# ADDRESSING BARRIERS TO MEDICATION ADHERENCE: AN EVIDENCE-BASED SCREENING INSTRUMENT VALIDATION STUDY

A Scholarly Project

Submitted to the

Faculty of Liberty University

In partial fulfillment of

The requirements for the degree

Of Doctor of Nursing Practice

By

Donna Jean Washburn

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Lynchburg, VA

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| Dr. Ken Thompson, PharmD | Date |

## ABSTRACT

Adherence to a prescribed medication regimen is often critical to successful disease management. Cancer diagnoses often further complicate control of the comorbid diseases. Older cancer patients with multiple comorbidities receiving chemotherapy treatment are at increased risk for adverse health outcomes from uncontrolled disease when nonadherent to their medication regimen. The intent of this pilot study was to test the validity of an evidence-based screening instrument designed to identify patients at risk for medication nonadherence and uncontrolled illness. The W-BMA (Washburn-Barrier to Medication Adherence) screening criteria were applied to retrospective data of cancer patients with multiple co-morbidities. SPSS was used to analyze the data using classification trees to compare the W-BMA screen with the current screens used in the clinic alone. The W-BMA identified a significantly larger number of patients with barriers than the current screens alone. Barriers found by the W-BMA screening instrument are strongly related to uncontrolled illness, and, these barriers are often multi-layered, impacting adherence and the health of the patient. Incidentally, there was strong evidence that patients who have barriers addressed by oncology support services (nurse navigation and social work) often fare much better than patients who do not. The instrument studied in this pilot project requires additional analysis and refinement, however, there is strong evidence that proper use of the W-BMA screening instrument used as part of a comprehensive medication adherence program may improve adherence and lower risk of uncontrolled illness and adverse events.


*Keywords*: Adherence, medication, barriers, screening, cancer, comorbidities, instrument

## Dedication

This work is dedicated to my family. Family is a word that has developed new meaning for me over the years as our family has grown to include loved ones in every sense of the word. I love you and owe you all thanks for your understanding and encouragement during this long endeavor. An extra, special thank you to my husband Loren. I love you and there are simply no words to adequately express my gratitude for your support throughout all my educational adventures.

Philippians 1:3-6 “I thank my God upon every remembrance of you, Always in every prayer of mine for you all making request with joy, For your fellowship in the gospel from the first day until now; Being confident of this very thing, that he which hath begun a good work in you will perform it until the day of Jesus Christ…”

## Acknowledgments

"Behold, I will do a new thing; now it shall spring forth; shall ye not know it? I will even make a way in the wilderness, *and* rivers in the desert." Isaiah 43:19

First, I must acknowledge the Lord and His merciful, gracious hand in my life. Much has transpired since beginning this program and sometimes the goal was very distant and dimly lit. Yet He kept the path clear and provided for every need as I journeyed on. I would like to express my gratitude to the Doctor of Nursing faculty, Project Chair, and Staff of Liberty University, as well as my DNP mentors in the practicum settings for sharing their invaluable knowledge and experience along with prayer, help, and encouragement during this journey. What a privilege and blessing it has been to learn from you all. My grateful thanks are also extended to the administration, physicians, nurses, and staff of Centra's Alan B. Pearson Cancer Center for the extra support that was pivotal to the conduct of this research. Your genuine concern for, and dedication to, each of your patients touches my heart and I hope that this research will in some way help you as you constantly look for ways to improve the already meticulous, compassionate care you provide for our loved-ones, friends and neighbors with cancer. To all of my dear colleagues and friends at Centra, thank you for your understanding and support throughout my degree completion. Finally, an extra special thanks to my family and friends for patience during this long haul and to my DNP cohorts near and far who made this entire process extra meaningful.

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## List of Abbreviations

American Medical Association (AMA)

American Society of Clinical Oncology (ASCO)

Cardiovascular Disease (CVD)

Chronic Obstructive Pulmonary Disease (COPD)

Centers for Disease Control and Prevention (CDC)

Centers for Medicare and Medicaid Services (CMS)

Continuing Medical Education (CME)

Diabetes Mellitus Type 2 (DM-2)

Doctor of Nursing Practice (DNP)

Eastern Cooperative Oncology Group (ECOG)

Electronic Medical Records (EMR)

Hypertension (HTN)

Institutional Review Board (IRB)

Institute of Medicine (IOM)

National Comprehensive Cancer Network (NCCN)

Oncology Care Model (OCM)

Oncology Nursing Society (ONS)

Patient Health Questionnaire-9 (PHQ-9)

Statistical Package for the Social Sciences (SPSS)

The Joint Commission (TJC)

Washburn-Barriers to Medication Adherence (W-BMA)

World Health Organization (WHO)

## SECTION ONE: INTRODUCTION

Adherence to a prescribed medication regimen is often critical to successful disease management. Non-communicable disease is expected to exceed 65% of the global burden of disease in 2020; however, 50% to 60% of patients are nonadherent to their prescribed treatment regimen (Lam & Fresco, 2015). Mental illness, diabetes mellitus type 2 (DM-2), cardiovascular disease (CVD), and/or chronic obstructive pulmonary disease (COPD) are common comorbid diseases seen with a primary diagnosis of cancer. Cancer diagnoses often further complicate control of the comorbid diseases, due to the often-overwhelming nature of cancer and its treatment on the patient and caregivers. Older cancer patients with multiple comorbidities receiving chemotherapy treatment are at increased risk for adverse health outcomes from uncontrolled disease when nonadherent to their medication regimen (Sarfati, Koczwara, & Jackson, 2016).

The intent of this pilot study was to test the validity of an evidence-based screening instrument designed to identify patients at risk for medication nonadherence and uncontrolled illness. The goal was to compare the number of patients identified at risk with this instrument with those identified by current screening methods for depression and distress alone, and to assess the sensitivity of both methods. The Washburn-Barriers to Medication Adhere (W-BMA) requires more time and attention than the current depression and distress screens. If an equivocal number of patients can be initially identified without this instrument, there is no need to use it as an initial screening method. Instead, patients could simply be identified by their high depression or distress screening scores and then further evaluated at another time by the instrument being studied. So, this author felt it was important to compare results of the W-BMA screen to the current screening methods alone to ensure that it is a more reliable and sensitive instrument. The

W-BMA screening criteria were applied to retrospective data of cancer patients with multiple comorbidities. Addressing barriers to adherence can be complex and time-consuming for healthcare providers, depending on the type, number, and extent of barriers present. Healthcare providers around the country may not always have the needed evidence-based instruments and support to address these barriers. The literature analyzed for this project contains clear evidence that there are numerous barriers that are proven to impede adherence. Nonadherence that goes unidentified, and is not adequately addressed, subsequently increases risk of uncontrolled illness and adverse health outcomes to the patient (American Medical Association [AMA], 2018; Centers for Disease Control and Prevention [CDC], 2017a).

An avoidable, adverse health outcome is not only detrimental to the patient, it also infringes on the time and resources needed for ongoing scheduled patient care and reduces reimbursement needed to help for efficient operation of the medical clinic. It is of growing importance for healthcare providers and the healthcare system to be as successful as possible in treating disease and managing health. In addition, The Joint Commission (TJC) and Centers for Medicare and Medicaid Services (CMS) both expect healthcare providers to assess inpatient and outpatient adherence to medication regimens and act on issues with adherence if possible (CDC, 2017a; Cawthorn, Mion, Willens, Roumie, & Kripilani, 2014). A formal, evidence-based process to identify and address the most impactful barriers to medication adherence is needed to help improve outcomes, reduce healthcare costs, and meet the expectations of regulatory and accrediting agencies.

Healthcare providers and patients may benefit from development of an efficient and effective evidence-based process to (a) identify signs of the most common, impactful barriers to medication adherence; (b) identify applicable resources to address each of these barriers; and (c)

consistently connect the patients to these resources. There is first, though, a need to develop a valid instrument that will assist healthcare providers to identify the individuals that have increased risk of adverse events from nonadherence to prescribed treatments. An instrument that is valid will fulfill its intended purpose. This pilot study tested the validity of an evidence-based screening instrument designed to screen individuals for potential barriers that are likely to decrease adherence to their prescribed medication regimen.

**Background**

The World Health Organization's (WHO, 2003) definition of adherence is "the extent to which a person's behavior corresponds with agreed recommendations from a healthcare provider." This definition includes the initiation, continuation, and discontinuation of therapy as directed (Lam & Fresco, 2015; WHO, 2003). While working in the outpatient setting recently, over a nine-year period, this researcher detected multiple complexities to medication adherence. There are, in fact, as many as 42 significant specific barriers to medication adherence as detected in one extensive meta-analysis of research (Irwin & Johnson, 2015). These barriers make assisting patients with successful medication adherence very complex. In addition, it is very apparent that there is currently little resource and time allocation for in-depth assessment of barriers to successful home medication management in the typical clinical setting. This is by no means unusual as healthcare settings of all types are pressed to be as efficient as possible when providing patient care. Clinical staff are encumbered with many responsibilities with immediate impact on patient care, and very reluctant to add tasks to their already busy day. Current initiatives to address important patient safety metrics tend to be shadowed by priority tasks with more immediate consequences. With these impediments, it is also likely that many barriers remain undetected and unresolved.

In considering prevention of nonadherence, one might ask if there is any benefit to checking in with patients who are at lower risk of nonadherence to help keep them from becoming nonadherant. Referral to the cancer support team is not likely necessary for those who are already adhering to maintain adherence. According to Lafeuille et al (2016) a review of Medicaid claims included 12,990 patients with schizophrenia age 25 to 64 on at least one antipsychotic medication. Patients who showed adherence at baseline (regularly filled their prescription) continued to remain adherent, especially when maintained on one simple regimen and not switched (Lafeuille et al., 2016). It is more feasible and probably more impactful to target those with a higher likelihood of medication nonadherence.

**Impact of nonadherence.** A CMS (2017a) report of national health expenditures for 2015 states that 324.6 billion dollars (10.1% of total United States health expenditures [CDC, 2017b]) was spent in that year alone on prescription drugs in the United States. Unfortunately, only about one quarter of medications are taken as prescribed (AMA, 2018; CDC, 2017a; Lam & Fresco, 2015). Various sources estimate that 50% to 70% of prescriptions make it to the pharmacy, 48% to 66% come out of a pharmacy, 25% to 30% are taken properly, and only 15% to 20% are refilled as prescribed (AMA, 2018; CDC, 2017a; Million Hearts, 2017). Patients who are Medicare/Medicaid eligible with three or more comorbidities and receiving chemotherapy are especially vulnerable to the consequences of nonadherence. Mental health and non-communicable disease are expected to exceed 65% of the global burden of disease in 2020; however, 50% to 60% of patients (especially those with chronic diseases) are nonadherant to the medicine prescribed (Lam & Fresco, 2015).

