2014

Implementation of a Depression Screening Protocol Specific to Implantable Cardioverter Defibrillator Patients; A Quality Improvement Project

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Final DNP Project Report

Implementation of a depression screening protocol specific to implantable cardioverter defibrillator patients; a quality improvement project

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Spring 2014

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Dedication

I would like to dedicate my graduate work to my wonderful, patient husband and my loving parents. They always encouraged, believed, and dreamed of only the best for me. Adopted as an infant, my parents lovingly sacrificed time and time again so that I might have every opportunity in life. I chose to pursue my doctorate and advanced practice nursing degree shortly after my mother's passing. I knew that she believed I would accomplish great things in life, most importantly loving God and loving people. My mother has gone to be with the Lord, but her love for me will always endure in my heart. The following poem was written by one of my mother's favorite poets. This poem illustrates the values that were instilled in me by wonderful Mom and Dad.

Mover of Mountains

Faith is a force that is greater

than knowledge or power or skill,

And the darkest defeat turns to triumph

if you trust in God's wisdom and will,

For faith is a mover of mountains —

there's nothing man cannot achieve

If he has the courage to try it

and then has the faith to believe.

- Helen Steiner Rice

Acknowledgements

I would like to thank Dr. Hardin-Pierce for her guidance and care over the past five years. I would also like to thank Dr. Moser for her feedback and direction on my manuscripts. I must thank the University of Kentucky Cardiology Fellowship program for participation in my study. This project could not have taken place without the support of Dr. Allison Bailey and Dr. Charles Campbell of the Gill Heart Institute. I would also like to thank Dr. Ziada who has been a wonderful clinical mentor and supporter of my graduate work. Lastly I would like to thank my fellow graduating DNP students who offered support and strength during this journey.

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Introduction to Final DNP Capstone Report

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Depression is an issue that is close to my heart. Members of my family, myself included, have battled depression. Working in the cardiac cath lab at the University of Kentucky Medical Center (UKMC) over the past five years has provided great insight into the cardiac population. Cardiac patients suffer from depression at a rate higher than the general population. I am particularly interested in depression in the heart failure and implantable cardioverter defibrillator population (ICD). This patient cohort deserves better management of depression by their cardiology teams.

In 2012 the American Heart Association (AHA) released a scientific statement including recommendations for depression screening and management in the ICD population. The statement suggested that more research was needed to determine the best method of depression screening for ICD patients. To determine this I turned to the wealth of information on depression in the more general population of heart failure. Manuscript one is a literature review of depression screening tools used in the heart failure population. Based on the evidence available, I have made recommendations for depression screening instrument use in the heart failure population.

Manuscript two takes somewhat of a left-turn and analyzes current legislation that if passed, could impact the psychosocial needs of the heart failure population in the United States. Using Kingdon's Stream Theory, I have unpacked The Patient Centered Quality of Care for Life Act (HR 1666) and assessed its potential impact in the heart failure community.

Manuscript three is the evaluation of my capstone research that has taken place over the past six-months. In response to the AHA statement released in 2012, I implemented a depression screening protocol specific to the ICD population in a UKMC cardiology clinic. Extrapolating from the evidence I found in my literature review of depression screening instruments used in heart failure patients, I applied the same principles the ICD patient population. Manuscript three reviews the methods and results of my work.

The overall focus of my capstone is to provide the best evidence to support process improvement for evaluating depression in patients with ICDs. Depression cannot be ignored in this population and must be addressed by cardiology providers.

The PHQ-9 and Other Depression Screening Instruments Used in Heart Failure Patients:

A Literature Review

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ABSTRACT

Background: Depression in the heart failure (HF) population has been widely studied and found to have profound implications for patients and the health care system. Heart failure patients who experience depression are more likely to be nonadherent to medical recommendations, and have increased mortality with higher healthcare resource use than non-depressed counterparts. Depression identification and treatment are necessary to prevent adverse outcomes. Objective: In this literature review, I analyzed literature in which depression screening instruments were either compared or individually evaluated in the heart failure patient population. I objectively determined the best fit for use by providers in primary care and inpatient settings. Methods: A review of the literature was conducted using CINHAL and PubMed databases. Focus was on research articles published within the last ten years that included comparison or analysis of a depression screening instruments in HF patients. Key search terms included: d*epression, heart failure, depression screening, and depression screening tools/instruments, depression assessment, and depression measurement in heart failure.* Eight articles met the inclusion criteria and were critiqued by an independent reviewer. Results: Many depression screening instruments that are currently being used in the HF population may not be ideal. Instruments found to be appropriately used in the HF population include: Hospital Anxiety and Depression Scale (sensitivity 100% Specificity 79%), Depression in the Medically Ill – 18 (PPV-47.5% NPV-93%), Depression in the Medically Ill – 10(PPV-40.2% NPV-93%), PHQ-9 (sensitivity 70% specificity 92%), PHQ-2 (sensitivity 90%

specificity 69%), PROMIS depression short form (sensitivity 89% specificity 82%), Diagnostic Interview Schedule (Sensitivity 80% specificity 84%), and Cardiac Depression Scale with a Moken scale analysis of low strength (H<0.40) and high reliability (Rho>0.8). Conclusions: Depression screening instruments are chosen based on validity and reliability with in a patient cohort, provider preference and ability to be used efficiently in the clinical setting. It was found that while categorical depression screening tools are more thorough, dimensional tools are more efficient. Additionally some dimensional tools were lengthy and may not be ideal for primary care or medical inpatient setting due to time constraints. The PHQ-9 was found to be a potential favorite with good internal consistency, reliability, and concurrent validity. PHQ-9 contains only nine questions and was the second shortest screening tool evaluated.

Key Words: depression, heart failure, depression screening tools, depression screening, depression screening tools/instruments, depression assessment, and depression measurement in heart failure.

INTRODUCTION

According to the American Heart Association (AHA), "heart failure (HF) is a chronic, progressive condition in which the heart muscle is unable to pump enough blood through to meet the body's needs for blood and oxygen." [1]According to the AHA 2014 Heart Disease and Stroke Statistics, approximately 5.1 million adult Americans have a diagnosis of HF.[2] This number is projected to increase to 8 million by 2030.[2] In 2010 HF was the chief complaint of approximately 1,801,000 physician office visits, 676,000 emergency room visits, and 236,000 out-patient visits.[2] This translates into enormous

healthcare costs. In 2012 the diagnosis of HF was estimated to cost $30.7 million dollars with a projected increase of over 125% or 69.7 billion dollars by the year 2030.[2] Heart failure causes increased morbidity and mortality, increased medical costs, and a significant decrease in quality of life.[3] Depression in this population further potentiates these complications. Independently, depression is estimated to cost over 83 billion medical and work place dollars per year.[3] Efforts are needed to identify depression in the HF population and to improve long-term outcomes. Many depression screening instruments are available to the provider; however, it is unclear which instruments are best used in specific settings. The purpose of this review is to analyze the literature in which depression screening instruments are either compared or individually evaluated in the HF population and to provide recommendations for use by HF providers.

BACKGROUND AND SIGNIFICANCE

HF is a pathophysiologic condition that is defined by a reduction of cardiac function.[4] This physiologic alteration results in the heart's inability to efficiently pump blood at a rate that meets the metabolic needs of the body. This affects the body's homeostasis and disrupts many organ functions. Four characteristics of HF that decrease quality of life include neurohormonal activation, decreased heart rate variability (HRV)/ rhythm disturbances, inflammation (cytokine release), and impaired platelet function.[3] Patients with HF have a higher prevalence of depression than individuals with other medical conditions.[5] Medically ill patients with depression have a reduction of adherence to directed therapy, as well as 50%-100% higher medical costs than their non-depressed

counterparts.[5] A reduction in depressive symptoms in HF and other medically ill patients improves adherence to therapy and decreases costs.[5,6] Patients with comorbid HF and depression must be identified and treated in order to reduce the financial and quality of life disparities within this population.

LITERATURE REVIEW

This review of the literature targeted research in which depression screening instruments are either compared or individually evaluated in the HF population. The English language PubMed and CINAHL databases were searched using search terms: depression, heart failure, depression screening tools, depression screening, depression screening tools/instruments, depression assessment, and depression measurement in heart failure.

Inclusion criteria for articles were as follows: published within the last 10 years, English language, full-text and include either a comparison or evaluation of a depression screening instrument used in the HF population. Studies included were randomized controlled trials, meta- analyses, literature reviews, and secondary analysis of randomized controlled trials that involved comparison or evaluation of depression screening instruments used in the HF population. Searching with these criteria produced 222 studies, the majority of which did not meet the inclusion criteria, leaving only 8 studies to be focused on for this literature review.

Characteristics of Instruments

According to the American Psychiatric Association (APA), a diagnosis of major depression is based on the identification of at least one of two core symptoms (A symptoms) with at least four or more secondary symptoms (B symptoms) for a total of five symptoms.[7] Minor depression is diagnosed in much the same way as major depression but with fewer than five total symptoms, one of which must be an A symptom.[7] In both depression categories, symptoms must be present for at least two weeks. Both A and B symptoms can be seen in Table 1 in the appendix section.[7] Depression screening instruments must be able to identify depressive symptomatology in the HF patient.

