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No Place for Distress: Implementing a Simple Tool to Screen and Address Distress Symptoms in an Adult Outpatient Cancer Center

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No Place for Distress: Implementing a Simple Tool to Screen and Address Distress Symptoms in an Adult Outpatient Cancer Center

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Abstract

**Background:** The Distress Thermometer (DT) is a simple and valid tool that should become the standard of care in the outpatient cancer setting to help clinicians better identify psychosocial distress at an early stage. The purpose of the project was to implement distress screening with the distress thermometer (DT) with problem list (PL) to screen and address distress symptoms in an adult outpatient cancer center.

**Method:** The distress screening pivotal visit was incorporated into the patient’s care plan at on day 8 on the 3rd cycle of the patients’ chemotherapy regimen. Patients graded their level of distress on the DT and identified the sources of their distress using the PL. A pre and post visit survey was done and analyzed using descriptive statistics. Pre-test and post-test DT scores were compared using and paired t-tests.

**Results:** A total of 83 patients received an initial distress pivotal visit and completed pre-test measures. Seventy-two completed post-test measures. Paired-t test indicated an average reduction in distress score SD 1.76 from an average baseline score of 4.1. Paired-t test score of 9.55 and P-value <0.0001, N =71. Of those who completed a post-test evaluation, 99% found the distress screening useful.

**Conclusions:** Our results indicate that the DT is a simple and valid tool for measuring distress in this outpatient cancer setting. There are many validation studies supportive of this finding and encourage its use oncology clinics. However, further study may be warranted to assess long-term benefits of distress screening.
Introduction and Background

A diagnosis of cancer can have a significant impact on patients and stimulate a cascade of emotional, physical and social reactions which can cause some level of distress in this patient population. Distress is a significant problem experienced by a vast majority of cancer patients. It is an indicator of suffering, and also a predictor of poor prognosis across the disease trajectory. It is common and treatable (ONS, 2014). In addition to the suffering, significant distress has been shown to cause dissatisfaction with care and a poor quality of life (Jacobsen & Ransom, 2007). Screening and early detection of distress can facilitate effective clinical intervention and improved patient outcome (Holland & Alici, 2010). There is strong evidence that psychosocial, behavioral and pharmacologic interventions can reduce or relieve distress and help increase patients’ compliance with treatments and improve outcome (Jacobsen & Ransom, 2007). Yet, oncology healthcare clinicians may underestimate psychological distress, underdiagnose and undertreat this condition. As a result, the quality of care in this patient population may be compromised. (Holland & Alici, 2010). The purpose of the project was to implement distress screening with the distress thermometer (DT) with accompanying problem list (PL) to screen and address distress symptoms in a large adult outpatient cancer center in Lehigh Valley.

The National Comprehensive Cancer Network (NCCN) practice guidelines for the Management of Psychosocial Distress, (2014) defines distress as a multifactorial distressing experience that may interfere with the ability to cope effectively with cancer, its physical symptoms, treatments and side effects extending across the continuum. The feelings range from vulnerability, deep sadness and fears progressing to disabling depression, anxiety, panic, social isolation and existential and spiritual crisis. Distress has a high prevalence in all types and stages of malignancies. Needs assessment surveys with the Distress Thermometer (DT) done in
outpatient clinics revealed 20% - 40% of cancer patients with significant levels of distress (Holland & Alici, 2010). Moreover, cancer research has been successful in increasing the overall survival rates in this population which unfortunately leads to symptoms contributing to higher levels of distress (Holland & Alici, 2010). These symptoms are many and not limited to include fatigue, pain, anxiety and depression, cognitive impairment such as ‘chemo brain’, nausea, vomiting, anorexia and fevers. These symptoms can hinder a person’s ability to perform daily activities and affect their quality of life (Holland & Alici, 2010).

The prevalence of distress varies by the type of cancer and is highest among patients with advanced stage of disease and poor prognoses (Holland & Alici, 2010). For example, while distress symptoms can be significant among patients with any cancer diagnosis, the literature explains that it is more often high among patients with lung cancer diagnosis. This may be so because lung cancer patients are often diagnosed with advanced disease and progress quickly through the disease trajectory. In some cases, their treatment options are also limited. As a result, distress is often more prevalent for lung cancer patients compared to patients with other cancer diagnoses. Moreover, in patients with lung cancer, family, emotional, physical symptoms, fatigue, depression and anxiety, pain and cognitive problems contribute to high levels of distress (Carlson, Walker, Groff, & Bultz, 2012).

According to the NCCN, (2014) distress should be identified, monitored, documented and treated promptly at all stages of the cancer trajectory. A gap analysis done for a large outpatient adult cancer center and identified a variance with current practice and recommendations for distress screening and management from the evidenced based literature. The clinical site lacked a tool specifically used for distress screening. Instead, the clinical site uses a Review of System (ROS) which records any symptoms with the severity that the patient
experienced since the last office visit. Hence, it is not adequate in addressing the psychosocial needs of our patients because these symptoms are not identified with the resulting distress level on the patient’s psychosocial being. Therefore, the effects of these problems go undiagnosed and untreated.

The American College of Surgeons (ACoS) and the Commission on Cancer (CoC) require cancer centers to screen for distress starting in 2015 as a new requirement for accreditation (ONS, 2014). Recommendations include the development of a treatment plan with referrals as needed to psychosocial resources. These referrals for the assessment and distress management should be considered part of the patient’s routine medical oncological care, and should be presented to the patient as such (Pirl et al., 2015). Distress screening is now considered the new standard for quality cancer care and should be integrated into the patients’ routine care plan (NCCN, 2014). The DT as recommended by NCCN to screen and manage distress will help oncology clinicians identify distress and include the appropriate management in their cancer care to improve patients’ compliance with their treatments, cancer outcome and quality of life. In addition, this health care quality intervention satisfied at least four of the six IOM aims which are efficient, effective, timely and patient-centered. The DT will provide a means to identify ‘distress’ and incorporate the appropriate care into the patients’ care-plan, at the time of the visit with expedition in treatment and follow up. At the same time it is cost effective since it will be incorporated into an existing medical system and is expected to improve patient satisfaction and outcome.

**Review of the Literature**

A comprehensive search of the literature for distress screening in cancer patients was completed. CINAHL and Google Scholar and PubMed databases were used with medical subject
headings (MeSH): Distress screening in cancer patients, distress thermometer and distress screening. The search yielded a total of 384 articles. Inclusion criteria were from the last 7 years for the most recent information, full-text articles, with subject distress thermometer. Exclusion criteria were greater than 7 years to eliminate older studies, pediatric patients and non-oncology patients. Of these 28 were selected, 14 of the 28 were selected for review. These 14 studies include 11 validation studies and 3 randomized controlled studies. The validation studies looked at the sensitivity, specificity and validity of the DT in addition to its effectiveness over time.

