**
Nausea	**Yes**	**No**	_____	**Yes**	**No**
Breathlessness	**Yes**	**No**	_____	**Yes**	**No**
Weight Loss	**Yes**	**No**	_____	**Yes**	**No**
Fatigue	**Yes**	**No**	_____	**Yes**	**No**
Stiff Joints	**Yes**	**No**	_____	**Yes**	**No**
Sore Eyes	**Yes**	**No**	_____	**Yes**	**No**
Wheeziness	**Yes**	**No**	_____	**Yes**	**No**
Headaches	**Yes**	**No**	_____	**Yes**	**No**
Upset Stomach	**Yes**	**No**	_____	**Yes**	**No**
Sleep Difficulties	**Yes**	**No**	_____	**Yes**	**No**
Dizziness	**Yes**	**No**	_____	**Yes**	**No**
Loss of Strength	**Yes**	**No**	_____	**Yes**	**No**

We are interested in your own personal views of how you now see your current illness.

Please indicate how much you agree or disagree with the following statements about your illness by ticking the appropriate box.

	VIEWS ABOUT YOUR ILLNESS	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
IP1*	My illness will last a short time					
IP2	My illness is likely to be permanent rather than temporary					
IP3	My illness will last for a long time					
IP4*	This illness will pass quickly					
IP5	I expect to have this illness for the rest of my life					
IP6	My illness is a serious condition					

IP7	My illness has major consequences on my life					
IP8*	My illness does not have much effect on my life					
IP9	My illness strongly affects the way others see me					
IP10	My illness has serious financial consequences					
IP11	My illness causes difficulties for those who are close to me					
IP12	There is a lot which I can do to control my symptoms					
IP13	What I do can determine whether my illness gets better or worse					
IP14	The course of my illness depends on me					
IP15*	Nothing I do will affect my illness					
IP16	I have the power to influence my illness					
IP17*	My actions will have no affect on the outcome of my illness					
IP18*	My illness will improve in time					
IP19*	There is very little that can be done to improve my illness					
IP20	My treatment will be effective in curing my illness					
IP21	The negative effects of my illness can be prevented (avoided) by my treatment					
IP22	My treatment can control my illness					
IP23*	There is nothing which can help my condition					
IP24	The symptoms of my condition are puzzling to me					
IP25	My illness is a mystery to me					
IP26	I don't understand my illness					
IP27	My illness doesn't make any sense to me					
IP28*	I have a clear picture or understanding of my condition					
IP29	The symptoms of my illness change a great deal from day to day					
IP30	My symptoms come and go in cycles					
IP31	My illness is very unpredictable					
IP32	I go through cycles in which my illness gets better and worse.					
IP33	I get depressed when I think about my illness					
IP34	When I think about my illness I get upset					
IP35	My illness makes me feel angry					
IP36*	My illness does not worry me					
IP37	Having this illness makes me feel anxious					
IP38	My illness makes me feel afraid					

CAUSES OF MY ILLNESS

We are interested in what <u>you</u> consider may have been the cause of your illness. As people are very different, there is no correct answer for this question. We are most interested in your own views about the factors that caused your illness rather than what others including doctors or family may have suggested to you. Below is a list of possible causes for your illness. Please indicate how much you agree or disagree that they were causes for you by ticking the appropriate box.

	POSSIBLE CAUSES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
C1	Stress or worry					
C2	Hereditary - it runs in my family					
C3	A Germ or virus					
C4	Diet or eating habits					
C5	Chance or bad luck					
C6	Poor medical care in my past					
C7	Pollution in the environment					
C8	My own behaviour					
C9	My mental attitude e.g. thinking about life negatively					
C10	Family problems or worries caused my illness					
C11	Overwork					
C12	My emotional state e.g. feeling down, lonely, anxious, empty					
C13	Ageing					
C14	Alcohol					
C15	Smoking					
C16	Accident or injury					
C17	My personality					
C18	Altered immunity					

In the table below, please list in rank-order the three most important factors that you now believe caused <u>YOUR illness.</u> You may use any of the items from the box above, or you may have additional ideas of your own.

The most important causes for me:-

1. _____
2. _____
3. _____

Items for IPQ-R Subscales

1. **Identity (sum of yes-rated symptoms in column 2 on p. 1)**

2. **Timeline (acute/chronic) items IP1 - IP5 + IP18**

3. **Consequences items IP6 - IP11**

4. **Personal control items IP12 - 1P17**

5. **Treatment control items IP19 – IP23**

6. **Illness coherence items IP24 – IP28**

7. **Timeline cyclical IP29 – IP32**

8. **Emotional representations IP33 – IP38**

9. **Causes C1 - C18 - do not use these as a scale. Start analysis with separate items - used as grouping variables (ie those who do/do not believe in a specific causal factor). With a sufficient sample size (n=85 or more), factor analysis can be used to identify groups of causal beliefs (eg lifestyle ; stress etc) which can then be used as sub-scales** (e.g. *see* Weinman et al, *in press).*

Reference

Weinman, J, ,Petrie, KJ, Sharpe, N & Walker, S . Causal attributions in patients and spouses following first-time myocardial infarction and subsequent lifestyle changes. *Br. J. Health Psychology, in press.*

Subject Code: _____

Below is a set of questions designed to gather information about you and your condition. Answer as many questions as you can. If you don't know, leave the item blank.