Comorbidities in cancer patients account for inferior survival rates (especially in adults diagnosed at an early age), poorer quality of life, and an increase in the cost of healthcare costs

compared to patients without comorbidities (Sarfati et al., 2016). CMS is taking special note of comorbidities previously not addressed during chart audits of its beneficiaries and TJC inspections of accredited organizations. One example is a new measure for diabetes that providers will be held accountable for and specifically examines adherence. One new measure is NQF 2468: Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus. CMS will look at databases of individuals prescribed at least two oral diabetes agents in 12 months. Specifically, they will look at adherence to the oral diabetes medications by checking if prescriptions are filled. In addition, this measure is paired with two additional measures to check adherence to statins and ACEIs and ARBs for individuals with diabetes (CMS, 2017).

**Complexity of assessing barriers to adherence.** There is great complexity in the concept of addressing barriers to adherence in an efficient and effective manner in a busy healthcare setting. Barriers may be numerous and intertwined in such a way that addressing a single barrier does not improve adherence. Many published efforts to address barriers to adherence discuss a single focus, such as literacy or reducing cost. At the University of Pennsylvania and Pennsylvania Presbyterian hospitals, 1,084 adult patients were surveyed to discover the issues they felt caused their readmission. The most common reasons included feeling unprepared for discharge, trouble with accessing medications, and lack of social support. Low socioeconomic status (Medicaid or uninsured) were more likely to report difficulty understanding and executing discharge instructions and adhering to medication regimens (Kangovi et al., 2012). In these examples, there may be many co-existing barriers that require alleviating to ensure successful medication adherence.

Complications to addressing adherence arise from the patients and the providers. A study by Flink & Ekstedt (2016) in Sweden examined the use of an education instrument that they hoped

would be used by nursing staff to improve discharge teaching and medication compliance. Information was given at discharge; however, the level of education provided was primarily driven by the needs of the staff, as opposed to the patient's level of understanding. Although the aim of the study was to see if the new instrument and process would improve adherence, it proved to have no impact due to the time limitations of the nurses (Flink & Ekstedt, 2016). It is very important to consider the feasibility of a process, as well as the culture of the setting, when implementing a new practice. A multidisciplinary task force created an inpatient COPD pathway (Brewer et al, 2016) which included standardized medication orders. Respiratory Therapists were trained to follow the program which included discharge teaching and patient materials. The Respiratory Therapists found that the primary medical team was unwilling to order specialty service consults. The therapists also found that patients felt the reason they were readmitted is that they felt they had been discharged too early on the previous admission. More data was required to evaluate the effectiveness of their intervention.Similar experiences are common in the local healthcare facilities as well, so any process implemented must be feasible and accepted by those who are crucial to its implementation. Assessing if an intervention is feasible and acceptable also requires examination of the available resources. An additional pharmacist-driven study evaluated the impact of providing medications immediately upon discharge to patients admitted to a psychiatric unit and found that this improved adherence to the treatment regimen (Tomko et al., 2013). This type of intervention is only feasible when a dispensing pharmacy is readily available.

Balling, Erstad, & Weibel (2015) report that the impact of pharmacist provided education at patient discharge reduced readmission rates. In addition to 1,011 patients involved in the study, 452 interventions were required by the pharmacist to intercept issues with the discharge

medication list. Barriers to adherence can start in the clinic or hospital setting due to medication reconciliation discrepancies (Balling, Erstad, & Weibel, 2015). Additionally, phone calls from pharmacists have been shown to reduce rates of rehospitalizations of cancer patients when the patients' adherence was assessed, questions answered, and any discrepancies addressed within 30 days of discharge (Patel, Nguyen, Bachler, & Atkinson, 2017). Again, although these were effective interventions, it is not feasible if it cannot be sustained. Pharmacy personnel in the healthcare setting are rarely available for consistently making follow up phone calls, or performing medication reconciliations.

To summarize the discussion of complexity, the feasibility of creating a new screening instrument may be questioned due to the existence of current instruments that can be used to assess medication adherence. One such questionnaire is called the 8-item Morisky Medication Adherence Scale, which is a validated instrument used to assess patients' medication taking behavior and barriers to adherence. It is considered a highly reliable instrument in patients with chronic diseases (Lam & Fresco, 2015). The scale is a patient questionnaire addressing forgetfulness, or choosing not to take a medication; however, it does not screen for some additional common impactful barriers such as financial constraints and educational barriers. It also relies on the patient to provide thoughtful, honest answers. This may also prove to be complex. To effectively impact adherence and reduce risk of uncontrolled illness with resulting adverse medical events, the complexities of this problem must be addressed. Clinic staff must have the time, support, and motivation to use a process consistently and as it is intended, for it to have the best impact on outcomes.

**Current efforts to address barriers to adherence.** The retrospective data used in this evidence-based research study was from records of patients treated at a local outpatient oncology

clinic. The clinic is one of a few hundred in the nation to achieve recognition for their quality care of oncology patients. Current quality assessments collected by the American Society of Clinical Oncology's (ASCO, 2016) Quality Oncology Practice Initiative report instrument indicate that medication follow up falls somewhat below standards in many outpatient institutions. CMS (2018) tracks outpatient quality measures, and according to their website, they plan to begin focusing on patients receiving outpatient chemotherapy. The local oncology clinic was involved in a pilot CMS program called the Oncology Care Model (CMS, n.d.). The Oncology Clinic in which this project was completed is one of 191 current practices taking part in the model. Patients who have had cancer treatment within 6 months and are eligible for Medicare benefits are enrolled in the oncology care model (OCM) cohort at the Hematology Oncology Clinic. The CMS expects OCM patients to receive enhanced services including care coordination and improved care plans to help prevent emergency room visits and hospitalization from the start of chemotherapy and for 6 months following a dose of chemotherapy. Barriers to medication adherence may result in unnecessary emergency room visits and/or hospitalization. There are many cancer care support system resources available, including navigators, social workers, care coordinators, and others who are in a unique position to assist the patients. However, like the vast numbers of care providers in the nation, they may not always have awareness of some of the most impactful needs of the patient. The intent of this pilot study was to test the validity of an evidence-based screening instrument intended to aid in identification of the most impactful barriers that decrease adherence to prescribed medications. It is hoped that reporting of this project creates awareness and an impetus for healthcare providers to screen for barriers and partner with other professionals in healthcare and community resources to find solutions to one of the most challenging patient care issues, medication adherence.

**Implications for practice.** Comorbidities in cancer patients account for inferior survival rates (especially in adults diagnosed at an early age), poorer quality of life, and an increase in the cost of healthcare costs compared to patients without comorbidities (Sarfati et al., 2016). When adding the consequences of nonadherence to the prescribed treatment regimen, the impact can be devastating. Mausbach, Scwab, and Irwin (2015) and Sarfati et al. (2016) stated that nurses can improve evidence-based practice guidelines for patients with comorbidities. This includes guidelines to both identify and address barriers to medication adherence. In such, nurses at all levels of practice can make a direct impact on mortality, cost of care, and quality of life (American Association of Colleges of Nurses, 2006). The healthcare system both locally, and as a whole, is impacted financially by medication nonadherence due to unplanned office visits, emergency department visits, or hospitalizations (CMS, 2017a, 2017b). One or more factors may comprise the barriers to adherence for a patient. These barriers may be intentional or unintentional, intertwined or independent, and might include financial, psychological, educational, medical, and behavioral components (AMA, 2018; Irwin & Johnson, 2015; ONS, 2016). Healthcare providers desire to understand how best to treat an individual's medical condition and deliver the best quality of care possible, while also working with healthcare administration to provide this care as efficiently as possible. Understanding what barriers exist for each patient that may prevent them from adhering to a prescribed treatment regimen is necessary for tailoring a treatment plan. There must also be a connection made to the resources that are available in answer to those barriers.

## Problem Statement

Oncology healthcare providers and cancer care support staff currently lack a formal evidence-based process to assess for the most common, impactful barriers to successful

medication adherence. Medication non-adherence is especially impactful in older cancer patients who have had cancer treatments. Individuals with warning signs of barriers to adherence may benefit from a referral to a member of the cancer care services support team, such as a navigator. Navigators and other support team personnel are currently available, and work with patients at various stages in their cancer journey. However, there currently is no instrument for providers to use for identification of the most common impactful barriers to care. Neither is there a consistent, formal process to help connect these individuals to locally available, applicable resources. A valid, evidence-based instrument to identify and address the most impactful barriers to medication adherence may help improve outcomes, reduce healthcare costs, and help meet the expectations of regulatory and accrediting agencies. Local healthcare providers do not currently have a valid, efficient evidence-based process to (a) identify warning signs of the most common, impactful barriers to medication adherence; (b) identify the applicable resources for each of these barriers; and, (c) consistently connect the patients to available resources. Due to the complexities of these steps, research must begin with a focus on the initial step of correctly identifying the population at risk. This is a pilot study to test the validity of an evidence-based screening instrument that identifies the most common, impactful barriers to medication adherence.

**Purpose of the Project**

The purpose of this study was to test the validity of an evidence-based instrument to screen for the most common, impactful barriers to medication adherence and evaluate if it was a more sensitive indicator of risk than the current screening methods alone. This instrument was tested on retrospective data of high-risk oncology patients. The pilot study evaluated the validity of the instrument, to see if it accurately identified CMS beneficiary cancer patients who had barriers to medication adherence and as a result, were more likely to have uncontrolled illness.

Patients who have some obvious warning signs of medication nonadherence, who are at high risk for emergency room use and hospitalization are currently referred, on occasion, to navigators for coordination of resource access and referral. It is hypothesized from information abstracted from the literature review in this project, that increasing intervention efforts to eliminate certain barriers to medication adherence will subsequently improve disease control, thus lowering the potential risk of emergency room use and hospitalization. Currently, the only warning sign to barriers for which referrals are consistently made, via use of validated instruments, is depression and distress. While depression is a significant barrier, and distress may result in adherence issues as well, they are not the only significant barriers found in literature. Oncology patients are also initially referred to a financial counselor to discuss costs specific to their cancer treatment; however, additional financial assistance may be needed further into the treatment period. Unless the patient reaches out for assistance, this barrier may go undetected. Additional barriers identified in the literature will benefit from intervention to help ensure that cancer patients remain as healthy as possible during their cancer treatments and recovery.

