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Elizabeth M. Archer-Nanda

Bellarmine University, earcher.nanda@gmail.com

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Assessing Quality Outcomes in a Behavioral Oncology Program: Capstone Project

Elizabeth M. Archer-Nanda

Bellarmino University

Author Note

Elizabeth Archer-Nanda, School of Nursing, Bellarmine University.

Elizabeth Archer-Nanda is employed by Behavioral Oncology, Norton Cancer Institute.

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Correspondence concerning this critique should be addressed to Elizabeth Archer-Nanda, Norton Cancer Institute, 3999 Dutchman's Lane, Plaza 1 Suite 1A, Louisville, KY 40207. Contact: [earchernanda01@bellarmine.edu](mailto:earchernanda01@bellarmine.edu)

### Abstract

The landscape of cancer care has changed dramatically over the past several decades. An illness that was once often fatal, now represents both an acute life threatening illness and a chronic condition. While there have been tremendous advancements in the treatment of the physiological aspects of cancer, management of related psychosocial and emotional issues have not seen this same progress. Limited information exists related to both the evaluation and outcome metrics associated with the screening and management of psychiatric sequelae after referral to specialized psychiatric services in cancer patient populations. This capstone project focused on (a) implementation of consistent use of the Patient Health Questionnaire 9-item (PHQ-9) survey for patients seeing a provider in the Norton Cancer Institute Behavioral Oncology Program (NCIBOP) at each outpatient visit, (b) assessment of patient outcomes for changes in depression scores, (c) review of clinical interventions by providers, and (d) identification of opportunities for integration of psychiatric practice guidelines. Evidence-based practice guidelines were incorporated. The major findings were sequential assessment paired with evidence-based interventions lead to statistically significant reduction in PHQ-9 and Distress scores.

*Keywords:* depression, distress, anxiety, coping, stress, cancer, psychosocial support, neoplasms, oncology, psychosocial support, psychotherapy, psychiatry, interventions, groups, quality of life, quality, outcomes, insurance, mental health coverage and patient education

### Introduction

In 2007, the Institute of Medicine (IOM) released a report, *Cancer Care for the Whole Patient: Meeting the Psychosocial Health Needs*, which underscored the importance of integrating mental health specialists into the care of cancer patients. It is reported that one in ten individuals have someone in their family dealing with cancer. In addition, it is projected that 40% of the United States population will receive a cancer diagnosis at some point (IOM, 2007; Meijer et al., 2011). Preliminary secondary analysis of the National Health and Nutrition Examination Survey (NHANES) 2003-2008 data revealed significant findings: (a) 9.5% of individuals with cancer meet criteria for Major Depression compared to 7.5% of non-cancer patients, (b) more cancer patients report moderate symptoms of depression (10.2% versus 7.1% respectively), and (c) cancer patients express more depressive symptoms (3.3 compared to 2.9) (Loprinzi & Archer-Nanda, 2013).

While the importance of emotional and psychological care is known, access to specialized psycho-oncology providers is limited, even absent in some institutions (Ferrell, 2005), placing responsibility to care for emotional needs on the medical team, nursing staff, and family caregivers. Among practices that do monitor for psychological distress and refer to specialized psychiatric providers, few have implemented systematic assessments of depression with valid and reliable tools (Carlson, Waller, Groff, Zhong, & Bultz, 2012; Jacobson, 2012). Opportunities exist to incorporate quality and outcome metrics associated with the screening and management of psychiatric sequelae in specialized psycho-oncology practices (Carlson et al., 2012).

Despite the importance of evidence-based care, there have been few studies addressing such interventions in the cancer patient population (Berard, 2001). This paper (a) describes the prevalence of depression in cancer patient populations, (b) explores the impact of untreated psychological and emotional sequela, (c) outlines a process improvement plan, and (d) defines quality metrics for the systematic assessment of depression in patients seen within an embedded psycho-oncology program. This paper reviews the integration of evidence-based practice guidelines.

### **Background and Significance**

#### **Adaptation to Illness**

At the onset of a cancer diagnosis, patients and families are faced with the challenge of adapting to a new illness and making a number of adjustments to meet the demands of the diagnosis. Growing improvements in the areas of early detection and prevention have changed the landscape of cancer from a disease that had been fatal in many instances to what is now a variety of different illnesses with a good prognosis and even potential for cure (IOM, 2007). With the myriad of treatment options available to cancer patients including chemotherapy, radiation therapy, and surgery, two-thirds of cancer patients live at least five years (Meijer et al., 2011). Despite the advancements in the physiological aspects of cancer treatments, the availability of treatment focusing on the psychological, social, and emotional aspects of cancer care have not kept pace (IOM, 2007). Although psychological distress is common in cancer patients, it often goes unrecognized and untreated (Berard, 2001; Bottomley, 1998; Dalton et al., 2009; Hopko et al, 2008; Luutonen, Vahlberg, Eloranta, Hyvari, & Salminen, 2011; Meijer et al., 2011; Newport & Nemeroff, 1998; Ryan et al., 2005; Shimizu et al., 2010).

Adaptation to a new normal within the context of cancer presents many challenges including financial, emotional, and knowledge based stressors (IOM, 2007). Patients face many obstacles that may preclude successful anti-cancer efforts. Among the most significant barriers cancer patients report are financial problems, inadequate or absence of health insurance, poor communication with physicians, and lack of psychosocial care (IOM, 2007). Each of these barriers has the potential to adversely impact health outcomes (IOM, 2007). It is reported up to one-third of cancer patients experience persistent distress, which may even interfere with treatment (Sellick & Edwardson, 2007; Singer et al., 2008). Fewer than half of patients who need psychiatric treatment receive this care (Fromer, 2006).

### **Prevalence of Depression in Oncology Patients**

Among psychological and emotional comorbidities in cancer patient populations, depression has received the most attention (Massie & Greenberg, 2004). Although more than 150 studies exist describing the prevalence of depressive disorders, this data has wide variability due to inconsistent methodology and differing inclusion criteria of depressive disorders (Dalton et al., 2009; Massie, 2004; Massie & Greenberg, 2004; Salvo et al., 2012). Prevalence data on depression in cancer patients ranges up to 60% in studies. There is clinical agreement that approximately 25% of cancer patients will experience a depressive episode resulting in the need for depression management (Bottomley, 1998; Massie, 2004; Pirl & Roth, 1999). This statistic becomes even more remarkable when compared to Meijer and colleagues (2011) report that the prevalence of depression in the general population is approximately 6%.

From an epidemiological perspective, enhanced understanding of cancer patient risks for depression and other psychological sequelae has potential to propel the inclusion of mental health interventions as a standard part of care onto the national agenda. There are no known epidemiological studies available describing the cancer patient's increased risk for depression, when compared to the general population using the NHANES data in the United States.

### **Systematic Assessment of Depression in Oncology Practices**

The diagnosis of depression can be easily overlooked and assumed by cancer clinicians to be an adaptation to illness with minimization of depression severity (Massie & Greenberg, 2004; Mystakidou et al., 2008). Since adaptation to illness can be enhanced through psychosocial interventions, screening individuals to determine the need for a psychiatric referral is an important component of care. Multiple studies have documented the importance of screening for and identifying patients at high risk for emotional distress (Bottomley, 1998; Holland et al., 2005; Hopko et al., 2008; McCorkle, Pasacreta, & Tuzh Tang, 2003; Meijer et al., 2011; Newport & Nemeroff, 1998; Norris, Pratt-Chapman, Noblick, & Cowens-Alvarado, 2011; Ransom, Jacobson, & Booth-Jones, 2006; Ryan et al., 2005; Salvo et al., 2012; Sellick & Edwardson, 2007; Shim, Shin, Jeon & Hahm, 2008; Shimizu et al., 2012; Smith et al., 2009; Thewes, Meiser, Tucker, & Scnieden, 2003; Vahdaninia, Omidvari, & Montazeri, 2010; Zabora, BrintzenhofeSzoc, Curbow, Hooker, & Piantadosi, 2001). Despite this evidence, screening for distress in this population is still not consistently done, with estimates that less than half of patients with distress are identified (Sellick & Edwardson, 2007). As few as 10% of patients are referred for specialty care with psycho-oncology providers, therefore limiting

opportunities to improve quality of life, treatment adherence, and potentially prognosis (Smith et al., 2009; Vahdaninia et al., 2010).