A randomized controlled trial by Carlson et al. (2012) looked at the screening of distress as the sixth vital sign in long cancer patients. The study not only justified the need for distress screening but the importance of the DT as a tool to use for screening. The patients were randomized as follows: a full screening group which included the DT, Canadian problem checklist, pain and fatigue thermometer, and the psychological screen for cancer part C, full screening plus personalized triage, or a minimal screening group with the DT plus usual care. The participants were assessed 3 months later. The patients were asked to rate their distress level on the DT and a review of diagnostic validity studies reported a pooled sensitivity of 77.1% and specificity of 66.1% of the DT. The study found that screening for distress with personalized triage resulted in the most benefit. In addition, they noted that the DT is meant to be used as a first-line screening tool that can direct the clinician to identify areas of concern for intervention. (Carlson, Walker, Groff, & Bultz, 2012)

**Sensitivity, Specificity and Cut-off Score of Distress Thermometer**

A study by Lazenby et al., (2014) examined the effectiveness of the DT to screen for distress in patients with advanced disease. There were 123 patients recruited with an average age of 59.9 years. All participants had stage 3 or 4 malignancies of which 40% gastrointestinal, 19%
The optimal distress cut-off score for clinical significant distress was >2/10 on the DT with a sensitivity of .96. This result on the DT was compared to a score of >5/10 on the patient health questionnaire (PHQ) with a sensitivity of .32 (Lazenby et al., 2014). Similarly, another study by Wang et al., (2011) assesses the sensitivity and specificity of both the DT and the Hospital Anxiety and Depression Scale (HADS). They found optimal cutoff on the DT to be 4 with sensitivity of 98% and specificity of 73%. The Hospital Anxiety and Depression Scale (HADS) had a cutoff score of 9 with a sensitivity and specificity 84% and 72% (Wang et al., 2011). The DT had a higher sensitivity and specificity when compared to HADS.

Grassi et al. (2013) also compared the DT and PL to the HADS and the 18 item brief symptom inventory (BSI-18). They found that mild DT scores were 4 and 5, moderate, 6 and 7 and DT scores >8 to be severe. In addition, DT cutoff scores greater than or equal to 4 were associated with a sensitivity of 0.80 and a specificity of 0.61. These results were better than the BSI-18 or the HADS, and they found that the DT was a simpler and easier tool for screening distress. In addition, when compared to HADS the DT has a higher sensitivity and specificity (Wang et al., 2011). In addition, Hegel et al. (2008) looked at the DT as a single tool for screening newly diagnosed breast cancer patient for distress. They also found a DT cutoff score of 7 to be an optimal trade-off between a sensitivity of 0.81 and a specificity of 0.85. Similarly, Bulli et al. (2009) determined that the optimal cutoff score on the DT was a 7 or above with a sensitivity of 0.73 and a specificity of 0.82 since they found that patients whose distress score was 7 or greater reported problems in all areas of the PL. Overall these studies conclude that the DT showed a higher sensitivity and specificity when compared to other psychosocial screening tools. In addition, the problem list identified the source of distress and the ultimate cut-off score.
for intervention which would aid oncologist with screening. Hence, it is an effective and simple tool for screening for distress symptoms in the cancer population.

**Validity and Reliability of DT**

Lazenby et al. (2014) looked at the distress thermometer as a valid tool to screen advanced cancer patients who are undergoing treatment for possible signs of distress. They found the DT to be a valid tool with good overall accuracy. Tang et al. (2011) also tested the validation and reliability of the DT in a total of 574 Chinese cancer patients. They found that a cutoff score on the DT was associated with an optimal sensitivity of 0.80 and specificity of 0.70 with the DT having a positive test-retest reliability ($r = 0.800, P=0.000$). They concluded that the DT was an acceptable tool for overall accuracy and reliability in testing distress severity and the specific problems causing the distress in cancer patients. Gessler et al. (2008) and Lim et al. (2014) tested the DT validity and compared it to other measures like the HADS. DT was found to be a valid, simple quick screening tool for cancer patients. In addition, Wang et al. (2011) supports the DT as a valid tool for screening distress among cancer patients since they found the DT to have both higher sensitivity and specificity of 98 and 73% respectively. There are two guidelines chosen: The NCCN Guideline, *Distress Management* provided the evidenced based DT with PL as a valid tool for distress screening in cancer patients and the National Guideline Clearing House *Depression in Adults* guideline supports the use of the DT for screening.

**Discussion on Evidenced-Based Intervention**

All studies found a significant prevalence of distress in the cancer patient population and that screening is warranted for the appropriate clinical intervention to improve quality of life and outcome. Overall the review of the literature favors the use of the DT as a simple, quick and effective tool for screening distress in the cancer population. Its use is encouraged in oncology.
clinics as it can provide the necessary information to address the causes of distress. It was found consistently to have a higher sensitivity and specificity when compared to other screening tools. The above review of studies concluded that a cutoff DT score of 4 is sufficient to indicate clinical distress with 7 or greater indicating significant clinical distress requiring intervention. This tool is an effective means in providing a way for oncology clinicians to measure and screen for distress and address its physical and psychosocial symptoms while at the same time identify more serious treatable illnesses like depression and anxiety. In addition, DT can improve communication between clinician and patient. It is quick, easy to use, hence suitable for a busy oncology practice (Gessler et al., 2008).

The evidence was appraised using John Hopkins Nursing Evidence-Based Practice (JHNEBP) for research studies (Newhouse et al., 2005) and the John Hopkins AGREE tool to appraise the guidelines (AGREE, 2014). The RCTs Evidence rated as Level 1, and the validation studies rated level II. This was considered based on randomization, adequate sample size, and definitive conclusions; moreover, the recommendations were consistent and based on comprehensive literature review. There were also guidelines used to support the DT as an effective tool for distress screening among oncology patients. The John Hopkins AGREE tool was used to assess the strength and consistency of the evidence of two guidelines, *Distress Management* and *Depression in Adults with a Chronic Physical Health Problem: Treatment and Management*. The AGREE tool analysis found that the guidelines are of high quality. The Distress Management Guideline provided the distress thermometer and problem list as an evidenced based tool for distress screening. Both guidelines according to the AGREE tool outlined a comprehensive scope and purpose with sufficient rigor of development, applicability, editorial independence and clarity of presentation. They were mostly supported with the highest
level of evidence through randomized controlled trials (RCT), meta-analysis, reviews of published meta-analysis and systematic reviews with tables to analyze the evidence. Both guidelines provided clear objectives and recommendations for the management of distress, distressed conditions and chronic physical conditions such as depression.

**Theoretical Framework**

The process of change involves many facets and is often a difficult one to achieve with efficiency and success. Using a theory guides and supports the change process to expedite and improve sustainability and long-term success (Zaccagnini & White, 2014). Havelock’s Change Theory was chosen to guide the implementation of distress screening because of its flexibility and applicability to fit the paradigm of distress screening implementation in our clinical setting. It provides a framework as a guide to steer a successful implementation process. *Appendix 2* illustrates Havelock’s theory. Havelock and Zlotolow (1995) described a six step process to help individuals working in reform at all levels in diverse situations to make successful innovation happen. These six stages of planned change can also be actualized through a compassionate approach to any specialty in health care. Havelock’s change theory outlined six specific steps suitable for needed change. The first stage is stage 0 which is referred to as *Care*. This stage 0 raises the awareness for change. Step 1, which is called *Relate*, focuses on building relationships. In step 2, titled *Examine*, the problem is diagnosed and in step 3, named *Acquire* resources are identified to address the problem. During step 4, called *Try*, a solution to the problem is chosen. In step 5, called *Extend*, the process is disseminated, diffused, and the approval of the team is obtained. The final step is the *Renew* phase (step 6) during which implementation of the process is stabilized (White & Dudley-Brown, 2012).
Havelock’s theory describes the required six steps for successful implementation of the DT in our practice. For example, stage 0 recognizes that there is a need to improve the quality of care for cancer patients while during the Relate stage the team comes together with a common interest to discuss what is best for the practice and the patients. In doing so, the problem of distress and the need for screening and treatment for the cancer patient population is recognized. During the Acquire period, a gap analysis is done to examine the current system in which our patients received their oncological care. Moreover, the cancer center’s inventory of resources is documented to address patients’ specific needs under the Acquire stage. The solution is to Try and implement the NCCN screening tool, the DT with PL to screen and identify the source of distress and address the problem to improve quality of care. During Extend period the stakeholders are more involved, as the clinical experts are consulted, and cancer committee meetings take place to discuss topics such as proposed change, expected outcomes, building the change into the existing system and testing for successful implementation via patients’ pre and post intervention satisfaction surveys and clinicians’ collaboration and forums. Discussions for modifications and maintenance of change also took place. The Renew phase stabilized the implementation process of DT and PL. For example, there was a distress pivotal visit (DPV) labeled new and a distress pivotal follow up visit (DPF) at different intervals as needed subjected to clinicians’ discretion. The visits were billable; hence, they provided value, while they improved the health of the patients. At the same time, the criterion as set forth by the Commission on Cancer (CoC) for practice accreditation was met. Havelock also summarizes three phases which frame out this implementation process: unfreezing phase, this is the initial phase, where the problem was identified, the stakeholders were consulted, and relationship building began to resolve the problem. The moving phase, was where a plan was identified and
the steps taken for implementation of the DT with PL as a systematic change. Then the
refreezing phase, when the surveys were evaluated, and the changes were made to improve the
QI project, and distress screening is maintained (Oates, 1997).