The reliability of the test was evaluated as well. Specificity was tested by analyzing the instrument's ability to identify, not only an increased number of patients at risk compared to informal referrals, but also whether or not the patients identified also have an increased percentage of uncontrolled illness, so as to minimize false identification of patients who are not at increased risk. For the instrument to be beneficial, it must not only correctly identify high-risk individuals, it must also not falsely identify an unacceptable number of individuals who are not truly at risk. This would make screening an unwieldy task that is too burdensome for the healthcare system. There may need to be some alterations made to the instrument, and additional future testing to ensure this is a useful instrument. The goal is to eventually introduce the

assessment instrument into practice and increase referrals to navigators who then can coordinate resources to assist patients with treatment adherence.

### Clinical Question

In a one-year retrospective review of CMS eligible outpatient records, does the use of a new evidence-based screening instrument developed from literature, compared to current screening methods alone, increase identification of patients with barriers to medication adherence?

## SECTION TWO: LITERATURE REVIEW

### Search Strategy

A search of CINAHL Plus with Full Text, Cochrane Library, JAMA, Journals@Ovid, MEDLINE, MEDLINE with Full-Text (EBSCO), Nursing and Allied Health, and ProQuest was completed. The keywords and Phrases used for the search included *readmission, rehospitalizations, cancer, oncology, diabetes type 2, depression, behavior, comorbidities, medication(s), adherence, nonadherence, compliance, noncompliance, barriers, obstacles, challenges, difficulties, issues, stigma, predictors, predicting, causes, drug therapy, polypharmacy, prescriptions, providers, outcomes, quality of life, algorithm, toolkit, questionnaire, assessment, instrument.* Parameters of the search were journal articles published, peer-reviewed, written in English with a focus on studies completed in the United States within five years. Literature generally up to seven years were included if data used was not primarily older than ten years. Additional searches were completed in the Liberty University Special Collections database and on the websites of the Centers for Disease Control, Centers for Medicare and Medicaid Services, Hospital Compare (Hospital Compare, n.d.), Kaiser Family

Foundation, Oncology Nursing Society, American Medical Association, AHRQ, World Health Organization, and the Patient Engagement Health Information Technology website.

Bibliographies were searched in articles and presentations for primary sources when needed. Research articles, using data more than ten years old, were discarded as were articles with insufficient data or concerning limitations. Also discarded were studies that identified barriers, or interventions not supported by the preponderance of the literature. In some cases, such as research on the impact of financial burden, literacy, and education on nonadherence, there was such an overwhelming amount of evidence that only a limited number of articles on those topics was retained and included. Melnyk Levels of Evidence was used to analyze the literature used in this project and includes Levels 1 through 7 with Level 1 systematic reviews, meta-analysis, meta-analysis with triangulation, clinical guidelines based on systematic reviews, and meta-analysis were given the most credence when evaluating evidence for impact of barriers and interventions. In all, 990 articles were reviewed and saved to EndNote for retrieval, while an additional number of electronic databases and information retrieved from both paper and online journals and textbooks were not counted. Out of those 990 research articles, 29 research articles accompanied by 26 additional reliable sources of evidence were deemed to be applicable and sufficient for creation of an evidence-based instrument for identifying potential adherence barriers and increasing patient referrals to effective resources for adherence issues.

## Critical Appraisal of Literature

**Select resources used for instrument development.** In researching various possible resources to implement in the clinical setting, several helpful toolkits were analyzed. Each one has been proven to be effective in its own way and for the purpose for which it was developed. A universal precautions toolkit exists for addressing low literacy in the healthcare setting. This

article (Weiss et al., 2016) emphasizes and recommends brown bag reviews of medication, as opposed to review of electronic or printed medication lists, for accuracy of assessment to help avoid issues caused by low literacy.

Routine medication reviews are completed regularly in clinical practice; however, it can be difficult to get an accurate picture of adherence during a brief and usually verbal review of medications. The “Universal Precautions” toolkit helps address literacy issues in medication adherence (Weiss et al., 2016). In this research review, patients were encouraged to bring their medications to the office so that a visual inspection could be performed. Bringing the medications resulted in a doubling of the number of drug therapy problems identified, as well as a doubling of the percentage of medication regimens revised. The office currently utilizes this for all new patients, as well as any patients who may be having difficulty with their medications. Not all physicians require this of all patients at every visit as suggested in this study.

The Oncology Nursing Society (ONS, 2016) developed an oral adherence toolkit with several individual instruments that may help assess and improve adherence. ONS has provided a similar toolkit for several years; the most recent updated in 2016. There are 13 individual instruments within the toolkit that may be used for assessing adherence, identifying risk factors, guiding patient education, identifying reimbursement and financial assistance resources, identifying food, drug and pathway interactions, sample treatment tracking calendars, methods to motivate, encourage, reconcile, and track medication adherence. In addition, there is an instrument that can be used to track readiness to change. According to ONS, patients may be able to provide their own warning of potential nonadherence by acknowledging they are not ready to change which includes starting a new therapy. Lastly, there is a resource list for patients and providers to aid in finding drug and cancer information, along with teaching materials from some

of the most reliable resources on cancer and pharmaceuticals. The toolkit contains a list of 13 patient assistance and reimbursement resources for helping cancer patients afford their medications. This toolkit contains very useful ideas for helping oncology nurses assist patients in adhering to their medication regimens. As previously stated, it may be difficult for clinical nurses to have the time to devote to the measures suggested in this toolkit. However, the individual instruments are evidence-based methods of helping patients overcome barriers to adherence.

The AMA (2018) Stepsforward education material and toolkit provides an education with CME credit available to healthcare providers along with a toolkit and support to help address nonadherence issues in their practice. The AMA cites eight steps to addressing nonadherence: (1) consider nonadherence first as the reason a patient's condition is not under control because "patients do not take their medications half the time" (par. 1); (2) develop a process for routinely asking about medication adherence; (3) create a blame-free environment to discuss medications with the patient; (4) identify why the patient is not taking their medication (eight common reasons are cited including: fear, cost, misunderstanding, lack of symptoms, depression, too many medications, worry, and mistrust); (5) respond positively and thank the patient for sharing their behavior; (6) tailor the adherence solution to the individual patient; (7) involve the patient in developing their treatment plan; and, (8) set up patients for success. The online education module accompanying this toolkit has an excellent educational component that is very quick and interesting to complete. It is a great guide in helping physicians and other healthcare professionals in discussions with patients regarding adherence.

These toolkits provide helpful guidelines for addressing some of the barriers that exist to medication adherence. An important emphasis is that of having an open and trusting relationship with the patient, as well as time to have the discussion about possible barriers. These toolkits and

guidelines are helpful for a focused subset of barriers and encouraging discussion; however, a more comprehensive screening instrument accompanied by purposeful interventions organized by dedicated staff may be more impactful in today's very complex patients.

**Appraisal of literature for categorized barriers.** Following are five categories of major adherence barriers, listed in order of impact, found in the literature to be the most commonly reported, most potentially impactful, and most feasibly actionable, with the accompanying research and comments.

***Financial and social barriers.*** Cost can be a deterrent to filling prescriptions; patients do not fill their prescriptions about a quarter of the time, and do not take them about half of the time (AMA, 2018). Single marital status, lower income, and having more than 10 medications were significantly associated with not filling medications. Reasons included cost by 23.5% of patients. Additional reasons include lack of time to go to the pharmacy, medication not delivered or dispensed, and inability to afford the medications (Wooldridge, Schnipper, Goggins, Dittus, & Kripalani, 2016). Hanson, Habibi, Khamo, Abdou & Stubbings (2014) conducted a pharmacy study to examine whether connecting patients with a team to help address the prohibitive expense of multiple sclerosis drugs would improve adherence. It was in fact proven helpful, although the team concept involving advanced providers was an expensive concept that would be difficult to reproduce and sustain. The cancer center employs financial navigators, social workers, and nurse navigators who may provide a more sustainable coordination of care.

Three major factors predict whether a patient can afford medication: (a) insurance coverage, (b) overall health, and (c) income. In addition, individuals who make under $50,000 a year in income are more likely to skip doses or stop taking their medication than individuals with higher income (National Community Pharmacists Association [NCPA], 2013). In a *New York*

*Times* online journal article, Frakt (2017) cited systematic reviews and randomized control trials analyzing several methods to address adherence, such as electronic reminders, pill organizers, and electronic reminder and feedback systems. The author concluded that reduced price, or free medications, are the only consistent predictors that patients will take and refill medication as directed: “For those with certain chronic conditions, extra help in affording medications can reduce adverse events and hospitalizations” (Frakt, 2017).

One in five adults reported taking at least four prescription drugs with 55% taking at least one. About 35% of patients taking four or more prescription pills reported taking lower dosage or skipped doses (and, if uninsured did not fill the prescription) compared to 25% of those taking three or fewer. Income of $40,000 a year or less was another predictive factor of lowering, skipping, or not filling a prescription (Kaiser Family Foundation, 2017a). Roop and Wu (2014) conducted an online survey of 5,000 oncology nurses. Of those nurses, 577 nurses responded and 51% of the nurses worked in practices that had developed specific policies, procedures, and resources for patients taking oral therapy. One of the most frequently identified barriers to adherence was cost. Irwin and Johnson (2015) cited cost or lack of insurance coverage was mentioned 26% of the time, and social support was a reported factor of nonadherence 32% of the time in their meta-analysis of qualitative research with triangulation to quantitative studies. At the University of Pennsylvania and Pennsylvania Presbyterian hospitals, 1,084 adults were surveyed to discover the issues they felt caused their readmission. Among the most common reasons included low socioeconomic status (Medicaid or uninsured) driven barriers of obtaining and adhering to medication regimens (Kangovi et al., 2012).

Additional financial and social barriers include marital status and geography (where the patient lives in relationship to healthcare and pharmacy). Single marital status is a significant

predictor of nonadherence according to one study (Greer et al., 2016). Multimorbidity was present in 36% of patients in a study of over 4,000 patients in the Netherlands by Aarts et al., (2015). In this review, low socioeconomic status was associated with increased comorbidities (70% vs. 61%); cardio and cerebrovascular diseases negatively impacted survival. One-year survival rate was 22% without comorbidity and 13% with Multimorbidity (Aarts et al., 2015). Geography is a type of social barrier that can be a significant hindrance for patients who live in rural areas, especially without reliable internet service (Heath, 2017).

*Associated suggested warning signs.* Financial and social warning signs include: Uncontrolled illness; Unfilled prescriptions or refills; Pill bottle contains more pills than it should based on fill date; Weekly pill container contains unopened days/unused pills; Patient comments on cost of care or states “Trying to save money”; Self-reported absence of social support; and Difficulty “getting into town” to make appointments (AMA, 2018; CDC, 2017a; Greer et al., 2016; Heath, 2017).

