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OF THE CES-D SCALE WHEN ASSESSING
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IN CANCER PATIENTS

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Coreen Jean Williams

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# TEST BIAS IN THE SOMATIC ITEMS OF THE CES-D SCALE WHEN ASSESSING DEPRESSIVE SYMPTOMATOLOGY IN CANCER PATIENTS

BY

Coreen Jean Williams

# A THESIS

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### ABSTRACT

# TEST BIAS IN THE SOMATIC ITEMS OF THE CES-D SCALE WHEN ASSESSING DEPRESSIVE SYMPTOMATOLOGY IN CANCER PATIENTS

BY

# Coreen Jean Williams

This study examines and compares responses to the Center for Epidemiologic Studies - Depression Scale (CES-D) obtained from cancer and non-cancer caregivers. This study supports the notion of a test bias in the scale when used with cancer subjects. The 288 cancer and 288 non-cancer caregiver subjects were selected from a convenience sample, matched by gender and total CES-D score, minimizing the effects of extraneous variables. Significant differences were noted between the groups in regard to the mean responses on three of four hypothesized somatic items of the CES-D. Apparently these items function both as indicators of depressive symptomology and of symptoms of cancer and cancer treatment. The four items selected include; appetite, effort, sleep, and get "going". When combined into a modified somatic subscale, significant differences were observed between the cancer and non-cancer comparison groups. This potential test bias of the CES-D has relevant implications when used to screen cancer patients.

To Billy and Jeremy Williams

iii

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#### Introduction

Depression is a common problem. So common in fact that studies have shown that 15% to 30% of adults at some point in their life will experience and be treated for clinical depression (Feightner & Worrall, 1990). A primary concern is the number of elderly who suffer from this malady and its sequelae. Although presence of depression in the elderly has been estimated to be as low as 5% of the population (Lamberty & Bieliauskas, 1993), the Epidemiologic Catchment Area Study identified 15% of the elderly community population aged 65 or older, exhibited depressive symptoms (Lamberty & Bieliauskas, 1993); other studies have confirmed these findings (NIH Consensus Conference, 1992). The National Institute of Health determined that this is a realistic estimate for the general population (NIH Consensus Conference, 1992).

There is considerable evidence indicating that depression at all ages is associated with a rise in medical morbidity and shortened life expectancy and this is especially true among the elderly (Caine et al., 1993). In the Epidemiologic Catchment Area study, patients aged 55 and over who had a major depressive disorder, had a mortality rate that was four times higher than the non-depressed age-matched controls. In addition, up to 15

percent of these patients required hospitalization and eventually succeeded in suicide (U.S. Department of Health and Human Services, 1993). In one study, nursing home residents who were admitted with a major depressive disorder had a 59 percent greater likelihood of death in the first year following admission when compared to residents without a major depressive disorder (U.S. Department of Health and Human Services, 1993). However, these studies have not established a cause and effect relationship. Despite this, the practitioner should consider the potentially detrimental effects of depression on an individual's physical and mental health. Even if the depression is treated, there is evidence suggesting that after recovery of a depressive episode there may not be a complete return of cognitive function in the elderly (Levy, 1991). Depression in the elderly is a major health problem faced by primary care providers. If depression is treated, quality of life may be enhanced.

In 1991 the Census Bureau identified 35 million persons aged 65 or older in the nation (1993). The projected rise in both numbers and the proportion of the total population consisting of the elderly during the years 2020 - 2050 is substantial due to the "Baby Boomers" (Bureau of the Census, 1993). It is estimated that there will be a 12.8% to 20.4% increase in the population of the elderly, so it is reasonable to expect that the numbers of depressed elders will also be on the rise (Benedict & Nacoste, 1990; Bureau

of the Census, 1993). Early diagnosis of depression is essential for appropriate management. Aggressive treatment of depression in the elderly could ultimately decrease mortality and reduce health care costs among the aged. While depression is prevalent among the patients seen in primary care settings, there remains doubt as to whether the available depression scales are bias-free screening instruments for persons exhibiting co-morbidity. As will be shown, assessing persons for depression becomes problematic when they have a major medical disease such as cancer.

Major depression occurs in nearly 25% of patients with cancer (U.S. Department of Health and Human Services, 1993). Cancer victims who have greater levels of disability and discomfort are at a particularly high risk of developing depression (U.S. Department of Health and Human Services, 1993). Studies that associate cancer and depression indicate that 25% of hospitalized cancer patients will satisfy the criteria established for major depressive disorder with depressed mood (Blazer, 1993). As high as 77% of bedridden cancer patients studied meet criteria for major depressive syndrome (U.S. Department of Health and Human Services, 1993). One problem, however, is accurate detection of depression in the cancer patient. Identifying depressed symptomology proves to be difficult due to the fact that cancer and its treatment often generate similar symptoms that are also associated with depression. As a

result, care for persons with cancer becomes more difficult to manage when it is compounded by unrecognized depression.

According to the U.S. Department of Health and Human Services (1993), "At least five reports suggest that primary care practitioners under diagnose and/or under treat depressive conditions" (p. 11). Although current evidence does not support routine screening for detection of depression, primary care providers need to have valid and reliable measures to assist in early detection of elderly persons at risk for developing depression (Feightner & Worrall, 1990; U.S. Preventative Task Force, 1989). The Center for Epidemiologic Depression Scale (CES-D) is one of the standardized instruments used by primary care providers as a systematic approach to screening persons for depressed mood, in addition to its use by researchers for populations based studies of depression symptomology (U.S. Department of Health and Human Services, 1993).

Because of this coupled role of the CES-D, it is imperative that this instrument be valid and reliable. Radloff's examination of this scale with healthy populations was "found to have very high internal consistency and adequate test-retest repeatability. Validity was established by patterns of correlations with other self-report measures" (Radloff, 1977, p. 385). However the use of this well known standardized instrument may present problems of validity when applied to unhealthy populations, especially when addressing populations with cancer.