**Project Design and Methods**

This quality improvement project was aimed at providing oncology clinicians the
opportunity to identify distress and provide the appropriate care to address the distress symptoms
in cancer patients for the purpose of improving outcome and quality of life. In order to address
this need, we implemented a distress screening pivotal visit using the NCCN evidenced-based
tool which consists of the distress thermometer with the accompanying problem list. The DT
scale range is 0 – 10 similar to the pain scale, with 0 being no distress and 10 representing
extreme distress. Based DT score and the source of distress as recorded on the PL
recommendations were made by the NP according to the NCCN guidelines on distress
management. Overall results and outcomes of the process were evaluated using pre and post
surveys which were analyzed using descriptive statistics and paired–t test.

The distress screening pivotal visit took place at cycle 3 day 8 of the patients’
chemotherapy regimen. Prior to the visit, a distress pivotal visit (DPV-30) and a distress pivotal
follow up (DPF-30) were added to the patients’ existing care plans in the electronic medical
records as a *quick* order. The patients were assessed by a nurse practitioner (NP) during a
scheduled 30-minute visit. Initially, these visits were done with the DNP candidate, but once the
process was stabilized all other outpatients NPs participated in distress screening visits with the
physicians helping the referral process for as needed screening. As part of documentation, there
was a distress pivotal visit alert that was checked at the time of the initial screening visit to
record that the patient had the distress screening. This option will also be a mode of generating
future reports to ensure compliance. The tool that was used is the NCCN DT with accompanying PL for screening which was scanned to the patient’s chart under distress screening. A billable distress clinical visit followed with the desired referrals and recommendations by the DNP candidate. There was a pre and post survey done at the visits administered by the NP and/or a medical student who was present at the visit. The pre-survey provided the baseline data of patients’ utility of the distress screening for comparison with the post-survey data after intervention. The surveys also assessed patient’s acceptability and perceived benefit of the program. The results were statistically analyzed using descriptive statistics and paired t test. 

Appendix 3 and Appendix 4 are illustrations of the pre and post surveys respectively.

A simple distress triage algorithm based on the NCCN guidelines to facilitate addressing distress symptoms at the distress screening visit is represented in Figure 1. NCCN provided an overall guideline for managing distress symptoms (Appendix 8). A DT score of <4 were assessed and documented as “no intervention needed.
Setting and Resources

The distress screening and follow up visits took place in the Hematology Oncology outpatient office. The practice has numerous comprehensive support services available. These include nurse navigators (both English and Spanish speaking), nutrition, physical therapy, occupational therapy, social work, psychiatric services, financial services, pain management, both home based and inpatient oasis-palliative care consult services, nurse practitioner managed survivorship PLACE (people living after cancer experience) and various multidisciplinary clinics (breast, lung, head and neck, genetics). Currently, in this practice some of these services were underused or not properly allocated due to lack of distress screening. The above mentioned services and resources were utilized to the fullest with appropriate referrals made in real time to a social worker, psychiatrist, nutritionist and others as indicated with the distress screening.
program. Any physical symptoms such as diarrhea, nausea and vomiting that is the source of the distress were addressed by the NP at the time of visit. This approach expedited interventions for physical symptoms and maximized the benefits that resulted from the DT screening program.

**Description of the population or community**

The community of interest was a large adult outpatient cancer center within the Lehigh Valley Physician Group known as John and Dorothy Morgan Cancer Center Hematology Oncology Associates. This cancer population includes all types of malignancies except gynecological cancers which are treated and managed by the GYN-Oncology group. The patient population both male and female range in age from 25 to 99 years old of various cultural backgrounds. Breast cancer is the biggest population with approximately 35% of cases, then lung with approximately 30%, colon and other GI cancers are approximately 20%, and all other malignancies which include but not limited to melanoma, kidney, sarcomas, thyroid, thymic, bladder, prostate, Hodgkin’s, Leukemia and multiple myeloma averages at approximately 15%. Distress screening became a part of the new patients’ care plans as inclusion criteria. In addition, established patients were scheduled for a distress visit when their DT score recorded at routine office visit was greater than or equal to 4. There are no exclusion criteria as it is recommended by the CoC that all patient should be screened to identify their distress levels at appropriate intervals and as clinically indicated (NCCN, 2015). However, for the study analysis of the DT implementation QI project exclusion criteria was a DT score of < 4 for established patients. All the patients selected had active disease and were undergoing chemotherapy treatments.

**Organizational analysis of project site.**

The project site was a large outpatient cancer center in the Lehigh Valley area. The practice group is made up of 17 medical oncologists, 4 outpatient nurse practitioners, 1 inpatient
nurse practitioner and 4 inpatient physician assistants. One of the physicians is the division chief, and one is the medical director for cancer research. There are medical assistant (MA) who put the patients in rooms to be seen by the provider. The medical assistants who record the patients’ vital signs and ROS also do patients’ blood draw for lab studies. There are medical secretaries who schedule patients for their visits, referrals and checkout patients after their office visit. We have two large locations and recently opened a new facility off campus to improve access to the rural patients. There are two hospital based multipurpose (MP) areas attached to each location and a smaller offsite multipurpose area at the newest location. Patients received their various chemotherapy treatments at the MP areas in addition to small procedures such as bone marrow biopsies, bladder instillation, intrathecal chemotherapy and intra-peritoneal chemotherapy treatments. The DNP candidate interacted with all facets of the multidisciplinary team in the office and educated the group, answered questions and acted as ongoing support to ensure the smooth implementation of the DT with accompanying PL.

**Evidence of stakeholder support.**

An initial presentation was made to all the practice doctors about the distress screening and the benefits in improving the lives of HOA cancer patients. Once the need and the benefits of distress screening were described, the practice physicians, nurses and support staff supported the implementation of distress screening for the overall benefit of the patients and practice. A stakeholder agreement in support of the project was signed. See evidence of stakeholder support in appendix 3.