There are few specialty-trained providers equipped to address the psychological and emotional needs of cancer patients. Although there is a significant body of literature supporting the psychological care for cancer patients, there is a gap with respect to program availability and practice (Greenberg, 2004; Pengelly & Purnell, 2009; Weinberger, Bruce, Roth, Breitbart, & Nelson, 2010). In recognition of this need, there are emerging models for enhancing collaboration between mental health and medical health homes (Druss & Mauer, 2010; Rhodes, Vieth, Kushner, Levy, & Asplin, 2009).

### **Evidence-Based Care**

Since the release of the IOM Report, *Crossing the Quality Chasm* in 2001, emphasis has been placed on ways healthcare systems can improve care. The report identified safety, patient centeredness, effectiveness, timeliness, efficiency, and equality as six overarching aims to better meet patient needs (IOM, 2001; Stanik-Hutt et al., 2013). Quality is representative of clinical interventions and patient perceptions of care that are both safe and effective (Stanik-Hutt et al., 2013). Implementation of processes and structured care interventions has the opportunity to improve quality and ultimately outcomes (Stanik-Hutt et al., 2013).

The integration of evidence-based practice guidelines in clinical settings is one approach to minimizing broad variation in care delivery across clinicians (IOM, 2001; Oldham, Golden, & Rosof, 2008; Wobrock, Weinmann, Falkia, & Gaebel, 2009). Depression remains one of the most prevalent and treatable mental health disorders (Kroneke, Spitzer, & Williams, 2001). One approach to enhance quality in psychiatric

practices is through use of valid and reliable patient questionnaires to assess patient outcomes (Oldham et al., 2008; Valenstein et al., 2004). Among depressed adults, medications and psychotherapy are both evidence-based interventions for treatment and management (Agency for Health Care Research and Quality [AHRQ], 2009; American Psychiatric Association [APA], 2010, 2012; Katon & Schulberg, 1992; O'Connor, Whitlock, Beil, & Gaynes, 2009).

Still, Oldham and colleagues (2008) have highlighted that psychiatry struggles as a discipline to adhere to evidenced-based treatment guidelines. Lack of awareness regarding guidelines, complexity of bio-psycho-social interactions, absence of psychiatric providers by region, and challenges to healthcare systems have all contributed to the underutilization of clinical practice guidelines (Oldham et al., 2008; Wobrock et al., 2009). As a result, mental health interventions are often without an evidence-based approach despite the known importance of delivering effective and scientifically based care (Aarons, 2004).

**Improved care from systematic assessment.** One systematic review of outcomes resulting from screening for depression in cancer patients exists (Meijer et al., 2011). The study authors identified nineteen studies addressing accuracy of screening including one trial evaluating treatment efficacy for Major Depression. No trials specifically examined changes in outcomes based on the implementation of screening alone (Meijer et al., 2011). McMillan, Small, and Haley (2011) conducted a study that showed standardized systematic assessment of depression by interdisciplinary teams among cancer patients enrolled in hospice care was associated with significant improvement in depression and quality of life. Complicating the issue of systematic

assessment in cancer patient populations is the lack of consensus among psycho-oncology providers regarding which psychometric instrument is most appropriate for use in this patient population.

### **Policy Support for the Integration of Psychosocial Assessment and Management**

At a national level the Commission on Cancer (CoC) is tasking oncology practices with finding ways to implement distress screening and referral to specialized psychosocial providers by 2015 (CoC, 2012; Edge & Bura, 2011; Jacobson, 2012). Through collaboration and oversight since the 2007 IOM report, efforts have expanded to include the provision of psychosocial screening and the addition of mental health providers to deliver this specialty care. With the support of multiple organizations, including the American Psychosocial Oncology Society (APOS), the National Quality Forum (NQF), the CoC and the American College of Surgeons (ACoS), the International Psychosocial Oncology Society (IPOS), and the Quality Oncology Practice Initiatives (QOPI), the importance of quality mental and emotional health interventions in cancer populations will continue to stay on the national agenda. Current QOPI metrics require the identification of emotional needs by oncology providers (QOPI, 2012).

In order to sustain and grow psychiatric programs within oncology practices, the identification of appropriate evaluation metrics is an important step that becomes even more urgent as our healthcare environment continues to change. Gaps exist in the cancer psychiatry literature related to the specific role of depression screening and process improvement initiatives for depression management in cancer patient populations. At the study site, Norton Cancer Institute (NCI), oncology providers assess for distress using the Distress Thermometer (DT) (Appendix A). Oncology providers then refer patients with

psychiatric needs for specialized mental health assessment by the providers. After referral to NCIBOP, an opportunity existed to implement systematic use of the PHQ-9 survey (Appendix B). The goal of this quality improvement project was to improve patient outcomes through sequential monitoring of depression with the PHQ-9 survey and the delivery of evidence-based treatment approaches.

### **Purpose**

The purpose of this quality improvement capstone project was to (a) implement the PHQ-9 survey at each visit for patients seeing a provider in the NCIBOP, (b) assess patient outcomes for changes in depression scores, (c) review clinical interventions by providers, and (d) identify opportunities for integration of psychiatric practice guidelines.

### **Review of the Literature**

A search of the databases Academic Search Premier, Cumulative Index of Nursing and Allied Health Literature (CINAHL), MEDLINE, PsychINFO, Psychology and Behavioral Sciences Collection and Newspaper Source was conducted. A combination of key words was used, in addition to appropriate subject terms including social support, psychiatry, depression, distress, anxiety, coping, stress, cancer, psychosocial support, neoplasms, psychotherapy, interventions, groups, quality of life, quality, outcomes, insurance, mental health coverage and patient education. References of selected studies were inspected for additional related papers. Dates were not specified for review based on the limited availability of relevant papers. Selection criteria included studies addressing the significance of psychosocial needs in cancer patients, screening and quality indicators related to the psychosocial care of cancer patients. Experts in the area of psycho-oncology were contacted for information. The recent IOM reports

addressing care for the whole patient, quality mental health care and crossing the quality chasm were also used for the purposes of this review.

### **Significance of Psychosocial Needs in Cancer Patients**

**Prevalence.** Cancer patients report significantly higher levels of distress than individuals in the general population and are at increased risk for mental health problems including depression and anxiety disorders (Bottomley, 1998; Corboy, McDonald, & McLaren, 2011; IOM, 2007; Jehn et al., 2012; Trinidad, Simopoulous, & Flosnik, 2011). The risk for depression in cancer patients is reported to be four times greater than in the general population (Blake-Mortimer, Gore-Felton, Kimerling, Turner-Cobb, & Spiegel, 1999; Bowers & Boyle, 2003; Massie & Greenberg, 2004; White & Macleod, 2002). Depression is reported as the number one psychiatric co-morbidity and is consistently rated as one of the ten most distressing symptoms for cancer patients, affecting up to 60% of patients during their illness (Badger, Braden, & Mishel, 2001; Bowers & Boyle, 2003; Breitbart, 1994; Fafouti et al., 2010; Hopko et al., 2008; Hosaka, Sugiyama, Tokuda, & Okuyama, 2000; Jehn et al., 2012; Massie & Greenberg, 2004; Montgomery, Pocock, Titley, & Lloyd, 2003; Pirl, 2004; Ross, Boesen, Dalton, & Johansen, 2002; Salvo et al., 2012; Spiegel & Giese-Davis, 2003; Spiegel et al., 1999; Spijker, Trijsburg, & Duivenvoorden, 1997; White & Macleod, 2002). During advanced stages of illness the incidence of depression increases from 20-25% to 50-70% (Bowers & Boyle, 2003; Breitbart, 1994).

**Risk of undiagnosed depression.** Mood disturbances such as anxiety and depression are often viewed as normal responses to a serious diagnosis like cancer (Massie & Greenberg, 2004; Spiegel & Giese-Davis, 2003) and have been identified as

the most common psychiatric comorbidities in cancer populations (Jehn et al., 2012; Salvo et al., 2012). Expected cognitive and behavioral responses often mask depression, causing it to remain undiagnosed and untreated in up to 80% of patients (Lloyd-Williams & Riddleston, 2002). There is a disparity between the number of patients experiencing psychological co-morbidities and the number of patients receiving appropriate referrals to specialized psychiatric providers.