# **Problem**

One dimension of the nursing process is focused on identifying symptoms of depression to provide prompt interventions to enhance well-being. The use of standardized instruments may facilitate early diagnosis of depression, especially in persons who may be at risk by the nature of their disease, such as cancer. Although there is evidence that depression is under diagnosed and cancer is a risk factor for developing depression, many individuals with this disease are not depressed and the implications of false-positive labeling may be harmful due to negative societal attitudes regarding psychiatric conditions (U.S. Preventative Task Force, 1989). The data obtained from survey instruments, even if standardized, needs to be interpreted with caution if there is a question of potential test bias in the scale. The CES-D Scale incorporates items that may also be indicators of cancer or treatment related symptoms. Therefore the patient with cancer may be responding to items based on their cancer symptoms resulting in CES-D scores that over estimate depression. A comparison of CES-D item scores will be made between the following two groups: cancer patients and non-cancer caregivers. caregiver subjects are not related to the cancer group. main problem addressed in this study is, do cancer patients display elevated mean scores on the somatic items of the CES-D Scale, when compared to the non-cancer respondents with same mood scores?

# <u>Hypothesis</u>

Cancer patients' CES-D scores will show greater dependence on the somatic item scores when compared to non-cancer caregivers, demonstrating that the CES-D Scale has a test bias.

# Measurement Theory

The measurement of a patient domain status such as depressive symptomology is most appropriately achieved through the use of a criterion-referenced approach (Waltz, Strickland, & Lenz, 1984). The predominant characteristic of criterion-referenced measures is that the interpretations are based on a specified domain rather than a specified population or group (Waltz, Strickland, & Lenz, 1984). A specified domain such as depression is often assessed through the use of summated rating scales. A self-report instrument like the CES-D Scale, provides an objective measure of depression that may assist the practitioner in diagnosing depression. This type of scale provides objective information through the narrow range of options given to the participant to construct their responses (Waltz, Strickland, & Lenz, 1984). By measuring the attributes of depression manifested by persons, it is possible to present a continuum on which to locate individuals representing the amount of the attributes of depression possessed by an individual. This information may assist in a differential diagnosis of depression (Waltz, Strickland, & Lenz, 1984).

The CES-D Scale addresses predetermined target
behaviors and has established "cut-off" scores for
depression. One area of concern is that these target
behaviors may not purely represent the specified domain of
depression in certain groups such as cancer patients, due to

the likely influence of other factors on the expected behaviors. "In the case of the criterion-referenced measurement, unless the standard or cut score has a high validity, the computation of a reliability index has little significance" (Waltz, Strickland, & Lenz, 1984, p. 188).

Subsequently, validity becomes an issue when using the CES-D to screen cancer patients for depressed mood. CES-D Scale purports to be a valid measure of depression in the general population. This validity may be threatened when the scale is applied to cancer patients. The reason for this is that some items of the CES-D may not be unique indicators of depression but may indicate the presence of physical symptoms among cancer patients. The symptoms may either be manifestations of the cancer itself or consequences of treatments such as chemotherapy or radiation. In theory, this represents a test bias of the CES-D Scale. If a practitioner uses the CES-D Scale to assist in the differential diagnosis of depression in cancer victims, there may be a threat to the decision validity if the cut score of 16 is used to determine depression. One of the limitations of the CES-D is that the cut-off scores have not been validated in clinical settings to determine the relationship of elevated scores to the actual diagnoses of a depressive disorder established through a clinical interview using DSM-lll criteria. The result may be an inaccurate classification of depressive symptomology among cancer patients. According to measurement theory, "it is

imperative that a criterion-referenced measure function in the manner consistent with the purpose for which it is designed and used (Waltz, Strickland, & Lenz, 1984, p. 200).

# Depression

Depression can be defined as "...a morbid sadness, dejection, or melancholy, distinguished from grief, which is realistic and proportionate to a personal loss" (Miller & Keane, 1992, p. 403). Depression derives from a mixture of factors such as "...heredity, biology, and psychology, and social and cultural processes" (Blazer, 1993, p. 21). It is essential when assessing persons for depression to look at these multifaceted determinants of depression in which perceived and actual losses play a major role (Benedict & Nacoste, 1990). The U.S. Department of Health and Human Services (1993) has identified the following risk factors associated with developing depression:

Prior episodes of depression, family history of depressive disorder, prior suicide attempts; female gender, age onset under 40; postpartum period; medical co-morbidity; lack of social support; stressful life events, current alcohol or substance abuse (p. 73).

Persons who exhibit symptoms of a depressed mood may or may not have a clinically diagnosed depressive condition.

Depressive conditions are classified as primary mood disorders according to the DSM-lll-R criteria and include the following subgroups: psychotic, melancholic, atypical, seasonal, postpartum psychosis/depression, dysthymic bipolar, and depression not otherwise specified (U.S. Department of Health and Human Services, 1993). A major

depressive episode does not only occur as part of a primary mood disorder, but can occur in other multiple, nonmood psychiatric and general medical conditions such as cancer or resulting from the use of certain prescribed medications (U.S. Department of Health and Human Services, 1993). Primary mood disorders are often associated with anxiety symptoms and complaints of vague somatic symptoms (U.S. Department of Health and Human Services, 1993). These somatic symptoms, as they relate to depression and comorbidity, are the focus of this study.

Somatic symptoms refers to psychogenic symptoms in which the patient presents with vaque physical complaints, often referred to as vegetative features which may include constipation, headache, chest tightness, dyspnea, musculoskeletal pain, anorexia, other gastro - intestinal symptoms, and fatique (Skodol-Wilson & Ren-Kneisl, 1990; Miller & Keane, 1992). The somatic melancholic features of major depression present as psychomotor retardation or agitation (U.S. Department of Health and Human Services, 1993). Other somatic features include over or under eating, weight gain or loss, sleep disturbances, low energy, and/or a feeling of heaviness in the arms and legs (U.S. Department of Health and Human Services, 1993). Some findings imply that in early development of major depressive disorders, atypical symptoms are likely to be manifested, while melancholic characteristics may be apt to appear later (U.S. Department of Health and Human Services, 1993).