Screening instruments are broken down into two categories: Categoric or diagnostic interview screening instruments and dimensional or self-reporting instruments. Categoric depression screening instruments are used by a systematically trained interviewer; however, dimensional instruments are based upon self-reporting and ranking of symptom severity by the patient.[8] Categoric instruments can be used to diagnose depression, as they are utilized by trained professionals.[8] Dimensional instruments are designed to detect depressive symptoms that are reflective of a likely depression diagnosis.[8] In this literature review, 1 out of 8 studies examined the use of categorical instruments.[9] Dimensional instruments were discussed in 5 out of 8 studies.[3,10-13] Dimensional and categoric instruments were evaluated in 2 out of 8 studies.[8,14] (see table 2 in appendix) Categoric instruments were found by one study to be more reliable in

detecting depression in HF that was previously not found by use of dimensional instruments.[8] However, dimensional instruments were found to detect the highest rates of depressive symptoms.[8] Categoric instruments depend on the accuracy of the interviewer for reliability.[8] Dimensional instruments depend on the forthcoming of the self-reporting patient.[8]

Appropriate Use

Several studies found in this review spoke to the overlap of symptoms between depression and HF.[3,8,9,14] Fatigue, weight changes, and poor concentration are just a few examples of symptoms that can be attributed to both depression and HF. Depression screening instruments used in this population will offer the most benefit when they are able to distinguish true depressive symptoms from physiologic changes occurring in the HF patient. Despite their extensive validity and reliability, several dimensional instruments are unfavorable in the HF population due to the inability of the instrument to account for symptom overlapping. These instruments include the Beck Depression Inventory (BDI), the Geriatric Depression Scale (GDS), the Center for Epidemiologic Studies-Depression Index (CES-D), the Hospital Anxiety and Depression Index, the Medical Outcome Survey-Depression Instrument, and the Zung depression Scale.

Conversely, recent research by Lee et al. found that depression screening instruments that include physical depressive symptoms to assess depression in HF patients do not necessarily falsely represent the relationship of depressive symptoms to cardiac even-free survival.[15] This means that use of depression screening tools that

include physical depressive symptoms can be used with confidence that the outcomes are accurate despite the presence of both affective and physical symptoms.[15] Clearly there is much debate within the literature.

Ease of use

Choosing a depression screening instrument is based on validity and reliability within a patient population, as well as the adaptability of the instrument for use. The categorical instruments (Cardiac Depression Scale & Diagnostic Interview Schedule), although accurate and able to diagnose depression, may not be the best choice for primary care providers as they are lengthy and require accuracy on the part of the interviewer.[8,9] This process can be time consuming for both patient and provider.

Dimensional instruments are certainly more convenient to the provider as they are primarily in patient self-reporting style.[8] Dimensional instruments such as the Patient Health Questionnaire (PHQ-9), the Patient Health Questionnaire (PHQ-2), the Hospital Anxiety and Depression Scale (HADS), and Depression in the Medically Ill (DMI-18/10) can range from 2-18 items per evaluation.[3, 11,12,13] Lengthier screenings may take more time for some patient populations depending on their reading and cognitive function. Dimensional instruments were also found by one systematic review to have higher frequencies of depression symptoms (21-60%) than categoric instruments (14-39%).[14] Convenience and higher frequencies of detection of depression symptoms are convincing qualities of this style of instrument. Interestingly, one recent study compared the methodology of administering dimensional tools (PHQ-9, HADS, and PROMIS-

depression short form 8a) in standard form versus individual-tailored computer-adaptive testing (CAT).[12] The research found that the diagnostic capability of these instruments were similar regardless of the administration method.[12] CAT had an advantage over traditional implementation in that it could be individually tailored to the respondent and therefore decrease the burden for some patients with differing mental capabilities.[12]

IMPLEMENTATION OF INSTRUMENTS

The studies analyzed in this review have been successfully implemented in a variety of settings in which they are being used to predict health behaviors and mortality rates. In a study by Bauer et al.[6], the PHQ-9 and HADS instruments were utilized to determine if improvement in depression also improved adherence to medical therapy in a group of cardiac patients.[6] The study looked at depression six months after hospitalization and found that improvement in depression symptoms appeared to improve compliance rates among cardiac patients.[6] A second study by Sherwood et al.[4] found that a BDI score of >10 to determine a hazard ratio of 1.56 (95% confidence interval) for the combination of death or hospitalization related to a cardiovascular event within a HF patient cohort.[4] The Heart Failure Adherence and Retention Trial (HART) was a behavioral trial that examined patient self-management and HF education as a means to improve patient outcomes.[16] This trial used the GDS with a cutoff point of >10 as a measure for depressive symptoms. HART found that patients who scored >10 on the GDS had significantly more hospitalizations per year than did the patients who scored <10.[16] The study concluded that depression was a major predictor of non-compliance to medical

therapy as well as hospital readmission. The study recommended that depression be identified as soon as possible in the HF patient.

Results

Many depression-screening instruments have been found to be valid and reliable in many patient populations. Identifying depression in the HF cohort can be a challenge for the provider, as many depressive and physical symptoms overlap. Choosing the best instrument for use in the population depends on the setting of the patient and provider. Instruments found to be reliable by this review in the HF patient included **HADS** with100% sensitivity and 79% specificity when cutoff score for depression was 8, 93% sensitivity and 85% specificity with a cutoff of 7, and 86% sensitivity and 79% specificity with a cutoff of 4.[3,11] **Depression in the Medically Ill -18 (DMI-18)** with a cut off of >14 showed a positive predictive value (PPV) of 47.5% and a negative predictive value (NPV) of 93.0%.[13] **Depression in the Medically Ill -10 (DMI-10)** which was most beneficial with a cut off of >6, had a PPV of 40.2% and NPV of 93.1%.[13] **PHQ-9** was found to have a sensitivity 54% and specificity 90% when cutoff >10 by Smith, however, Hammash et al. found the PHQ-9 to have a sensitivity of 70% and specificity of 92% when the cutoff was 10.[3,10] **Patient Health Questionnaire-2 (PHQ-2)** was found reliable with a sensitivity 90%, and specificity 69%.[3] **PROMIS-Depression short form** was also found to be reliable in this population with a sensitivity of 89% and specificity of 82% when the sum core was 9.5.[12] Categoric tools found to be appropriate for use in the HF population were the **Diagnostic Interview Schedule (DIS)**

with a sensitivity of 80% and a specificity of 84% and the **Cardiac Depression Scale (CDS)** with a Mokken scale analysis of low strength (H<0.40) and high reliability (Rho>0.8).[9,14] Despite a negative review by Smith, the BDI and GDS were found by others to be reliable depression screening instruments, and in some cases, the gold standard for depression screening, however, the issue of potential symptom overlapping and length of instrument prevented theses instruments from being recommended by this review. [3,8,10,11]

Categoric instruments that utilize interview techniques by a trained professional may be too lengthy for the HF provider in both the clinic and hospital settings. However, these instruments may be useful for further investigation once depressive symptoms have been identified.

Dimensional instruments are a good option for depression screening by the HF provider both in clinic and in-patient settings and offer an array of choices for the provider. The literature seems to be conflicted as to which dimensional instruments are best for use in HF patients. For example, the HART study found that the GDS may not have been the best option in that study based on a sensitivity of 56.3% and a specificity of 73.6%.[16] Other instruments, such as the BDI, HADI, and CES-D, contain 14-20 items per inventory. While found to be sound choices by many researchers, these instruments may prove too difficult and lengthy in some populations. Patients who are elderly or have difficulty reading may have challenges completing assessments such as these.

The HART study also suggested that the PHQ-2 may be the most useful instrument as it only contains two questions which can be administered into routine patient encounters.[16] The PHQ-9 should be considered applicable in this patient population as it contains nine items. Hammash et al. found that the PHQ-9 was a consistent and reliable depression screening instrument and supported its consistency when compared to the BDI as the gold-standard.[10] The BDI has long been used for depression screening in many patient populations; the PHQ-9 has now been determined to be equivocal. The nine-item self-reported screening may be the best combination of known depression screening methods for HF patients due to its confirmed vality and reliability and its versatile use as either a categoric or dimensional tool.[3,8,10,12] Recent research has also verified that the PHQ-9 can be used in HF patients with out worry of overestimation of depressive symptoms and outcomes.[15]

Discussion

Recommendations for inpatient HF depression screening methods are extrapolated from the literature and evaluated based on validity and reliability and ease of use for patient and provider. In order to create a streamlined approach, the PHQ-2 can be used for every in/out patient encounter. The two item screening can provide evidence based direction for providers. If the screening is positive, the provider can administer the PHQ-9 either by interview or self-reporting method, for further delineation of depressive symptoms.[3,10,12] Treatment can then be directed based on the severity of the depressive

symptoms. Other categoric interview instruments may be of use once the initial screening has occurred and depression has been identified.

In a clinic setting, the PHQ-9 may be given to the patient for self-reporting while he or she is filling out other pertinent forms. The 9-item inventory will take less time than many of the other self-reporting instruments. The patient can present the form to the physician during the office visit for further review. In this setting, the PHQ-2 followed by administration of the PHQ-9 may take additional time that could be saved by the patient self reporting on only one instrument and presenting it for review. The provider can quickly look at the form and determine if there is a need for further investigation based on a cutoff score of 10 or greater. The PHQ-9 can also be given in an interview format by the provider, which may increase accuracy and consistent use of the instrument. The PHQ-9 has published recommended treatments depending on score and severity of depression.[17] This algorithm would be most useful for providers if easily accessible. This methodology will vary among providers and settings.