A systematic review of psycho-oncology literature reported 29% of cancer patients experienced depression (Hotopf, Chidgey, Addington-Hall, & Ly, 2002; Salvo et al., 2012). Researchers examining the prevalence of depression found that 29% of 524 patients screened were depressed, a value two times greater than for non-cancer patients (Gruneir, Smith, Hirdes, & Cameron, 2005). Interestingly, these individuals were also less likely to receive antidepressant therapy (Gruneir et al., 2005). Only 30% received antidepressants and only 20% were seen by a mental health professional (Gruneir et al., 2005). Remarkably, cancer patients who were not depressed were more likely to be followed by a psychiatric provider than those with clinical depression (Gruneir et al., 2005).

Hwang and colleagues (2004) in a study of veteran patients, found higher levels of psychological distress to be associated with an overall sense that needs were not being met across the care spectrum. In another study of long-term cancer survivors, those with higher levels of distress remembered their experience as more negative, with more challenges both physically and psychologically (Maliski, Sarna, Evangelista, & Padilla, 2003).

Houts and colleagues (1986) assessed areas of unmet need during cancer treatment in both patients and caregivers. The most frequently reported unmet need was emotional problems reported by 25% of respondents (Houts et al., 1986). In a comparative study, Barg and associates (2007) used qualitative interviews to assess the continuance of unmet psychosocial needs. Two-thirds of these respondents reported one or more unmet psychosocial need during treatment (Barg et al., 2007). Psychological needs have been found to be second only to assistance with daily living with cancer patients rating psychological needs higher than information or other support needs (Sanders, Bantum, Owen, Thornton, & Stanton, 2010). These studies indicate that although efforts exist to ameliorate distress in cancer patients and meet the psychosocial needs of patients, there is still a lot of work to be done (Barg et al., 2007; Houts et al., 1986; Sanders et al., 2010).

**Biopsychosocial factors associated with depression in cancer patients.**

Shimizu and colleagues (2012) presented findings from the largest study to date examining biopsychosocial risk factors for the development of depression in lung cancer patients. These researchers found that patients who reported low fighting-spirit, hopelessness/ helplessness, anxious preoccupation, and high scores for neuroticism were all at increased risk for development of depression (Shimizu et al., 2012). Patients with a tendency for neuroticism contribute to burden on medical systems, increase medical costs and have increased risk for depressive illness (Cuijpers, Smit, Penninx, de Graaf, & Beekman, 2010; Shimizu et al., 2012). These studies indicate the significance of unmet emotional needs in patients with cancer and their caregivers.

### **Consequences of Unmet Psychosocial Needs**

Left untreated, unmet psychological and emotional sequelae have significant consequences. Psychological impairment and the presence of mental health problems including depression, anxiety, post-traumatic stress symptoms (PTSS), and post-traumatic stress disorder (PTSD) contribute to role impairment, reduced compliance with medical treatments, reduced quality of life, increased medical costs, prolonged hospitalizations, higher utilization of medical care, impacts symptom severity, and poor medical outcomes (Akechi et al., 2003; Badger et al., 2001; Bowers & Boyle, 2003; Breitbart, 1994; Greiner et al., 2005; IOM, 2007; Kissane, 2009; Montgomery et al., 2003; Newport & Nemeroff, 1998; Passik & Breitbart, 1996; Pirl & Roth, 1999; Ransom et al., 2006; Ryan et al., 2005; Salvo et al., 2012; Sellick & Edwardson, 2007; Shimizu et al., 2012; Spiegel & Giese-Davis, 2003; Thewes et al., 2003; Valente & Saunders, 1997). In addition, failure to assess depression in cancer patients ignores depression as a treatable illness and inadequately attributes depression as a possible result of a deeper physiological process that may need further evaluation (Akechi et al., 2003; Bowers & Boyle, 2003; Breitbart, 1994; Greiner et al., 2005; Massie & Greenberg, 2004; Mystakidou et al., 2008; Passik & Breitbart, 1996).

Depression contributes to impairment in personal, social, occupational, and family functioning (Dalton, Laursen, Ross, Mortensen, & Johansen, 2009; Hopko et al., 2008; Wobrock, Weinmann, Falkai, & Gaebel, 2009). Untreated distress and lack of available psychosocial support place families at risk for role strain and impairment in family functioning (Akechi, et al., 2007; Salvo et al., 2012; Vahdaninia, Omidvari, & Montazeri, 2010). As distress exists along a continuum, waiting until severe levels of distress occur,

fails to provide timely care that could prevent catastrophic results (Paterson et al., 2001). In severe cases, depression may even lead to an enhanced desire for sooner death or suicide (Akechi et al., 2007; Breitbart et al., 2000; Chochinov et al., 2005; Greneir et al., 2005; Hooper, Vaughan, Tennant, & Perez, 1997; Kugaya et al., 1999; Suarez-Almazor, Newman, Hanson & Bruera, 2002).

Cancer patients are at increased risk for suicide. Many factors contribute to this increased risk including pain, physical symptoms, advanced illness with poor prognosis, depression resulting in hopelessness, delirium and disinhibition, loss of control and helplessness, preexisting psychopathology, suicidal history, and inadequate social support (Akechi et al., 2010; Breitbart, 1994; Massie & Greenberg, 2004). Patients suffering severe depression are at risk for a desire for sooner death, suicide, and may even request physician-assisted suicide (Akechi et al., 2010; Blake-Mortimer et al., 1999; Greneir et al., 2005; Shimizu et al., 2012).

Individuals with cancer and concurrent depression and anxiety have more difficulty with somatic concerns, disability, more unexplained symptoms, and increased symptom severity (Greneir et al., 2005; IOM, 2007; Shimizu et al., 2012). Co-morbid psychiatric illnesses have been associated with unhealthy behaviors and reduced adherence to anti-neoplastic treatments (Greneir et al., 2005; IOM, 2007). Distress can contribute to a reduced level of hope, thus translating to a belief that cancer treatments are not worthwhile and contributing to poor follow-through with potentially curative treatments. Optimism relates to an underlying capacity for resilience, which leads to greater ability for problem solving, enhanced coping strategies, and an ability to find

meaning in illness (IOM, 2007). The presence of psychological distress reduces these functions and increases the risks of possible long-term complications (IOM, 2007).

### **Screening for Depression using the PHQ-9**

In efforts to improve quality healthcare for mental health conditions, the IOM (2006) recommended clinicians use reliable and valid patient questionnaires routinely to assess progress and outcomes in patients. An extensive database of psychometric scales exists within the field of psychiatry. However, further research is needed within the field to strengthen the recommendation toward a single tool (Wobrock et al., 2009). A well-studied, reliable, and valid tool for the measurement of depression is the PHQ-9 (Arroll et al., 2010; Dominquez-Rafer & Lin, 2011; Kronke et al., 2001). The PHQ-9 is a brief tool that is used with medically complex patient populations, including the cancer patient population (Fann et al., 2009; Manea, Gilbody, & McMillan, 2012; Oromo, Fann, Weymuller, Macharia, & Yueh, 2006; Thekkumpurath et al., 2011). Using a cut-off score of greater than or equal to 8, Thekkumpurath and colleagues (2011) reported the PHQ-9 to be 93% sensitive and 81% specific. There is currently no benchmark data related to use of the PHQ-9 in cancer patient populations. An opportunity exists to establish benchmarks within the field of psychiatry and psycho-oncology. Studies detailed in this paper including the PHQ-9 and sequential assessment of depression are included in the literature matrix in Appendix C.

The PHQ-9 is a brief scale by comparison to many other depression measures and consists of the criteria on which the diagnosis of depression is based, making this tool partner well with a clinical interview (Kroenke & Spitzer, 2002; Rodin et al., 2006). The NQF endorses outcome measurements for mental health, including measures that focus

on depression and the use of standardized psychometric scales, specifically the PHQ-9 (2011). Epidemiological studies including NHANES and Behavioral Risk Factor Surveillance System (BRFSS) use the patient health questionnaire series (PHQ-8/9) for assessment of depression to gather national study data (Centers for Disease Control [CDC], 2012; NHANES, 2013).

**Current practice with psychometric scales.** Currently broad variability exists among measurements used in psychiatry and psycho-oncology departments. The IOM report (2006) describes that as few as 27% of studies reviewed showed adherence to clinical guidelines and as few as 10.5% of individuals were found to receive evidence-based interventions. A recommendation exists for patient centered decision-making and engagement in care, including information regarding options for and effectiveness of treatments (IOM, 2006).