*Associated examples of recommendations/resources/expert advice supported by literature.*

Associated examples of recommendations, resources and expert advice supported by literature include:

1. Consider lower cost medications (CDC, 2017a). Many methods of encouraging adherence may lack sufficient data to prove efficacy. However, providing free or low-cost drugs is a well-supported, effective intervention (Frakt, 2017).
2. Referral to oncology nurse navigator for coordination of interventions and care:

- The patient may choose not to spend money on medications for many reasons. However, if patient is eligible for assistance, explore whether patient knows about available resources and understands how to utilize these resources.
- If an employee, provide with the health network resource information through human resources providing free financial counseling services.
- Refer to oncology social worker and/or financial counselor. Often, these individuals will access pharmaceutical, pharmacy, and laboratories that often have patient assistance programs which many times can be located on their website or made available by calling their main contact numbers. Patient may also need assistance understanding Medicare/Medicaid benefits and services.
- ONS (2016) Oral Adherence Toolkit contains a list of thirteen reimbursement and patient assistance resources.
- Consider living situation and location, access to transportation, fuel, and availability of reliable internet and/or phone service before recommending services that require travel or internet-based interventions such as telehealth classes.
- Consider community health partnerships such as paramedic program to check on health and well-being as well as home environment safety check (Heath, 2017).
- There is not a one-size-fits-all method to encourage adherence, so it is important to tailor each individual's treatment plan to their needs to avoid waste. However, in all cases, efforts to lower cost of medication for patients results in better adherence according to the literature.

***Depression/distress/anxiety.*** In a meta-analysis by Mausbach et al. (2015), over 17,000 women were evaluated for association of depression and adherence to oral anticancer therapy.

Greater depression was in fact associated with lower adherence. This resulted in increased mortality, increased medical costs, and worsened quality of life. Patients who are depressed or anxious are less likely to take their medications (AMA, 2018). If a patient has a history of mental health disorders, such as depression, anxiety, or addiction, he or she is less likely to adhere to their medication regimen (Million Hearts, 2017).

Greer et al. (2016), in a systematic review of adherence to oral chemotherapy agents, reported that depression played a significant role in nonadherence, with some rates dropping to about 50% at the five-year follow up. Adjuvant endocrine therapy adherence was lower in women with depressive symptoms, especially in younger women just starting endocrine therapy. Individuals with depression have greater non-adherence than patients without depressive symptoms. In this study, women with lower adherence were also found to have a shorter time to recurrence of their cancer, increased medical costs and worsened quality of life (Bender et al, 2014; Mausbach et al., 2015). Long-term distress may be a predictor of non-adherence (Aikens, Trivedi, Aron, & Piette, 2015).

*Associated suggested warning signs.* Associated suggested warning signs include: Uncontrolled illness; PHQ-9 Depression screen Score of 15 or higher (Patient fills out PHQ-2 followed [if indicated] by the PHQ-9 questionnaire). A score of 15 or higher on PHQ-9 indicates a moderately severe depression barring other causes such as thyroid disorder (Maurer, 2012); NCCN Distress Score of 4 or higher; and Anxiety.

*Associated examples of recommendations/resources/expert advice supported by literature.*

Associated examples of recommendations, resources, and expert advice supported by literature include:

1. Consider antidepressants. The AMA (2018) recommends treatment of depression to aid in better adherence, and the ONS provides information gleaned from an extensive review of literature on medication adherence. Treatment of depression is found to be an intervention that is likely to be effective to increase adherence to prescribed treatments (Spoelstra, & Sansoucie, 2015).
2. Referral to oncology nurse navigator for coordination of interventions and care:
    - Early treatment of depressive symptoms (Mausbach et al., 2015; Spoelstra & Sansoucie, 2015).
    - Confirm that physician has been notified of PHQ-9 score of 15 or higher and consider work up and/or referral to mental health professional.
    - Connect with family or social support
    - Healthcare institutions' mental health web page often lists various resources for support of depression and other mental health issues.
        - If employee, provide with resource information through human resource partners to explore possible availability of free financial counseling services.

***Medical.*** (Includes Side effects/Effectiveness/Medication Reconciliation Issues/relationship with provider/multiple comorbidities/Polypharmacy) Murphy, Bartholomew, Carpentier, Bluethmann, and Vernon (2012) reviewed 29 peer-reviewed primary studies of female breast cancer survivors taking endocrine therapy published between 1998 and 2012. Nonadherence rates were as high as 71% at five years. Factors in this category found worsened adherence included older age and side effects. Although this study is older, it provides an important level one review of data that is still applicable today and supported by additional research, especially concerning older age and side effects. The previously mentioned study by

Roop and Wu (2014) found that one of the most frequently identified barriers to adherence was adverse effects of the medication.

The greater the number of different medications prescribed and the higher the frequency, the more likely that a patient will be nonadherant to their medication regimen (AMA, 2018). The relationship to the provider is also a predictive factor in adherence. “Mutually respectful collaboration with providers” is one key to improving adherence (CDC, 2017a). A meta-analysis of qualitative research with triangulation to quantitative research revealed a 42% frequency of provider relationship as a predictor of adherence in the qualitative literature. A positive relationship facilitates adherence while a negative relationship does the opposite (Irwin, & Johnson, 2015).

Additionally, advertisements, news coverage, and stories can have a negative effect and/or cause mistrust. Patients are less likely to fill their prescription if they do not trust the prescriber (AMA, 2018). Side effects were also common reasons for stopping medication in 21% of self-reported reasons for nonadherence in a national telephone survey of 1,020 adults with chronic illness and four or more medications (NCPA, 2013). Side effects were found 40% of the time in the qualitative literature in a meta-analysis of research regarding nonadherence (Irwin, & Johnson, 2015). A qualitative study of Turkish migrants with type 2 diabetes found that nonadherence may be impacted by different beliefs about medications (Peeters et al., 2015).

Barriers do not always originate with the patient. Barriers to adherence can start in the clinic or hospital setting due to medication reconciliation discrepancies (Balling et al., 2015). Although questionnaires can be time prohibitive to administer, some can be effective for assessing nonadherence. Effective interviewing is an easy, low-cost method to assess a patient’s

adherence. Although knowledge may not accurately reflect adherence, knowing that they will be asked about medications by their provider may encourage adherence (Lam & Fresco, 2015).

As mentioned in the financial and social category, single marital status, lower income, and having more than 10 medications were significantly associated with not filling medications. Reasons included cost by 23.5% of patients. Additional reasons include lack of time to go to the pharmacy, medication not delivered or dispensed, and inability to afford the medications (Wooldridge et al., 2016).

*Associated suggested warning signs*. Associated suggested warning signs include: Uncontrolled illness; lack of expected side effects; Distressed about side effects; prescription not filled or refilled at expected rate; Late stage of cancer; Poor physical status; provider relationship strained; no show for appointments and reluctance to reschedule; requesting a different provider; patients' significant other expresses concerns about patient not following treatment regimen (AMA, 2018; CDC, 2017a; Irwin & Johnson, 2015; Verbrugghe, Verhaeghe, Lauwaert, Beeckman, & Van Hecke, 2013).

*Associated examples of recommendations/resources/expert advice supported by literature.*

Associated examples of recommendations, resources, and expert advice supported by literature include:

1. Minimize side effects (CDC, 2017a).
2. Referral to oncology nurse navigator for coordination of interventions and care:
    - Follow up with phone calls to assess adherence, answer questions, and address any discrepancies (Patel et al., 2017).

- Assess patients for possible perspectives of medication based on ethnic beliefs (Peeters et al., 2015).
- Consider motivational interviewing as opposed to traditional counseling to develop a rapport with patient to enhance trust and adherence to prescribed therapies (ONS, 2016).
- Encourage patients to stick with regimen for medications that tend to become more tolerant over time.
- Assess for medication reconciliation errors and drug-drug or drug-food interactions.
- Some medications can be taken at bedtime to ensure that the period with most prominent side effects occur during sleep.
- Early follow up with medication reconciliation is important (Balling et al., 2015).
- Follow up with patients who have missed follow up appointments

***Behavioral/lifestyle.*** (Associated themes: Forgetting/Don't think it's needed/Didn't "agree" to take it/Don't like taking it/ too busy/Away from home/no established routine). Forgetting was the number one self-reported reason for nonadherence in a national telephone survey (NCPA, 2013). However, additional research reviews of studies comparing reminder methods to control groups revealed that this may not be as large of an impact as previously reported (Frakt, 2017). Frequency of forgetfulness was 38% and doubting necessity was 35% in a meta-analysis of research with triangulation (Irwin & Johnson, 2015). In the same study, pill burden is mentioned with 25% frequency and regimen complexity 22% of the time.

As mentioned in the financial and social category, single marital status, lower income, and having more than 10 medications were significantly associated with not filling medications. Reasons included cost by 23.5% of patients. Patients who express that they are tired of taking

medications are providing a warning sign that they are nonadherant (Million Hearts, 2017). Additional reasons include lack of time to go to the pharmacy, medication not delivered or dispensed, and inability to afford the medications (Wooldridge et al., 2016).

*Associated suggested warning signs.* Associated suggested warning signs include: Uncontrolled illness; Prescription not refilled at expected intervals; Pill bottle contains more pills than it should (check fill date); forgets; complains of being tired of taking medications, or too many medications; weekly/daily pill box contains unopened/unused pills; reluctance to accept a change in regimen; preference to be "prescription free" or "all natural" or other alternatives (Irwin & Johnson, 2015; Million Hearts, 2017; NCPA, 2013; Wooldridge et al., 2013).