The differential diagnosis of somatic symptoms is complex since this syndrome is not unique to major depression but may also be seen in "...diabetes, pituitary, adrenal and thyroid disorders, malignancies, infections, neurologic disorders, autoimmune disorders, cardiovascular disease, vitamin/mineral deficiency and/or excess state" (Caine et al., 1993, p. 7), "... arthritis, vision and hearing impairment, diabetes, ischemic heat disease, hypertension and stroke" (U.S. Department of Health and Human Services, 1993, p.5). From 12 to 36 percent of patients with these types of disorders have observable depressive symptoms (U.S. Department of Health and Human Services, 1993).

Substantial controversy has occurred concerning the standard for identifying depression in the physically ill and in the elderly. It is often difficult to discriminate somatic symptoms that are often associated with depression from those that may be a result of an illness and/or the aging process. Although there is wide recognition that through all stages of the life cycle the core signs and symptoms of depression remain the same, evidence suggests that vegetative symptoms are prevalent among the elderly with a higher incidence of weight loss as compared to younger persons (Caine et al., 1993; Blazer, 1993). Blazer (1993) identifies that there is a higher percentage of reported retarded activity in the elderly that may in part be secondary to physical disabilities, but argues that

"...motivational difficulty is a frequent cause of inability to initiate activity as well" (p. 34) and contends that endogenous symptoms may indicate subsyndromal depressive episodes for numerous elderly.

There is a lack of studies addressing co-morbidity of medical illness and depression. In addition, only a limited number of studies have been able to replicate differences in reported symptoms of depression between younger and older patients whereas many studies have identified numerous similarities, therefore, suggested discrepancies should be viewed as tentative (Caine et al., 1993).

Like many other instruments, the CES-D has items that assess somatic symptoms which may indicate a relevant comorbidity not related to depression (Caine et al., 1993).

One advantage the CES-D offers is fewer somatic items as compared to other more commonly used depression scales such as the Beck's Depression Inventory (BDI) (Welch & Ellis, 1991). "Despite attempts to move this confound, medical illness emerges consistently as the most common clinical feature associated with depressive symptoms and diagnoses in community, outpatient, and inpatient samples" (Caine et al., 1993 p. 14). As a whole, an inflation in the somatic subscales has not been demonstrated in several studies such as:

...did not confirm the common clinical stereotypes that ascribe greater somatization, hypochondria, and agitation to the elderly depressed compared

with younger depressed. Clinical presentation was relatively uniform across older and younger depressives in the study of 400 patients seen in outpatient clinics. All had a primary diagnosis of major depression according to DSM-lll-R. (Blazer, 1993, p. 33).

Similarities in results have been found in studies using the CES-D Scale. Correlations between depression and the somatic factor were unaffected by age in both men and women (Coyle & Roberge, 1992; Foelker & Shewchuk, 1992; Hertzog, Van Alstine, Usala, Hultsch, & Dixion, 1990; Radloff & Teri, 1986; Murrell, Himmelfarb, & Wright, 1983). However, generational differences were noted among the Mexican-American population among the CES-D factor loadings (Liang, Van Tran, Krause, & Markides, 1989). Contrary to the Liang et al. study, the majority of the literature supports the use of the CES-D with a broad range of ages including the elderly.

Gatz and Hurwicz (1990), hypothesized the existence of a bias in the CES-D scale, suggesting that the elderly population in general would have higher scores on the somatic items as compared to other age groups. Gatz and Hurwicz (1990), performed a longitudinal study using four age-cohort groups. A non-relational sample was obtained in a random fashion. Gatz and Hurwicz (1990) were unable to confirm "the hypothesized role of somatic and psychomotor retardation items on the CES-D Scale in accounting for

elevated self-reported depression scores in old age"

(p.289). This study revealed a significant main effect for health among all age groups, "with poorer self-reported health being associated with more depressive symptoms" (Gatz & Hurwicz, 1990, p.286). However, this does not necessarily suggest that the CES-D is a valid instrument for assessing depression in elderly persons because the somatic items were combined to create a somatic subscale. The potential problem of a formulated somatic subscale is that some of the items on this subscale may not represent somatic symptoms such as the response, "I was bothered by things that usually don't bother me" (Radloff, 1977). This could also be viewed as being a depressed affect instead of being somatic in nature.

# Depression in Cancer

Cancer patients are susceptible to depressive disorders because of multiple risk factors that are likely to be present such as recent losses, and poorly controlled pain (U.S. Department of Health and Human Services, 1993). Other risk factors include psychological responses to the prognosis and loss of function (U.S. Department of Health and Human Services, 1993). Certain medications may cause idiosyncratic reactions in the severely ill such as cimetidine and ranitdine, which have been shown to cause depressive mood disorders (U.S. Department of Health and Human Services, 1993). The assessment of depression in

cancer patients becomes increasingly complicated because of the multiple factors that may influence the patients symptoms.

Symptoms and treatments of cancer often lead to similar somatic symptoms seen in depression. This overlapping of symptoms of the two diseases may make it difficult to interpret the scores obtained on the somatic items of the CES-D. These symptoms also vary among individuals depending on their type of cancer and treatment. The following symptoms that are commonly seen in cancer and treatment of cancer are: anorexia, jaw pain, taste changes, mucositis, esophagitis, dysphagia, nausea and vomiting, anemia, fatigue, and malaise (Patrick, Woods, Craven, Rokosky, & Bruno, 1991). Peck and Boland reported that the majority of the patients studied who received radiation therapy had symptoms of fatique, dry mouth and anorexia (King, Nail, Kreamer, Strohl, & Johnson, 1985). Side effects of chemotherapy also result in symptoms similar to the somatic effects of depression. Patients have reported somatic side effects of several cancer drug regimens which include: nausea and anticipatory nausea, vomiting, mouth sores, diarrhea, constipation, weight gain/loss, restlessness, sleep disturbance, and weakness (Love, Leventhal, Easterling, & Nerenz, 1989).

Guidelines established by the U.S. Department of Health and Human Services (1993) emphasize the importance to differentiate cancer from depressive symptoms:

It is essential to separate the symptoms of cancer or its treatment from those of a depressive disorder. A history and clinical interview are needed for a definitive diagnosis. The symptoms of persistent dysphoria, feelings of helplessness and worthlessness, loss of self-esteem, and wishes to die are the most reliable indicators of clinical depression in patients with cancer (p. 62).