A better understanding of a patient's baseline presentation allows for ongoing assessment of interventions and identifies opportunities to focus on targeted areas for clinical improvement (Oldham et al., 2008). The methodology and implementation of quality improvement initiatives within the mental health arena is in its very early stage of development. A dearth of information exists within the mental health community with regard to consistently used metrics and benchmarking to assess clinical and functional outcomes (Hermann, Leff, & Lagodmos, 2002; Valenstein et al., 2004). A gap remains between clinical care and evidence based practice guidelines (Hermann et al., 2006; IOM, 2006). The APA endorses pharmacotherapy, supportive psychotherapy, and combined medication management and psychotherapy as efficacious in depressed patients (2010, 2012). After integration of evidence-based practice interventions within practices,

anticipated outcomes include improvement in depressive symptoms, reduced recurrence risk, and reduction in depression related morbidity and mortality (APA, 2010).

### **Theoretical Framework**

Many factors influence an individual's ability to react to stressful situations including culture, ethnicity, personal history, and even personality (Folkman & Moskowitz, 2004; Garland & Bush, 1982). A theoretical structure assists our understanding of the complexities of coping and how individuals manage internal and external stressors (Folkman & Moskowitz, 2000; Folkman & Moskowitz, 2004). Within the theoretical model of stress and coping, it becomes possible to appraise the value an individual attributes to events, while also determining how the individual manages these events (Lazarus & Folkman, 1984; Folkman & Greer, 2000). This understanding provides a foundation for the promotion of psychological well-being through exploration of meaning, goal creation, and determination of patient perspective (Folkman & Greer, 2000).

Individual adaptation to illness exists along a continuum (Holland & Freeland, 2006; Lazarus, 1974). The integration of illness-related factors and disease specific interventions impact individual coping. A myriad of coping mechanisms are necessary as an individual undergoes cancer treatment. Identification of patients with concurrent mental health disorders provides insight to individuals who may be at risk for impaired coping. Sequential assessment of depressive illness provides a measurement at several points in time and may provide insight to psychological and emotional adaptation as it occurs over time. Enhancement of coping strategies provides benefit to patients and minimizes weakened problem solving.

## **Methods and Procedures**

### **Model of Evidence-Based Practice**

This pilot project implemented routine assessment with the PHQ-9 to illustrate changes in the patients' subjective experience. The PHQ-9 was obtained prior to the initiation of treatment and at each follow up appointment with NCIBOP providers to ascertain changes in patient symptoms. Providers in the department were educated on evidence-based practice interventions as part of the preparation for this quality improvement project. In an effort to reduce treatment variability, evidence-based interventions and best-practice guidelines were incorporated consistently among providers. Though it was beyond the scope of this pilot project, ongoing data tracking has continued to occur for the identification of additional practice improvement initiatives. Baseline data obtained through this process and quality improvement project are described in Appendix D.

### **Intervention and Implementation Timeline**

The implementation of this process and quality improvement project consisted of a number of phases (see Appendix E) leading up to this capstone project completion. Regular meetings began in August 2012 with the physician leader in the department, the Director of Quality, CNO, and NCIBOP team to provide education, rationale for sequential assessment with the PHQ-9, and evidence-based treatment guidelines. Initial exploration of the NCIBOP as a microsystem in September 2012 provided an in-depth understanding of the department characteristics, patient population, departmental processes, and preliminary departmental outcome data. Limited availability of outcome data reinforced the need to operationalize departmental processes and capture outcomes.

A comprehensive review of the literature identified the implementation of routine psychometric assessment with the PHQ-9 as an acceptable approach to understand outcomes and integrate evidence-based practice interventions. As the Norton Healthcare (NHC) system transitioned to the new EMR, EPIC, the PHQ-9 was incorporated into the visit navigator for NCIBOP providers. Initial discussion of implementing the PHQ-9 at initiation of care and regular intervals began in September 2012. To ensure availability of the PHQ-9 in the EMR, routine meetings were held with the ISA/IT team.

Departmental processes to include the PHQ-9 at initial and follow up visits began in January 2013. As this project-necessitated considerable pre-work, the capstone project was initially discussed with the chair and committee members in October 2012. This capstone project was formally proposed and approved by the capstone committee in May 2013. Ongoing visits were made to clinical managers and support teams throughout this project to enhance process consistency and sustain support. Regular updates were provided to NCI leaders to sustain support for the project. Weekly NCIBOP team meetings continued throughout 2013 to reinforce provider accountability for PHQ-9 entry, documentation of the diagnostic assessment, treatment recommendations (pharmacological and non-pharmacological), and the plan for follow up care. The project budget is described in Appendix F.

### **Setting and Population**

NCI is part of the NHC system and has practice sites at each of the four adult hospitals in Louisville, KY, as well several other locations within Kentucky and Southern Indiana. The practice employs 35 physicians and 22 advanced practice registered nurses (APRN) in medical, surgical, gynecological, radiation, orthopedic, neurological, and

behavioral oncology. The NCIBOP is a fully embedded psychiatric program offering a spectrum of services to help medically complex patients and families deal with cancer and related quality of life issues. The program is comprised of one physician, three advanced practice nurses, a part time social worker, a nurse, and two administrative staff.

A clinical microsystem assessment was completed for the NCIBOP. Chart reviews of patients seen in the department revealed 59% of patients seen within the department were diagnosed with and being treated for a depression spectrum disorder. Consistent with the psycho-oncology literature, depression is the number one mental health diagnosis within the department.

### **Sample**

Forty-one patients seen for an initial evaluation in the outpatient setting between January 1, 2013 and March 31, 2013 were included; 107 were excluded. Study participants included males and females greater than 18 years of age with an oncologic diagnosis. Individuals seen through the department who did not have a cancer diagnosis (family members or those with benign disorders), inpatient consultations, and individuals seen for less than two visits were excluded.

### **Intervention**

Sequential assessment of depression using the PHQ-9 was implemented. The information technology (IT) team was consulted to build the PHQ-9 template and synopsis reporting features into the Electronic Medical Record (EMR) to enhance data aggregation opportunities. PHQ-9 scores were entered into the EMR by the NCIBOP providers for comparison of subsequent scores against baseline data. Evidence-based practice guidelines related to the treatment and management of depression were

disseminated to the provider team. Practice observations and opportunities for enhancing care with evidence-based interventions were shared with the NCIBOP providers.

**Instrument.** The PHQ-9 survey is based on the diagnostic criteria for depression and pairs with a clinical interview to determine the presence of depressive illness (Kroenke, Spitzer & Williams, 2001; Kroenke & Spitzer, 2002; Lowe, Kroenke, Herzog, & Grafe, 2004; NQF, 2011; Spitzer, Kroenke & Williams, 1999). The tool consists of 9 questions with scores ranging from zero to three to determine the presence and severity of depressive illness. Scores 1-5 indicate minimal depression, 6-10 mild depression, 10-14 moderate depression, 15-19 moderately severe depression and 20-27 severe depression (Kroenke et al., 2001; Kroenke & Spitzer, 2002; Spitzer et al., 1999). Using a cut-off score of 10 or higher, the tool has a high sensitivity (0.93) and specificity (0.85) and acceptable positive and negative predictive values (Wittkamp et al., 2009). The PHQ-9 has demonstrated capacity to ascertain depression outcomes (Lowe et al., 2004). This tool is simple and cost-effective. The PHQ-9 is a free resource with no copyright or distribution restrictions. This one-page screening tool was acceptable and easy for both patients and clinicians to use.

### **Data Collection**

New patient charts were reviewed for the presence of documentation of the PHQ-9 in the EMR. Data was gathered on all newly referred patients to the NCIBOP meeting inclusion criterion from January 1, 2013 through March 31, 2013. A six-month retrospective chart review concluded September 30, 2013. Data was de-identified to maintain patient privacy.

Data aggregation was an ongoing process; the PI analyst and the department manager shared responsibility for data collection with quality assurance checks to ensure data integrity. Socio-demographic data included age, gender, race, ethnicity, educational level, religious affiliation, marital status, and employment status. Clinical data included cancer type and stage. Socio-demographic and clinical data were extracted from patient charts. Provider documentation in the EMR was reviewed for (a) PHQ-9 entry at each visit, (b) psychiatric diagnosis, (c) treatment plan and rationale (including psychopharmacological intervention and non-pharmacological interventions), (d) goals of care, and (e) plan for follow-up care. Data was aggregated and entered into a spreadsheet for analysis and ongoing observation.