*Associated examples of recommendations/resources/expert advice supported by literature.*

Associated examples of recommendations, resources, and expert advice supported by literature include:

1. The S.I.M.P.L.E. method recommended by the Million Hearts (2017) program may help improve adherence. S.I.M.P.L.E. stands for Simplify the regimen; Impart knowledge; Modify the patients' beliefs and behavior; Provide communication and trust; Leave the bias; and Evaluate adherence (Million Hearts, 2017).
2. As previously mentioned, the study by Murphy et al. (2012) found factors such as switching therapies to make regimens easier improve adherence, and behavioral factors that improved therapy were referral and follow up by an oncologist for specific oncology therapy; otherwise, patients tend to discontinue their oncology therapies earlier than recommended.
3. Referral to oncology nurse navigator for coordination of interventions and care:

- Methods to encourage patient adherence recommended by ONS (2016) include reminder instruments such as calendars, pill diaries, pill boxes with compartments for time of day for each day of the week, electronic reminders such as alarms, timers, smartphone apps, glowing or electronic pill containers, and medication dispensing machines.
- Involve support systems, encourage routines, review at each visit, and reminder calls (CDC, 2017a).
- Medication that requires taking with or without food or limits a food that is desired, such as grapefruit, can deter adherence. Work with patient to find a compromise or alternative therapy.
- Taylor interventions to patient to assess methods of remembering medications. Try less expensive methods first, such as a daily pill container, because more expensive electronic reminders have not proven to make a more significant impact (Frakt, 2017).
- Patient monitoring and multicomponent feedback such as blood pressure checks and communication with provider office combined with education are most likely to be effective for adherence especially as it relates to forgetting or ambivalence (Spoelstra, & Sansoucie, 2015).
- Patients most often forget their medications in the evening, weekends (especially Sunday), and holidays. Encourage patients to use a consistent method to remember medications even during these times that routine may change (Vervloet et al., 2013). Examples of reminders that may help are combinations such as smartphone reminder apps and travel cases for taking medication away from home.

***Educational.*** (knowledge deficits including general knowledge/limited English proficiency/functional/Cognitive/Psychological limitation; also, Literacy/Health literacy/Vision Impairment limiting ability to read educational materials/Memory impairment/misconceptions/distrust) Education appears to be one of the most studied methods of improving medication adherence. However, in relationship to the first four barriers above, the impact of education is less supported by the literature discovered in this review. One can find individual studies that support education and show limited improvement. However, it is important to note that one-time education without additional support or follow up drops off in effectiveness over time according to the literature.

Barthélémy et al. (2014) studied patient adherence to oral targeted therapies, hormonal therapies, chemotherapies, and their attitudes, in a prospective study of 201 cancer patients. Patients who took hormonal therapies for five or more years tended to drop off in adherence. Patients were asked how well informed they felt about their therapy. The researchers concluded that patients who were better informed had better adherence. The researchers concluded by suggesting that better education and education repeated at intervals throughout the therapy time period could be beneficial to increasing adherence to oral therapies of all types. This article supports initial and ongoing education as an effective means of increasing medication adherence.

A randomized controlled trial conducted by Moss, Lowe, Frampton, and Revell (2014) of 45 hospitalized patients being discharged on warfarin were divided into two groups: one receiving the usual care, and the other provided with structured counseling and an educational video. Both groups were administered questionnaires at discharge and again at 3 months. Both groups were also assessed for satisfaction and time in therapeutic INR. Patients who received the intervention had significantly better knowledge of their therapy than the control group. In

addition, they also reported improved satisfaction and better time in the target INR range. This study suggests that a structured educational program at implementation of an oral medication improves knowledge, satisfaction, and therapeutic benefits of the drug.

Predictors of nonadherence include limited English language proficiency, low literacy, and patient states he/she does not believe in the benefits of medication or believes they are not necessary or even harmful (Million Hearts, 2017). Patients who do not understand the purpose, side effects, or expected time before it is effective may result in nonadherence. This is true in patients with chronic illness because there is often no obvious result, so the patient may think it is not doing anything for them and stop taking it (AMA, 2018). The ONS review of literature recommendations suggest that in 2014 there was not enough information to establish education as an effective means of promoting adherence (Spoelstra, & Sansoucie, 2015). However, an additional study published by the ONS in 2015 cites medication knowledge was mentioned 25% of the time as a barrier to adherence in an extensive meta-analysis of qualitative studies triangulated with quantitative studies (Irwin & Johnson, 2015).

A TJC study (Cawthon, Mion, Willens, Roumie & Kripalani, 2014) assessing the feasibility of a three-question literacy instrument states that addressing health literacy is a national health priority, and Standard PC.02.02.01 is reflected in the statement suggesting that the hospital effectively communicates to patients when providing care, treatment, and services (par. 2). TJC defines health literacy as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (par. 1). It is a necessary skill for successful navigation of the health care system, communication with providers, and management of chronic conditions. However, an estimated 90 million adults in the United States have low health literacy which is

associated with lower rates of preventive care, poorer disease control, and greater mortality, as well as increased health care utilization and costs (Cawthon et al., 2014). Inability to read and understand directions on pill bottle labels may be due to small print, confusing medical terms, or abbreviations (CDC, 2017a). Patients with higher levels of education typically are correlated with better health, have had more health education, and can advocate better for themselves (Heath, 2017).

A structured, nurse-led teaching program that included follow-up phone calls at set intervals had encouraging results in lung cancer patients taking an oral chemotherapy drug (Boucher, Lucca, Hooper, Pedulla, & Berry, 2015). In a systematic review of randomized control trials, it was proven that group psychoeducation was effective in improving medication adherence in adults suffering from schizophrenia (Al-Batran, 2015). A study conducted by pharmacists at MD Anderson Cancer Center in Texas showed reduced hospitalization when patients were contacted by a pharmacist within 30 days of discharge to have adherence assessed, questions answered, and any discrepancies addressed (Patel et al., 2017). An additional pharmacist-driven study evaluated the impact of providing medications immediately upon discharge to patients admitted to a psychiatric unit and found that this improved adherence to the treatment regimen (Tomko et al., 2013). This is not feasible when a dispensing pharmacy is not readily available. However, it may be helpful to utilize this method if available in the future.

To discover the issues they felt caused their readmission, 1,084 adult patients were surveyed. The most common reasons included feeling unprepared for discharge and lack of social support. Low socioeconomic status (Medicaid or uninsured) were more likely to report difficulty understanding and executing discharge instructions (Kangovi et al., 2012).

*Associated suggested warning signs.* Associated suggested warning signs include: Uncontrolled illness; Reluctance, difficulty, or inability to read and/or understand pill bottle or written instructions when asked; medication not taken correctly; calls pills by color, size, and shape but cannot tell you what they are for; has not filled prescription; significant other takes care of all paperwork, low socioeconomic status (AMA, 2018; CDC, 2017a; Irwin & Johnson, 2015).

*Associated examples of recommendations/resources/expert advice supported by literature.*

Associated examples of recommendations, resources, and expert advice supported by literature include:

1. Reduce complexity of regimen.
2. Referral to oncology nurse navigator for coordination of interventions and care:
    - Using fifth- to sixth-grade reading level with pictures and teach-back methods may help patients feel better prepared for discharge and to care for themselves (Parr, 2017).
    - Consider referral for group psychoeducation for patients with diagnosed mental illness.
    - Structured educational sessions and follow up calls (Boucher et al., 2015).
    - Ensure patient understands the benefits of adherence and harms of nonadherence, involve support system, encourage routines, adherence instruments such as electronic devices, and reminder calls (CDC, 2017a).
    - Use blister packs, pill boxes/containers separated by day of week and time of day, request packaging and instructions with large font, provide instructions with large

font in layman's terms at reading level fifth-grade or lower (CDC, 2017a; ONS, 2016).

- Explore ways to provide medications immediately to patients when prescribed, especially for those with psychiatric diagnoses (Tomko et al., 2013).
- Early follow up with medication reconciliation important (Patel et al., 2017).
- Surveillance for patients at risk to catch missed follow up appointments.

**Conceptual Framework/Model**

The Iowa Model (2015) provides the conceptual framework and direction for this project. This model blends principles of frameworks including Transforming Care at the Bedside, Transtheoretical Model, and Institute of Medicine (Hall & Roussel, 2014). The Iowa Model provides a practical step-by-step guide for implementation of evidence-based projects from identifying the trigger to disseminating the results. Working in a multidisciplinary clinic with oncologists, advanced practice providers, and a large team of support personnel requires consideration of the complexities of cancer care and thoughtful integration of any change into practice, so that it is completed in an organized format (Hall & Roussel, 2014). The Iowa Model framework provided the framework, and more specifically, provided direction when a comprehensive instrument to screen for all of the primary barriers was not found.

This project utilized the Iowa Model (2015) identification of triggering issues and opportunities to guide the project towards creation of an evidence-based instrument. As evidenced by the literature discussed earlier, these triggering issues and opportunities are well-validated. As directed by the Iowa Model, a pilot study became the focus of this project and creation of the instrument resulted. The instrument was studied in part to see if a practice change

might be beneficial and feasible in the oncology clinic setting. It was decided to test the instrument on retrospective data to help determine whether the instrument will work as desired, to identify patients who are at increased risk for uncontrolled illness, emergency room visits, and hospitalization. After the data was collected, and statistics were completed, the final steps in the Iowa Model (2015) help to determine if a change is appropriate for adoption into practice. Results show that this is in fact a feasible screening method, so next steps are to begin integrating and sustaining the practice change and further refining the instrument. The instrument is the first of three parts to addressing nonadherence (as mentioned previously), so in addition to implementation, steps will need to be taken to help develop action plans for addressing each barrier and tailoring interventions to the patient to aide in adherence.

Identifying issues such as the impact of medication nonadherence and the impact on the clinic, accrediting agency requirements, and philosophy of care guided by the oncology organizations such as ASCO and ONS guided the researcher to consider all of the implications of a proposed research study. As a part of the process of working through the Iowa Model, there are built in fail-safes to appropriately re-route the project and the efforts should it be needed. The researcher must ensure that effort going into any project is a priority for the institution, that there is sufficient evidence to conduct the project, and that the evidence will lead to an appropriate change in practice. In addition to development of the instrument, a team is formed consisting of OCM personnel, in particular the navigator who will be one of the primary individuals utilizing the instrument should it be evidenced that it has significant usefulness.

The Iowa Model encourages, and accounts for, the interdisciplinary approach needed to implement an evidence-based practice change. Interdisciplinary teamwork is a natural element of cancer care which includes involvement of patients in the process, as seen in the Iowa Model

revised June of 2015 (The Iowa Model Collaborative, 2017). The Iowa Model guides the application of research to practice promoting increased quality of care (Mateo & Foreman, 2014).

## Theoretical Framework

**Theory of transitions.** Theory of transitions provides the theoretical framework for this project. Dr. Afaf Ibrahim Meleis' theory of transitions provides a theoretical framework that helps identify possible root causes for variables in expected behaviors, relationship among the variables, and a framework for examining the outcomes (Im, 2013). Transitions occur when people go through various stages and situations in life. These stages include developmental (e.g., adolescence to adulthood), situational (e.g., getting married or moving to a new neighborhood), health/illness (e.g., diagnoses of cancer), and/or organizational types of changes (e.g., promotion at work or taking on a new responsibility in the church) (Im, 2013). In addition to the change itself, there are factors that can also influence how the person is impacted by the change such as multiple changes at one time, the point in one's life that the change occurs, or the awareness and time span over which the change occurs (Im, 2013). The theory described by Im (2013) helps explain why some people go through change well and others do not. The theory of transitions may be very useful when examining the variables and their relationship to the ability of a person to successfully transition to a state of accepting and successfully managing their disease(s).