**Facilitators and barriers.**

There were facilitators as well as barriers to implementing this project. Having a direct clinical experience with the practice for more than five years allowed the opportunity to easily
assess the distress screening need for the practice’s patient population. There were many meetings with the chief of the practice who was very supportive of the project proposal. Hence, it was feasible to secure him as a mentor to the project. Initially, the preparation for the new electronic medical system placed a strained on the preparation for the implementation process. For example, the implementation of the electronic codes for the visits were delayed. Moreover, there was an initial period for testing the implementation process through a capstone study of 83 patients with various cancer diagnoses and stages done at our two locations for various patient demographics. The distress pivotal visit was done after the 3rd cycle on the 8th day of treatment (C3D8) unless the appointment time had to be adjusted to alleviate scheduling clashes and availability.
### Table 1

<table>
<thead>
<tr>
<th>Goals</th>
<th>Objectives</th>
<th>Outcomes Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>To achieve an awareness of the available resources for HOA oncology patients</td>
<td>To implement the use of an evidence-based distress screening tool in an adult oncology population To provide a means where all our oncology clinicians can readily effectively screen for distress</td>
<td>Systematic integration of evidence-based distress screening tool within clinical protocols and the electronic medical record, and consistent delivery of these protocols across the targeted population</td>
</tr>
<tr>
<td>To improve patients’ overall satisfaction with their oncology care in relation to their distress management</td>
<td>To examine the effects of implementation of an evidenced-based distress screening tool on patients’ distress</td>
<td>Patients who receive distress screening &amp; follow-up reported statistically-significant improvements in distress levels with improvement in symptoms Patients reported that the program is useful and acceptable.</td>
</tr>
<tr>
<td>To decrease patients’ psychosocial distress associated to the cancer diagnosis and associated treatments.</td>
<td>To evaluate feasibility and acceptability of distress screening in an outpatient oncology clinical setting Application for accreditation as stated by the Commission on Cancer</td>
<td>The Hematology Oncology practice will meet criteria for future accreditation as a result of distress screening implementation</td>
</tr>
<tr>
<td>To improve patients’ quality of life and compliance with cancer treatments</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Implementation Plan

The implementation plan involved different stages and factors coordinated for the implementation to be successful. There were many ongoing meetings and consultations with the stakeholders to determine what is best for our practice and our patients. A newly implemented alert immediately generated a quality check list (QCL) to the nurse practitioner’s QCL inbox whenever a new care plan was approved for a patient. This alert stated “schedule for distress pivotal visit”. The nurse practitioner then reviewed the chart and scheduled the visit accordingly. At the visit, the PL was reviewed with the patient and a DT score marked on the DT by the patient to indicate the level of distress. This was done with the help of the medical assistant. A review of systems, a complete or focused exam was completed by the NP, and a pre-evaluation survey was administered by the NP or the medical student if the student was present. The source of distress was addressed based on the PL. Referrals were made when necessary with a follow up visit at the clinician’s discretion.

This follow up visit was conducted in the same format as the initial visit and reassessed initial problem and new problems if needed. At the follow up visit, there was a post-evaluation survey done with the patient, sometimes with the help of medical student. This post-evaluation survey recorded patients’ acceptability as it pertained to their improvement since their initial distress was addressed. The medical record computer alert option was checked for record keeping and full documentation completed to the patients’ chart. The visits and services were billed as a level 4 or 5 depending on the nature of distress and complexity of the decision making. The goal was to change practice and maintain the process for all existing and new patients. Descriptive statistics and the Paired t test were used to analyze and compare the data collected from the pre and post surveys to compare results and measure outcome. See Appendix 3
and Appendix 4 for an example of the pre and post surveys. Figure 2 below is a diagram illustrative of the distress screening process.
Cost-Benefit Analysis/Budget

The cost for the healthcare quality project to implement a simple tool to screen and treat distress was minimal as it is a systematic change. There is an existing computer based documentation medical record. Currently, the patients are put in rooms by the medical assistant who filled out the review of system with the patient. The problem list (PL) and distress thermometer (DT) was incorporated into this existing system with no additional cost to the practice.

Cost Analysis

There was no new cost to the implementation of distress screening as it was a systematic change to the existing medical record and routine flow of the clinic. It is more a revenue generating quality improvement change since the visits are billable and reimbursed by patients’ medical insurance plans. Moreover, the benefits of this health care quality project cannot only be viewed in light of monetary gains and savings but as an added value to patients’ care, quality and staff satisfaction. Many studies have found that a fairly significant number of cancer patients experience high levels of distress. Moreover, the prevalence of distress varies by the type of cancer and is highest among patients in their advanced level of disease and poor prognosis (Holland & Alici, 2010). In light of this, implementation of this QI project provides a simple tool for oncology clinicians to identify and address this disabling symptom that seems to accompany patients on their cancer journey. According to studies, implementation of this simple tool the DT with the PL can contribute to clinical provider-patient communication with improvement in patients' emotional well-being. Screening for distress is feasible, inexpensive and acceptable with good patient recruitment and retention rates (Velikova, 2010). In addition,
supporting patients appropriately at critical points of their cancer journey have the potential to reduce the development of significant psychiatric morbidity as well as cancer symptoms mortality (Velikova, 2010). With this formal distress screening program, oncology providers have the opportunity to screen and identify patients at an early stage who require assistance with emotional needs. They are able to provide necessary interventions that will help patients manage and better cope with the effects of treatment, thus improving and or maintaining their quality of life during cancer treatment. In some cases, patients can return to fully functional lives and survivorship after treatment (Velikova, 2010).

**Ethics and Human Subjects Protection**

The project was described to Institutional Review Board (IRB) for the oncology clinic as a QI project to be implemented on site to screen and address distress symptoms in their cancer patient population as required by the Commission on Cancer (CoC). The NCCN DT and PL was used as our tool for distress screening. The pre and post patient survey that were used at the visits were included for IRB review. As a result, the Institutional Review Board approved the quality improvement project and exempted it from IRB oversight. See Appendix 5 for IRB correspondence letter.

**Results**

A total of 83 participants took part in the initial screening and survey study. Of these, 36.3% were male and 63.6% were female median age of 61.2 years. Of these participants, 31% had a diagnosis of breast cancer, 15% lung cancer diagnosis, 10% lymphoma disease, 11% diagnosis of pancreatic cancer, 8% diagnosis of colon cancer, 6% head and neck cancer diagnosis and 19% representative of other malignancies (Table 2). All 83 patients received an initial distress pivotal visit and completed a pre-survey. There were 5 patients lost to follow up who did
not complete a post-survey. There were 6 surveys with missing data and were excluded from the analysis. Additionally, one patient completed a pre and post survey but did not include the distress score. Hence, this survey was also excluded from the paired-\(t\) test analysis. Out of 77 patients who completed a pre-survey 77% stated that their distress started since their cancer diagnosis, and 55% attributed their distress to physical symptoms.

Table 2

| Demographic Data on Patients Screened for Distress During Chemotherapy Treatment |
|---------------------------------|---------------------------|
| Participants  \(n = 77\), Median Age = 61.2 years | Male 36.3%, Female 63.6% |
| Type of Cancer | Percentage |
| Breast | 31% |
| Lung | 15% |
| Lymphoma | 10% |
| Pancreatic | 11% |
| Colon | 8% |
| Head & Neck | 6% |
| Other | 19% |

Out of 72 patients who completed pre and post-surveys, 94% reported that the causes of their distress were both identified and addressed, and 93% stated that their assessment was either good or excellent. A total of 87% reported either complete or partial resolution of distress as a result of this intervention. In addition, overall 99% completing both pre and post-surveys found distress
screening useful. The mean pre-intervention score was 4.2, and mean post intervention score was 2.1, median score was a 2 (subjective, 0-10 scale with 0 indicating no distress and 10 representing extreme distress). A paired-\( t \) test was conducted to compare the difference between the means of the pre and post-test DT scores. There was a significant difference in the scores for pre-test (M=4.14, SD 2.58) and post-test (M=2.14, SD=1.75) distress level; \( t(70) =9.55, \ p<0.0001 \). There was a significant difference between the pre and post-test DT scores. These results suggest that distress screening and management have a positive effect on the patients’ distress level. Specifically, our results suggest that with distress screening the levels of patients’ distress decreased.