### **Data Analysis**

Data was analyzed using Stata, College Station, TX, version 12.0. Inferential statistics were run with paired-samples t-test analysis to identify changes in PHQ-9 and distress scores pre/post NCIBOP intervention. Descriptive statistics were run for analysis of clinical and socio-demographic data, means (95% Confidence Interval [CI]) were calculated for continuous variables and proportions (95% CI) were calculated for categorical variables. Statistical significance was established as  $p < 0.05$ . Content analysis of provider feedback is described.

### **Approval for Implementation**

The study was reviewed by the Western Institutional Review Board (WIRB) and was granted a waiver of authorization (approval #1140717). The Norton Healthcare Office of Research Administration (NHORA) approved the study (NHORA #13-N0160). Required documentation describing the study was filed with Bellarmine University's

Institutional Review Board (Non-BU IRB Submission Summary Form). Approval was received from the departmental providers, the capstone committee, and NCI executive leadership.

**Ethical considerations.** This process improvement initiative was implemented to develop a procedure for sequential assessment with the PHQ-9 at NCIBOP provider visits. Completion of the PHQ-9 remained voluntary. Patients were educated regarding the rationale for routine assessment and quality measures to enhance the delivery of quality care. The Director of Quality and the PI nurse were engaged in data collection and auditing of study data to ensure maintenance of objectivity.

#### **Evaluation Plan**

Using the initial PHQ-9 and subsequent assessment score, the impact of the implementation of sequential monitoring with the PHQ-9 was measured. Changes in PHQ-9 scores were considered a measure of clinical effectiveness. Programmatic outcome metrics were aggregated and ongoing process improvement efforts were maintained to ensure the continuation of evidence-based treatment approaches. Aggregated data provided an overview of patient outcomes and reflected a high level of quality care delivered through the department. Capability to focus on group outcomes rather than individual outcomes provided an optimal foundation for ongoing departmental quality improvement initiatives (Dulgacz, 2006; Oldham et al., 2008).

Collateral feedback from providers about the process and utility of the project was obtained during provider team meetings (Appendix G). The provider team agreed the PHQ-9 was easy for patients to use, is important to administer routinely, and has been helpful in guiding treatment decisions.

## Results

### Descriptive Analysis

The majority of the sample was married, Caucasian females. The mean age of participants was 58 (SD=11.3) years of age. On average, patients were seen for 5.5 (SD=3.1) visits. Socio-demographic characteristics are presented in Table 1.

Table 1

*Sociodemographic Characteristics of the Study Group (N=41)*

Characteristic	n	Proportion (%)
<b>Gender</b>		
Male	9	21.90
Female	32	78.00
<b>Race</b>		
Caucasian	36	94.70
African American	2	5.26
<b>Marital status</b>		
Married	26	65
Divorced	5	12.5
Widowed	4	10.0
Separated	1	2.5
Never Married	3	7.5
Partner	1	2.5
<b>Educational attainment</b>		
Some high school	4	10.5
12 <sup>th</sup> grade	12	31.5
Some college	11	28.9
Bachelor's	8	21.0
Post-graduate	3	7.8
<b>Employment status</b>		
Employed	18	45.0
Unemployed	4	10.0
Retired	9	22.5
Disabled	9	22.5
<b>Religions Affiliation</b>		
Yes	21	72.4
No	8	27.5

Cancer diagnostic and staging variables were obtained (see Table 2). Cancer staging was obtained, however caution should be taken when interpreting this variable. The medical record did not always clearly describe times of progression or remission.

Table 2

*Cancer Associated Characteristics and Staging (N=41)*

Characteristic	n	Frequency (%)
<b>Cancer Diagnosis</b>		
Hematological Malignancy	3	7.3
GI Cancers	1	2.4
Colon Cancer	3	7.3
Brain Tumors	3	7.3
Breast Cancer	14	34.1
Gynecological Cancers	6	14.6
Lung Cancer	4	9.7
Pancreatic Cancer	1	2.4
Head and Neck Cancers	1	2.4
Other	5	12.1
<b>Cancer Stage</b>		
Stage 0	1	2.4
Stage I	9	21.9
Stage II	13	31.7
Stage III	4	9.7
Stage IV	12	29.20
Remission	2	4.80

The most frequent diagnosis among participants was breast cancer (34.1%). Psychiatric diagnosis was most often reported as Unspecified (36.5%) or Major Depression (26.8%). Psychiatric diagnosis among study participants is displayed in Table 3. Behavioral Oncology visit process variables included the frequency of completion of the PHQ-9 across visits.

Table 3

*Psychiatric Diagnostic Characteristics (N=41)*

Characteristics	n	Frequency (%)
Psychiatric Diagnosis		
Depression	15	36.50
Major Depression	11	26.80
Unspecified Anxiety	7	17.00
Unspecified Mood Disorder	4	9.70
Bipolar Disorder	1	2.40
Adjustment Disorder with Mixed Features	3	7.30

At initial evaluation, the PHQ-9 was entered into the EMR 92.6% of the time; at follow up visits the PHQ-9 was entered 84.1% of the time (Table 4). Table 5 overviews provider-prescribing. Some patients received more than one psychopharmacological intervention.

Table 4

*Provider Process Variables and Proportions (N =41)*

Provider Process Variables	Proportion (%)
PHQ-9 entered at Initial Evaluation	92.68
PHQ-9 entered at Follow Up Visit	84.19
Psychiatric Diagnosis Documented	100
Plan of Care and Rationale Documented	100
Plan of Care Included Supportive Psychotherapy	100
Plan of Care Included Medication Management	89

Table 5

*Provider Prescribing Characteristics (N =41)*

Prescribing Characteristics	n	Proportion (%)
Plan of Care Included Antidepressants	31	75.60
Plan of Care Included Mood Stabilizers	9	21.90
Plan of Care Included Anxiolytic	20	48.8
Plan of Care Included Sleep Aid	8	19.50

**PHQ-9 and distress intervention analysis.**

The forty-one participants pre/post intervention assessments were analyzed for changes in PHQ-9 scores (total score and individual question scores) and changes in distress score using the paired samples t-test. Patient initial PHQ-9 scores were compared with their final PHQ-9 scores. PHQ-9 total mean scores decreased from 11.34 (SD=6.1) pre-intervention to 8.43 (SD=5.27) post-intervention; this reduction in PHQ-9 total score was statistically significant ( $p = 0.0098$ ). All individual PHQ-9 questions showed a reduction in score post-intervention. Four specific items showed statistically significant reduction in post-intervention scores: feeling down, depressed or hopeless ( $p = 0.011$ ), trouble with sleep ( $p = 0.01$ ), feeling bad about yourself or that you are a failure or have let your family down ( $p = 0.006$ ), and difficulty with psychomotor agitation or retardation ( $p = 0.054$ ). In addition, distress scores were significantly reduced after intervention with NCIBOP providers ( $p < 0.001$ ).

Table 6

*Mean Differences in PHQ-9 Total and Item Scores (N = 41)*

Indicator	Pre-Intervention	Post-Intervention	t-value	p-value
Total PHQ-9 Score	11.34 ( $\pm 6.18$ )	8.43 ( $\pm 5.27$ )	2.71	$p = 0.009^*$
Anhedonia	1.20 ( $\pm 1.00$ )	1.14 ( $\pm 0.88$ )	0.66	$p = 0.515$
Depressed	1.51 ( $\pm 1.07$ )	1.09 ( $\pm 0.88$ )	2.66	$p = 0.011^*$
Sleep	1.80 ( $\pm 1.16$ )	1.24 ( $\pm 1.09$ )	2.68	$p = 0.011^*$
Fatigue	2.12 ( $\pm 0.93$ )	1.70 ( $\pm 0.96$ )	1.83	$p = 0.75$
Appetite	1.43 ( $\pm 1.02$ )	1.21 ( $\pm 1.15$ )	1.03	$p = 0.311$
Failure	1.02 ( $\pm 1.25$ )	0.53 ( $\pm 0.83$ )	2.91	$p = 0.006^*$
Concentration	1.24 ( $\pm 1.11$ )	0.95 ( $\pm 1.18$ )	1.27	$p = 0.209$
Psychomotor	0.76 ( $\pm 0.99$ )	0.39 ( $\pm 0.80$ )	1.99	$p = 0.054^*$
Suicide	0.17 ( $\pm 0.49$ )	0.07 ( $\pm 0.34$ )	1.16	$p = 0.253$
Distress Score	3.80 ( $\pm 3.68$ )	0.90 ( $\pm 1.78$ )	5.03	$p = 0.000^{**}$

Note.  $*p < 0.05$ .  $**p < 0.01$ .