CONCLUSION

It is clear that many depression-screening instruments are available for use in the HF population. Many instruments have been reviewed and validated in the literature. No one instrument can be said to be the best or single standard for any and every situation. It may be best to take each provider and each patient into consideration when deciding on a depression screening instrument. The most vital recommendation made from this review is that standardized screening for depression in HF patients is a necessity for the benefit

of both the patient and the health care community. The PHQ-9 alone or preceded by the PHQ-2 is a reasonable option and is supported by the literature for use in the HF population.

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WHAT'S NEW?

- Not all depression-screening instruments are equal within the heart failure population and setting must be considered when choosing a depression-screening instrument.
- PHQ-9 may be a reasonable choice for primary care and inpatient settings as it is a brief 9-item survey that can be implemented by the provider or delivered to the patient for self-reporting.

Table 1: Symptoms and Severity of Major Depression According to the American Psychiatric Association[14]

Symptom Group	
A symptoms:	- Depressed, sad mood most of the day - Markedly diminished interest or pleasure in all or almost all activities most of the day, nearly every day
B symptoms:	- Weight loss or weight gain, or decreased or increase in appetite - Insomnia or hypersomnia - Psychomotor agitation/retardation - Fatigue or loss of energy - Feeling of worthlessness or inappropriate guilt - Diminished ability to think or concentrate or ambivalence - Thoughts of death or suicidal ideation
Severity	
Mild:	- At least one A and four B, ability to function normally but with substantial and unusual effort
Moderate:	- A severity between mild and severe
Severe	- Presence of most symptoms and observable disability (affection work or childcare)

Table 2: Depression screening instruments discussed in this review:

Tool	**Studies**	**Description**	**Recommendation**
DIS	Johansson et al. (2006)	Categoric – Provider interview	Best used by psychiatric services or as follow up to positive screening tool.
CDS	Ski et al. (2012)	Categoric – Provider interview	Used only in HF populations and as follow up to positive screening.

BDI	Hammash et al. (2013), Johansson et al. (2006), Delville et al. (2008)	Dimensional – Patient self-reporting	Can be used for primary care or inpatient and as a single tool or as follow up to positive screening. Use with caution, may not account for symptom overlapping in HF patients.
PHQ-9	Hammash et al. (2013), Smith (2010) Fischer et al. (2013) Johansson et al. (2006)	Dimensional – Patient self-reporting Categoric – Provider interview	Can be used for primary care or inpatient and as a single tool or as a follow up to positive screening.
GDS	Johansson et al. (2006), Delville et al. (2008), Haworth et al. (2007),	Dimensional – Patient self- reporting	Can be used for primary care or inpatient. Comes in a 30 and 15 item formats. Can be used as a single tool or as follow up to positive screening. Use with caution, may not account for symptom overlapping in HF patients.
HADS	Johansson et al. (2006), Haworth et al. (2007), Smith (2010) Fischer et al. (2013)	Dimensional – Patient self – reporting	Can be used for primary care or inpatient. Requires a reduced cut off point of 8 in the HF population.
CES-D	Smith (2010), Johansson et al. (2006), Delville et al. (2008)	Dimensional – Patient self-reporting	Was not found to be favorable in the HF population due to symptom overlapping.
Hospital Anxiety and Depression Index	Smith (2010), Delville et al. (2008)	Dimensional- Patient self-reporting	Was not found to be favorable in the HF population due to symptom overlapping.
Medical Outcome Survey-Depression Instrument	Smith (2010), Johansson et al. (2006), Delville et al. (2008)	Dimensional – Patient self-reporting	Was not found to be favorable in the HF population due to symptom overlapping.
Zung Depression Scale	Smith (2010), Johansson et al. (2006), Delville et al. (2008)	Dimensional – Patient self-reporting	Conflicting evidence regarding usefulness in HF population. Use with caution as it may not account for symptom overlapping.
DMI-10/18	Smith (2010) Hilton et al. (2006)	Dimensional – Patient self-reporting	10 and 18 item format may be used in primary care and inpatient care.

			Found to account for symptom overlapping by exclusion of somatic items.
PHQ-2	Smith (2010)	Dimensional – Patient self-reporting	2 item inventory in yes/no format. Found useful in primary care and inpatient care as screening only. Must be followed up by diagnostic tool.
PROMIS- Depression Short Form	Fischer et al. (2013)	Dimensional- Patient self-reporting	8 item likert scale that can be completed and scored via hard copy method or Computer Adaptive Test (CAT). Useful in primary care and inpatient care

The Patient Centered Quality Care for Life Act and Heart Failure

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The Patient Centered Quality Care for Life Act and Heart Failure

Statement of the problem:

Seriously ill patients with chronic health conditions and their caregivers have complex needs that our health care system is ill prepared to meet. Independent of new healthcare policy and expenditures, a patient-centered approach to care can improve patient and care giver outcomes (Dudas et al., 2012;Meier, 2011; Mirzaei et al., 2013). The Institute of Medicine (IOM) defines patient-centered care as "Health care that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients' wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care"(IOM, 2001).

In April of 2013, the Patient Centered Quality Care for Life Act (House of Representatives, HR 1666) was introduced to the House of Representatives by Representative Emanuel Cleaver of Missouri. This piece of legislation was supported by 47 cosponsors and has been referred to the subcommittee on health. HR 1666 has many components and legislative directives that would support patient-centered care efforts for many patient cohorts. The following items are included in HR 1666 and would become law upon this bill being passed by both the House and Senate:

- Formation of a stakeholder strategic summit via the Department of Health and Human Services (DHHS) to analyze barriers and solutions to patient-

centered care in chronic illness. Participants of the summit would include Federal and private organizations.

- Amendments to the Public Health Service Act, which would require the Centers for Disease Control and Prevention (CDCP) to provide grants for education and awareness of palliative care for seriously ill patients, families, and health care professionals.
- Direction of the Health Resources and Services Administration (HRSA) to provide medical professional workforce training to promote patient-centered care of seriously ill patients with chronic diseases.
- Update to the 2002 HRSA report, "The Supply, Demand and Use of Palliative Care Physicians in the United States."
- Establishment of a Quality of Life Advisory Committee to assist the CDCP and HRSA to conduct quality of life education and awareness dissemination for cross agency implementation.
- Expand national research programs, via the National Institutes of Health (NIH), regarding symptom management, palliative, psychosocial, and survivorship care.

Background and significance of the issue:

Patient-centered care has been studied in many patient populations and is an effective approach to improving outcomes in those with chronic illnesses (Meier, 2011; Mirzaei et al., 2013; Poochikian-Sarkissian, Sidani, Ferguson-Pare, & Doran, 2010).

More specifically, the patient-centered approach is associated with improved patient outcomes in the heart failure population (Dudas et al., 2012). According to the American Heart Association (AHA), "heart failure (HF) is a chronic, progressive condition in which the heart muscle is unable to pump enough blood through to meet the body's needs for blood and oxygen"(American Heart Association [AHA], 2012). According to the Center for Disease Control (CDCP), approximately 5.7 million Americans are currently living with chronic heart failure (CDCP, 2013). Half of these Americans will die within 5 years of being diagnosed (CDCP, 2013).

The AHA recently released a Scientific Statement entitled "Decision Making in Advanced Heart Failure" (Allen et al., 2012). This statement introduces the concept of shared decision making between clinicians and heart failure patients, which follows the principle of patient-centered care as defined by the IOM (Allen et al., 2012, p. 1929). The Affordable Care Act also addresses patient-centered care, devoting 4 pages to shared decision-making and collaboration of care initiatives (Allen et al., 2012).

Quality of life issues such as uncertainty and depression are common in the heart failure population and further potentiate medical complications (Dudas et al, 2012). Patients with heart failure who have depressive symptoms have increased morbidity of up to 4 times the national average (Moraska et al., 2013). Heart failure patients have a higher prevalence of depression than other medical populations (Moraska et al., 2013;Taylor et al., 2008). Depression rates in heart failure patients are consistently higher than in the general population and are thought to range from 5-10% (Moraska et al., 2013). Research

has demonstrated that a reduction in depressive symptoms in heart failure and medically ill patients improves adherence to therapy and decreases medical costs (Taylor et al., 2008; Bauer et al., 2012). It is estimated that heart failure costs are approximately $34.4 billion US dollars each year, which includes the cost of health care services, medications, and lost productivity (CDCP, 2013). Adherence to medical therapy is necessary to improve quality of life and reduce additional medical costs. A recent study by Bauer et al. (2012) found that a reduction of depression in cardiac patients resulted in increased adherence to medical therapy over a 6-month period of time. A patient centered approach that includes psychosocial interventions is needed in order order to reduce health care costs and increase quality of life among the heart failure population.

The items covered in HR1666 would benefit the heart failure population and other patient cohorts by mandating that a patient-centered approach become a regulated model in more healthcare outlets. It would also provide channels for grant money to be funneled into patient-centered education for medical providers and family. Additionally, HR 1666 would open up the channels for further research by the NIH into palliative care and psychosocial interventions that would best serve heart failure patients as well as other chronically ill individuals (H.R. 1666, 2013).