Figure 3. shows a distribution of Distress Thermometer (DT) scores reported by patients before clinical intervention (“Pre-Intervention”, shown in heavy blue) and following clinical intervention (“Post-Intervention”, shown in light blue). Figure 3. shows a shift to the left, or right- skewed representing lower DT scores in patients following our intervention and illustrative of improvement in distress. Moreover, in view of our skewed results we looked at the median score which indicated that the most likely post intervention distress score was a 2 which indicates mild distress.
Figure 3. Distribution of DT Scores

Discussion / Interpretation

This project was presented as an initial affirmation of the clinic’s ability to reduce the clinical distress experienced by the patients during their chemotherapy regimen. However, it was not optimum care to conduct distress screening at the routine treatment assessment and nadir visits due to the magnitude and complexity of stressors. In addition, treatment visits were for the purpose of assessing treatment readiness and nadirs used for assessing the side effects of the chemotherapy treatments. Hence, we detailed our clinic’s efforts to adhere to NCCN distress screening management guidelines and created a designated visit for this sole purpose. With distress pivotal screening visit, our patients reported reduction in their distress with screening and intervention. The implementation of DT was cost effective as it was a systematic change that was incorporated into the existing medical system. Moreover, the DT with PL implementation is
also revenue generating as the DPV-30 and DPF-30 are billable visits reimbursed by patients’ medical insurances. In addition, the DT and screening meets the requirements of the new guidelines set forth by the Commission of Cancer (CoC) for accreditation. Moreover, this intervention is appropriate for this target population as cancer patients who are known to experience significant distress as a result of diagnosis and treatment.

We found that patients were very receptive to screening and were more open to discussing their stressors at a designated visit for this purpose. In addition, we saw reduction in distress and in some cases significant reduction and better coping with cancer and chemotherapy treatments. Our study yielded an average of 2 points reduction in distress score which appears to be clinically-significant as well as statistically-significantly ($P = <0.0001$).

To our knowledge evaluating this pre and post-test design with a comprehensive approach to distress management has not been defined in the literature. However, many studies have documented that the DT is a simple, reliable and valid tool in screening patients in this population for distress. For example, Tang et al., (2011) tested the validity and the reliability of the DT. A total of 574 Chinese cancer patients were recruited to test the validity of the DT relative to the Hospital Anxiety and Depression Scale (HADS) and Symptom Checklist 90 (SCL-90). The patients with a distress score of 4 or greater that was caused by emotional problems were assessed using the MiNi International Neuro-psychiatric interview, another group of 106 patients in stable condition filled out the DT at the based time and 7 – 10 days later. They found that with a DT cut-off score of 4 optimal sensitivity (0.80) and specificity (0.70) relative to HADS with greatest sensitivity (0.87) and specificity (0.72) against SCL-90. The study also showed that the DT has test-retest reliability ($r=0.800$, $p=0.000$). As with our study, after interventions were done for distress management patients were reevaluated using the DT. The
results showed that the DT was sensitive to changes in distress levels in patients previously screened. Hence, the project also indicated that the DT may potentially be useful as a method or tool of evaluation of the impact of intervention in patients whose screening showed moderate to severe distress.

In our study, the DT demonstrated reliability, efficacy and sensitivity identifying patients’ distress both initially and after intervention. Gressler et al. (2008) prospective validation study recruited 171 outpatient oncology patients to validate the DT against HADS, General Health Questionnaire-12 (GHQ-12) and Brief Symptom Inventory-18 (BSI-18) initially and at 4 and 8 week intervals. Gressler et al. (2008) results showed that the DT changed significantly following the criterion measures. In addition, the results also confirmed that the DT can be used to monitor change in distress over time as in the test-retest reliability capability. Wang et al. (2011), study examined the efficacy of the HADS and the DT. They reported that when compared to the HADS the DT not only had higher sensitivity but the specificity was also higher than HADS. Moreover, the DT’s accompanying PL was also found to be a reliable tool and that the physical, social, emotional and spiritual domains correlated strongly with the DT score (Tuinman, Gazendam-Donofrio, & Hoekstra-Weebers, 2008). As with our study, participants correlated their score effectively to the problem list. For example, 55% of participants indicated that their distress was caused by physical symptoms. After intervention for these symptoms patients indicated a lower distress score on the DT. Meijer, Roseman & Delisle et al. (2013), state that pharmacological and behavioral interventions benefit and improve the distress symptoms in adult cancer patients.

Much scientific progress has been made toward reducing the associated physical distress associated with cancer diagnosis and the treatment regimens. For example, targeted cell-
therapies tend to cause reduced systemic toxicities compared to traditional chemotherapy. In addition, treatment delays and modifications, dose reductions, the use of supplemental medicine to reduce the physiological effects (such as anti-emetics and anti-diarrheal) are also incorporated into patients’ care plans. These advancements represent significant oncological breakthroughs, and the medical management of cancer as a continuous evolving specialty. However, the cancer diagnosis itself can have a devastating effect on practically all facets of a person’s life. Hence, the formal publication of distress screening guidelines by the NCCN represents the acknowledgement and the need for more action. It demonstrates the fact that physicians cannot always wait for further medical developments while accepting the current physical and emotional distress of cancer patients undergoing treatment. As a local leader in the field of healthcare, this large cancer center in the Lehigh Valley area has undertaken the initiative to adhere to these NCCN guidelines. Hence, the design of the DT is positioned to meet the required standards for distress screening established by the American College of Surgeons Commission on Cancer effective 2015.

**Limitations**

There were some minor barriers to the DT Quality improvement project. For example, limited resources involved one psychiatrist available to the cancer patients who also provides services for non-oncology patients. This created some minor difficulty with access to psychiatric care and availability of appointments when urgently needed. We were able to utilize our social worker to the fullest extent, and when needed, antidepressants were started by the NP sometimes with the physician’s guidance. Moreover, those patients with an extensive psychiatric history already had an established psychiatrist to whom they could easily be referred. Some administrative and clinical stakeholders for the project were less receptive to systematic change, and generated
negative feedback which states that this intervention will create too much additional workflow, or canceled appointments without communication or rescheduling. Moreover, there was also some resistance to change from the cancer support and clinical nurse specialist team who do not fully understand the overall goals, objectives and outcome benefits of the distress screening program for our patients. This was alleviated with the support of the practice director, the chief and some of our physicians. In addition, there was ongoing education and questions answered by the DNP candidate. The learning curve for office support staff and registered nurses was a long process. Another barrier was the implementation of a new electronic medical system that coincided with the new distress screening process. This caused some delays in the initial set up and recruitment, in addition to our short time period of 4 months which may have contributed to the small sample size. This also posed some difficulty in navigating two systems, with one system still within a learning curve. The overall distress screening visits were mostly difficult and time consuming.