Your age at your last birthday: _____

Gender: Male Female

Ethnic heritage: Hispanic/Latino Not Hispanic/Latino

Race:
White Asian Other (please write in)

_____

Native American or Alaska Native

Black/African American Pacific Islander/Native Hawaiian

Marital status:

Unmarried Married

Living situation: (circle one)

Living with Spouse, Partner or support person(s) Living alone
Other _____

Are you currently receiving chemotherapy? Y N

Are you currently receiving radiation therapy? Y N

Are you a smoker? Y N In the past

How long ago was your lung cancer diagnosed? _____

Stage: _____

Concurrent illnesses _____

APPENDIX C

IRB Approvals and Correspondence

OREGON HEALTH & SCIENCE UNIVERSITY
Research Integrity Office, L106 (503) 494-7887

MEMO

Date: July 28, 2003

To: *Teresa T. Goodell MN*

JUL 2 8 2003

From: Gary T. Chiodo, DMD, Chair Institutional Review Board, L106
Susan Hansen, MD, MPH, Co-Chair, Institutional Review Board, L106
Charlotte Shupert, PhD, Manager, Research Integrity Office, L106

Subject: ***7589, EXP***
Illness Appraisal and Symptom Dimensions in Lung Cancer.

Initial Study Review
Protocol/Consent Form Approval

We received your response to the IRB requirement(s) on 07/28/2003.

Your PRAF dated 05/29/2003 and received 06/24/2003, regarding internet advertising, recruitment at OHSU and the Portland Veterans Administration Medical Center, and the addition of a summary for subjects, was reviewed and administratively approved by the IRB on JUL 2 8 2003

Your protocol is approved for one year effective JUL 2 8 2003

Your combined consent/authorization form is approved by the IRB effective JUL 2 8 2003.

You may use only copies of the attached approved consent/authorization form for the informed consent process. Please write the date of annual protocol approval in the upper right hand corner on the first page of the consent/authorization form. If you submit a revised consent/authorization form for approval during the coming year, please type the annual protocol approval date on the first page when revising the form.

Your web advertisement, flyer, three questionnaires, demographics sheet, and sample subject summary are approved by the IRB effective JUL 2 8 2003

This study met the criteria for EXPEDITED IRB review based on Category # 7 [1], research employing survey and interview methodologies.

OHSU subjects must receive a copy of OHSU's Notice of Privacy Practices.

Accounting for disclosures is not needed because all subjects will sign a combined consent form/HIPAA Authorization.

This approval may be revoked if the investigators fail to conduct the research in accordance with the guidelines found in the Roles and Responsibilities document (http://www.ohsu.edu/ra/rso/rgc/randr.pdf). Please note that any proposed changes in key personnel must be submitted to the IRB via a PRAF and approved prior to initiating the change. If you plan to discontinue your role as PI on this study or leave OHSU, you must arrange either (a) to terminate the study by so notifying the IRB and your department head, or (b) propose to transfer the responsibility of the PI to a new faculty member using a PRAF.

Investigators must provide subjects with a copy of the consent form, keep a copy of the signed consent form with the research records, and place a signed copy in the patient's hospital/clinical medical record (if applicable).

Analyst: Wendy Doggett/4

[1] 63 FR 60364-60367 (November 9, 1998)

If this project involves the use of an Investigational New Drug, a copy of the approved protocol must be forwarded to the Pharmacy (Pharmacy Services - Investigational Drugs, CR9-4).

If this is a cancer study, we will notify the OHSU Cancer Institute of the IRB approval. If this is a clinical research study, we will notify the General Clinical Research Center (GCRC) of IRB approval.

OREGON HEALTH & SCIENCE UNIVERSITY
Research Integrity Office, L106 (503) 494-7887

MEMO

Date: June 30, 2003

To: *David Underriner, Administrator, Providence Health System*
Jean Sork, RN, Regional IRB Research Study Coordinator, PHS
Principal Investigator Teresa T. Goodell, MN, Oregon Health & Science University
Margaret McMahon, ANP, Oregon Health & Science University/OCI

From: Gary T. Chiodo, DMD, Chair, Institutional Review Board, L106
Susan Hansen, MD, MPH, Co-Chair, Institutional Review Board, L106
Charlotte L. Shupert, PhD, Manager, Research Integrity Office, L106

JUN 30 2003

Subject: *7589*

Illness Appraisal and Symptom Dimensions in Lung Cancer

Special Communication

On February 04, 2003, Oregon Health & Science University (OHSU) waived IRB review and oversight of this study to Providence Health System (PHS). This waiver was effective February 13, 2003, when David Underriner signed the attached agreement.

At that time, the investigators did not intend to recruit subjects from OHSU. On May 29, 2003, however, the investigators requested permission to expand recruitment to include OHSU. As a result, OHSU is withdrawing its IRB Authorization Agreement effective immediately and will begin review for initial approval.

While this study is under review, investigators are expected to conduct the research in accordance with the guidelines found in the Roles and Responsibilities document (http://www.ohsu.edu/ra/rso/rgc/randr.pdf).