Because of the overlay of symptoms between depression and cancer/cancer treatment, criteria have been developed to replace somatic items with psychologic questions to eliminate the potential bias that somatic questions may pose for persons with cancer (Blazer, 1993). Thus, items that address psychologic symptoms were used to substitute somatic items to enhance the identification of patients with true depression. It was found that major depression was diagnosed much less frequently than when DSM-111-R and RDC criteria were used suggesting that there is a bias in assessing depression in cancer victims when self-report questionnaires contain somatic items (Blazer, 1993). However, a dilemma of using instruments that do not assess somatic symptoms of depression is the possibility of obtaining false negative results. Depression is not merely

a disturbance in mood but also results in somatic manifestations.

# Detection

The majority of persons with depression are diagnosed by primary care providers who uncover the ambiguous meaning of the somatic complaints that their patients present with (Blazer, 1993; U.S. Preventive Services Task Force, 1989). Self-report questionnaires can serve as an effective screening tool for assessing depressed mood. The ease in administration of the Center for Epidemiologic Depression Scale (CES-D) fosters its use in ambulatory settings as seen by its use in non-psychiatric populations (Radloff, 1977; Devins and Orme, 1986; Radloff and Locke, 1986). Although self-reports of depression are not diagnostic they are helpful in detecting even milder cases of mood disorders due to the sensitivity in identifying depressive symptoms. Once an individual is assessed as having depressed mood, the need for further evaluation is based upon the clinician's judgement of the situation. The differential diagnosis of depressive disorders is based upon a qualified clinician's interview of the client to determine if his/her symptoms meet the criteria for a depressive disorder according to the DSM-111 criteria (American Psychiatric Association, 1987).

Respondents to the CES-D instrument indicate self reported symptoms of depression experienced within the last week by answering 20 items. Each item has four responses

scored from 0 to 3 with potential outcome scores for the total scale ranging from 0 - 60. The CES-D is reproduced in Appendix A (Radloff, 1977, p. 387). For each item, the patient chooses one of the four given responses that reflect the frequency/duration of depressive symptoms experienced during the past week (Devins & Orme, 1986).

The anchors assigned to these values are labeled as follows: 0 indicates that a feature has occurred "rarely or none of the time" (less than 1 day); 1 indicates "some or a little of the time" (1-2 days); 2 indicates "occasionally or a moderate amount of time" (3-4 days); and 3 indicates "most or all of the time" (5-7 days) (Devins & Orme, 1986).

There is an increased likelihood of depression among individuals who exhibit higher CES-D scores. The following suggested cut-off scores indicate levels of depression: 0-15 "not depressed"; 16-20.5 "mild depression"; 21-30.5 "moderate depression"; and 31 or higher indicates severe depression (Devins & Orme, 1986). However, the validity of such cut-off points depends, among other factors, on the unbiasedness of the total scale scores.

Thus, the perplexing problem of identifying depressed mood calls for the need to improve clinical diagnostic techniques in addition to improving standardized self-report instruments used in depression research. Many self-report instruments like the CES-D have a somatic factor as an

indicator of depression that may in actuality inflate the scores (Kessler, Foster, Webster & House, 1992). The potential for false positive places patients at risk for enduring a costly, diagnostic work-up for depression (Radloff & Teri, 1986). Although a false positive result does not jeopardize the patient as greatly as a false negative result, the perceived societal stigma of mental illness is notable. This potential test bias of the CES-D in regards to the somatic factor when assessing cancer patients for depression is the basis of this proposed study.

Radloff (1977) deduced four factors from the CES-D instrument which include: depressed affect, positive affect, somatic and retarded activity and interpersonal factors. The same four sub-scales were replicated in a factor analysis conducted by Devins and Orme (1986). The CES-D items that the somatic and retarded activity factor represents are the following questions from the self-report instrument:

- I was bothered by things that usually don't bother
   me.
- 2. I did not feel like eating; my appetite was poor.
- 5. I had trouble keeping my mind on what I was doing.
- 7. I felt that everything I did was an effort.
- 11. My sleep was restless.
- 13. I talked less than usual.
- 20. I could not get "going" (Radloff, 1977).

Some of the factored items of the CES-D somatic sub-scale overlay with the reported somatic symptoms of cancer symptoms and or treatment. In this study, the following CES-D items have been identified as a modified somatic sub-scale, since, according to the literature, these items may also represent the symptoms of cancer and or its treatment:

- I did not feel like eating; my appetite was poor.
- 7. I felt that everything I did was an effort.
- 11. My sleep was restless.
- 20. I could not get "going" (Radloff, 1977).

Cancer symptoms and symptoms of cancer treatment are similar in nature to those addressed in the modified somatic sub-scale. Martin & Soja (1989) identified that "the diagnosis of depression can be further hampered by the frequency of vegetative signs, such as fatigue, weight loss, anorexia, and insomnia in the terminal cancer patient (p. 250). The somatic symptom of anorexia and weight loss identified by item number two regarding a poor appetite, may possibly be attributed to the postulates of altered serotonin metabolism responsible for cancer-associate anorexia (Holleb, Fink & Murphy, 1991). In addition, tumors adjacent to and within the gastrointestinal tract may result in decreased intake due to dysphagia, or reduced gastric capacity which may also lead to nausea and vomiting (Holleb et al., 1991). Certain cancers also produce malabsorption syndromes and abnormalities in substrate metabolism leading

to weight loss (Holleb et al., 1991). Adding to this dilemma, the treatment of cancer can result in similar symptoms. It has been well established that the treatment of cancer frequently has the side effect of anorexia and weight loss. For example, treatment of pain with morphine derivatives induce gastric stasis, often producing nausea and vomiting which may contribute to anorexia and weight loss (Martin & Soja, 1989). Radiation therapy may produce side effects of anorexia, nausea, vomiting, indigestion, sore throat, difficulty in swallowing, and changes in saliva (McCorkle, 1987).