Meleis began developing the theory of transition in the 1970s as she studied immigrant populations and their health. The theory was developed from a borrowed sociology theory called "Role Insufficiency Theory" (Im, 2013, p. 254). Meleis saw that immigrants often neglected preventive health measures, such as preventive health screenings, due to lack of connection to their surrounding new community. Immigrants often neglected health problems due to language

barriers as well. In addition, they were often away from family and others that would normally support them to seek healthcare. Role supplementation is one aspect of the role insufficiency theory that Meleis stated can be provided by nurses. Nurses can play a role and step in (supplement) where needed to provide education, support, and specific nursing interventions. Meleis stated that the goal of healthy transition is "...the mastery of behaviors, sentiments, cues, symbols associated with new roles and identities and nonproblematic processes" (as cited in Im, 2013, p. 255).

In the adult outpatient cancer clinic, individuals seeking cancer treatment come from all walks of life, varying social circumstances, accompanying health conditions and behaviors, and a wide range of accompanying cultural beliefs, attitudes, preparation, and knowledge. These are known in this theory as transition conditions that can facilitate or inhibit transition during illness (Im, 2013). Adherence to medication regimens, especially for those with cancer and accompanying comorbidities, are especially at risk if they cannot successfully transition to a state of successful adherence to the oncologists prescribed treatment regimen.

This theory will be helpful to inform why some patients may have a more difficult time adjusting to a needed change, no matter how beneficial it might be. Nurses, especially nurses practicing at an advanced level, can help patients transition by assessing a person's readiness, educating patients to help prepare and guide them, and providing role supplementation. Coaching significant others is also an important skill of the advanced practitioner to guide them in role supplementation when necessary to aid in transition from wellness, to a journey through illness and either back to wellness, or to a new state of normal again (Meleis, 1975).

The Doctor of Nursing Practice (DNP) role is in a unique position to use the concepts of this theory to inform an evidence-based project for the purpose of aiding patients to successfully

transition to a state of medication adherence. In as much, this will help address one of the most impactful challenges by those experiencing a new or existing cancer diagnosis. Recognizing and appropriately addressing the various factors that play into a person's successful transition to a state of adherence from nonadherence is imperative for ensuring success of the project.

## Summary

**Implementation of an evidence-based screening instrument.** There were no instruments found in literature to assess for presence of the most common, impactful potential barriers in a single, comprehensive format. As patients are moved quickly through a clinic setting, this inability to efficiently screen for barriers and funnel to available resources such as navigators, negatively impacts likelihood of adherence to prescribed medications in complex patients with multiple comorbidities. Referral to healthcare personnel for intervention is key to the success of the use of this instrument. The search for an organized referral method to ensure that patients at high risk of uncontrolled illness and resultant adverse events such as rehospitalizations, are provided with maximum available support services is not new or unusual. A large healthcare organization in North Carolina is conducting a large study in 40 inpatient units with a similar purpose (Duncan et al., 2017). Patients discharged home with stroke are enrolled in a COMPASS Care plan that includes referral to a nurse who makes a phone call within two days of discharge and sees the patient within two weeks. During the phone and in-person visit, the patient is assessed for social and functional determinants of health and provided with an individualized care plan that includes utilizing community resources and planned follow up. A secondary outcome of this study is medication adherence. The authors cited CMS as an indication for devising better follow-up care of hospitalized patients. The study is ongoing currently (Duncan et al., 2017). As posited earlier, an instrument to help healthcare workers to

discover the full gamut and complexity of the barriers to adherence is essential before moving forward with interventions.

To create an instrument that is as efficient and effective as possible at discovering barriers, a multitude of evidence from research was used to organize the instrument into major categories of barriers with warning signs to make assessment as efficient as possible. The evidence was divided into similar categories, for identifying similar problems. There is some slight overlap in some of the categories, and again, this only illustrates some of the complexity of this task. In addition to categorizing barriers in an evidence-based fashion, accompanying recommendations were added to help address each of the categories of barriers. The result is an instrument with five categories of major adherence barriers found in the literature to be the most commonly reported, most potentially impactful, and most feasibly actionable. Potential warning signs of each of the barriers are listed to help alert healthcare personnel to further evaluate for a barrier. This could be likened to symptom alerts for various medical conditions in that some symptoms may occur with a variety of problems, but when further evaluated, a disease or condition can be pinpointed and treated.

When combined with a robust patient navigator program and a variety of referral resources, the screening instrument will assist healthcare personnel to refer patients for follow up and intervention for their adherence barriers. The key to the effectiveness of this instrument as supported by literature, is the mechanism for comprehensively identifying multiple, complex, intertwining barriers and referring the patients to a navigator to coordinate needed interventions. The desired result is to increase adherence, lower incidence of uncontrolled illness, and avoid adverse events requiring emergency room visits and hospitalizations.

## SECTION THREE: METHODOLOGY

### Design

This study was an evidence-based practice study utilizing the Iowa Model for Evidence-Based Practice. The Iowa Model guides the researcher to design and pilot a practice change when sufficient evidence is available. Otherwise it directs to test a change in practice with a pilot study (Iowa Model Collaborative, 2017). Due to inability to locate a comprehensive instrument containing all of the major barriers identified in the literature, an instrument was developed using the evidence found and a study conducted. The pilot study design was a retrospective, quasi-experimental, observational comparison study to evaluate the validity of a new evidence-based screening instrument. Identification of barriers, interventions or potential interventions, and ramifications such as uncontrolled illness, unplanned clinic visits, or emergency room visits, or hospitalizations, were evaluated on the select group of patients. Patient data was evaluated to determine what barriers were identified and if referrals were made using current methods. Next, the instrument was applied to evaluate the same patients in this population to see if additional barriers listed in the screening instrument were identified. Of those who had barriers according to both the current and the new screening methods, there was an evaluation of sensitivity of the screening methods by calculating the percentage of those patients who had uncontrolled illness and/or events that might have been preventable.

The qualified CMS OCM patient population was chosen through a report run using eligibility criteria described in setting and population. The identified population was further analyzed for evidence-based warning signs of potential medication nonadherence using the new evidence-based instrument. Within the subset of patients identified to have warning signs, it was noted how many were referred to oncology support services for any of the existing applicable

adherence warning signs such as depression, distress, or financial issues (following the initial financial counseling appointment recommended to all newly diagnosed cancer patients).

There is future potential to also evaluate specificity of the instrument. Due to the retrospective nature of this study, it was not possible to assess accurately for specificity, because it was not the practice to assess and record every data point in the instrument. This was not unexpected, because there was no formal process for collecting each one of the specific data points in the instrument as it does not currently exist. False negatives in this study (patients who had uncontrolled illness, but no barrier found in the medical record) could be attributed to the fact that patients may have had barriers that simply were not detectable in the retrospective data. Therefore, the primary objective in the data analysis following data collection, was to evaluate the instrument for sensitivity alone, and note the limitations of the study for specificity. This knowledge will be useful in discussion of the follow-up results as it relates to the risk for uncontrolled illness and possibly increase in unplanned clinic visits, emergency room visits, and hospitalizations or rehospitalizations.

At the time of the study, the clinic providing the retrospective data did not use a screening instrument designed to assess for medication adherence, risks, barriers, uncontrolled illness, adverse events, or otherwise. However, each patient prescribed chemotherapy treatment was seen at least once for insurance and financial benefits investigation, and regularly screened for depression using common depression and distress instruments. This researcher wanted to evaluate if the more comprehensive screening instrument developed from literature for this study would be more effective in identifying patients at risk for uncontrolled illness or if these existing screening instruments could be coincidentally just as adequate. The dependent variable is number of patients identified with barriers to medication adherence. Independent variables

include previous identification of risk using depression and distress screening instruments alone versus the new evidence-based toolkit containing five categorized barriers that include the scores obtained on the current depression and distress screening instruments. The additional important aspect of this study was to ensure good sensitivity of the new instrument. This was tested by determining how many patients identified also had uncontrolled illness. An extra measure was used in data evaluation to discover which barrier categories identified in this research had the greatest impact on patients with uncontrolled illness.

**Measurable Outcomes**

**Measurable outcome 1.** A statistically significant increase in percentage of prevalence of high-risk CMS OCM patients identified with potential actionable barriers to medication adherence using the W-BMA screen compared to current screening methods alone.

**Measurable outcome 2.** Instrument sensitivity: Patients who are identified to be at risk due to barriers found during W-BMA screening will have a significant incidence of uncontrolled illness, making use of the instrument to help prevent uncontrolled illness and resulting risk of adverse events worthwhile to the organization.

**Setting**

The retrospective data used for this study was from a local oncology clinic in Virginia. At the time of the study, the clinic was involved in implementation of a system to become compliant with new CMS standards related to the IOM's 13 standards included in their report, Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis (Institute of Medicine, 2013). This researcher discussed the study with some key stakeholders at the cancer center. The consensus of leaders approached about this research topic was that it complemented the goals and objectives that were currently in place to comply with the new quality standards for cancer

care. The providers of the clinic were aware of the CMS OCM initiatives and the complexity of meeting the goals. The key stakeholders at this clinic were seeking methods to address issues such as medication adherence and decreasing emergency room visits and hospitalizations for CMS OCM patients. They were very open to working with individuals, such as this researcher, who might offer help and support. There was brief, yet crucial input provided by clinic staff to help determine most appropriate population and population subset for this study. Clinic staff assisted with providing the list of patients who met the criteria as well. The real time investment will occur during possible future implementation and study of the W-BMA instrument; however, the clinic has invested in a CMS OCM nurse navigator who is available to help support implementation of the screening instrument, and to embrace a change that would help them provide better care, improve quality scores, and decrease costs.

**Population**

This retrospective review of data included CMS patients enrolled in the OCM program at a standalone community cancer center in Virginia. Located within two blocks, the community is also served by an approximately 300-bed hospital which is designated a level-two trauma center and part of a multi-facility healthcare system. At the time of this study, the two-story cancer center contained an eight-physician medical oncology practice, infusion center, and clinical research department on one floor, and on the other, a three-physician radiation oncology practice. Administrative support services located in the cancer center included an oncology nurse navigator team, social workers, dietician, nurse educator, and genetic counselor.