WD/4

IRB#: 7580

Version Date: 03/20/2002

'03 FEB 24 PM 2:06

IRB Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution A):
_____Providence Health System

IRB Registration #: _____ Federalwide Assurance (FWA) #, if any: FWA 00001033 (Exp 8/28/04)

Name of Institution Relying on the Designated IRB (Institution B):
Oregon Health & Science University_____

OHRP Federalwide Assurance (FWA) #: 00000161

The Officials signing below agree that Oregon Health & Science University may rely on the designated IRB for review and continuing oversight of its human subject research described below: (*check one*)

(___) This agreement applies to all human subject research covered by Institution B's FWA.

(_X_) This agreement is limited to the following specific protocol(s):

Name of Research Project: Illness Appraisal and Symptom Dimensions in Lung Cancer.
Name of Principle Investigator: Teresa T. Goodell, RN, CNS
Sponsor or Funding Agency: NIN-NINR Award Number, if any: _____

(___) Other (*describe*):

The review and continuing oversight performed by the designated IRB will meet the human subjects protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the terms of its OHRP-approved Assurance. This document must be kept on file at both institutions and provided to OHRP upon request.

Signature of Signatory Official (Institution A): David Underriner Date: 2/13/03

Print Full Name: DAVID Underriner Institutional Title: Administrator

Signature of Signatory Official (Institution B): [signature] Date: 2/4/03

Print Full Name: Susan Hansen PhD Institutional Title: OHSU IRB Co Chair

OHSU Cancer Institute

MEMORANDUM IRB # 7589

DATE: January 17, 2003

TO: Teresa Goodell, RN, CNS

FROM: Margaret McMahon, ANP
Director, Clinical Research Management
Oregon Cancer Institute, CR 145

RE: **ONC-02122-LX (Attachments 30-33)**
Illness Appraisal and Symptom Dimensions in Lung Cancer

Upon review of your response to the Clinical Research Review Committee's (CRRC) concerns at the December, 2002 meeting, the CRRC has approved your revised protocol with a priority score of 1.7. The protocol has been sent to the OHSU IRB for their review.

All future protocol revisions or amendments, serious adverse event forms and continuing reviews will need to be submitted to OHSU CI prior to IRB submission.

If you have questions or concerns, please contact me at 494-6349.

OHSU Cancer Institute

MEMORANDUM

DATE: December 18, 2002

TO: Teresa Goodell, RN, CNS

FROM: Margaret McMahon, ANP
Director, Clinical Research Management
OHSU Cancer Institute, CR 145

ONC-02122-LX
Illness Appraisal and Symptom Dimensions in Lung Cancer

The Clinical Research Review Committee (CRRC) reviewed your protocol December 11, 2002. The primary reviewer recommended approval of this dissertation study. One issue pointed out is that the time given for completing the questionnaire was given once as 20–30 minutes and another time as 20-60 minuets and should be consistent. An optional suggestion was for clarification of rationale and number of subjects participating in the interview phase of the study. The biostatistical reviewer questioned why one power analysis was done using a significance level of 0.05 and another one using 0.10. With no justification for using both, he asked that the investigator choose one.

Pending response to the reviewers' concerns, the protocol was approved with a priority score of 1.7. The reviews are attached. If you have questions or concerns, please contact me at 494-6349.

(Attachments 30-33)

CRRC PRIMARY REVIEW ABSTRACT TEMPLATE

(Template revision date 8/15/01)

December 9, 2002
ONC-02122-LX
Illness Appraisal and Symptom Dimensions in Lung Cancer
PI: Teresa Goodell, CNS, RN
Sponsor: Lillian Nail, PhD, RN, FAAN

CRRC PRIMARY REVIEWER:

Note: No data will be collected at OHSU. Teresa Goodell is a doctoral student at OHSU School of Nursing. Data will be collected through the Providence Health System

DESCRIPTION OF STUDY

The purpose of this dissertation study is to better understand relationships between certain attitudes and beliefs and the perception of symptoms in people with lung cancer. This is a cross-sectional exploratory, two-phase study, using a convenience sample of 60 adults with non-small cell lung cancer recruited from physician offices, outpatient chemotherapy and radiation oncology departments. In addition, some subjects may be self-referred. Questionnaires measuring illness attitudes, symptoms, and optimism will be completed by 60 subjects. A subset of the subjects will provide additional information through a semi-structured interview.

OBJECTIVES

Questions are generated for both study phases. Those for phase one of the study are: 1) Are there relationships among the components of illness appraisal and symptom distress, intensity, and frequency in people with lung cancer? and 2) Do the components of illness appraisal predict symptom intensity, frequency, and distress in a manner consistent with self-regulation theory? The research question for phase two is: 1) How do lung cancer pateints describe the term "symptom distress?"

BACKGROUND AND RATIONALE

The PI provides an extremely well written background section, highlighting the theoretical components and gaps in the science that this proposal will address.