In spite of the multiple barriers encountered over the course of implementation, this project can boast significant strengths. The study was cost effective and well suited for the population intended. The outcome was well supported by the literature. In addition, the entire process was quick to conduct, and patients were relatively easy to enroll. Consequently, the outcome was achieved in a short time after the initial intervention at the distress pivotal visit because participants did not require long follow up periods. Furthermore, distress screening was implemented into an existing system with an established base, so it incurred no additional cost. In some cases, patients with severe physical symptoms wanted to quit chemotherapy because of the side effects although they were responding well to treatments as indicated on their computerized tomography (CT) scan. However, with distress screening and interventions patients’ compliance was increased as well as
their survival time since they completed their treatments. Hence, distress screening with this particular group provided sufficient evidence to change practice.

**Conclusions**

This study demonstrates the meaningful use of the DT with the management of cancer related psychosocial distress. It further shows that the DT is a simple and valid tool for measuring distress in an outpatient cancer setting. It fosters compliance with utilization both on the patient and the clinician as well, and is noted to improve patients’ outcome. From the literature review, the DT is acceptable and reliable as a screening tool to identify the contributing factors that cause distress severity in cancer patients which can contribute to poor outcomes. The DT is encouraged in oncology clinics since screening will provide the necessary information for oncology clinicians to identify patients at an early stage who require assistance with emotional needs. We expect that our oncology clinicians will be more comfortable with providing this screening for our cancer population. This distress screening program is maintained as an integral part of our patients’ oncology medical care to enable oncology clinicians to provide the necessary intervention that will help patients manage and better cope with the effects of diagnosis and treatment. Moreover, better management of distress in this patient population can improve or maintain their quality of life throughout their cancer diagnosis and treatment trajectory. This project primarily sought to serve the patients seen in this particular outpatient clinic, and secondarily, to document the change in these patients’ lives. In addition, it will supplement the knowledge for recommendation of distress screening to the general community of oncology practice. A further larger, confirming study may be needed to address the small sample size. In addition, there may also be a need for further study in the assessment of the clinical long term benefit of distress screening on the quality of life of cancer patients.
References


the UK and does it measure change over time? A prospective validation study. *Psycho-Oncology, 17*, 538-547. doi:10.1002/pon.1273


Lazenby, M., Dixon, J., Bai, M., & McCorkle, R. (2014). Comparing the distress Thermometer (DT) with the patient health questionnaire (PHQ)-2 for screening for possible cases of depression among patients newly diagnosed with advanced cancer. *Palliative and Supportive Care, 12*, 63-68. doi:10.1017/S1478951513000394

doi:http://dx.doi.org/10.1016/j.comppsych.2014.01.008


Since your last office visit how distress have you been?

**Figure 4. Distress Thermometer**

Please indicate your level of Distress on the thermometer
And the possible cause(s) on this Problem List (PL)

<table>
<thead>
<tr>
<th>Practical Problems</th>
<th>Family</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transportations</td>
<td>YES  NO</td>
</tr>
<tr>
<td>Finances</td>
<td>YES  NO</td>
</tr>
<tr>
<td>Treatment Decisions</td>
<td>YES  NO</td>
</tr>
<tr>
<td>Physical Problems</td>
<td>Emotional</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>YES  NO</td>
</tr>
<tr>
<td>Mouth sores</td>
<td>YES  NO</td>
</tr>
<tr>
<td>Appetite</td>
<td>YES  NO</td>
</tr>
<tr>
<td>Constipation/Diarrhea</td>
<td>YES  NO</td>
</tr>
<tr>
<td>Physical changes</td>
<td>YES  NO</td>
</tr>
<tr>
<td>Fatigue</td>
<td>YES  NO</td>
</tr>
<tr>
<td>Chemo Brain (memory loss)</td>
<td>YES  NO</td>
</tr>
<tr>
<td>Difficulty with ADLs</td>
<td>YES  NO</td>
</tr>
<tr>
<td>Fevers</td>
<td>YES  NO</td>
</tr>
</tbody>
</table>

**Figure 5 – Chart for problem list (PL)**
Appendix 2.

Figure 6. Havelock’s Theory. Havelock & Zlotolow (1995).
Distress Screening Pre-Evaluation Survey

1. What part of your life is contributing to your distress today?
   a. Physical/Pain/Body.
   b. Relationship/Family/Social.
   c. Financial.
   d. Uncertainty about Cancer Diagnosis / Treatment Plan.
   e. Other (please explain): _________________________________.

2. When did your current level of distress begin?
   a. Before my cancer diagnosis
   b. Since my cancer diagnosis.
   c. Since my last office visit.

3. What is your confidence level this distress can be resolved (expectations?)?
   a. 5 (very confident).
   b. 4 (somewhat confident).
   c. 3 (neither confident nor unconfident).
   d. 2 (somewhat unconfident).
   e. 1 (completely unconfident).

4. What are your expectations for today?
   a. 5 (complete resolution of distress).
   b. 4 (moderate resolution of distress).
   c. 3 (partial resolution of my distress).
   d. 2 (minor resolution of my distress).
   e. 1 (no resolution of my distress).

*Figure 7. Pre-evaluation survey*
Appendix 4.
Distress Screening Post-Evaluation Survey

1. Since your last distress evaluation visit, has your level of distress:
   a. 5 (complete resolution of my distress).
   b. 4 (partial resolution of my distress).
   c. 3 (no change of my distress).
   d. 2 (some increase of my distress).
   e. 1 (large increase of my distress).

2. At your last distress evaluation visit, do you feel as though the causes of your distress were:
   a. Both Identified and Addressed.
   b. Identified Only.
   c. Neither identified nor addressed.

3. How well did the assessment visit identify the stressors in your life?
   a. 5 (excellent).
   b. 4 (good).
   c. 3 (moderate).
   d. 2 (fair).
   e. 1 (poor).

4. How well did the assessment visit address the stressors in your life?
   a. 5 (excellent).
   b. 4 (good).
   c. 3 (moderate).
   d. 2 (fair).
   e. 1 (poor).

5. To what extent did you find your distress screening useful?
   a. 3 (very useful)
   b. 2 (little useful)
   c. 1 (not at all useful)

Figure 8. Post evaluation survey
Appendix 5.

Figure 9. Stakeholder Agreement
Appendix 6.

Figure 10. IRB Correspondence Letter
Appendix 7.

Human Research Protection Office

Determination of Human Subject Research
Application to the Institutional Review Board

The UMass Amherst IRB is required to prospectively review and approve all research involving human subjects. This application helps determine if your project involves human subject research as defined by federal regulations.

**INSTRUCTIONS for INVESTIGATORS:**
1. See Determining Whether IRB Review is Required for an Activity.
2. If the investigator is faculty, complete this form in its entirety and submit with any applicable survey instruments or questionnaires via email attachment to the Human Research Protection Office at humansubjects@ora.umass.edu
   If the investigator is a student, forward the completed application to your Faculty Sponsor for review and approval. The Faculty Sponsor then submits the form with any applicable survey instruments or questionnaires to the HRPO via email with his or her endorsement of the project or activity.
3. The UMass Amherst IRB will determine whether your research needs additional IRB review and notify you with a Memorandum of determination in an email attachment
4. Do NOT begin data collection prior to receiving IRB determination

<table>
<thead>
<tr>
<th>(HRPO Use Only) Determination based on following rationale:</th>
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<table>
<thead>
<tr>
<th>HRPO use only</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB No. _______________</td>
</tr>
<tr>
<td>Received email notification</td>
</tr>
<tr>
<td>Emailed IRB determination</td>
</tr>
<tr>
<td>☐ Project does NOT need IRB review.</td>
</tr>
<tr>
<td>Date: _______________ Initials: ________</td>
</tr>
<tr>
<td>☐ Project DOES need IRB review.</td>
</tr>
<tr>
<td>Date: _______________ Initials: ________</td>
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</tbody>
</table>