## **Discussion**

### **Evidence-Based Practice Interventions**

Previous study has identified variances among cancer patients diagnosed with depression and those who receive antidepressants (Gruneir et al., 2005). In 2006, the IOM reported less than 11% of patients receive interventions based on evidence. The integrated psycho-oncology program in this study implemented a model for evidence-based practice. Providers were accepting of systematic screening with the PHQ-9. Review of provider documentation revealed adherence to evidence-based interventions; 100% of patient charts reviewed included a psychiatric diagnosis, 89% of patients agreed to medication interventions for clinical disorders, 100% of patients received supportive psychotherapy, and 100% of the reviewed notes explained the treatment rationale and plan for follow up. Evidence-based care delivered in this program far exceeds the national norm described in the IOM (2006) report. Statistically significant reductions in both PHQ-9 score and Distress scores reflect high quality care. Quality care was delivered similarly across several practice sites and multiple providers.

The CNO and the Director of Quality remained engaged and supportive throughout the project. The project was viewed as an important quality improvement initiative for the cancer institute and was adopted as one of the quality studies for the Cancer Committee and accreditation through the CoC. No significant barriers were encountered. Availability of outcome data reflecting a significant improvement in PHQ-9 scores from initial assessment has been helpful in reinforcing the importance of maintaining processes for quality care delivery.

**Strengths and Limitations**

This study had a number of methodological strengths and weaknesses. The dual role of the principle investigator and program provider posed a potential study weakness; audits to ensure data quality by the PI nurse and Director of Quality minimized this study risk and interpretation bias. Despite the small sample size, sequential assessment with the PHQ-9 and delivery of evidence-based interventions seems to be associated with reduction in depression. The homogeneity of the sample is both a strength and weakness; study data is primarily relatable to women with breast cancer. Further investigation with larger samples would be helpful to determine generalizability. Absence of a comparison group and baseline data poses an additional study limitation.

The clinical setting allowed for significant control of the processes and range of clinical interventions delivered by program providers. NCIBOP providers sustained engagement with this initiative and belief in the benefit of consistency among providers; this may be due to the small size of the department and may take more time to adapt into larger practice settings. Opportunities continue to exist to enhance front-end processes with the provision of the PHQ-9 survey to patients upon arrival for appointments.

**Recommendations**

The implementation of quality and process improvement initiatives provides a foundation for aggregating department specific outcomes. Study data may be helpful for establishing benchmarks internally and with other psycho-oncology practices. Multi-center collaboration studies are needed to more clearly understand the unique needs of specialized patient populations. As the national healthcare agenda continues to evolve, metric based outcome studies will be necessary to articulate the importance of mental

health interventions. Continual tracking should ensue beyond the study period to assure the continuation of evidence-based practice and screening with the PHQ-9. With the advent of the medical home and further integration of mental health providers into medical settings, the capacity to fully explain the added value of specialized mental health services and to advocate for these services is more important than ever before.

### **Future Research**

Future studies with larger samples across multiple cancer centers are needed to fully understand the impact of sequential assessment of depression with PHQ-9 on outcomes. Additional study of prevalence and penetrance of psycho-oncology services within this cancer center may be helpful. Preliminary analysis of the NHANES data described in this study revealed statistically significant differences in the rates of cancer patients meeting criterion for major depression when compared to non-cancer patients; gaps in this area of the literature reinforces the priority for epidemiological study in psycho-oncology. Additional study evaluating reduction in depression scores and the impact this has on quality of life are needed.

### **Conclusions**

As bio-medical approaches to treatment continue to advance, psychosocial interventions supporting quality of life will have to keep pace (IOM, 2007). As the field of psycho-oncology continues to grow, oncology providers will need to support thorough psychosocial assessments and psychiatric measures to fully describe patient and program outcomes. With the inclusion of psychosocial measures for accreditation at the majority of cancer centers nationwide, cancer centers will be pushed to screen for psychological sequelae as a routine part of care (COC, 2012; Jacobson, 2012; Jacobson, 2013). Once

patients enter care with specialized psychiatric providers, the ability to measure outcomes is important for describing clinical care, advocating for resources, and sustaining psychiatric programs. Use of the PHQ-9, a reliable and valid measure of depression severity (Kroneke et al., 2001), at routine intervals in specialized cancer mental health settings, provides a metric for ongoing analysis of patient outcome data. Evidence supports the use of validated screenings as a way to minimize treatment variability. Combined with comprehensive medication management and psychotherapeutic interventions, patients are likely to have the most optimal outcomes (AHRQ, 2009; NQF, 2011).

Findings from this study are suggestive that the implementation of quality metrics, sequential assessment with validated tools, and the integration of evidence-based treatment guidelines are feasible. Aggregation of patient outcome data showed statistically significant improvement in PHQ-9 scores after intervention with the NCIBOP providers when using evidence-based treatment approaches. With the evolution of healthcare policy and a rising demand for quality, the establishment of standards for care and the inclusion of quality metrics are necessary to effectively measure patient outcomes.

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*Appendix A*

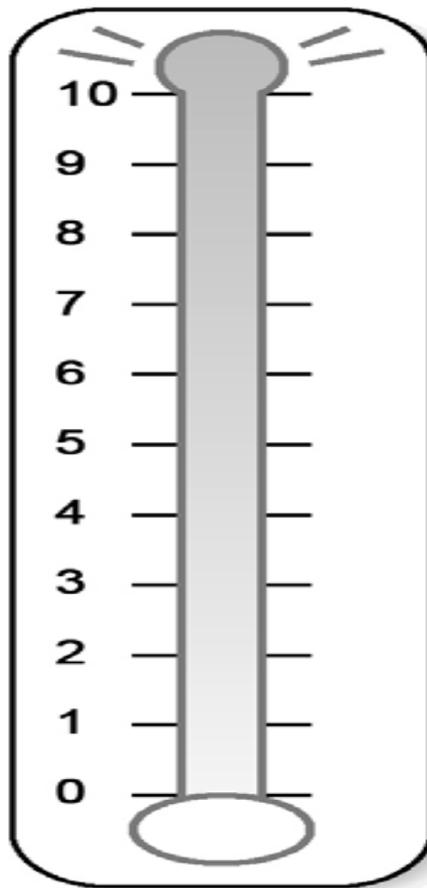
## Distress Thermometer

**SCREENING TOOL FOR MEASURING DISTRESS**

## Instructions:

First please circle the number (0-10) that best describes how much distress you have been experiencing in the past week including today.

Extreme distress



No Distress

We want to make sure we are providing you with excellent care. This survey helps us to assess your needs; if you would like to see either a social worker or Behavioral Oncology provider, please let us know. You may contact the Behavioral Oncology Program at (502) 899-2673.

*Appendix B*

Patient Health Questionnaire (PHQ-9)

Patient Name: \_\_\_\_\_ Date: \_\_\_\_\_

Over the *last 2 weeks*, how often have you been bothered by any of the following problems?

(use “✓” to indicate your answer)

	Not at all	Several days	More than ½ the days	Nearly everyday
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling/staying asleep or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite - being so fidgety or restless that you have been moving around more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Add columns				
TOTAL				
If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?				
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult	
<i>(Healthcare Professional: For interpretation of TOTAL, see accompanying scoring card).</i>				

*Appendix C*

## Literature Matrix

<b>First Author/ Year</b>	<b>Purpose / Aims</b>	<b>Study Design</b>	<b>Instrument</b>	<b>Sample size / Statistics</b>	<b>Results</b>	<b>Conclusions / Recommendations</b>	<b>Limitations</b>	<b>Quality of evidence</b>
Arroll, (2010).	Validation of PHQ-2 & 9 item tools.	Randomized Control Trial (RCT)	PHQ-2 & PHQ-9, Composite International Diagnostic Interview (CIDI).	2,642 Patients completed the PHQ-9 and the CIDI. Likelihood ratios and $\chi^2$ .	Sensitivity and Specificity of the PHQ-2 were 86% and 78%. Sensitivity and specificity for PHQ-9 were 74% and 91% for score 10 or higher.	A PHQ-9 score of 10 or greater is sensitive and specific for detection of depression.	External Validity, conducted in New Zealand.	Level 1, Strong Evidence.
Dominguez-Rafer, (2011).	Determine sensitivity and specificity of the PHQ-2 & 9	Evidence Based Practice Guideline	PHQ-2 & 9	15,000 patients / Psychometric review. Includes 28 Meta-analysis.	Cutoff point >10, pooled studies with 15,000 patients found 91-94% specificity, 77-81% sensitivity	PHQ-9 Score of 10 or grater was found to have acceptable sensitivity and specificity.	Limited information about study populations.	Level 1, Strong Evidence.