The cancer center participated in interdisciplinary comprehensive cancer conferences and tumor board meetings and had been awarded quality program recognitions for oncology care and various other programs for several years in a row. Patients enrolled in the OCM program at the

cancer center are generally at least 65 years of age or older and have received cancer treatment within the last 6 months. Patients over 65, especially those with multiple comorbidities, receiving chemotherapy treatment are at increased risk for adverse health outcomes when nonadherent to their treatment regimen (Sarfati et al., 2016). The qualified CMS OCM patient population was chosen because of their vulnerability to adverse health outcomes and need for improved medication adherence screening barriers.

Inclusion to the study required that patients had at least two visits within the previous year, and that they were enrolled in the OCM program which indicates that they were Medicare recipients and had received chemotherapy treatment. The sample was selected via a report identifying those patients who were enrolled in the OCM program and had multiple visits within the retrospective time frame. The researcher's previous experience working with this patient population, as well as the vulnerability of this population to adverse events from nonadherence, combined with a setting in which the stakeholders are open to development and implementation of a screening instrument, made this the ideal setting and population for this study.

There were 759 patients enrolled in the OCM program at the time of the random selection for the study making up the population of focus for this research. The researcher requested that the administrative personnel collecting the sample for the study select every third patient to ensure a systematic sampling of the population. This sample was provided in the form of a list which was kept locked to ensure privacy. The population sample studied included 250 OCM patients treated and seen at the clinic at least twice in the previous year. Most of the population was born between 1934 and 1950 with a mean, median, and mode of 1944. English was the primary language spoken by almost 99% of the sample that included 119 male patients and 131

females. The average number of prescribed medications in this sample was 10 with 10% taking over 20 medications each.

The profile of a typical subject of this research, based on evaluation of findings, can be described as a 74-year-old English-speaking woman living on social security with Medicare insurance. She has been diagnosed with cancer within the last year and had chemotherapy treatments, which may have been ongoing. She must return to the oncology office on a regular basis for treatment and/or evaluation of adverse effects of the chemotherapy treatment and have lab and radiology tests to evaluate for treatment effectiveness and recurrence of the cancer. In addition to her cancer diagnoses, she has multiple comorbidities including DM-2, and HTN which require that she see her general practitioner and possibly another specialist on a regular basis. She has been prescribed about 10 medications that she must take on a daily or prn basis. This number does not include any chemotherapy (intravenous or oral) or medications given in conjunction with the chemotherapy to prevent adverse reactions or immediate side effects. Neither does this number account for over-the-counter medications such as allergy or cold remedies, sleep aides, pain relievers, vitamins, or herbal supplements. Her medication list that she provides to the oncologist does not match what she provides to healthcare personnel as an inpatient. She lives with her spouse and has a less-than-ideal physical status (ECOG 1) spending a majority of the day sitting down or in bed due to not feeling well. Her blood glucoses are typically elevated at each clinic visit. Multiple consecutive elevated blood pressure readings indicate she may have uncontrolled stage two hypertension.

**Ethical Considerations**

Completion of Collaborative Institutional Training Initiative required training for protection of human subjects (see Appendix C) by both the study chair and the researcher helped

to ensure that ethical standards were upheld in the conduct of the research. The study was approved by both the Institutional Review Boards (IRBs) of the university and the healthcare institution. In addition, the study was reviewed by the Nursing Research Council of the healthcare institution. A copy of approval letters are included in the appendices (see Appendix F). As this is a retrospective chart review with collection of only de-identified data that cannot be traced back to any individual patient and obtaining consent would create the only identifiable attachment to the study, no consent was required. Although data will be de-identified, the key and all sensitive patient information was kept secure in a locked office and/or on a secure electronic file requiring a password and will be destroyed following completion of all research surrounding this instrument.

**Data Collection**

The historical medical records of 250 OCM patients were reviewed one at a time using the data collection instrument coded for use with the Statistical Package for the Social Sciences (SPSS) analysis. This researcher extracted, recorded, and coded the data for this study. A data collection sheet was used for each individual patient and later entered into SPSS. Two separate electronic medical records (EMRs) were in existence at the time of the study. To ensure that all applicable data was included, both EMRs were thoroughly reviewed.

After the patient identification code was transcribed to the data collection sheet, a note was made of the patient's year of birth and gender. Data was first reviewed for the presence of PHQ-9 depression screen score of 15 or higher and an NCCN Distress score of 4 or higher. Following that, it was noted if any interventions took place for the screening scores. This data was recorded on the data collection sheet.

Following a review of current screening methods, the researcher then analyzed the patient record to extract warning signs as listed in the W-BMA screening instrument. The W-BMA screening instrument includes the depression and distress screening results as part of the comprehensive review of risk. Any warning sign found in the record resulted in a positive screen for the category in which it applied. Also noted and recorded were applicable interventions, signs and symptoms of uncontrolled illness, and unplanned healthcare visits. The primary purpose for collecting the data in this manner was to collect the data needed to evaluate the desired measurable outcomes for this study. First, to see if there was an increase in percentage of patients identified with actionable barriers to medication adherence compared to those identified in current screening methods alone. Second, to see if there is instrument sensitivity as predicted. The secondary purpose for collecting this data in this manner was to evaluate the W-BMA screening tool for future refinement and to learn from any incidental findings. SPSS coding was performed as specified in Appendix G.

**Instruments**

An extensive search did not reveal an instrument that would efficiently and effectively identify all the major barriers to adherence found in the literature review in an organized way. As a result, this study became an evidence-based pilot study to evaluate an instrument that would fulfill this purpose. To create an instrument that would be as efficient and effective as possible, an extensive review of evidence from research was organized into major categories of barriers with warning signs. The evidence was divided into similar categories with well-documented research addressing each category. Over 40 barriers were identified; however, many of these could be classified into a major barrier such as financial or medical. As a result, five major barrier classifications with warning signs were developed, along with recommended strategies

for addressing each category according to the literature found. The result is an instrument with five categories of major adherence barriers found in the literature to be the most commonly reported, most potentially impactful, and most feasibly actionable determined by the review of literature and experience. Experience is an expected component of evidence-based practice but was used cautiously in this study. Potential warning signs of each of the barriers are listed to help alert healthcare personnel to a potential barrier. The literature review contains a detailed description of the evidence used to support each of the five categories of barriers. The categories of the W-BMA include Financial/Social Support, Depression/Distress/Anxiety, Medical Related, Behavior/Lifestyle, and Education. The W-BMA was prepared with future dissemination in mind and includes talking points and review of literature for each category for quick reference. See Appendix D for the full four-page instrument. The basic W-BMA (Washburn_Barrier to Medication Adherence Risk Assessment) Screening Instrument developed for data collection for this study is pictured in Figure 1 on the next page.

| **Barrier:** | **Warning Signs:** | **Notes: (referrals/interventions)** |
|---|---|---|
| ☐ **Financial/Social Support** | ○ Age 65 or higher and one or more of the following:<br>○ Unmarried and/or absence of social support<br>○ Medicaid eligible<br>○ Income less than 50,000 dollars/year<br>○ Limited pharmacy access (location of residence related to pharmacy, resides outside of city, lack of transportation) | |
| ☐ **Depression/ Distress/ Anxiety** | ○ PHQ-9 Depression screen Score of 15 or higher<br>○ NCCN Distress Score of 4 or higher<br>○ Diagnoses of anxiety, or on medication for anxiety | |
| ☐ **Medical Related Concerns**<br><br>*Related cues: Side effects/Effectiveness/Medication Reconciliation Issues/relationship with provider/multiple comorbidities/ Polypharmacy/ Poor Performance Score (ECOG)/cancer therapy last 6 months* | ○ More than 10 medications<br>○ Uncontrolled illness<br>○ Unexpected side effects and/or lack of expected side effects<br>○ Distressed about side effects<br>○ Prescription not filled or refilled at expected rate<br>○ Late stage of cancer<br>○ Poor physical status (ECOG 1 or over)<br>○ Provider relationship strained<br>○ No show for appointments and reluctance to reschedule/Requesting a different provider<br>○ Significant other concerns about not following treatment regimen | Record # of meds here:_____ |
| ☐ **Behavior/Lifestyle**<br><br>*Related cues: Forgetting/Don't think it's needed/Didn't "agree" to take it/Don't like taking it/ too busy/Away from home/no established routine* | ○ Prescription not refilled at expected intervals<br>○ Pill bottle contains more pills than it should based on fill date (If it is the original bottle)<br>○ Taking additional unprescribed herbal or "natural" substances<br>○ Tobacco, ETOH abuse, illegal drug use<br>○ Weekly/daily pill box contains unopened/unused pills<br>○ Reluctance to accept a change in regimen<br>○ Preference to be "prescription free" or "all natural" or other alternatives | |
| ☐ **Educational**<br><br>*Related cues: Knowledge deficits including general knowledge/limited English proficiency/functional/Cognitive/Psychological/Health literacy/Vision Impairment/Hard of Hearing/Memory impairment/misconceptions /Distrust* | ○ English is not first language<br>○ Reluctance, difficulty, or inability to read and/or correctly explain written medication instructions (on pill bottle or med list)<br>○ Medication not taken correctly<br>○ Identifies medications by color, size, and shape but unable to explain what medications are, or what they are for.<br>○ Has not filled prescription/reluctant to answer questions about compliance with regimen<br>○ Significant other takes care of all paperwork<br>○ Known memory impairment | |

| **Uncontrolled Chronic Illness:** | **Signs/Symptoms:** | **Related Medication if applicable:** |
|---|---|---|
| ☐ **Diabetes** | | |
| ☐ **Hypertension/ CVD** | | |
| ☐ **Renal Impairment** | | |
| ☐ **Sustained uncontrolled depression or Mental Illness** | | |
| ☐ **COPD/ Asthma** | | |
| **Unplanned Care:** | Sign/Symptom/Diagnoses | Related medication if applicable |
| ☐ **Clinic Visit** | | |
| ☐ **Emergency Room Visit** | | |
| ☐ **Hospitalization** | | |
| Note if support services were involved throughout the retrospective service dates yes/no | | |

*Figure 1.* Washburn_Barrier to Medication Adherence Screening Instrument. Copyright 2018

The W-BMA instrument, along with the methods for data collection and data analysis were reviewed by both university and healthcare IRBs as part of the study approval process and approved for data collection for this study. For data analysis of the first outcome, the information was grouped into one dependent variable—number of patients detected by the instruments in question, and two independent variables—number of patients with high depression and/or distress score known as current screen and number of patients with at least one of the five barriers known as W-BMA instrument or W-BMA screen. For data analysis of the second outcome, any one or more types of incidences of uncontrolled illness was recorded as an event

for sensitivity and specificity tests. Although there were no expectations that all warning signs would be evident in the process of data collection, the education barrier category and clinic visit category were both difficult to assess with confidence. However, even though there was not enough evidence to factor these into data collection, leaving education in the barrier assessment category is supported by literature and leaving clinic visits in the assessment for adverse events may be useful for future testing of financial impact.