Scores from the item "My sleep was restless" may be characteristics of uncontrolled pain and/or corticosteroid treatments, since both frequently produce insomnia (Holleb et al, 1991). Radiation has been shown to produce disturbances in sleep (McCorkle, 1987). In addition, opioid analgesics have produced bizarre dreams and nightmares which may add to restless sleep (Martin & Soja, 1989).

The items "I could not get going" and "I felt everything I did was an effort" may be a manifestation of the effects of opioid analgesics, which often produce drowsiness (Martin & Soja, 1989). This coupled with the exhaustion produced by fighting severe chronic pain, inadequate rest, weakness resulting from decreased nutritional status all may add to diminished energy in lieu of depressive symptoms.

### Methods

# Research Design

Permission has been provided to perform this secondary analysis on data from the following grant supported studies. "Family Homecare for Cancer-A Community-Based Model" (#1 R01 NR01915) funded by the National Center for Nursing Research, Barbara A. Given and Charles W. Given, Principal Investigators; "Caregiver Responses to Managing Elderly Patients at Home" (#R01 AG06584) funded by the National Institute on Aging, Charles W. Given and Barbara A. Given, Principal Investigators; "Impact of Alzheimer's Disease on Family Caregivers" (#R10 MH41766) funded by the National Institute of Mental Health, Charles W. Given and Barbara A. Given, Principal Investigators; and "Caregiver Responses to Managing Elderly Patients at Home" (#2 R01 AG06584) funded by the National Institute on Aging, Charles W. Given and Barbara A. Given, Principal Investigators.

The present study is concerned with measurement bias in the responses to CES-D items by cancer patients. The main strategy to discover measurement bias in responses was to compare a sample of cancer patients to a sample of non-cancer caregivers who were matched on their combined total CES-D score and their gender. Thus, for every female caregiver with a CES-D score of, say, 14 there would be a matched case among the cancer patients. Having identical distributions of CES-D scores among the cancer patients and

the non-cancer comparison group eliminates one source of possible bias in the comparison, namely, that the contribution of individual scale items to the total scale score varies depending on the overall level of depression.

Thus, the main purpose of matching cancer and noncancer caregivers on their total CES-D scores is that, under the condition of identical total score distributions in the two comparison groups, unbiasedness in individual item responses should result in the same contributions that individual item scores make to the total scale score. use of caregivers for the non-cancer group limits this study since it is not known whether caregivers responses to the CES-D produce biases of their own. In addition, the health history of these caregivers is unknown. There is a possibility that the caregiver sample may have individuals who have cancer. It is assumed that the prevalence of cancer in the caregiver group is not higher than any other group. Because there is already existing evidence for gender biasedness of some CES-D items (Stommel et al, 1993), gender was also included as a matching criterion. Although it was not feasible to use age as an additional matching criterion, both subject groups were drawn from samples with similar age distributions, resulting in small differences in mean age between the two groups (3.5 years difference).

# Sample Procedures

The sample for this study involved 288 persons diagnosed with cancer and 288 persons who were either long term caregivers for a family member with dementia or long-term caregivers of physically disabled persons. Both cancer patients and caregivers were drawn from larger data sets representing a total of 367 cancer patients and 1212 caregivers. Of this total sample, 288 cases in each group fulfilled the matching criteria and were included for the following study.

# Data Collection procedures

Participants in all of the studies were mailed self-administered questionnaires. Confidentiality had been maintained through the use of identification numbers.

University Committee on Research Involving Human subjects at Michigan State University approved use of the identified sample of this study (Appendix B).

# Data Analysis

Descriptive statistics were employed to analyze characteristics of the cancer and non-cancer samples. These characteristics include; age, sex, race, marital status, education level, employment status, household income, and total number of persons in the household. Differences in demographic variables between the cancer and non-cancer caregiver groups were examined using Chi-Square statistics

or t-tests. The internal consistency of the modified somatic subscale was analyzed using Chronbach's Alpha.

The research hypotheses were addressed comparing both item and subscale characteristics for the cancer and non-cancer samples. Two-tailed t-tests were employed to test for equality of means between the comparison groups. ANOVA was utilized to identify the source of significant variation in the relative contribution of the somatic subscale item scores to the total CES-D Scale score. Data were analyzed using the SPSS-WIN 6.1 statistical program.

#### Results

The findings described in this section were based on data obtained from 576 completed self-reported CES-D questionnaires, consisting of 288 cancer and 288 non-cancer subjects that were eligible for this study. Tables showing the results of the inter-item correlations of the somatic and total scale scores are incorporated.

## Sociodemographic Characteristics

The independent groups sampled (cancer and non-cancer) were sex matched with 138 males and 150 females each. groups were then matched by total CES-D scores. The average age for the total sample drawn was 61 years with a range of 22 to 86 years. Significant differences between the groups were noted (p<.001), however, they amounted to a difference of only 3.5 years on average. Ninety-four percent of the participants were white, predominantly married (85%), with no significant differences between the two groups (p>.48). The average number of persons residing in the household were two persons, again, with no significant difference between the groups (p>.16). The average income among all of the subjects were \$30,106 annually, ranging from a low income of \$1000 per year to a high of \$115,000 annually. Differences in income among the groups were not significant (p.054). Complete data are not available to analyze educational levels among the subjects.

A significant difference was observed between the cancer and non-cancer groups in regards to employment status. Among the cancer group, 75% were employed full-time whereas 68% of the non-cancer caregiver population were not employed with only 24% working full-time (see Table 1). One probable reason for this is that persons who are not employed are more apt to become caregivers given they are likely to have more free time or a less demanding schedule.

Table 1
Chi-Square Tests for Differences in Group Means

	Percentage	Percentage	
<u>Variable</u>	Cancer Cases	Non-Cancer Case	<u>es</u>
Not Employed	32%	68%	
Part-Time	47%	53%	
Full-Time	75%	25%	
Chi-Square	<u>Value</u>	<u>DF</u>	P-Value
Pearson	93.87757	2	<.001

.40512

Cramer's V

### Scale Characteristics of the Cancer and Non-Cancer Samples

<.001

Cronbach's Alpha was employed to test the internal consistency of the Center for Epidemiologic Depression Scale. Alpha coefficients of .60 - .70 are acceptable when making group-level comparisons (Polit & Hungler, 1991). The total scale (20 items) coefficient alpha of n=576 was .89.