Conceptual Framework and Analysis of the Issue:

To analyze the many political and policy intricacies surrounding this issue and the implementation of HR 1666, John Kingdon's Streams Theory was utilized (Kingdon,

2011). This theory focuses on problems, policy, and politics and how they converge to impact public agenda and legislation. The problem stream focuses on why the issue is of importance and what is currently being done about the issue. The policy stream looks at ideas about the issue and ways of correcting the problem such as legislation or non-judicial measures and alternatives. The political stream focuses on the current political climate and what other current political issues could possibly advance legislation or constrain it. Kingdon's theory suggests that when the right policy window is open and problems, policy, and political climate are all in alignment, issues become more visible on the national or local legislative agendas (Kingdon, 2011). This theory doesn't forecast that an issue or policy will become law but it does provide a modal of how legislation and political issues are brought into the public eye and the political agenda.

The Problem Stream

Chronic illnesses such as heart failure are common diagnosis in most healthcare institutions. Heart failure alone represents over $34 million healthcare dollars annually (CDCP, 2013). Individuals with illnesses such as cancer, respiratory disease, kidney and liver failure have high healthcare utilization needs and would benefit from a patient-centered care approach. Currently there is a need for public involvement and education regarding patient-centered care for seriously ill patients and families. According to HR 1666, awareness and demand for symptom management that coincides with medical treatment would improve the quality of life for patients and their loved ones (H.R. 1666, 2013).

In accordance with a patient-centered approach, utilization of collaborative palliative care is also appropriate for seriously and chronically ill patients at any stage of illness and should be better implemented in today's healthcare models. In a recent pilot study, patients with heart failure who were recipients of palliative care were found to have better perceived control and a reduction in symptom distress (Evangelista, 2014). Early palliative care was also found to improve quality of life and mood when offered to patients with metastatic non-small-cell lung cancer (Temel et al., 2010). Palliative care is one way of providing a patient-centered approach to the seriously and chronically ill and is supported by the legislation in HR 1666.

The Patient Centered Quality of Care for Life Act proposes that less than one third of cancer patients and survivors collaborated with by their doctors regarding their own quality of life (H.R. 1666, 2013). A 2002 report commissioned by HRSA projected that the United States would be lacking palliative specialist and recommended increased education and training across all medical specialties that serve seriously ill patients (Cohen & Salsberg, 2002; Lupu, 2010). This warning has not been heeded and palliative medicine and collaboration continue to be at a loss in most healthcare outlets. Several IOM reports regarding palliative care, survivorship, psychosocial care, and pain management have also called for increased training in symptom management and collaboration of care among patients, families, and caregivers (IOM, 2001,2006,2007,2011). Again, these reports have not been sufficient to induce the paradigm change required to improve seriously ill patient's satisfaction with their care.

Key Stakeholders: One of the primary components to HR 1666 would be to convene a patient-centered health care and quality of life stakeholder strategic summit to evaluate barriers to patient-centered health care as well as identify solutions to improve quality of life among seriously ill patients in the current healthcare environment. The primary stakeholders in HR 1666 include DHHS, CDCP, HRSA, and NIH. The adoption of HR 1666 would directly impact these organizations and require changes to policy and the appropriation of funds. Federal agencies such as the Agency for Healthcare Research and Quality the Centers for Medicare and Medicaid Services, Department of Veterans Affairs, and the Department of Defense would also be included in the stakeholder summit. Private organizations such as health insurance organizations, non-profit organizations, and faith community representatives would be asked to the summit as well. Other key stakeholders in HR1666 would be organizations that are currently supportive of the bill. These organizations include:

Supporting Organizations of HR 1666	
American Cancer Society Cancer Action Network	American Academy of Hospice and Palliative Medicine
American Academy of Pain Management	American Childhood Cancer Organization
American Osteopathic Association	American Society for Pain Management Nursing
American Society of Clinical Oncology	Association of Oncology Social work
Cancer Support Community	C-Change
Center to Advance Palliative Care	Hospice and Palliative Nurses Association
LIVE**STRONG** Foundation	National Alliance for Caregiving
National Association of Social Workers	National Coalition for Cancer Research
National Coalition for Cancer Survivorship	National Comprehensive Cancer Network
National Palliative Care Research Center	Oncology Nursing Society
Society for Social Work Leadership in Health Care	Supportive Care Coalition
The Catholic Health Association of the United States	([HR 1666 Supporters], 2013)

The organizations listed in this section have direct impact on the care of seriously ill individuals and have the ability to change the status quo of our current healthcare system. It is clear that there is a problem with the way chronic and seriously ill patients are managed in today's healthcare model. Changes must be made not only for financial reasons, but also to improve the lives of such a large population of Americans.

The Policy Stream

The policy stream surrounding HR 1666 is tumultuous with the Affordable Care Act being implemented and its impact on the health care delivery system. Interestingly enough, in 2012, Representative Emanuel Cleaver tried to introduce The Patient Centered Quality Care for Life Act under the 112th congress. It was also referred to the subcommittee on health where the legislation died. This is potentially the course for the current version of the bill despite a lack of opposition to the initiatives and overwhelming support of many special interest groups. Timing is everything and currently too many current policy changes seem to overshadow the potential adoption of HR 1666.

Alternatives: For years organizations that support palliative and psychosocial care measures have shown the benefit of patient centered care for our seriously and chronically ill patient populations. Patient navigators and psychosocial support in these patient populations is often talked about; however, little has been done formally to change the way these services are delivered. It seems that unless national legislation is made that forces the regulatory healthcare bodies to change their approach; little can be expected in the way of organized change. It is clear that simply letting the body of

literature speak for its self will not be enough for the seriously ill persons who are in need of patient centered care now.

The Affordable Care Act (ACA) has many components and calls for many changes to current health care models. The ACA calls for an increase in quality of care and for healthcare agencies to be reimbursed based on quality measures (H.R. 3590, 2011). The hope is that healthcare outcomes will be evaluated against the quality of care provided. Reimbursement will be based on the value of the quality of care. These standards will force healthcare agencies to look at evidenced based methods of providing quality care. Patient centered care will be necessary when quality and values are driving the decisions on how healthcare expenditures are made. Education and research will be needed to provide a patient centered approach and to offer palliative care and psychosocial services. This may potentially lay the way for HR 1666 to be enacted into law which will help unify the organizations such as DHHS, CDCP, HRSA, and NIH under one umbrella of patient centered implementation.

The Political Stream

Political factors: The Patient Centered Quality of Care for Life Act is a bipartisan bill. There are 10 republican and 57 democrat cosponsors (H.R. 1666, 2013). There is no political opposition to this piece of legislation; however, it has not ben widely publicized. It is currently under review by the House Subcommittee on Health. The current economic situation regarding healthcare may constrain action of this legislation. There seems to be a substantial amount of uncertainty in the current political environment regarding the

launch of the ACA. Part of HR 1666 is to require grant money to be provided by the CDCP for education regarding palliative care for families and healthcare professionals. HR 1666 also calls for the establishment of a quality of life advisory committee to assist the CDCP and HRSA as well as expanded research programs through the NIH. These initiatives will cost these organizations funds that may not be available as we launch National healthcare reform. The political climate is not currently ripe for this kind of health care initiative to be launched. However, as we see changes made to reimbursement policy and quality of care become more and more pressing, the right political time for HR 1666 may be soon at hand. According to Kingdon's stream theory, the political window of opportunity must be perfectly ready for the problems, policy, and the politics to line up in such as way that the primary issue takes center stage (2011). This alignment is not quite ready but is soon to come. When The Patient Centered Quality Care for Life Act was introduced in 2012, it only had 27 cosponsors. The 2013 version had 67 cosponsors and numerous special interest groups supporting it. The political time has changed drastically since the first attempt at passing this bill and will continue to change over the next several years. Legislation that would force regulatory agencies such as DHHS, CDCP, HRSA, and NIH to seriously implement patient centered care strategies would make a tremendous difference on conditions such as heart failure and other chronic illnesses that are known as high healthcare dollar diagnosis.

Policy Options:

The evidence regarding the heart failure patient population is clear, patient centered care that includes psychosocial support, palliative care, and shared decision-making is best practice (Allen et al., 2012; Moraska et al., 2013). This is applicable in multiple patient cohorts as evidenced by the IOM's *Crossing the Quality Chasm's* definition of patient-centeredness as "providing care that is respectful and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions" (Committee on Quality of Health care in America and IOM, 2001). Many aspects of health care are leaning toward a patient-centered approach such as the advent of the electronic health records that offer access to patient health information as well as consumer reports that disseminate medical information to patients and families (Mann, 2013). Even the Food and Drug Administration has adopted a new program called Patient-Focused Drug Development, which collaborates with patients in specific disease populations (Mann, 2013, p. 1).

It seems there are only two options for the Patient Centered Quality Care for Life Act. First option is to adopt the legislation and have an organized approach to implementation of patient-centered care into already established healthcare organizations. Second option is to let the legislation die and allow the growing body of literature and other organizations individually develop varying interpretations of what this concept means and how it will function from one healthcare outlet to the next.

The Commonwealth Fund believes that the adoption of improvement models for improving care at the end of life will take more than just the creation of innovative programs (Hostetter & Klein, 2012). Improvements to patient-centered care that includes palliative care implementation and end of life care will take organized education and collaborative learning approaches (Hostetter & Klein, 2012). Perhaps passing legislation and the concepts proposed in HR 1666 will provide the structure and processes needed to implement patient-centered care models appropriate to the growing population of chronically and seriously ill.