<b>First Author/ Year</b>	<b>Purpose / Aims</b>	<b>Study Design</b>	<b>Instrument</b>	<b>Sample size / Statistics</b>	<b>Results</b>	<b>Conclusions / Recommendations</b>	<b>Limitations</b>	<b>Quality of evidence</b>
Fann, (2009)	Assess validity and feasibility of PHQ-9 admin on touch screen.	Prospective Cohort Study	PHQ-9	342 patients two tailed independent t-test and ANOVA; $\chi^2$	Mean scores between 11-13 for moderate depression. Acceptable validity and feasibility.	PHQ-9 using touch screen was feasible and valid tool for depression in CA pt population.	Needs additional study to enhance external validity. Only 50% completed full tool.	Level 2, Good Evidence.
Kroenke, (2001).	Determine reliability, validity and operating character of PHQ-9	Prospective Cohort Study	PHQ-9	3,000 PC pt and providers repeated in 3,000 GYN pt. Correlations	Scores of 5, 10, 15 serve as cutoffs for mild, moderate and severe depression. Pairs with DSM-IV diagnostic criteria and clinically valuable.	PHQ-9 is a reliable and valid measure of depression severity. As depression severity increases, functional status decreases. Useful tool clinically and for research.	Strength-external validity supported through second study with GYN cohort. Weakness response bias: self-administered scale.	Level 2, Good evidence.

<b>First Author/ Year</b>	<b>Purpose / Aims</b>	<b>Study Design</b>	<b>Instrument</b>	<b>Sample size / Statistics</b>	<b>Results</b>	<b>Conclusions / Recommendations</b>	<b>Limitations</b>	<b>Quality of evidence</b>
Kroenke, (2002)	The PHQ-9: A new Diagnostic and Severity Measure/ Comparison to PHQ-8.	Cross-Sectional Study Design.	PHQ-9/ PHQ-8	IMPACT Study on PHQ-9 severity. 150-intervention patients correlation of measures at baseline were determined.	PHQ-8 & 9 share likelihood to determine presence of depression, and operating character.	Description of PHQ-9 as a well validated tool in 2 large studies most common used tool in clinical and research settings	Small sample size, change in administration of tools. Exclusion of suicide question in 8 item tool.	Level 2, Good evidence.
Manea, (2012)	Study aimed to determine the optimal cut-off score for diagnosing depression with the Patient Health Questionnaire (PHQ-9)	Meta-analysis.	PHQ-9	Pooled 7,180 patients. Bivariate meta-analysis to determine specificity and sensitivity, positive and negative predictive values.	18 validation studies, 11 gave detail regarding diagnostic properties of PHQ-9. Pooled specificity 0.73, variable sensitivity.	Meta Analysis found 18 studies that reviewed diagnostic properties of the questionnaire, specificity 73% for score 10. Sensitivity variable scores between 8-11.	Ranges of cut-off scores; some variability in study methodology.	Level 1, Strong evidence.
Meijer, (2011)	Assess effect of screening on depression outcomes, compared depression	Systematic Review	Varied by study.	2,302 studies were identified to determine if screening impacts	5 of 2,302 were selected for full article review.	19 Studies of screening accuracy, 1 MDD treatment RCT, No RCT on depression outcomes. A gap exists in the	Gap in literature around benefit of screening on depression outcomes.	Level 1, Strong evidence.

<b>First Author/ Year</b>	<b>Purpose / Aims</b>	<b>Study Design</b>	<b>Instrument</b>	<b>Sample size / Statistics</b>	<b>Results</b>	<b>Conclusions / Recommendations</b>	<b>Limitations</b>	<b>Quality of evidence</b>
	treatment to usual care, compared screening instrument to criteria for MDD.			depression.		literature regarding the impact of screening on depression in cancer patients.		
O'Connor, (2009).	Screening for depression in adult patients in PCP offices. Multi-focus study.	Systematic Review	Tools varied by study.	38,843 patients screened identified 1,908 depressed patients.	33 articles reviewed, screening alone did not improve depression. There are no harms to screening. Psycho-pharm and therapy are effective in older adults.	Organized review of depression screening. Encouraged screening in situations where it is possible to have support and monitoring of treatment in patients who are depressed.	Limited control for confounding variables to depression, limitations to systematic methodology among studies. Multiple screening tools, unclear if best choice exists.	Strong evidence. Level 1.
Rodin, & Supportive Care Guidelines Group of Cancer Care Ontario Program in Evidence-Based, (2007).	Study was conducted to evaluate the efficacy of pharmacological and non-pharm interventions for depression in cancer patients.	Systematic Review	Inclusion: systematic reviews, meta-analysis, evidence-based practice guidelines, or RCT/ non-randomized observational trials. All studies had outcome	Variable by study, no pooled sample provided. Multiple statistical analysis run due to study complexity.	Limited information about efficacy for pharmacological and psychosocial interventions in cancer patients. Evidence from study includes	11 trials included with pharmacological/ non-pharm interventions. Cochrane systematic review- based on healthy adults included.	No systematic screening tool in place to identify depression or sequentially monitor. Identifies literature gap; also Cochrane review for depression management is	Strong evidence. Level 1.

First Author/ Year	Purpose / Aims	Study Design	Instrument	Sample size / Statistics	Results	Conclusions / Recommendations	Limitations	Quality of evidence
			measure of depression symptoms.		deductions made from healthy adults.		based on healthy individuals, not unique needs of cancer patients.	
Thekkumpurath, P. (2011).	Screening for major depression in cancer outpatients: the diagnostic accuracy of the 9-item patient health questionnaire	Systematic Review	PHQ-9	4,264 pooled patients. ROC analysis.	PHQ-9 with a cut-off score of $\geq 8$ had acceptable sensitivity and specificity to identify MDD in cancer patients.	PHQ-9 is an acceptable tool for use in cancer patients and takes only approximately 2 minutes to complete.	Self response bias. Two stage process to determine presence of depression may have missed cases of MDD. Was not inclusive of all cancer types. Limited clinical data to identify confounders. Delayed SCID.	Strong evidence. Level 1.
Thewes & Greater Southern Area Health Service Screening Collaborative (2009).	To determine feasibility and usefulness of depression screening in cancer outpatient setting.	Pilot Study	Distress Thermometer (DT)	43 participants. Univariate and multivariate analysis.	44% met criteria for having additional needs for psychosocial care with validated DT. 86% sensitivity,	Though screening with DT did not increase the number of referrals, it did reduce the amount of time before patients were offered referral.	Very small sample size.	Fair evidence. Level 3.

First Author/ Year	Purpose / Aims	Study Design	Instrument	Sample size / Statistics	Results	Conclusions / Recommendations	Limitations	Quality of evidence
					77% specificity. Screening did not increase referral rates, but did reduce time to referral for specialized care.			

*Appendix D*

Quality Improvement Evaluation Plan

Outcome/ Process Indicator	Measure/ Operational Definition	Rationale for Measure Selection	Data Collection Approach	Benchmark	Improvement Goal
PHQ-9 Questionnaire is administered to each patient at initiation of care with the department.  (Assessment Measure)  (Long term goal)	Percentage of patients with the principle diagnosis of depression that has the PHQ-9 documented at time of initial evaluation.  Numerator: Number of new patients who are seen for depression who fill out the PHQ-9 at the first visit during a specified time period (example: January 1 through February 1).  Denominator: The number of new patients seen in the department during the specified time period with the diagnosis of depression.  Exclusions: individuals with primary bipolar disorder, personality disorder or those who have died (NQF, 2011).	PHQ-9 is a reliable, validated and standardized tool. The survey is brief compared with other psychometric measures. (Kroenke et al., 2001; Kroenke, & Spitzer, 2002; NQF, 2011)	The assigned provider will enter PHQ-9 data into the EMR.  PI nurse will complete ongoing PI with data analysis and aggregation monthly by the quality director.	Internal goal. No benchmark data is available in the cancer patient population.	Baseline Result: 92%  Goal: Maintain > 90% PHQ-9 entered at the initial outpatient visit
Reassessment with PHQ-9  (Assessment Measure)  (Long term goal)	Percentage of patients receiving treatment with BHONCP who complete PHQ-9 reassessments.  Numerator: Number of patients seen for depression in the department who fill out the PHQ-9 at three-month follow-up.  Denominator: The number of follow	Changes in score on standard psychiatric rating scale. This is a patient-centered measure, which also impacts	The assigned provider will enter data into EMR, making accessible for data collection.  PI nurse will complete ongoing PI with data analysis and	Internal goal. No benchmark data is available in the cancer patient population.	Baseline Result: 84%  Goal: Increase to 90% PHQ-9 entered at follow-up visits