The strong alpha coefficients obtained in this study reaffirm that the Center for Epidemiologic Studies

Depression Scale is a robust self-report questionnaire.

The four items of the CES-D Scale selected because of their characteristics of possible indicators of cancer symptoms (I did not feel like eating; my appetite was poor; I felt that everything I did was an effort; My sleep was restless; I could not get "going") were used to create the modified somatic subscale for this study, which also showed acceptable reliability, alpha .70. The reliability coefficient of the modified somatic sub-scale also remained strong among the individual comparison groups: alpha .71 for the cancer group and alpha .66 for the non-cancer group. These findings suggest that the modified somatic subscale demonstrates a satisfactory level of reliability (Polit & Hungler, 1991). The individual somatic item characteristics for both cancer and non-cancer samples are displayed in Table 2. A two-tailed t-test was utilized to test if there are mean differences between the cancer and non-cancer groups. A significant difference was identified with two of the four items of the modified somatic subscale. These two items were: I did not feel like eating; my appetite was poor (p<.001) and I could not get "going" (p<.01). When nonparametric procedures were used, three of the four somatic subscale items produced significant differences between the two groups (see Table 2).

Table 2

Item and Subscale Characteristics

## Item Characteristics of Cancer and Non-Cancer Samples

Subscale		Scale <u>Mean</u>	Scale <u>S.D.</u>	t-test Equality of Means
Poor appetite	ca non-ca	.9028 .3576	.928 .620	p=<.001
Everything an effort	ca non-ca	1.0764 .8542	.827 .800	p=.614
Restless sleep	ca non-ca	1.0243 1.0278	.785 .809	p=.796
Could not get going	ca non-ca	.9097 .6667	.712 .673	p=<.01

## Non-Parametric tests

Subscale	Mann-Whitney U/ Wilcoxon Rank	Kolmogorov/ <u>Smirnov</u>
Poor appetite	p=<.001	p=<.001
Everything an effort	p=<.001	p=<.05
Restless sleep	p=.92	<b>p=1.0</b>
Could not get going	p=<.001	p=<.001

## Correlation Matrix For Total Sample N-576

	CESD2	CESD7	CESD11	CESD20
CESD2	1.0000			
CESD7	.3724	1.0000		
CESD11	.2763	.3181	1.0000	
CESD20	.3614	.5449	.3385	1.0000

## Inter-item Correlations

Mean .3703 Minimum .2763 Maximum .5449 Range .2686 Variance .0077

Reliability Coefficients of four items Alpha = .6969

Table 2 (cont'd)

#### Subscale Characteristics

## Correlation Matrix For Cancer Patients (N=288)

	CESD2	CESD7	CESD11	CESD20
CESD2	1.0000			
CESD7	.400	1.0000		
CESD11	.3380	.3245	1.0000	
CESD20	.3608	.5381	.3903	1.0000

## Inter-item Correlations

Mean .3919 Minimum .3245 Maximum .5381

Range .2135 Variance .0054

Reliability Coefficients of four items Alpha = .7138

## Correlation Matrix For Non-Cancer Patients (N=288)

	CESD2	CESD7	CESD11	CESD20
CESD2	1.0000			
CESD7	.2882	1.0000		
CESD11	.2443	.3184	1.0000	
CESD20	.2869	.5304	.3179	1.0000

## <u>Inter-item Correlations</u>

Mean .3310 Minimum .2443 Maximum .5304

Range .2861 Variance .0093

Reliability Coefficients of four items Alpha = .6616

#### Percentages of Somatic Scale Score Among Groups

The percentage of somatic contribution to the total CES-D score was determined by dividing summated scores of somatic items by summated scores of all CES-D items.

Differences between the cancer and non-cancer groups were

evident. As mentioned, the CES-D scale is multidimensional due to the complexity of depression. In the CES-D scale, the construct of measuring depressive symptoms has been conceptually separated into four factors, which consist of depressed affect, positive affect, somatic and retarded activity and interpersonal factors (Radloff (1977). However, in this study, the somatic and retarded activity subscale was modified to identify the CES-D items that most closely overlap with the symptoms of cancer and cancer treatment. Thus, this study does not propose a test bias of all the items that have clustered into the specified factor of somatic and retarded activity (Spector, 1992). However, for the modified somatic subscale, the cancer group revealed a 32.34% somatic subscale score contribution whereas the non-cancer sample demonstrated a 22.74% contribution, as displayed in Table 3. In other words, the modified somatic subscale contributed almost one third to the cancer subjects total scale score. But only about one fifth to the total CES-D scores of the non-cancer caregivers. This difference is statistically significant (F < .001). By contrast, there was no difference in the percentage contribution of the somatic scale scores based on age or sex (see Table 3).

Table 3

Percentages of Somatic Scale Score Among Groups

## Source of Variation

Age in y	years	
•	64 and under	27.5%
	65 and older	27.58%
Sex		
	Female	28.01%
	Male	27.03%
Study gr	roups	
	Cancer	32.34%
No	on-Cancer	22.74%

### ANOVA

Source of <u>Variation</u>	Sum of Squares	df	Mean Square	F-Ratio	Sig <u>of F</u>
Main Effects	13426.524	3	4475.508	12.862	<.001
Age Groups	.815	1	.815	.002	.961
Sex Groups	146.492	1	146.492	.421	.517
Study Groups	13279.218	1	13279.218	38.161	<.001

Finally, there were 17 cases for whom the somatic items of the modified subscale made up the total CES-D score. These subjects were of interest and were identified according to age, sex and study group. There were no differences in age, however, those who reported only somatic symptoms were predominantly female (77%) and 64% were cancer subjects. One could venture to say that these 17 individuals may have been physically ill or had an anxiety disorder.