**Institigator Information**

<table>
<thead>
<tr>
<th>Investigator Name: Ramona E. Chase</th>
<th>UMass Affiliation: DNP student / Candidate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department: Nursing</td>
<td>Email: <a href="mailto:rhchase@umass.edu">rhchase@umass.edu</a></td>
</tr>
<tr>
<td>Faculty Sponsor (if applicable): Dr. Rachel Walker / Dr. J. Choi</td>
<td>Department: Nursing</td>
</tr>
<tr>
<td>UMass Affiliation: Professor / Capstone Chair / Com. Member</td>
<td>Email: <a href="mailto:r.walker@umass.edu">r.walker@umass.edu</a></td>
</tr>
</tbody>
</table>

**Project Information**
**Project Title:** No Place for Distress: Implementing a Simple Tool to Screen and Address Distress Symptoms in an Adult Outpatient Cancer Center

<table>
<thead>
<tr>
<th>Is project supported by funding?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒ No</td>
</tr>
<tr>
<td>☐ Pending * Please identify your anticipated funding source: <a href="#">Click here to enter text.</a></td>
</tr>
<tr>
<td>☐ Yes * Please identify your funding source: <a href="#">Click here to enter text.</a></td>
</tr>
</tbody>
</table>

* If federally funded, provide copy of grant proposal with this form.

**Purpose of the project:** Provide a 5-10 sentence lay description and what you hope to learn from this project To implement the Distress Thermometer with the problem list to screen and address distress symptoms in the adult hematology oncology populations. A pre and post patient survey that will not include patient identification information will also be used at the visits. The survey is intended to focus on patient acceptability with the screening and referral process and patient perceived success with the DT with PL distress screening program.

**Describe the location where the project will take place and all project procedures:** The distress screening and follow up visits will take place in the Hematology Oncology outpatient office. The practice has numerous comprehensive support services available. These include nurse navigators (both English and Spanish speaking), nutrition, physical therapy, occupational therapy, social work, psychiatric services, financial services, pain management, both home based and inpatient oasis-palliative care consult services, nurse practitioner managed survivorship PLACE (people living after cancer experience) and various multidisciplinary clinics (breast, lung, head and neck, genetics). The project will be an initial distress pivotal visit for patients with a distress score of 4 or greater and those patients with no prior screening. Patient will complete the problem list as to the source of their distress and indicate their level of distress on the distress thermometer. Patients will be assessed and treated accordingly or referred for additional services.

**Instructions:** Complete Section A as applicable to determine if activities in which you will be engaged meet the definition of human subject research.

**SECTION A: Activities Determined by the UMass Amherst IRB not to Represent Human Subject Research**
1. **Course-Related Activities**: The project is limited to course-related activities designed specifically for educational or teaching purposes where data is collected as part of a routine class exercise or assignment and is **not intended** for use outside of the classroom. However, if students practice research methodologies on human beings, they should still be instructed in the ethical conduct of such activities and be advised to obtain informed consent from their practice subjects.

   **NOTE**: IRB approval is required if a student is involved in an activity designed to teach research methodologies and the instructor or student wishes to conduct further investigation and analyses in order to contribute to scholarly knowledge.

2. **Oral History**: The project is limited to oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings.

   **NOTE**: IRB approval is required when the oral history activities are intended to produce generalizable conclusions (e.g., that serve as data collection intended to test economic, sociological, or anthropological models/theories).

3. **Journalism/Documentary Activities**: The activities are limited to investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis.

   **NOTE**: IRB approval may be required when journalists conduct activities normally considered scientific research intended to produce generalizable knowledge (e.g., systematic research, surveys, and/or interviews that are intended to test theories or develop models).

4. **Information-gathering interviews**: The activity focuses exclusively on interviewing or surveying participants about his or her expert knowledge about products or policies rather than people or their thoughts regarding themselves (e.g. interviewing librarians about inter-library loan policies or rising journal costs).

   **NOTE**: Interview questions will need to be reviewed by the HRPO. If the activity involves collecting demographic information about participants it may require IRB approval.

5. **Case Report**: The project consists of a case report or series which describes an interesting treatment, presentation, or outcome. A critical component is that nothing was done to the patient(s) with prior “research” intent.

   **NOTE**: For case reports, HIPAA requires that the disclosure of an individual’s protected health information must be authorized by that individual. If a case report contains any of the 18 protected health information identifiers as defined by the HIPAA regulations, a signed authorization (using the authorization form from the entity that holds the record) to disclose this information must be obtained from the individual(s) whose information is being disclosed.
6. **Program evaluation/Quality Improvement/Quality Assurance Activities:** The activity is conducted to assess, analyze, critique, and improve current processes within the institutional setting to include projects designed to improve current processes involving health care delivery in the institutional setting. The intent is **not** to generate conclusions that can be applied universally outside of the immediate environment where the project occurred.

   a. ☒ The activity does not involve randomization into different treatment groups.
   b. ☒ The activity is not designed to be applied to populations beyond the specific study population.

**Note:** *Quality improvement* projects are designed to improve the performance of any practice in relation to an established standard. *Quality assurance* projects are activities that are designed to determine if aspects of any practice are in line with established standards. Service surveys issued or completed by University personnel for the purposes of improving University services/programs or for developing new services or programs for student, employees or alumni may fall into this category. Investigators who plan to conduct a QI/QA project, should ensure that they have received approval from any applicable committees within their department or the site at which the activity will occur.

7. **Evidence Based Practice Intervention:** The project or activity is designed to use best available evidence to make patient care decisions. The project is focused exclusively on translating evidence and applying it to clinical decision-making to improve health care delivery, i.e. it is designed to close the gap between research being conducted and the practice.

**Note:** “Practice” refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success.

8. **Public Use Datasets:** The project is limited to analyzing de-identified data contained within a publicly available dataset. Below are examples of data sources that qualify as **not** human subjects research (unless the researcher has received restricted use data):


Other:

NOTE: IRB review is required if the publicly available data set contains identifiers, or if the merging of multiple data sets might result in identification of the subjects. In both cases, Exempt Category #4 may apply.

9. ☒ De-Identified Private Information or Human Biological Specimen: The project is limited to the use of existing and/or prospectively collected de-identified private information and/or human biological specimens (hereafter referred to as “specimens”). IRB Approval is not required if you can confirm the following:

a. ☒ The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

b. ☒ The investigator can confirm that the use of the private information or specimens is not in violation of the terms of use under which the information or specimens were/will be collected; and

c. ☒ The investigator will only receive information or specimens that are fully de-identified. Deidentified means that the materials to be studied are devoid of any of the 18 Protected Health Information elements set forth in the Privacy Rule, as well as any codes that would enable linkage of the information or specimens to individual identifiers. Note: To be considered de-identified, nobody, including individuals who are not involved in the conduct of the project, should be able to link the information or specimens back to identifiers. and

d. ☒ Specimens are not being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, and

e. ☒ The records/images/charts that are being collected for this study are not from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.
10. ☒ **Coded* Private Information and/or Human Biological Specimens:** The project is limited to the use of existing and/or prospectively collected coded private information and/or human biological specimens (hereafter referred to as “specimens”). IRB Approval is not required if all of the following conditions apply to the project:

a. ☒ The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

b. ☒ The investigator(s)** cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:

   (1) ☒ The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that HHS regulations do not require that the IRB review and approve this agreement);

   (2) ☒ There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or

   (3) ☒ There are other legal requirements prohibiting the release of the key to investigators, until the individuals are deceased, and

c. ☒ Specimens are not being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, and

d. ☒ The records/images/charts that are being collected for this study are not from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.