Best Policy Conclusions:

Implementation of evidence-based practice should not require national legislation. However, many healthcare systems may not be as motivated for issues such as palliative care and symptom management when compared to new innovative treatments that promise high reimbursement rates. Healthcare is changing and part of this reform may include a shift to value-based reimbursement (Agency for Healthcare Research and Quality [AHRQ], 2013). This shift will require that healthcare outlets take a more targeted approach to patient-centered care as an attempt to reduce healthcare use and improve patient satisfaction. In this case, HR 1666 should be supported by health care professionals, special interests groups, and non-profit organizations as it is a literature supported legislative intervention to change the way seriously ill patients are cared for.

Strategies for Moving Forward:

Adoption of HR 1666 into law would provide legislation that would organize the implementation of patient-centered care into existing healthcare delivery systems. The HR 1666 bill would provide grants for palliative care education for families and health care workers. Increased research of palliative, psychosocial, and symptom management strategies would be a bi-product of the passing of this legislation. The benefits provided by this bill will impact multiple seriously and chronically ill individuals . Agencies and special interest groups who are particularly focused on palliative and patient-centered care must support HR 1666 in order to gain public interest. The heart failure community will be particularly benefited by this legislation. The American Heart Association has yet to formally support this bill. The theology of HR 1666 is in agreement with the scientific statements made by the AHA (Allen et al., 2012). Endorsement by the AHA would help further public and political interest in this bill. Petitions for AHA support are recommended.

Supporters of HR 1666 need to capitalize on the current political climate to make the case for the legislation. Value-based reimbursement and accountable-care models will rely on the best evidence-based practice to reduce healthcare costs and improve patient satisfaction. This evidence will continue to point to patient-centered care models which include, palliative care, symptom management, and psychosocial support as the most appropriate and cost-effective intervention for seriously and chronically ill patients.

Kingdon' s "political window" of opportunity is close at hand for HR 1666; however supporters need to get more public interest for this bill (Kingdon, 2011). Unfortunately implementation issues with the Affordable Care Act have taken the limelight currently. HR 1666 may have to wait until the quality measures of the ACA have had time to be enacted. This will afford supporters of HR 1666 additonal time to gain national support and publicity. Healthcare agencies such as university medical centers and the Veteran's Association will certainly be expected to comply with value-based quality initiatives and should support HR 1666 and promote the passing of the legislation. Legislation in HR 1666 will provide necessary services and grant money to help organizations be successful at implementing patient-centered care models uniformly.

Potential Unintended Consequences:

A potential unintended consequence of the enactment of HR 1666 is unforeseen cost. Several aspects of the bill will require funding such as the stakeholder strategic summit, education grants, professional workforce training, quality of life advisory committee, and expanded research by the NIH (H.R. 1666, 2013). These aspects of the bill may be costly initially but may prove to be cost-effective once appropriate services are implemented in established heath care systems. A published cost-benefit analysis would be beneficial in gaining support and public acknowledgement of HR 1666.

Another potential consequence of this legislation is a significant reduction in healthcare usage. While this sounds positive and desirable, low inpatient census and fewer ER and outpatient visits could lead to a reduction in revenue for healthcare

providers. However, these agencies may recover these costs by developing palliative care and symptom management services to offer their patient populations.

Lastly, insurance coverage of these services may be an issue for some patient populations. According to the ACA, increased access to psychosocial and palliative care should be covered; however as this remains to be seen in real-time. Issues could arise with covered benefits (H.R. 3590, 2011).

Implementation/Enforcement Issues:

Implementation and enforcement of HR 1666 may be difficult if the primary stakeholders do not have good buy-in to the legislation. Most importantly, the strategic summit hosted by the DHHS would be most beneficial to start implementation of the items listed in HR 1666. This summit will help organize efforts and recognize were barriers lie among affected organizations and health care outlets.

Implementation issues could arise for the CDCP regarding the education grants for palliative care for seriously ill patients, families, and health care professions if a good strategy is not in place for grant qualification. The CDCP must make clear criteria for awarding grant money. Implementation of HR 1666 could become difficult for the HRSA regarding the provision of professional workforce training if an organized methodology is not systematically used in all healthcare outlets. Also the establishment of a quality of life advisory committee to aid the CDCP and HRSA in the dissemination of education and implementation will be necessary to avoid implementation and enforcement issues regarding HR 1666.

The NIH may face implementation issues regarding the expansion of national research programs in the areas of symptom management, palliative, psychosocial and survivorships care as there may be low incentive to conduct this research. Once grant money is available this may become a more popular area of research.

Conclusions:

The Patient Centered Quality Care for Life Act is a beneficial and necessary piece of legislation for patients and families dealing with chronic and serious illness. This legislation is also necessary for the healthcare industry as it will ultimately save money and promote evidence based practices that have been proven to reduce hospital stay and healthcare use. This piece of legislation is particularly necessary for patients with heart failure and other "high-dollar" diagnosis as the objectives of the bill will provide better symptom management, psychosocial resources, and palliative care for these individuals. Organizations such as the American Heart Association should support this bill as it is in agreement with the current body of literature produced by the AHA regarding patient-centered care. Moreover, this legislation will be necessary to support the objectives and laws that are provided in the Affordable Care Act and currently of interest in many healthcare outlets and organizations.

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Implementation of a depression screening protocol specific to implantable cardioverter defibrillator patients; a quality improvement project

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Implementation of a depression screening protocol specific to implantable cardioverter defibrillator patients; a quality improvement project

Abstract

Background: Depression in patients with implantable cardioverter defibrillators (ICD) is a problem that has not been well addressed by providers. In 2012 the American Heart Association (AHA) released a scientific statement that recommended structured and routine depression screening of these patients. The AHA statement also recommended further research on depression screening instruments and their use with this population.
Aims: 1.) To develop and implement an evidenced based depression screening protocol appropriate for patients with an ICD seen in an outpatient setting. 2.) Evaluate provider knowledge about depression screening (? Is this what you mean) and depression screening practices before and after the depression screening protocol implementation. 3.) Determine the efficacy of protocol implementation by evaluating provider screening practices and recommendation for treatment.
Setting: A small cardiology clinic affiliated with the University of Kentucky Cardiology Fellowship program.
Participants: 18 general cardiology fellows who conduct clinic hours on Monday and Wednesday afternoons in the specified clinical setting.
Methods: An evidenced based depression screening protocol was created using the Patient Health Questionaire-9 (PHQ-9). Participants were asked to use this screening instrument to evaluate all patients with an ICD who were seen in their clinic over a 14-week period. Participants were to document the screening in the clinic note and bill appropriately for the diagnosis of ICD. Participants also were surveyed on their knowledge and depression screening practices within this patient population before and after implementation of the protocol. A chart review was conducted at the end of the pilot study to evaluate provider adherence with the protocol. Process evaluation was conducted at the mid and end points of the pilot study.
Results: The pre and posttest data showed an increase in formal depression screening, use of depression screening instruments, and knowledge base after protocol implementation. Posttest data showed that 64% of participants reported that they formally screened ICD patients compared to only 11% stating they screened pre protocol. Pre test data suggests that 89% of participants used a formal instrument 0/10 encounters compared to posttest data which suggests that 93% used an instrument at least 1-10/10 encounters. There was also a 38% increase in knowledge base about depression in the ICD population post protocol implementation. The primary barrier to depression screening identified by participants was lack of time. Chart review data was influenced by potential billing inconsistencies and poor attendance of ICD patients to the clinic during the pilot period. This led to little documented evidence of provider adherence to the protocol in the study

setting. Of the charts available for analysis, 50% contained proper execution of the depression screening protocol. It is important to note that participating physicians have interactions with ICD patients in settings outside the study clinic and may have incorporated depression screening practices in other patient encounters. This may explain the improved scores of the pre/post test that are not reflected in the chart review data. Process evaluation data suggested that participants were equally prepared and satisfied with the process at the mid and end points of the pilot study.
Conclusions: This quality improvement project was successful in creating and implementing a depression screening protocol in a small cardiology outpatient clinic. There was also marked success in provider knowledge and depression screening practices based on the results of pre/post test. In accordance with the scientific statement by the AHA, further research is recommended on best practice for depression screening of the ICD population.

Introduction

The rate of , implantable cardioverter defibrillator (ICD) implantation has increased to 250,000 per year in the United States (Dunbar et al., 2012). Although many patients and families with an ICD adjust well psychologically, some patients experience anxiety and depressive symptoms in light of life-changing illness and uncertainty (Dunbar et al., 2012). Recent research by Suzuki et al. (2010) has determined that depression is common and persistent in the ICD population regardless of the medical reason for implantation. Suzuki (2010) also found that despite the indication for implantation, depression in this population is associated with increased risk for ICD shocks.

The coexistence of depression with chronic illness is associated with increased ambulatory care, emergency department visits, days spent in bed due to illness, and functional disability (Lichtman, 2009). Medically ill patients with depression have a

reduction of adherence to directed therapy, as well as 50%-100% higher medical costs than their non-depressed counterparts (Taylor et al., 2008). Research has shown that a reduction in depressive symptoms in HF and medically ill patients improves adherence to therapy and decreases medical costs (Taylor et al., 2008; Bauer et al., 2012). Thus, early detection of depression in patients with an ICD may prevent a decrease in quality of life, and if treated effectively, result in a reduction in health care usage and cost.

Currently there are no national guidelines for treating depression in patients with an implantable cardioverter defibrillator (ICD). The American Heart Association (AHA), however, recently endorsed psychosocial recommendations from a scientific statement about the psychological response patients and families have to ICD implantation. The AHA statement does provide recommendations for practice, which include education and depression assessment pre and post implementation (Dunbar et al., 2012).