#### Discussion

## Research Ouestion

The research question of inquiry in the study was, "Do cancer patients display elevated mean scores on the somatic items of the CES-D Scale, when compared to the non-cancer respondents with similar mood scores?" On the basis of the literature, four items of the CES-D Scale were singled out as most likely to also function as indicators of cancer or treatment-related symptoms. Upon comparison of the cancer and non-cancer caregiver group, significant differences for three of the four somatic items of the modified somatic subscale (poor appetite, everything an effort, and could not get "going") were observed. The findings stating the modified somatic subscale contributed to one third of the cancer subjects total scale score, is notable. information supports the theory that a test bias of the CES-D Scale may exist when used with persons diagnosed with cancer. This potential bias of overestimation of depression scores may impact decisions made by primary care providers using the CES-D as a screening instrument for depression among cancer populations.

The findings of insignificant differences in the somatic subscale scores among different age groups merits attention. Some of the current literature has challenged the use of instruments that contain somatic items to measure depressive mood symptoms among elderly persons (Caine et

al., 1993). It has been contended that these scales may create a test bias due to the common incidence of comorbidity, thus resulting in an overlay of symptoms among the different disorders. However, this study which is consistent with Gatz and Hurwicz (1990), supports the use of the CES-D with a broad range of ages including the elderly.

#### Limitations

The chief limitation of this study was the use of a special population as a comparison group. The control group was selected from an independent sample of caregivers. Hence, the comparison group does not represent the normal population since caregivers often have unique problems related to care giving and lack of social support. Therefore, these findings are not generalizable to the general population. In addition, these results may not be repeatable if the comparison group is not selected from a caregiver population.

## Recommendations for Future Research

Future research is needed to build more solid evidence to support the assumption of a somatic test bias of the CES-D when used with cancer subjects. The more knowledge clinicians and researchers have regarding standardized instruments, such as the CES-D, the more useful the tool becomes. Future research addressing how depressive symptomology correlates with the diagnosis of clinical

depression, would provide helpful information for the application of the CES-D as a screening instrument for depression. Former validity studies of the CES-D have shown sufficient correlations with structured psychiatric interviews, but more are needed to strengthen its use (Feightner & Worrall, 1990).

A study could be conducted using cancer subjects with a comparison group that more closely represents the general population. The CES-D Scale could be administered concurrently with a structured psychiatric interview of the subjects using criteria for depressive disorder according to DSM-111 criteria. Subjects could be matched according to gender and total CES-D score greater than 16. Correlational studies could be made between CES-D scores of the subjects with an actual diagnosis of depressive disorder. One might hypothesize, due to the potential somatic test bias of the CES-D Scale, there would be a increased percentage of cancer subjects who scored higher on the CES-D modified somatic subscale items, but were not clinically diagnosed with a depressive disorder.

Additional studies are needed to replicate the findings in this study that support the use of the CES-D in elderly populations. Of related interest would be to study the relationship between the number of symptoms and the somatic subscale to identify.

Since three of the four somatic subscale items seemed to follow the expected pattern, one can adjust for this bias

in cancer populations by reducing the contribution of these three items to the total scale score to the level typical for the general population.

## Implications for Advanced Nursing Practice

It is essential for primary care providers to be responsive to potential depression experienced by their patients. Although self-report questionnaires are a convenient method of obtaining information about an individual, caution must be used when interpreting the results. The clinician must use discretion when using information obtained from scales that support the diagnosis suspected. This study was performed to challenge the validity of the CES-D when used with cancer patients, a population that primary care providers are apt to screen for depressive symptomology. It cannot be assumed that all cancer patients are depressed. The occurrence of significant results in regard to the somatic test bias among cancer subjects, reinforces the need to scrutinize findings obtained from standardized instruments when used as screening tools.

There has been a growing emphasis on identifying patient outcomes in regards to the interventions of healthcare providers. Outcome measurement is not a new idea to health care providers. Development of the Professional Standards Review Organization, prompted by legislation in 1972 (P.L. 92-603), had intentions of fostering process and

outcome based care (Waltz et al., 1984). The Joint Commission on Accreditation of Health Care Organizations (JCAHCO) has an "Agenda for Change" that incorporates into the plan to assess the organizations process of measurement and outcomes of care as criteria for accreditation (JCAHCO, 1995). This idea has been expanded to the concept of reimbursement based on outcomes achieved. This trend may prompt practitioners to use standardized instruments to provide measurable, objective data for assessing patient needs and outcomes.

The concern of this researcher is for the beginning practitioner with limited Mental Health experience. There is an added likelihood that a screening instrument such as the CES-D may be used in primary care settings due to the awareness of prevailing under diagnosis of depression. The CES-D has been used in clinical settings to assist in identifying psychologic distress, it was not designed to be a diagnostic tool to detect clinical depression (Feightner & Worrall, 1990). Even though it is well documented in the literature that the CES-D was not designed to be a diagnostic tool, a novice may not clearly distinguish these differences. If this were the case, the practitioner may falsely label this person as having mental illness. This labeling could have detrimental consequences.

There continue to be misconceptions about mental illness among social, political and medical climates that may have negative affects on the individual (Johnson, 1993).

In the past, labeling has affected the care and treatment of some individuals (Johnson, 1993). Legislation in recent years has provided law to protect the individual rights, but the potential for inconsistent care still exists among the mentally ill (Johnson, 1993).

The novice practitioner may be more apt to rely more heavily on the results of an instrument, such as the CES-D. Decisions may be based predominantly on the total CES-D score, versus using other indicators that a more seasoned practitioner might employ. The reasonable belief that persons with cancer are at risk for depression, combined with lack of experience with mental illness, elevated CES-D scores may cue the practitioner to treat or refer an individual to a psychiatrist or counselor if depressive symptoms are identified.

The consequence of the CES-D test bias in the somatic area with cancer patients is false positive scores. Given the above scenario, one repercussion of this test bias is the potential for unnecessary costs to the patient since a referral to a psychiatrist/psychologist is a likely intervention. If the practitioner chooses to treat the individual, the risk of treatment may outweigh the benefits due to the potential side effects of antidepressant medications. The costs of unnecessary treatment with medication and the likelihood of ongoing diagnostic tests to screen for drug toxicity all have a price. Persons assessed as having depression are going to require follow up-visits

which will be added costs to the patient for use of the providers time. The providers practice may also have repercussions of misdiagnosis if he/she is not reimbursed for care provided due to the lack of desired outcomes.