STUDY DESIGN AND METHODS

This student-generated, cross-sectional, exploratory, two-phase study is designed to elicit the patients' perspective about illness attitudes, symptom characteristics of frequency, intensity, and distress, and optimism in a group of outpatient adults with various stages of non-small cell lung cancer, and to explore the meaning of the term "symptom distress" to these people. Questionnaires about each of these aspects will be completed by a convenience sample of 60 patients, recruited through the Providence Health System from private doctors; offices as well as from outpatient chemotherapy and radiation departments. The questionnaires are established in this field and are The Memorial Symptom Assessment Scale, The Illness Perception Questionnaire-revised, and The Life Orientation Test-Revised. Subjects will either complete the questionnaires that day, or mail the completed questionnaire back to the investigator in a pre-paid envelope. Subjects also will be asked if they will give permission to be contacted again within 6 months, if needed, based on questions about their information provided. In addition, a subset of the subjects will be interviewed about their symptoms and about their responses to the "distress" aspect of the questionnaire. The number of subjects in phase-two (interviews) is not clear. The proposal states that "The first thirty subjects will be asked to take part in the interviews, as will all non-smokers, women, and people of racial or ethnic minorities taking part in the study." (page 8). It is not clear how many interviews are to be completed or the rationale for the selection criteria. Inclusion of such information would add to the soundness of the proposal. The study investigator, an advanced pratice nurse experience in working with lung cancer patients, will ask people to take part in the study when they visit their doctor's office. The interviews will be tape-recorded and transcribed for analysis.

ELIGIBILITY CRITERIA
General inclusion and exclusion criteria are described in the proposal. Patients in various phases of treatment with various stages of cancer will be recruited as subjects. Such a heterogenous sample may pose challenges for some statistical analysis.

TREATMENT CHARACTERISTICS (if applicable)
This section is not applicable to this proposal.

ETHICAL CONSIDERATIONS
The actions outlined regarding ethical and regulatory considerations are appropriate.

TRANSLATIONAL POTENTIAL
This is a beginning study by a predoctoral nursing student. It is a reasonable first step in a program of study with adults experiencing lung cancer and symptoms/symptom management

PRIORITY SCORE AND CRRC APPROVAL RECOMMENDATIONS
With inclusion of the requested minority information, the priority score for this investigator-initiated study is 1.7

After scoring please bullet out recommendations that MUST be completed prior to CRRC approval. (if any)

After scoring please bullet out recommendations that would strengthen the proposal (if any).
1. Clarification of rationale and number of subjects participating in the interview phase of the study (phase two).

CONFLICT OF INTEREST

I certify that I have no conflict of interest in reviewing this study in accordance with the OHSU Conflict of Interest in Research Disclosure Policy.

NAME AND TITLE
N

BIOSTATISTICS
CLINICAL RESEARCH REVIEW COMMITTEE
PROTOCOL REVIEW WORKSHEET

Date of Meeting: December 11, 2002
ONC-02122-LX
Illness Appraisal and Symptom Dimensions in Lung Cancer
PI: Teresa Goodell, RN, CNS

	OUTSTANDING 1.0-1.5	EXCELLENT 1.6-2.0	VERY GOOD 2.1-2.5	GOOD 2.6-3.5	ACCEPTABLE 3.6 -5.0
Study Design					4.0
Primary and Secondary objectives clearly defined				2.6	
Data Collection Plan					3.6
Confounding and Other Independent Variables Delineated				3.0	
Method of Data Analysis Clearly Stated and appropriate for study objectives				3.0	
Sample size justification					4.0
Randomization method described (for randomized study only)					NA

To check a box, first click on it. A message box will appear. Click on the radio button "checked" under Default Value.

☐ **Approved**
☐ **Disapproved**
☒ **Approved Pending Minor Changes** SCORE _____

)MMENTS: [type comments here]

Why was the power analysis done using a significance level of 0.05 and another one using 0.10. There seems to be no justification for using both are necessary. Please choose one.

I certify that I have no conflict of interest in reviewing this study in accordance with the OHSU Conflict of Interest in Research Disclosure Policy.

Name of Reviewing Biostatistician: _____ Date: 12/04/02

CLINICAL RESEARCH ADMINISTRATION
CLINICAL RESEARCH REVIEW COMMITTEE
PROTOCOL REVIEW WORKSHEET

Date of Meeting: December 11, 2002
ONC-02122-LX
Illness Appraisal and Symptom Dimensions in Lung Cancer
PI: Teresa Goodell, RN, CNS

	OUTSTANDING 1.0-1.5	EXCELLENT 1.6-2.0	VERY GOOD 2.1-2.5	GOOD 2.6-3.5	ACCEPTABLE 3.6 -5.0
Patient Registration		1.8			
CRF's / Submission Schedule					
Schedule - Study Calendar					
Resource Utilization					
Study Budget		NIH-NINR			
Consent Form					
Eligibility Criteria					
Inclusion of Women and Minorities					
Accrual Time Frame					
Sample Size Clearly Defined		▼			
Competing Protocols		None			
Ethical / Regulatory Considerations		None			

To check a box, first click on it. A message box will appear. Click on the radio button "checked" under Default Value.

- ■ **Approved**
- ☐ **Approved with Minor Changes**
- ☐ **Disapproved**
- ☐ **Administratively Withdrawn**

SCORE: 1.8

COMMENTS: [type or write comments here]

certify that I have no conflict of interest in reviewing this study in accordance with the OHSU Conflict of Interest in Research Disclosure Policy.

eviewed by: _____ Date: 11-26-02

OHSU Institutional Review Board

PROJECT REVISION/AMENDMENT FORM

Federal regulations require IRB approval before implementing proposed changes.