Outcome/ Process Indicator	Measure/ Operational Definition	Rationale for Measure Selection	Data Collection Approach	Benchmark	Improvement Goal
	<p>up patients who are seen within the department for depression at three months.</p> <p>Exclusions: individuals with primary bipolar disorder, personality disorder or those who have died (NQF, 2011).</p>	<p>patient safety, efficiency, equity and timeliness (IOM, 2006).</p> <p>Engages patient in symptom assessment and treatment planning. (IOM, 2001)</p>	<p>aggregation monthly by the quality director.</p>		
<p>Patients with Major Depressive disorder receive an adequate medication trial</p> <p>(Treatment Measure/ Process measure)</p> <p>(Medium term goal)</p>	<p>Proportion of patients who are prescribed an antidepressant for treatment.</p> <p>Numerator: Number of patients who meet criteria for depressive illness who are on a medication for a specified time frame.</p> <p>Denominator: Number of patients who meet criteria for depression who are seen by the department during a specified time frame.</p> <p>Exclusions: individuals with primary bipolar disorder, personality disorder or those who have died (NQF, 2011).</p>	<p>Depression is treatable with anti-depressant medication.</p> <p>Effective and Equitable care are two of the aims of the IOM report (2001; 2006). Ensuring that patients have equal access to medication and are provided services based on knowledge.</p> <p>A good evidence level is described</p>	<p>Medication is entered into the EMR and can be found on the patients updated medication list.</p> <p>Data collection will occur through PI audits of patient charts to establish results and identify practice variances.</p>	<p>Internal goal; no benchmark data available.</p>	<p>Diagnosis was recorded on 100% of patients.</p> <p>When indicated, medications were offered and prescribed (89% agreed to medications).</p>

Outcome/ Process Indicator	Measure/ Operational Definition	Rationale for Measure Selection	Data Collection Approach	Benchmark	Improvement Goal
		through the AHRQ- Level A rating (AHRQ, 2009; Katon & Schulberg, 1992; O'Connor et al., 2009)			
Patients with Major Depressive disorder receive Supportive Psychotherapy or another validated therapy modality  (Treatment Measure/ Process Measure)  (Medium term goal)	Portion of patients who receive psychotherapy.  Numerator: Number of patients who receive psychotherapy.  Denominator: Number of patients with a depression diagnosis seen within the department during the specified time frame.  Exclusions: individuals with primary bipolar disorder, personality disorder or those who have died (NQF, 2011).	Several types of psycho-therapy including Cognitive Behavioral Therapy, Supportive Therapy and Inter-Personal therapy have shown efficacy in the treatment of depression (American Psychiatric Association [APA], 2012; AHRQ, 2012).  A good evidence level is described through the AHRQ- Level	The treating provider will enter the therapy modality into the EMR; data accessible to the PI nurse and director of quality through the EMR.  Data collection will occur through PI audits of patient charts to establish results and identify practice variances as directed by the quality team.	Internal goal; no benchmark data available.	100% of charts reviewed stated delivery of supportive psychotherapy.

Outcome/ Process Indicator	Measure/ Operational Definition	Rationale for Measure Selection	Data Collection Approach	Benchmark	Improvement Goal
<p>Patients report improved symptom status with either individual or combined psychotherapy and medications</p> <p>(Outcome measure)</p> <p>(Long term goal)</p>	<p>Portion of patients who are receiving trials on antidepressant therapy with or without combined psychotherapies who show improvement in PHQ-9 scores over a specified period of time.</p> <p>Numerator: People who show a reduction in PHQ-9 scores at six months.</p> <p>Denominator: People who are treated for six months from initial treatment for depression who are receiving psychotherapy with or without medication management with initial and six month PHQ-9 scores.</p> <p>Exclusions: individuals with primary bipolar disorder, personality disorder or those who have died (NQF, 2011).</p>	<p>A rating (AHRQ, 2009; APA, 2012).</p> <p>This outcome relates to patient centered care, one of the six quality domains identified by the IOM (2001, 2006). Additionally this relates to the delivery of effective, efficient and safe care as described by the IOM; with integration of evidence-based practice (2006).</p>	<p>Aggregated PHQ-9 scores from initial through follow ups available on flow sheet in EMR.</p> <p>Results will be aggregated on a quarterly basis to capture department outcomes with focus on system improvement, rather than individual reports.</p>	<p>Internal goal; no benchmark data available.</p>	<p>Total PHQ-9 mean scores decreased from 11.34 (6.1) pre-intervention to 8.43 (5.27) post-intervention (<math>p &lt; 0.05</math>).</p> <p>Patients studied revealed EBP interventions led to statistically significant improvement in PHQ-9 scores.</p>
<p>Provider will use PHQ-9 tool to modify treatment plan if score rises</p> <p>(Outcome Measure)</p> <p>(Long term goal)</p>	<p>Portion of patients who are receiving trials on antidepressant therapy with or without combined psychotherapies who show increase in PHQ-9 scores over a specified period of time.</p> <p>Numerator: People who show an increase in PHQ-9 scores at six months.</p>	<p>This relates to the delivery of effective, efficient and safe care as described by the IOM (2006). This supports the integration of evidence-</p>	<p>Aggregated PHQ-9 scores from initial through follow ups available on flow sheet in EMR.</p> <p>Evidence of provider integration of score and formulation of</p>	<p>Internal goal; no benchmark data available.</p>	<p>100%</p> <p>Patient charts were reviewed, in patients where depression scores worsened, providers made adaptations to the treatment regimen</p>

<b>Outcome/ Process Indicator</b>	<b>Measure/ Operational Definition</b>	<b>Rationale for Measure Selection</b>	<b>Data Collection Approach</b>	<b>Benchmark</b>	<b>Improvement Goal</b>
	<p>Denominator: People who are treated for six months from initial treatment for depression who are receiving psychotherapy with or without medication management with initial and six month PHQ-9 scores.</p> <p>Exclusions: individuals with primary bipolar disorder, personality disorder or those who have died (NQF, 2011).</p>	<p>based care with use of standardized instruments to inform care decisions.</p>	<p>treatment plan based on patient results will be available in provider documentation.</p> <p>Results will be aggregated on a quarterly basis to capture department outcomes with focus on system improvement, rather than individual reports.</p>		



## Appendix F

## Budget

<b>Expense</b>	<b>Item</b>	<b>Quantity</b>	<b>Unit Cost</b>	<b>Total Cost Monthly</b>	<b>Annualized Expense</b>
Office Supplies	Copies for PHQ-9 Scales for Patients	150	\$0.20	\$30	\$360
	Copies for Educational Materials (Leadership and Departmental)	200	\$0.20	\$40	\$480
	Mental Health Quality Resource Books	2	\$60	\$120	\$120
	<b>Subtotal</b>				<b>\$960</b>
Wages	Manager/ Senior Leadership Salaries	640	\$50	\$2667	\$32,000
	Quality Personnel Salaries	20	\$45	\$75	\$900
	PI Nurse Salary	120	\$32	\$320	\$3840
	Provider Salary Dollars	50	\$62	\$258	\$3100
	EPIC Staff Salary	40	\$35	\$117	\$1400
	<b>Subtotal</b>				<b>\$41,240</b>
Survey Instrument	PHQ-9	No Cost	\$0	\$0	\$0
	<b>Subtotal</b>				<b>\$0</b>
<b>Total Cost</b>					<b>\$42,200</b>

*Appendix G*Provider Feedback on PHQ-9 Integration (Focus Group)

1. Do you find the PHQ-9 easy for patients to use?
2. How important do you think it is to administer the PHQ-9 at every patient visit?
3. How important has the PHQ-9 been in guiding treatment decisions?
4. What value do you see in using the PHQ-9 to benchmark with similar programs?
5. Do you think information from the PHQ-9 will be useful in establishing department guidelines?