It is clear that the process of diagnosing depression is difficult. The clinical interview is essential in the diagnosis of depression, however, there is also risk of a similar bias in using the standardized questions developed for the clinical interview. DSM lll-R criteria is used in the clinical interview for identifying major depressive disorder. The following areas are addressed:

- depressed mood (sometimes irritability in children and adolescents) most of the day, nearly every day.
- 2. Markedly diminished interest or pleasure in almost all activities most of the day, nearly every day.
- 3. Significant weight loss/gain.
- 4. Insomnia/hypersomnia.
- 5. Psychomotor agitation/retardation.
- 6. Fatigue (loss of energy).
- 7. Feelings of worthlessness (quilt).
- 8. Impaired concentration (indecisiveness).
- 9. Recurrent thoughts of death or suicide (U.S. Department of Health and Human Services, 1993, p. 18).

To be diagnosed with major depressive disorder the patient must have at least five of the above symptoms during the same period with depressed mood or loss of interest in pleasure (U.S. Department of Health and Human Services, 1993). The symptoms are present nearly every day for at least two weeks and are present for most of the day (U.S. Department of Health and Human Services, 1993). A major depressive disorder is a constellation of emotional,

cognitive, behavioral and somatic signs and symptoms that are not separate entities. If a person exhibits some of these symptoms but does not meet the DSM 111-R criteria for a major depressive disorder, they are classified as depression not otherwise specified (DNOS) (U.S. Department of Health and Human Services, 1993). The DNOS classification is not currently recognized as a formal diagnosis and be more difficult to identify, yet many persons may fall into this category who may require treatment (U.S. Department of Health and Human Services, 1993). Like the CES-D, the DSM lll-R criteria identifies many symptoms that are somatic in nature which may create a bias of the interview if used with persons exhibiting comorbidity such as cancer. This potential bias may create an error in the estimate of depressive symptoms exhibited by the patient.

It is essential that the results of this study, and similar studies that suggest bias in measurement scales, be disseminated in to the academic arena. Educators of various healthcare professionals at every level, including continuing education instruction, need to communicate how these findings may enhance the appropriate use of instruments when applied in clinical settings.

The CES-D continues to be an effective screening instrument for assessing depressive symptoms in healthy populations. It can also aid the practitioner in assessing these symptoms in persons with other disorders such as

cancer. Like with any standardized instrument, interpretation of results needs to be done with discretion. It is known that individual items scores may reveal relevant information that may not be reflected in total scale scores. The application of this assumption may aid the practitioner in the decision-making process regarding patient care.

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#### APPENDIX A

# The CES-D Scale: A Self-Report Depression Scale For Research In The General Population

#### CES-D Scale

INSTRUCTIONS FOR QUESTIONS: Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week. HAND CARD A.

Rarely or None of the Time (Less than 1 day)
Some or Little of the Time (1-2 Days)
Occasionally or a Moderate Amount of Time (3-4 Days)
Most or All of the Time (5-7 Days)

### During the past week:

- 1. I was bothered by things that usually don't bother me.
- 2. I did not feel like eating; my appetite was poor.
- 3. I felt that I could not shake the blues even with help from my family or friends.
- 4. I felt that I was just as good as other people.
- 5. I had trouble keeping my mind on what I was doing.
- 6. I felt depressed.
- 7. I felt that everything I did was an effort.
- 8. I felt hopeful about the future.
- 9. I thought my life had been a failure.
- 10. I felt. fearful.
- 11. My sleep was restless.
- 12. I was happy.
- 13. I talked less than usual.
- 14. I felt lonely.
- 15. People were unfriendly.
- 16. I enjoyed life.
- 17. I had crying spells.
- 18. I felt sad.
- 19. I felt that people dislike me.
- 20. I could not get "going".

APPENDIX B

#### APPENDIX B

## U.C.R.I.H.S. Approval

## MICHIGAN STATE UNIVERSITY

April 28, 1995

TO: Coreen J. Williams

5411 Truckey Rd. Alpena, Mi. 49707

IRB#: RE:

TITLE:

95-219 TEST BIAS IN THE SOMATIC SUBSCALE OF THE CENTER FOR EPIDEMIOLOGIC STUDIES DEPRESSION SCALE WHEN ASSESSING DEPRESSION IN CANCER PATIENTS

REVISION REQUESTED: CATEGORY:

APPROVAL DATE:

N/A 1-E 04/28/95

The University Committee on Research Involving Human Subjects' (UCRIHS) review of this project is complete. I am pleased to advise that the rights and welfare of the human subjects appear to be adequately protected and methods to obtain informed consent are appropriate. Therefore, the UCRIHS approved this project and any revision listed above. above.

REMEWAL:

UCRIHS approval is valid for one calendar year, beginning with the approval date shown above. Investigators planning to continue a project beyond one year must use the green renewal form (enclosed with the original approval letter or when a project is renewed) to seek updated certification. There is a maximum of four such expedited renewals possible. Investigators wishing to continue a project beyond that time need to submit it again for complete review.

REVISIONS: UCRIHS must review any changes in procedures involving human subjects, prior to initiation of the change. If this is done at the time of renewal, please use the green renewal form. To revise an approved protocol at any other time during the year, send your written request to the UCRIHS Chair, requesting revised approval and referencing the project's IRB # and title. Include in your request a description of the change and any revised instruments, consent forms or advertisements that are applicable.

PROBLEMS/ CHANGES:

Should either of the following arise during the course of the work, investigators must notify UCRIHS promptly: (1) problems (unexpected side effects, complaints, etc.) involving human subjects or (2) changes in the research environment or new information indicating greater risk to the human subjects than existed when the protocol was previously reviewed and approved.

RESEARCH **GRADUATE STUDIES** 

OFFICE OF

If we can be of any future help, please do not hesitate to contact us at (517)355-2180 or FAX (517)336-1171.

University Committee on Research Involving

Human Subjects (UCRIHS)

Michigan State University 232 Administration Building East Lansing, Michigan 48824-1046

> 517/355-2180 FAX: 517/432-1171

David E. Wright Ph. UCRIHS Chair

DEW: pjm

Sincerely,

cc: Manfred Stommel