Please complete this form and attach changed research documents. Change means any change, in content or form, to the protocol, consent form, or any supportive materials (such as Investigator's Brochures, questionnaires, surveys, advertisements, results from related studies, etc.)

Principal Investigator: Teresa T. Goodell, RN, CNS Date: 5-29-03

Contact: same IRB# 7589/ONC-02122-LX

Phone #: 503 522 2076 Mail Code: SON - ADMIN

Study/Protocol Title:I Illness Appraisal and Symptom Dimensions in Lung Cancer

THE CURRENT STATUS OF THE OHSU PROJECT IS (Check one; provide # of subject as requested):

[X] Currently in progress (subjects entered:) # 6

[ ] Project not yet started (no subjects entered)

[ ] Closed to subject entry (remains Active; # of subjects still on medication/intervention): _____

THIS SUBMISSION CHANGES THE STATUS OF THIS STUDY IN THE FOLLOWING WAY(S):

[ ] Protocol Revision

[ ] Protocol Amendment

[ ] Close to Subject Entry

[ ] Revised Consent Form (two copies, one with changes highlighted, the other without)

[ ] Addendum (New) Consent Form

[X] Other (specify) – change in recruitment methods

If you would like to terminate this study, please submit a Project Termination form available at: http://www.ohsu.edu/ra/forms.shtml#hsf

1. Briefly describe, and explain the reason for, the *revision* or *amendment*. ***Highlight, or otherwise indicate, any changes/revisions/additions to consent form / protocol / research questionnaire / other study document(s), or the PRAF will be returned to you.***

Innovative recruitment strategies involving the Internet and more sites are being added to the study because of slow accrual. **First**, permission has been requested, but not yet granted, to post one message monthly to the public bulletin boards maintained by the website lungcancersurvivors.org. The text of the monthly message is attached on a separate sheet. Interested subjects will email lungcancerstudy@hotmail.com, an account set up exclusively for the study, to contact the investigator, who will mail the study forms to the subject with a self-addressed, stamped envelope. **Second**, an application has been made to the Portland Veterans Administration Medical Center IRB under the sponsorship of Dr. Mark Deffebach, division of pulmonary and critical care medicine, to recruit subjects there. **Third**, discussions are underway with Dr. Vandy Sherbin, OHSU pulmonologist, regarding recruitment of outpatients from her practice. **Fourth**, an advertisement will be placed by OHSU University News & Publications on the OHSU research recruitment page. The text of this message has been edited by U N & P and is attached. **Fifth**, subjects are offered the opportunity to receive a one-paragraph written summary of the results of their surveys as remuneration for taking part in the study. This information has been added to the consent form.

2. Does this revision/amendment revise or add a genetic component? Yes [ ] No [X]
If yes for OHSU studies, please see the OHSU IRB sample genetic consent form (www.ohsu.edu/ra/forms.shtml#hsf).

3. Does the change affect subject participation (e.g. procedures, risks, costs, etc.)? Yes [X] No [ ]
Adds opportunity to receive a brief written summary of their results. This will require subjects to share their addresses with the investigator.

4. Does the change affect the consent document? *Please discuss briefly.* Yes [X] No [ ]
If yes, please include the revised consent form with the changes highlighted. ATTACHED

Please submit to RC&A, Mail Code L106 (Suite 125, ADP Building). Questions: 503-494-7887

Subjects are informed that they will have an opportunity to receive a brief summary of their survey results, if they wish. This will require sharing of subjects' addresses with the investigator, as will recruitment over the Internet. As with other identifying information in this study, however, subjects' addresses will not be traceable to subjects' names, as they will be recorded on the survey forms, not on the consent forms or authorizations. For subjects who are contacted via the Internet, access to their medical records will not be possible, so as much information as possible will be gleaned directly from the patient.

Susan T. Goodell RN CNS — Signature of Principal Investigator

6-18-03 — Date

FOR OHSU CANCER INSTITUTE PROJECTS ONLY

Cancer Institute Signature — Date

TO BE COMPLETED BY IRB		**FOR IBC (HUMAN GENE TRANSFER) PROJECTS ONLY**	
IRB Signature	Date	**IBC Signature**	Date

Please submit to RC&A, Mail Code L106 (Suite 125, ADP Building). Questions: 503-494-7887

Summary of Consent Form Changes

The brief description on page one has been re-worded to better reflect the aims. On page two, the demographic questionnaire has been added to the description of what subjects will do in the study. The minimum length of interviews has been reduced as a result of experience with the interviews already done. Subjects are offered a brief summary of their survey results as a benefit of taking part. The required HIPAA authorization language has been added. The contact person (page 5) has been changed, because the original contact person is no longer at OHSU. Subjects are given the option (page 6) of whether or not to share their phone numbers and allow the investigator to contact them again within six months, if needed.

Dear _____ 6-17-03

Thank you for giving of your time to take part in the study "Illness Appraisal and Symptom Dimensions in Lung Cancer." Below is a summary of your results:

Illness Appraisal

You indicated that you believe there is a great deal you can do to influence your illness, and that you feel like you understand your illness fairly well. You believe that treatment will control your illness effectively and that the illness will last a fairly long time. You indicated that you feel somewhat depressed or blue about the illness.

Optimism

Your score on the LOT-R was 16 of a possible twenty points. This indicates that you are moderately optimistic in general.