There is no specific depression screening method for ICD patients currently used in the cardiology clinic of our large, tertiary referral academic medical center. Interviews with multiple cardiology providers have verified that in light of the recent AHA recommendations, there is a need for a clear depression screening protocol for ICD patients in the clinic setting. Current clinic documentation of review of symptoms includes a mini depression screening that is often overlooked and "ineffective," according to the co-director of the clinic. Local depression statistics for this population are unknown. However, based on the overwhelming evidence provided in recent literature, it is assumed that local depression rates in ICD patients are similar to those found in the

literature. Provider knowledge of depression screening may be lacking and there is not an appropriate depression-screening instrument used in the clinical practice

Objectives of this study:

1. Create an evidence-based depression screening and treatment protocol specific to the ICD population for physician use in the outpatient clinic setting.
2. Evaluate physician knowledge and depression screening practices before and after implementation of a depression screening and treatment protocol.
3. Determine efficacy of the screening and treatment protocol in promoting physician depression screening, and recommendation of treatment when appropriate.

Guiding question:

Will implementation of an evidenced based depression screening protocol specific to ICD patients improve provider knowledge and screening behaviors in a small cardiology clinic setting?

Methods

Study Population:

The study population included cardiology physicians who are currently practicing at a local university medical center. There are a total of 18 physicians on this service. The investigator recruited these physician participants by providing an educational presentation as a guest speaker during a daily cardiology conference. All physician participants were asked to be part of the study and were considered a purposive sample.

Selection criteria for this study were as follows: Over age 18, current member of the group of cardiology physicians, currently conducting cardiology clinic hours on Mondays and Wednesdays in the specified clinic, and currently evaluating cardiology patients who have ICDs. Consent for participation was obtained during the cardiology conference session. This study sample was evaluated as a group and no individual was singled out as compliant or non-compliant with study criteria.

The patients screened by physician participants were also considered participants. Evidence of physician adherence with the screening and treatment protocol was obtained from the medical record of the patients being screened. The primary investigator had no interaction with the screened patients. A waiver of consent for these participants was obtained.

Study Design:

We used a one-group pretest- posttest design. Participating physicians were surveyed regarding their current knowledge of depression in ICD patients as well as their current use of standardized depression screening instruments. Education regarding the population and the protocol implementation was given after collection of the survey. Protocol implementation was conducted over a 14-week period following baseline data collection. See appendix A: section 2 and 3 for and example of the depression screening protocol. We encouraged the consistent use of the screening and treatment protocol by participants via regular visits to the cardiology clinic. Physician adherence to the protocol was evaluated via a chart review of the electronic medical record at the end of the

protocol implementation period. Adherence was determined by evidence of physician documentation of screening as well as documentation of recommended treatment and follow-up based on depression screening results. A process improvement survey was also given midway through the study and again at the end in order to identify opportunities for process improvement and for future implementation of the protocol.

Study Procedures:

The protocol included the use of the Patient Health Questionnaire – 9 (PHQ-9) for screening of patients with ICDs in the Monday/Wednesday cardiology clinic times. This screening instrument and recommended treatment follow-up interventions have been widely used in the heart failure patient population. The PHQ-9 has been found to have good validity and reliability as a screening instrument for depressive symptoms in heart failure patients who present with many physical and psychological issues (Kroenke, Spitzer, & Williams, 2001; Kroenke & Spitzer, 2002; Lee, Lennie, Heo, & Moser, 2012). The screening protocol for this study is consistent with what is recommended by the American Heart Association and in the instruction manual for the PHQ-9, which is copyrighted by Pfizer (Dunbar, 2012; Patient Health Questionnaire [PHQ] Screeners, n.d.). See Appendix A: Section 2 and 3 for the PHQ-9 screening instrument, scoring system, and recommendations for follow-up treatment that were used by physicians to screen for depression in patients with ICDs. Laminated copies of the PHQ-9 screening instruments were given to the participating physicians and were also made available to the clinic staff for physician use during clinic times. The PHQ-9 laminated screening

instruments were designed as a guide for multiple uses. No data, markings, or information was recorded on the instruments themselves. The participating physicians were also given a laminated pocket reference card that contains the recommended treatment and follow-up interventions based on the scoring system of the PHQ-9. The recommendations are published in association with the instrument and are based on the research of the primary developers (Kroenke & Roberts, 2002).

The physician's protocol also included prompts for documentation of the depression screening in the medical record at the bottom of the laminated provider reference card. A negative screening was to be documented in the medical record as "the patient was screened for depression via the PHQ-9 and was not found to have any depressive symptoms at this time." A positive depression screen was to be documented in the medical record as "the patient was screened for depression via the PHQ-9 and was found to have (mild, moderate, moderately severe or severe) depression with a score of...." See Appendix A: Section 3 for sample documentation statements for physician use. This provided us with documented evidence of provider adherence at the end of the pilot study.

The physician participants were given the following resources on the back of their protocol reference cards: the phone number to the closest emergency department, local psychiatric services, and the Comprehensive Care Center. We also was provided a list of Wal-Mart $4 prescriptions as an aid for participating physicians when determining medical therapy of select patients.

Evaluation methods:

Evaluation of provider adherence with the screening and treatment protocol was conducted by a chart review at the end of the 14-week pilot study. This was performed via use of the electronic medical record. The patients were identified by a list generated by the cardiology billing coder. This list included patients who have a documented Implantable Cardioverter Defibrillator (ICD-9 billing code V45.02) and who were seen in the clinic during the time period of the study. This list contained the medical record numbers of applicable patients. This list was kept confidential. Patients were de-identified by numbering system (pt.#1, 2, 3…) for data analysis purposes. The data extracted from the medical record included: physician documentation of depression screening, depression screening score, and physician documentation of appropriate treatment or follow up based on the protocol. These treatments or follow-up included: recommended follow-up depression screening, recommendation for counseling, pharmacotherapy, psychotherapy, and expedited mental health referral. Please see Appendix A: Section 4 for an example of the data collection instrument used for verifying provider adherence.

An anonymous pre/post test survey was created and given prior to protocol implementation and administered to the participating physicians at the end of the pilot study. This survey assessed physician knowledge of depression in the ICD population as well as current screening practices before and after participation in the protocol. The survey was collected anonymously. No names of participating physicians were associated

with any specific surveys and results were evaluated as a group versus individual analysis. See appendix A: section 1 for an example of the pre/post survey given to participating physicians.

A process evaluation survey about the use of the screening protocol and the ease of use for physicians in the clinical setting was given to participating physicians midway through the pilot study and as well as at the end. This evaluation is provided in the Tool Kit for Promoting Evidence-Based Practice (Titler, 2002). This process evaluation will help guide future implementation of the protocol. See appendix A: section 5 for an example of the process evaluation survey.

Analysis:

Data was analyzed using IBM SPSS software version 21 (IBM SPSS, Armonk, NY). Frequency data was collected to evaluate the impact of the intervention on participating providers scores on the 11-item pre/post test survey of knowledge of depression in ICDs and current practices. See Appendix A: section 1 for an example of the survey. Items from the pre/post test that involved knowledge of depression in the ICD population, current depression screening practices, and perceived barriers to systematic depression screening were analyzed by percentages pre and post intervention.

Frequency data was used to evaluate the level of adherence to the depressions screening protocol based on the following categories: documentation of screening, screening score, follow-up depression screening recommended, recommendation for

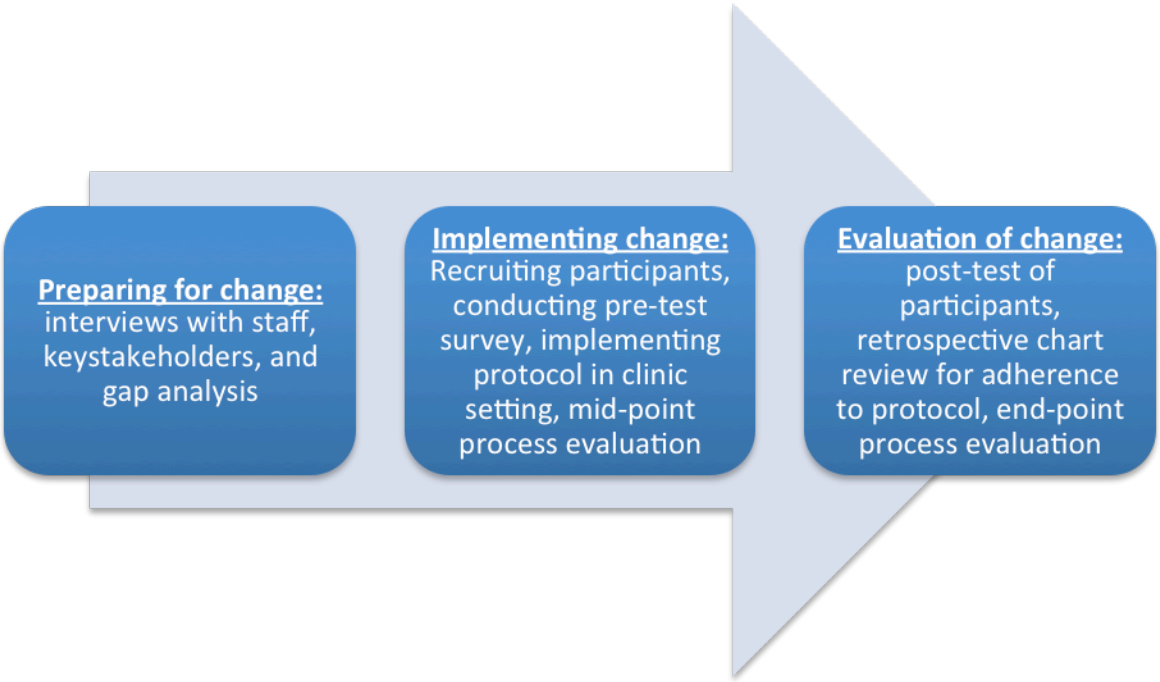
counseling, pharmacotherapy prescribed, psychotherapy referral, and expedited referral to mental health specialist. See Appendix A: section 4 for data collection categories.