From the Office for Human Research Protections (OHRP) guidance document dated October 16, 2008: *Coded means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

**Investigator includes anyone involved in conducting the research. The act of solely providing coded private information or specimens (for example, by a tissue repository) does not constitute involvement in the conduct of the research. If the individuals who provide coded information or specimens collaborate on other activities related to the conduct of this research with the investigators who receive such information or specimens, then the IRB would consider such additional activities to constitute involvement in the conduct of the research. Examples of such additional activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research.
11. ☐ Decedents: The project involves research that is limited to death records, autopsy materials, or cadaver specimens. If the project involves the use and/or collection of Protected Health Information (PHI), HIPAA regulations apply to decedent research. As the Privacy Board, the IRB Office requires that you confirm the following conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(ii)(iii), have been met.

   a. ☐ The use will be solely for research on the information of a decedent; and
   b. ☐ The Principal Investigator has documentation of the death of the individual about whom information is being sought, and
   c. ☐ The information sought is for the purposes of the research

Note, however, that this exception may not be available for decedent Information that contains Psychotherapy Notes or Information relating to HIV, mental health, genetic testing, or drug or alcohol abuse.

☐ Consumer expenditure Survey: http://www.bls.gov/cex/
☐ General Social Survey: http://www3.norc.org/GSS+Website/
☐ National Center for Education Statistics (NCES): http://nces.ed.gov/
☐ Survey of Income and Program Participation: http://www.census.gov/sipp/

Other:

NOTE: IRB review is required if the publicly available data set contains identifiers, or if the merging of multiple data sets might result in identification of the subjects. In both cases, Exempt Category #4 may apply.
9. De-Identified Private Information or Human Biological Specimen: The project is limited to the use of existing and/or prospectively collected de-identified private information and/or human biological specimens (hereafter referred to as “specimens”). IRB Approval is not required if you can confirm the following:

f. The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

g. The investigator can confirm that the use of the private information or specimens is not in violation of the terms of use under which the information or specimens were/will be collected; and

h. The investigator will only receive information or specimens that are fully de-identified. Deidentified means that the materials to be studied are devoid of any of the 18 Protected Health Information elements set forth in the Privacy Rule, as well as any codes that would enable linkage of the information or specimens to individual identifiers. Note: To be considered de-identified, nobody, including individuals who are not involved in the conduct of the project, should be able to link the information or specimens back to identifiers. and

i. Specimens are not being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, and

j. The records/images/charts that are being collected for this study are not from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.

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c. The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

d. The investigator(s)** cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:

(1) The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that HHS regulations do not require that the IRB review and approve this agreement);

(2) There are IRB-approved written policies and operating procedures for a repository or data
management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or

(3) ☒ There are other legal requirements prohibiting the release of the key to investigators, until the individuals are deceased, and

e. ☒ Specimens are not being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, and

f. ☒ The records/images/charts that are being collected for this study are not from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.

From the Office for Human Research Protections (OHRP) guidance document dated October 16, 2008: *Coded means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

**Investigator** includes anyone involved in conducting the research. The act of solely providing coded private information or specimens (for example, by a tissue repository) does not constitute involvement in the conduct of the research. If the individuals who provide coded information or specimens collaborate on other activities related to the conduct of this research with the investigators who receive such information or specimens, then the IRB would consider such additional activities to constitute involvement in the conduct of the research. Examples of such additional activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research.

11. ☐ Decedents: The project involves research that is limited to death records, autopsy materials, or cadaver specimens. If the project involves the use and/or collection of Protected Health Information (PHI), HIPAA regulations apply to decedent research. As the Privacy Board, the IRB Office requires that you confirm the following conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(ii)(iii), have been met.

   d. ☐ The use will be solely for research on the information of a decedent; and

   e. ☐ The Principal Investigator has documentation of the death of the individual about whom information is being sought, and

   f. ☐ The information sought is for the purposes of the research

Note, however, that this exception may not be available for decedent Information that contains Psychotherapy Notes or Information relating to HIV, mental health, genetic testing, or drug or alcohol abuse.
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**Note, however, that** this exception may not be available for decedent Information that contains Psychotherapy Notes or Information relating to HIV, mental health, genetic testing, or drug or alcohol abuse.

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**Instructions**: If your activity does not fall into the categories described in Section A, continue to Sections B and C to assess whether your activity is defined as research per regulations set forth by the Department of Health and Human Services (DHHS) and/or the Food and Drug Administration (FDA).

### Section B. Activities Subject to HHS Human Subject Regulations (45 CFR 46)

1. **Is the activity RESEARCH: a systematic investigation designed to contribute to generalizable knowledge?**

   TIP: If the activity is characterized by a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question and the intention of the investigation is to generate conclusions that can be applied universally, outside of the immediate environment where the investigation occurred (i.e., the classroom, hospital, department), then the activity meets the definition of research.

   ☐ Yes, Go to #2 ☒ No, Go to FDA Section C

2. **Does the research involve obtaining information about LIVING individuals?**

   ☐ Yes, Go to #3 ☐ No, Go to FDA Section C

3. **Does the research involve collecting data through intervention (i.e., physical procedures or manipulation of the environment) or interaction (i.e., communication or interpersonal contact between investigator and person) with the individuals?**

   ☐ Yes, IRB review required. ☐ No, Go to #4

   Go to FDA section C to assess if FDA regulations apply to your study.

4. **Does the research involve collecting identifiable information (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?**

   ☐ Yes, Go to #5 ☐ No, Go to FDA Section C
5. Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public)

☐ Yes, IRB review required
☐ No, Go to FDA Section C

Go to FDA section C to assess if FDA regulations apply to your study.

Section C. Activities Subject to FDA Human Subject Regulations: If your answer is “yes” to any of the three questions below, IRB approval is required and the FDA regulations apply to your study.

1. Is this is an experiment that involves a test article * and one or more human subjects, and the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit? A subject is an individual (either health or a patient) who is a recipient of the test article or a control.

*Test article Test article means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug, and Cosmetic Act.

☐ Yes, IRB review required
☒ No

2. Is this a clinical investigation or research involving one or more human subjects to determine the safety or effectiveness of a device? A subject is an individual (healthy or has a medical condition or disease) on whom or on whose specimen an investigational device is used, or who participates as a control.

☐ Yes, IRB review required
☒ No

3. Is this an experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects? This excludes the use of a marketed drug in the course of medical practice. A human subject is an individual (healthy or patient with a disease) that participates either as a recipient of the investigational new drug or as a control.

☐ Yes, IRB review required
☒ No

Instructions: If IRB review is required, you must submit a NEW STUDY application to the IRB in e-protocol.

Section D. Investigator Responsibilities and Assurances

• I certify that the information provided in this determination form and in all attachments is complete and accurate.
• I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants and for the ethical conduct of this activity.
• If determined to meet the regulatory definition of human subject research, I agree to comply with all UMass Amherst policies and procedures, the terms of its Federal-wide Assurance, and all applicable federal, state, and local laws regarding the protection of human participants in research.
• I certify that the proposed project has not yet been done, is not currently underway, and will not begin until IRB determination and/or approval has been obtained.

Investigator Signature

Name: Ramona E. Chase

Date: 10/16/2015
Figure 11. UMass IRB Application
Figure 12. NCCN Guidelines for Distress Management