Symptom measure

Your answers on the symptom measure indicate that you had experienced 15 of the 32 symptoms listed within the past week at the time you filled out the forms. For you, fatigue and loss of strength were the most distressing symptoms, and shortness of breath and pain were the most intense. None of the symptoms was extremely intense or extremely distressing to you.

I hope you find this information interesting. If you have any comments, concerns or questions about this information, please do not hesitate to call me at (503) 522-2076 or email me at lungcancerstudy@hotmail.com. Thank you once again for taking part in this study.

Sincerely,

Teresa T. Goodell, RN, CNS, CCRN, CS

Text of OHSU research website message and lungcancersurvivors.org message:

Lung Cancer Patients Needed for Symptom Study

Sixty people with non-small-cell lung cancer are needed to take part in a study examining the influence of beliefs about lung cancer on symptom distress. Study participants will fill out four questionnaires, and 20 people will also be interviewed by the investigator about their symptoms and how they perceive them. Filling out the questionnaires takes about 20 minutes. The interviews take 15 to 60 minutes. All study participants will have an opportunity to talk about their illness with the investigator, a clinical nurse specialist and an Oregon Health & Science University School of Nursing doctoral candidate. Study participants may request a brief summary of their own survey results, if they wish. Contact Teresa Goodell, R.N., C.N.S., at 503 522-2076 or lungcancerstudy@hotmail.com to learn more about the study.

Providence | Health System

Institutional Review Board

4900 N.E. Glisan
Portland, Oregon
97213-2967

Tel 503.215.6512
Fax 503.215.6632

January 8, 2003

Teresa Goodell, RN, CNS
Providence St. Vincent Medical Center
Oregon Medical Laser Center

RE: EXPEDITED STUDY REVIEW AND APPROVAL FOR:
02-152 Illness Appraisal and Symptom Dimensions in Lung Cancer

Dear Ms. Goodell,

This letter represents review and approval of your study proposal (undated), recruitment flyer (undated), Consent to Contact Form (undated), schedule of events (undated), Illness Perception Questionnaire – IPQ-R, Memorial Symptom Assessment Scale and LOT-R survey (all undated) demographic form (undated), and consent form (final revisions were received January 8, 2003). These study materials were expeditiously reviewed and approved by Laurie Skokan, PhD, Acting IRB Chairperson on December 18, 2002.

The consent form for this study is IRB date-stamped 12-18-02. Please use only this version when enrolling subjects in this study.

This study is active/open until December 17, 2003. A Continuing Review report must be sent to the IRB by this date.

Any/all changes that you make to this study, forms, questionnaires, and consent form must be reviewed and approved by this IRB before they are implemented.

This study review and approval will be reported to the full-board committee at the January 28, 2003 meeting.

It has been a pleasure reviewing your study and working with you. Good luck with this study, and call us any time you have questions.

Sincerely,

Jean Sork

Jean Sork, RN
Regional IRB Research Study Coordinator

Providence | Health System

Institutional Review Board

4900 N.E. Glisan
Portland, Oregon
97213-2967

Tel 503.215.6512
Fax 503.215.6622

July 23, 2003

Teresa Goodell, RN, CNS
Oregon Health & Sciences University
School of Nursing, Doctoral Candidate

Re: **EXPEDITED APPROVAL OF PROTOCOL MODIFICATION FOR:**
02-152 Illness Appraisal and Symptom Dimensions in Lung Cancer

Dear Ms. Goodell,

This letter represents expedited review and approval of the protocol modification for the above study dated June 12, 2003. This modification involves a new study recruitment strategy/message (Internet), subjects may choose to receive feedback about their survey results, two additional sites are being added for recruitment (OH & SU and Portland Veterans Administration), and consent form revisions. Additionally, a PHS Authorization to Use and Disclose Protected Health Information form will be used by PHS staff to obtain patient permission before you contact potential subjects about this study. This protocol modification was approved by Laurie Skokan, PhD, Acting IRB Chairperson on July 23, 2003.

The study summary for internet posting and the letter for patient results have been noted to be versions "7-23-03" by this IRB so that the date is easily identified. You may use clean copies of these 7-23-03 documents when recruiting and communicating with subjects.

Please use only this IRB date-stamped Authorization to Use and Disclose PHI form (7-23-03) when recruiting patients in this study; and use only this IRB date-stamped consent form ("PM: 7-23-03") when enrolling subjects in this study.

The members will be informed about this expedited study modification at the August 26, 2003 full-board meeting.

Sincerely,

Jean Sork, RN
Regional IRB Research Study Coordinator

5/2003

PROVIDENCE HEALTH SYSTEM INSTITUTIONAL REVIEW BOARD
PROTOCOL/CONSENT FORM MODIFICATION

ATTACH A COPY OF THE AMENDMENT / REVISION NOTICE

PROVIDENCE IRB STUDY #: 02-152 OHSU Cancer Ctr # ONC-02122-LX

STUDY TITLE: Illness Appraisal & Symptom Dimensions in Lung Cancer

PROTOCOL AMENDMENT # / REVISION # / NOTICE AND DATE: #2

PRINCIPAL INVESTIGATOR: Teresa T. Goodell, RN, CNS

NAME, PHONE # AND E-MAIL ADDRESS OF PERSON FILLING OUT THIS FORM:

Innovative recruitment strategies involving the Internet and more sites are being added to the study because of slow accrual. **First**, permission has been requested, but not yet granted, to post one message monthly to the public bulletin boards maintained by the website lungcancersurvivors.org. The text of the monthly message is attached on a separate sheet. Interested subjects will email lungcancerstudy@hotmail.com, an account set up exclusively for the study, to contact the investigator, who will mail the study forms to the subject with a self-addressed, stamped envelope. **Second**, an application has been made to the Portland Veterans Administration Medical Center IRB under the sponsorship of Dr. Mark Deffebach, division of pulmonary and critical care medicine, to recruit subjects there. **Third**, discussions are underway with Dr. Vandy Sherbin, OHSU pulmonologist, regarding recruitment of outpatients from her practice. **Fourth**, an advertisement will be placed by OHSU University News & Publications on the OHSU research recruitment page. The text of this message has been edited by U N & P and is attached. **Fifth**, subjects are offered the opportunity to receive a one-paragraph written summary of the results of their surveys as remuneration for taking part in the study. This information has been added to the consent form. See attached sample feedback letter.

CONSENT FORM CHANGE(S): Yes X No ____

IF YES, ATTACH A COPY OF REVISED CONSENT; USE A YELLOW HIGHLIGHTER TO DISTINGUISH ALL CHANGES.

SUMMARY OF CHANGES:

Two additional sites are being added and other recruitment strategies are being implemented.

INVESTIGATOR'S SIGNATURE Teresa T. Goodell RN CNS **DATE** 6-12-03

CHAIRPERSON APPROVAL Carrie Skotka **DATE** 7/23/

- MENTION OF "INTERVIEW" AS CLARIFICATION IN STUDY PROCEDURES
- SUBJECTS CAN REQUEST FEEDBACK ABOUT THEIR RESULTS
- HIPAA INCLUDED IN THE BODY OF THE CONSENT FORM.

Lung Cancer Patients Needed for Symptom Study

Sixty people with non-small-cell lung cancer are needed to take part in a study examining the influence of beliefs about lung cancer on symptom distress. Study participants will fill out four questionnaires, and 20 people will also be interviewed by the investigator about their symptoms and how they perceive them. Filling out the questionnaires takes about 20 minutes. The interviews take 20 to 60 minutes. All study participants will have an opportunity to talk about their illness with the investigator, a clinical nurse specialist and an OHSU School of Nursing doctoral candidate. Contact Teresa Goodell, R.N., C.N.S., at 503 522-2076 or lungcancerstudy@hotmail.com to learn more about the study.

Dear _____ Date

Thank you for giving of your time to help with the study "Illness Appraisal and Symptom Dimensions in Lung Cancer." The results of your three surveys are as follows:

IPQ (Illness Perception Questionnaire) – How you see your illness.

Your responses showed that you expect your illness to last a long time, and that you find some aspects of the illness confusing. They showed that you expect treatment to help, and that you feel fairly sure that your own habits can change the course of the illness. Your responses also showed that you feel blue or depressed about the illness, and that smoking and heredity caused your illness.

LOT (optimism questionnaire) – How hopeful you usually are.

Optimistic people tend to see things more positively than pessimistic people. Your score was in the middle range, indicating you are not especially optimistic nor pessimistic.

MSAS (symptom questionnaire) –Your symptoms.

Of the thirty-two symptoms on this questionnaire, worry, pain and difficulty sleeping were the most distressing. You have had 18 of the 32 symptoms on the questionnaire. None of your symptoms was extremely sever or extremely distressing for you.

I hope you find this information interesting. If you have questions or concerns about it, please do not hesitate to phone me at (503) 5322-2076 or email goodellt@ohsu.edu. As you know, your information remains confidential, and if the study results are published or presented in meetings, your name will be kept secret. Thank you once again for taking part in this study.

Most sincerely,

Teresa T. Goodell, RN, CNS

VERSION 7-23-03

Report of Institutional Review Board #2

Project/Program Title: **Illness Appraisal and Symptom Dimensions in Lung Cancer (w/Teresa Goodell, RN) (VA #06-1303)**

Principal Investigator: **Mark E. Deffebach, M.D.**

VAMC: **Portland** Review Date: **08/13/2003**

Items Reviewed:
Abstract (10/09/2003; 10/09/03 rcvd)
Abstract (06/02/2003)
Advertisement (10/09/2003; 10/09/03 rcvd)
Advertisement (08/05/2003; 8/5/03 rcvd)
Consent Form (10/09/2003; 10/09/03 rcvd)
Consent Form (08/04/2003)
Initial Review Questionnaire (10/09/2003; 10/09/03 rcvd)
Initial Review Questionnaire (06/02/2003)
Response Letter (10/09/2003; 10/09/03 rcvd)
Email b/t A Lacey & T Goodell re: recruit process (08/01/2003)
OHSU IRB Approval (07/28/2003; 10/09/03 rcvd)
Participant letter w/results and feedback (06/11/2003)
Questionnaire / Survey - demographics (06/11/2003)
Questionnaire / Survey - Illness Perception Questionnaire (06/11/2003)
Questionnaire / Survey - Memorial Symptom Assessment Scale (06/02/2003)
Protocol Revision (10/09/2003; 10/09/03 rcvd)
Safe Harbor De-Identification Certification Form (06/02/2003)