The results of the process evaluation monitor are analyzed by mean score of both the midpoint and endpoint surveys. Results of this survey provided information on how the participants perceived the implementation process.

Results

This quality improvement project took place in a small cardiology clinic setting. The participants of the study included 18 physicians who conducted a general cardiology clinic on Mondays and Wednesdays from 1pm-5pm. The physicians rotated turns in the clinic with 3-4 participants in the clinic during specified clinic times. A member of the cardiology faculty at the local university oversaw physician participants during clinic times. This faculty member was not a participant in the study but provided support to the primary investigator and participants during the pilot period. Support from the cardiology department was maintained throughout the pilot study.

This process improvement study was guided by the Toolkit for Promoting Evidence-Based Practice (Titler, 2002). The following diagram shows the progression of the intervention.



Support for this implementation was consistent throughout the pilot phase. Physician participants continually provided positive feedback and expressed ongoing adherence to the protocol. However, throughout the implementation it became clear that physician participants were not able to use the screening protocol as often as had been expected due to low volume of ICD patients being seen in the clinic. This was reported to us as "abnormal" by the clinic staff and participating physicians. A study extension was obtained in order to compensate for the low volume of ICD patients being seen. Despite low number of opportunities to use the screening protocol, participants remained committed to the process and when asked, produced their laminated protocol cards during random visits to the clinic setting.

The pre/post test survey results:

(Table 1)

Pre/post test survey result by Individual question:	**Pre-test responses: (n=18)**		**Post-test responses: (n=14)**	
	Agreed	**Neutral or Disagreed**	**Agreed**	**Neutral or Disagreed**
Untreated depression is a problem in ICD patient population.	16.67 strongly agree, 44.44% agree	33.33% neither agree/disagree, 5.56% disagree	42.86% strongly agreed, 42.86% agreed	14.29% neither agree/disagree
Untreated depression negatively impacts overall health.	33.33% strongly agree, 55.56% agree	11.11% neither agree/disagree	50% strongly agree, 50% agree	
Untreated depression negatively impact medical compliance.	22.22% strongly agree, 62.11% agree	16.67 neither agree/disagree	42.86% strongly agree, 57.14% agree	
After assessing an ICD patient, can you tell if they are depressed?	94.44% sometimes	5.56% no never	14.29% always, 85.71% sometimes	
To determine depression in the ICD patient, participants use:				
Sad Face/Demeanor	83.33% agreed	16.67% disagreed	71.43% agreed	28.57% disagreed
Negative comments made by patient to determine depression.	71.22% agreed	27.78% disagreed	85.71% agreed	14.29% disagreed
Report from spouse/caretaker to determine depression.	83.33% agreed	16.67% disagreed	85.71% agreed	14.29% disagreed
Other indicator	5.56% agreed	94.44% disagreed	14.29% agreed	85.71% disagreed
Out of 10 ICD patient encounters, how many times do you formally screen for depression using a standardized instrument?	88.89% - 0/10 5.56% - 1/10 5.56% - 8/10		7.14% - 0/10 14.29% - 1/10 7.14% - 2/10 21.43% - 5/10 14.29% - 7/10 14.29% 8/10 21.43% 10/10	
When formally screening patients for depression participants use:				
PHQ-9	5.56% agreed	94.44% disagreed	64.29% agreed	35.71% disagreed
Beck	0% agreed		14.29% agreed	85.71% disagreed
HADS-A/D	0% agreed		7.14% agreed	92.86% disagreed
Other standardized instrument	5.56% agreed	94.44% disagreed	7.14% agreed	92.86% disagreed

Do not use a formal screening instrument	88.9% agreed	11.11% disagreed	35.71% agreed	64.29% disagreed
Participants manage depression in ICD by:				
"wait and see" approach	5.56% agreed		0% agreed	
Manage personally with medication	44.44% agreed		57.14% agreed	
Refer for management	50% agreed		42.86% agreed	
If a simple depression screening protocol were readily available, would you be more likely to diagnose/manage?	88.24% agreed	11.76% disagreed	92.86% agreed	7.14% disagreed
Knowledge base:				
Up to 46% of ICD recipients report depression (true)	100% agreed		100% agreed	
Negative psychosocial response to ICD therapy is NOT associated with poor outcomes. (False)	100% disagreed		100% disagreed	
Patients who have and ICD for primary prevention have a greater understanding of their disease and prognosis than patients who have received an ICD due to cardiac arrest or sustained arrhythmia. (False)	100% disagreed		14.29% agreed	85.71% disagreed
Up to 45% of ICD patient with emotional distress do not receive treatment. (True)	94.44% agreed	5.56% disagreed	100% agreed	
AHA recommends use of an organized screening instrument to evaluate ICD patients for emotional distress. (True)	88.24% agreed	11.76% disagreed	100% agreed	
Depression screening during office visits benefits ICD patients. (True)	100% agreed		100% agreed	
Barriers identified by providers regarding properly screening ICD patients for depression.	Lack of access to screening instruments, lack of time, do not keep up with depression guidelines, prefer not to manage depression, lack of ability to monitor treatment and improvement in symptoms		Time constraints, lack of time, lack of time and too many things to remember, time constraints and out of scope of practice	

There were a total of 18 participants who completed the pretest survey and only 14 who completed the posttest. The 4 study participants who did not complete the

posttest were no different demographically from the study sample; however, they were unable to be contacted for post testing. The results of the pre and post survey show an increase of knowledge and screening practices by the study participants after the protocol implementation. The posttest results show that there was an over all increase in formal screening by participants. At the time of the pre test, only 11% said they formally screened patients compared to 64% posttest. The posttest results showed that 93% of participants used a formal depression screening instrument at least 1-10/10 encounters as compared to 89% who stated they used a formal instrument 0/10 at the time of the pretest. Pre and posttest results both show that participants are willing to diagnose and manage depression in this population if a simple depression screening protocol were readily available (88% agreed pre/ 93% agreed post). Pretest data revealed that 41% of participant answered the knowledge base series of questions correctly prior to protocol implementation as compared to 57% who answered correctly post implementation. According the pre/post data over all knowledge and screening practices improved by the end of the pilot study.

Retrospective chart review results:

To determine adherence to the depression screening protocol, a chart review was conducted. Charts of ICD patients seen in this cardiology clinic during the 14-week pilot study were audited by billing code for ICD to determine the efficacy of the protocol implementation. See Appendix A: Section 4 for an example of the adherence data collection form. Only 4 charts were found to contain the billing code for ICD during the

14-week pilot period. This was significantly less than expected based on reports by the participants. This low number of charts audited may have been a result of few ICD patient encounters as well as improperly billed clinic visits. Of the 4 charts audited, 2 contained documentation of screening. This documentation also contained course of action by provider, which was in adherence to the screening instrument. See table 2 for data collection. According to the data collected there was a 50% adherence rate with the protocol, however, the accuracy of the billing process remains questionable. Since the protocol relied upon use of the appropriate billing code for ICD to capture patients who were eligible for screening by participants, it is impossible to determine the efficacy of the screening protocol in regards to participant adherence.

Chart review Results:

(Table 2)

Patient Number (1,2,3…)	Doc. Of Screening (1-yes, 2-No)	Screening Score From Doc. (actual score)	Follow up depression screening recommended by provider (1-yes, 2-No)	Recs. for counseling by provider (1-yes, 2-no)	RX prescribed By provider (1-yes, 2-No)	Psych. Therapy Referral (1-yes, 2-no)	Expedited Referral to mental health (1-yes, 2-no)	Right treatment Based on PHQ-9 score (1-yes, 2-no)
1	2							
2	2							
3	1	0	2	2	2	2	2	1
4	1	11	2	2	1	2	2	1

Process evaluation results:

A process evaluation, adapted from the IOWA model of evidence based practice implementation, was used to evaluate the preparation and satisfaction of participants (Titler, 2002). This evaluation was given to the study sample mid-way through the pilot period and again at the end. See Appendix A. Section 5 for an example of the survey. Based on a likert scale, a score was given to each survey, which ranged from 9-36. The higher the score, the more prepared and satisfied the participants were with the process. A total of 10 participants completed the process evaluation at the mid-point with a mean score of 30.7. A total of 13 participants completed the process evaluation at the end-point with a mean score of 29.8. Participants clearly had the same perceptions of preparedness and satisfaction with the process at the mid and end point of the pilot period.