COMMITTEE FINDINGS:

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or a surrogate who possesses standard reading and comprehension skills. ◉ Yes ○ No ○ N/A
2. The informed consent is obtained by the principal investigator or a trained and supervised designee under suitable circumstances. ◉ Yes ○ No ○ N/A
3. Every effort has been made to decrease risk to subject(s)? ◉ Yes ○ No ○ N/A
4. The potential research benefits justify the risk to subject(s)? ◉ Yes ○ No ○ N/A

5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met: (a) the research cannot be done on competent subjects; (b) there is no risk to the subject, or if the risk exists the direct benefit to subject is substantially greater; (c) if an incompetent subject resists, he will not have to participate; (d) if there exists any question about the subject's competency, the basis for decision on competency has been fully described. ◉ Yes ○ No ○ N/A

6. If the subject is paid, the payment is reasonable and commensurate with the subject's contribution. ○ Yes ○ No ◉ N/A

7. Members of minority groups and women have been included in the study population whenever possible and scientifically desirable. ◉ Yes ○ No ○ N/A

8. Comments: (Indicate if Expedited Review)
Approval for initial review.

Continuing Review: **07/14/2004**
Approval Expiration: **08/12/2004**

RECOMMENDATION: ◉ Approve ○ Disapprove / Revise

SIGNATURE OF CHAIRPERSON	DATE
Wayne M. Clark, M.D., Chairperson	11/06/2003

IRB APPROVAL - Initial Review

Date: November 6, 2003
From: Lisa Gunion-Rinker, IRB Coordinator Lisa Gunion-Rinker
Investigator: Mark E. Deffebach, M.D.
Protocol: Illness Appraisal and Symptom Dimensions in Lung Cancer (w/Teresa Goodell, RN) (VA #06-1303)
ID: 01075 Prom#: N/A Protocol#: N/A

The following items were reviewed and approved at the 08/13/2003 meeting, contingent upon minor stipulations in each item marked with an asterisk (*):

- Abstract (10/09/2003; 10/09/03 rcvd)
- Abstract (06/02/2003)
- Advertisement (10/09/2003; 10/09/03 rcvd)
- Advertisement (08/05/2003; 8/5/03 rcvd)
- * Consent Form (08/04/2003)
- * Initial Review Questionnaire (06/02/2003)
- Response Letter (10/09/2003; 10/09/03 rcvd)
- Email b/t A Lacey & T Goodell re: recruit process (08/01/2003)
- OHSU IRB Approval (07/28/2003; 10/09/03 rcvd)
- Participant letter w/results and feedback (06/11/2003)
- Questionnaire / Survey - demographics (06/11/2003)
- Questionnaire / Survey - Illness Perception Questionnaire (06/11/2003)
- Questionnaire / Survey - Memorial Symptom Assessment Scale (06/02/2003)
- Protocol Revision (10/09/2003; 10/09/03 rcvd)
- Safe Harbor De-Identification Certification Form (06/02/2003)

Consent Form (08/04/2003) was returned to you with minor stipulations. The following revised items incorporate the stipulations and are now approved:

- Consent Form (10/09/2003; 10/09/03 rcvd)

Initial Review Questionnaire (06/02/2003) was returned to you with minor stipulations. The following revised items incorporate the stipulations and are now approved:

- Initial Review Questionnaire (10/09/2003; 10/09/03 rcvd)

Approval is granted for a period of 12 months and will expire on 08/12/2004. Your Continuing Review is scheduled for 07/14/2004.

The protocol was determined to have the following level of risk:

Minimal

As a reminder, this IRB approval is contingent on conducting the study in the manner it was presented. This includes the following assurances, which were provided when the initial review questionnaire was signed and submitted:

·To promptly report proposed changes in the research activity to the IRB and not initiate changes until they have been approved by the IRB.
·To report deaths of VA patients on protocols within 24 hours to the IRB, and all other serious adverse events (expected or unexpected) or any unanticipated problems involving risk to subjects, to the IRB within 10 days of occurrence.
·To forward the original signed consent form to the Research Service within 72 hours of obtaining patient's consent and to maintain a copy in the study files.
·To take responsibility for maintaining IRB approval, including furnishing the IRB with relevant information when requested.
·To immediately activate the electronic research FLAG□for all patient enrolled in this study if the IRB designates this as a project with high or moderate risk.
·To be responsible for the ethical conduct of this project and for protecting the rights and welfare of the subjects.
·That patient confidentiality will be maintained as stated in the research project application.
·That you will use and disclose VHA patients' protected health information only as outlined in the application.

Please be reminded also that, per medical records regulations, the social security number must be on every page of the informed consent form. In addition, the HIPAA authorizations, if separate from the informed consent form, should always be submitted to the Research Service with the consent form.

Project personnel must be updated as appropriate and obtain IRB approval prior to new staff working on a project/interacting with participants.

HIPAA regulations now require that research records be maintained for 6 years after the study is completed, or longer if required by the sponsor.

Approval by each of the following is required prior to study initiation:
Institutional Review Board #2
Research & Development Committee

Approval for study initiation is contingent upon your compliance with the requirements of the Research Service for the conduct of studies involving human subjects.