Discussion

In accordance with the AHA scientific statement released in 2012, this quality improvement project attempted to implement a structured depression screening protocol specific to the ICD patient. The AHA scientific statement does not specify which screening instrument is optimal for this population, however, further research was recommended (Dunbar et al., 2012). The PHQ-9 was determined to be a reasonable choice for this population based on extrapolation from literature regarding depression in the heart failure population. Implementation of the protocol was widely supported by the division of cardiology at a local university and satellite clinic. Initial participation was 100% by all 18 cardiologist selected for this study. Although willing, participants were

unfortunately afforded few opportunities to enforce the protocol due to lack of ICD patients being seen in the clinic during the pilot period. In addition, proper billing code use is also questionable based on the unexpectedly few charts available for audit after the 14-week pilot study. Posttest participation included only 14 of the original participants. It is unclear why 4 participants failed to complete the study; however, vacations and other obligations may have played a role. Despite these challenges, pre and posttest data suggests that there was an improvement in participant knowledge and screening practices within this patient population. It is important to note that participating physicians have duties outside of this clinic setting and potentially have incorporated screening practices from this protocol in other patient encounters. This would explain why pre/post data suggests high adherence to the protocol.

Limitations:

The limitations of this study include small sample of participating physicians. This quality improvement project was created to be a small pilot study conducted by only one primary investigator, however, implementation results may be different if conducted with a larger group of providers. Length of pilot period was also a limitation. Implementation of this protocol over a longer length of time may have improved adherence and attitudes among the culture of the clinic. Opportunities for participants to use the protocol were few. Unfortunately the cardiology clinic saw an unusually low number of patients with ICDs during the pilot phase. The protocol usage and adherence may have been more successful if conducted in a cardiology clinic dedicated to heart

failure or electro-physiology. Reliance on proper billing coding for capturing adherence data collection proved to be a strong limitation of this study. Perhaps incorporating other billing codes into the protocol may improve data collection. Also, introducing billing prompts for providers in the electronic medical record may also be helpful for future implementation of the protocol. Moreover, implementation of this protocol may be better suited for settings in which ICD patients are seen regularly.

Conclusions:

This quality improvement project attempted to provide evidence to support the AHA scientific statement released in 2012 (Dunbar et al.). In doing so, a standardized depression screening protocol using the PHQ-9 was implemented in a small cardiology clinic setting. Despite few opportunities to use the screening instrument, the objectives of this quality improvement project were met. An evidence-based protocol was created and implemented. Knowledge and screening practices of participants were evaluated pre and post implementation, and efficacy of the implementation was evaluated. Knowledge and screening practices of participants improved based on the pre/post test after the protocol implementation; however, it is unclear if the protocol implementation was effective in the clinic setting due to low number of ICD patients seen in clinic as well as possible inaccurate billing. Again, it is important to note that participating physicians may have incorporated the protocol into practice outside of the study clinic setting, and thus shown and improvement in knowledge and practice on the pre/post test that was not able to be verified via the chart review methods of this study. Perceived barriers to implementation

of screening practices by participants included lack of time and ability to monitor patient outcomes. Further research on ways of improving these barriers may be beneficial. This protocol may serve as a model for future depression screening implementation in multi-disciplinary setting.

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Conclusion to Final DNP Capstone Report

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In conclusion I would like to once again emphasize the importance of addressing depression in the heart failure and ICD population. Manuscript one focused on the body of knowledge regarding depression screening instruments used in heart failure patients. From this review, an evidence based depression screening protocol was created for use in the ICD population. Manuscript two reviewed current legislation that may improve the quality of life for patients with heart failure and other chronic illnesses. Manuscript three evaluated the evidenced based depression screening protocol implementation in a UKMC cardiology clinic. More research is necessary to determine the best method of changing practice and improving outcomes for heart failure and ICD patient populations.

Appendix A:

1. **Pre/Post Test**
2. **Screening instrument for use by providers**
3. **Recommended treatment/follow-up and documentation statements**
4. **Process evaluation instrument**

1. Pre/Post Test:

To start a few questions about you and your practice.

1. What is your current position? *Circle one.*

   1. UK Gill Heart Cardiology Fellow 2. Other *(specify)* _____

2. How strongly do you agree or disagree with each of the following:	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Untreated depression:					
a. Is a problem in the ICD patient population?	1	2	3	4	5
b. Negatively impacts the overall health of individual ICD patients?	1	2	3	4	5
c. Negatively impacts medical compliance of individual patients?	1	2	3	4	5

3. After you are done assessing an ICD patient, can you tell if they are depressed?

   1. Yes, always 2. Sometimes 3. No, never

4. Which of the following indicators do you use to determine if an ICD patient is depressed? *Circle all that apply.*

   a. Sad face and demeanor
   b. Negative comments
   c. Report from spouse or caretaker
   d. None of these
   e. Other *(specify)* _____

5. Out of every 10 times you see an individual ICD patient, how many times do you **formally** screen (using a standardized instrument) for depression? If every time/visit with a patient, enter 10, if never, enter 0.

   /__/___/ Times out of 10 visits formally screen for depression

6. Which of the following standardized instruments do you use? *If never formally screen, circle item "e".*

   a. PHQ-9
   b. Beck
   d. Other *(specify)* _____
   e. Don't use formal screening instrument

c. HADS-A/D

7. How do you manage depression in your ICD patients? *Circle one.*

1. Use a "wait and see" approach
2. Manage it myself with medications
3. Refer for management
4. Other *(specify)* _____

8. If a simple depression screening protocol were readily available to you, would you be more likely to diagnose and manage depression in your ICD patients?

0. No
1. Yes

9. In general, what percentage of ICD recipients have anxiety? Your best guess is fine. *Circle one.*

1. 5%
2. 20%
3. 40%
4. 85%
5. Other *(specify)* _____%

10. Please indicate whether the following statements are true or false. Your best guess is fine.

		True	False
a.	Up to 46% of ICD recipients report depression	1	0
b.	Negative psychological response to ICD therapy is NOT associated with life-threatening outcomes	1	0
c.	Patients who have received an ICD for primary prevention have a great understanding of their disease and prognosis than patients who have received an ICD due to cardiac arrest or sustained arrhythmia	1	0
d.	Up to 45% of ICD patients with emotional distress receive no treatment	1	0
e.	The AHA recommends that providers (Electro physiologists, Cardiologists, Nurses, and Primary Care Providers) use an organized screening instrument to evaluate ICD patients during follow-up for evidence of emotional stress	1	0
f.	Screening for depression during office visits can benefit the ICD patient	1	0

11. Please use the space below to enter any barriers you face in your practice when deciding whether or not to screen ICD patients for depression. For example, lack of time, lack of access to screening instruments, your patients don't require screening, etc.

2. PHQ-9 Assessment Instrument:

FOR PHYSICIAN USE:

Step 1: Does the patient have an Implantable Cardioverter Defibrillator? Yes – continue questionnaire, No- STOP NOW.

Step 2: PHQ-9

Over the last 2 weeks, how often have you been bothered by any of the following problems?				
	Not at all	Several days	More than half the days	Nearly every day
Little interest in or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3
Trouble falling or staying asleep, or sleeping too much	0	1	2	3
Feeling tired or having little energy	0	1	2	3
Poor appetite or overeating	0	1	2	3
Feeling bad about yourself – or that you are a failure or have let yourself or family down	0	1	2	3
Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
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 a lot more than usual	0	1	2	3
Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3
Add up columns:				

Total Score:

*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___

3. Recommended treatment/follow-up and documentation statements:

Interpretation of Total Score:

- **Add up totals from each column of the instrument and combine together for a total score**
- **Shaded areas are considered positive symptoms. Refer to PI for PHQ-9 Manual**

PHQ-9 Scores and Proposed Treatment Actions * PHQ-9 Score	**Depression Severity**	**Proposed Treatment Actions**
0 – 4	None-minimal	None
5 – 9	Mild	Watchful waiting; repeat PHQ-9 at follow-up
10 – 14	Moderate	Treatment plan, considering counseling, follow-up and/or pharmacotherapy
15 – 19	Moderately Severe	Active treatment with pharmacotherapy and/or psychotherapy
20 – 27	Severe	Immediate initiation of pharmacotherapy and, if severe impairment or poor response to therapy, expedited referral to a mental health specialist for psychotherapy and/or collaborative management

(Kroenke, 2002)

PLEASE DOCUMENT THE FOLLOWING STATEMENTS IN THE CLINIC NOTE:

POSITIVE SCREEN: "The patient was screened for depression via the PHQ-9 and was found to have (mild, moderate, moderately severe or severe) depression with a score of..."

NEGATIVE SCREEN: "The patient was screened for depression via the PHQ-9 and was not found to have any depressive symptoms at this time."

5. Process evaluation instrument:

Process Evaluation Monitor

- Adapted from the Toolkit for Promoting Evidence-Based Practice

Directions: Please circle the number that best communicates your perception about your use of the Depression Screening Protocol for ICD Patients.

	Strongly Disagree	**Disagree**	**Agree**	**Strongly Agree**
1. I feel knowledgeable to carry out the depression screening protocol.	1	2	3	4
2. Implementing the depression screening protocol enhances job satisfaction of the fellowship.	1	2	3	4
3. I feel supported in my efforts to implement the depression screening protocol.	1	2	3	4
4. I feel well prepared to carry out the depression screening protocol with the assistance from others.	1	2	3	4
5. I am able to identify factors that relate to depression in the ICD population.	1	2	3	4
6. I am able to identify and carry out the essential activities of the depression screening protocol and recommended interventions.	1	2	3	4
7. I had enough time to learn about the depression screening protocol before it was implemented.	1	2	3	4
8. We are managing depression in the ICD population better with the use of the protocol.	1	2	3	4
9. The protocol enables me to meet psychosocial needs of most ICD recipients.	1	2	3	4

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