**Intervention**

An extensive, comprehensive literature review was completed in 2017 and early 2018 followed by development of the W-BMA instrument. The healthcare professionals assigned to work with OCM patients were consulted for feasibility input and to discuss a method of collecting a systematic patient sample. IRB approval was requested in late March and obtained in June 2018. Data collection was immediately started, following obtaining the list of sample patients from the quality coordinator. The qualified CMS OCM patient population was identified, and the retrospective chart review completed at the end of July 2018. The data extracted from the record was coded and entered into SPSS. A statistician was consulted in mid-August, and in mid-September of 2018 analysis was completed which then allowed for recording of the results of the retrospective study in this paper.

**Feasibility Analysis**

This study was feasible in that it required very limited initial resource of time, not more than one hour from two specific healthcare personnel dedicated to this population to provide input into instrument feasibility as well as the patient sample list. Approximately half a ream of paper was utilized for 250 printed data collection instruments. The time needed to conduct the

study fit within the available dedicated DNP practicum time of the researcher, thus no salary was required for the majority of work done on the study.

**Data Analysis**

The Iowa Model Collaborative (2017) directs to use a pilot study when implementing evidence into practice. This plus using retrospective data, was important when testing the validity of this newly developed instrument. This pilot evidence-based practice research study included a systematically chosen sample of OCM patients and examination of retrospective data from their records for up to one year before IRB approval between June 1st, 2017 and May 31st, 2018. This research focused on two measurable outcomes to pilot an evaluation of the validity of the W-BMA instrument. This instrument was compared to existing screening methods alone to rule out the possibility that it is as effective in identifying patients at risk for nonadherence and resulting uncontrolled illness. All statistical analysis on this data was completed using IBM SPSS Statistics for windows vs. 25 (IBM Corp, 2017). The sample was chosen to ensure a 95% to 99% confidence interval with 1% to 5% margin of error. Specific tests were performed to evaluate each outcome; however, a statistician was consulted, and a classification tree recommended to assess independent variables that were the most impactful in patients with uncontrolled illness as found in the retrospective data. The classification tree was useful in incorporating the intent of this screening instrument into a visual useful in ongoing evaluations, and possible future development of a guide to prioritization of barrier interventions.

For SPSS analysis purposes, the researcher coded data as described in Appendix G. Data was grouped and coded to transform data into dichotomous output and entered into SPSS in separate variable fields used to perform the statistical tests. The uncontrolled event fields were recorded as either yes (1) there was an uncontrolled illness of some type, or no (2) there was no

uncontrolled illness found for that patient. The data used specifically for each measurable outcome was coded in a similar fashion as described below. This provided simple nominal data for use with the statistical tests.

**Measurable outcome 1.** The first measurable outcome of interest was to evaluate whether there was a statistically significant increase in percentage of prevalence of high-risk CMS OCM patients identified with potential actionable barriers to medication adherence compared to current screening methods alone. Data collected on the current screening instruments was coded to indicate the result, whether the screen was found to be positive or negative for a risk factor. If either the current depression and/or distress screening instruments was found to be abnormal, this was recorded as a positive result for the independent variable of current screening methods. Yes (1) if positive and if within normal range, a no (2) for negative was recorded for that variable. The same method was carried out with the second independent variable, the W-BMA screening instrument. The patients' records were further evaluated for all five categories of risk, and if there was at least one barrier found, it was recorded as a positive finding. If any one of the five major barrier categories were marked as positive (meaning warning signs of a barrier existed) the variable was marked yes (1) or if none were found it was marked no (2) for negative.

The hypothesis was that the W-BMA screen would identify more people at risk for nonadherence than the current screening method alone. To evaluate the data, a paired T-test was planned first to compare the population before and after application of the new screening instrument. A paired T-test is used for comparison when two different methods of measurement are applied to the same subjects (Mathematics Learning Support Centre, n.d.). Although a T-test might be used due to the nominal or dichotomous variables (Sullivan, 2017). The test was not

appropriate here partially due to the distribution of data before and after the instrument was applied. A normal distribution is required for accurate results in this test. To evaluate whether the results disproved the null hypothesis that the current depression and distress screening method will be as effective in identifying patients at risk for nonadherence as the new screening instrument, a simple frequencies table was produced in SPSS.

**Measurable outcome 2.** Instrument sensitivity: The hypothesis of this outcome is that patients who are identified to be at risk due to barriers found during retrospective screening will also have a significant incidence of uncontrolled illness. As a result, it is hoped that investing the time to use the W-BMA instrument to proactively help prevent uncontrolled illness and resulting risk of adverse events will be worthwhile to the organization. Sullivan (2017) states that screening tests are not for the purpose of making a medical diagnoses. They are intended to identify individuals most at risk.

Although sensitivity testing was easily applied to these study results, specificity was evaluated, but not significant in this study because of the retrospective nature of the study. False negatives (patients who had uncontrolled illness and/or adverse events but no identified barriers) in this study could be attributed to the fact that patients may have had barriers that simply were not detectable in the retrospective data. Further research is needed to evaluate instrument specificity.

## SECTION FOUR: RESULTS

### Descriptive Statistics

This was a retrospective, quasi-experimental, observational, comparison pilot study using three statistical tests on dichotomous data. A sample of 250 out of a population of 759 patients was systematically selected for improved probability sampling. Frequencies run in SPSS

provided information on difference between the number of patients identified with potential actionable barriers to medication adherence using the W-BMA screen (97.6% [86.0% with associated medication]) compared to current screening methods alone (28.4%).

Next, a sensitivity and specificity tests were analyzed for the second hypothesis to evaluate if the instrument was correctly identifying patients at risk for uncontrolled illness. Patients with any identified risk factors were evaluated for uncontrolled illness. In previous discussion, it was established that specificity testing was not feasible for this retrospective data. Sensitivity test resulted in 83.2% of patients identified with barriers had an uncontrolled illness and 86.2% of patients with barriers had uncontrolled illness related to a prescribed medication.

Classification tree results were as follows: 184 out of 250 (73.6%) of W-BMA screened patients had uncontrolled illness or events consisting of extra clinic visits, emergency room visits, or hospitalizations. Of those patients, 82.8% had barriers in the category of medical related concerns undetected with current screen methods and had uncontrolled illness. For those patients either without barriers, or whose medical related barriers were fully addressed by a healthcare worker, 34% had uncontrolled illness. The Chi-square test imbedded in the classification tree results is indicative that the variables are in fact dependent.

Of interest, notice again the less-than-ideal specificity, indicated below in Figure 2, probably primarily due to use of retrospective data. The W-BMA instrument includes warning signs that are not always historically recorded, so where W-BMA results were negative for barriers, there may in fact be a barrier leading to the uncontrolled illness. This is where additional study of the W-BMA instrument may be beneficial. In patients where the W-BMA instrument identified behavior and lifestyle concerns undetected by current screening, 80% ($P < .0009$) of those individuals had uncontrolled illness or events.

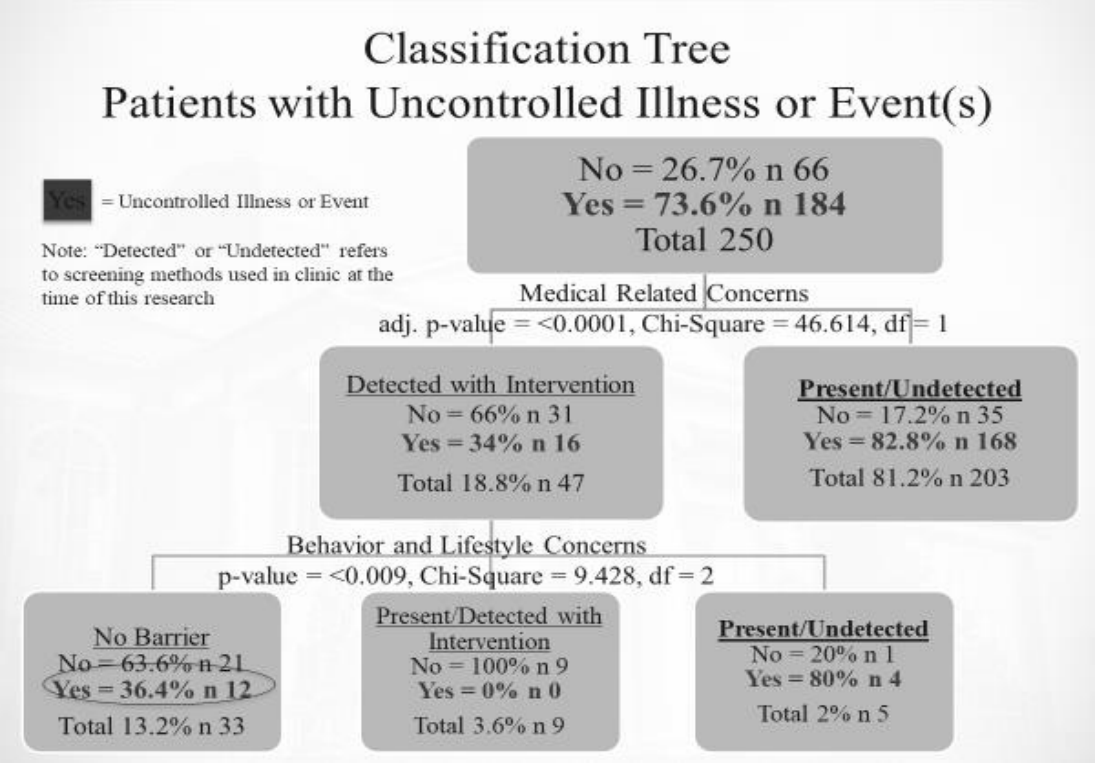


*Figure 2*. Classification tree: Patients with uncontrolled illness or event(s).

To further evaluate the impact of barriers found by the W-BMA instrument, over half (56.6%) of the time, uncontrolled illness was found in patients prescribed a medication for their illness. Of those patients for which medication was prescribed, 62.0% ($P < .0002$) had undetected medical related barriers using current screening methods. These patients had incidence of uncontrolled illness, despite having a medication prescribed for that illness. From the original (56.6%) group of patients with uncontrolled illness related to medication prescriptions, 29.0% ($P < .0002$) of those individuals had barriers detected and addressed, yet still had incidence of uncontrolled illness. These patients also had behavior and lifestyle concerns which went undetected in four out of nine patients resulting in an 80.0% incidence of uncontrolled illness when not detected and addressed.

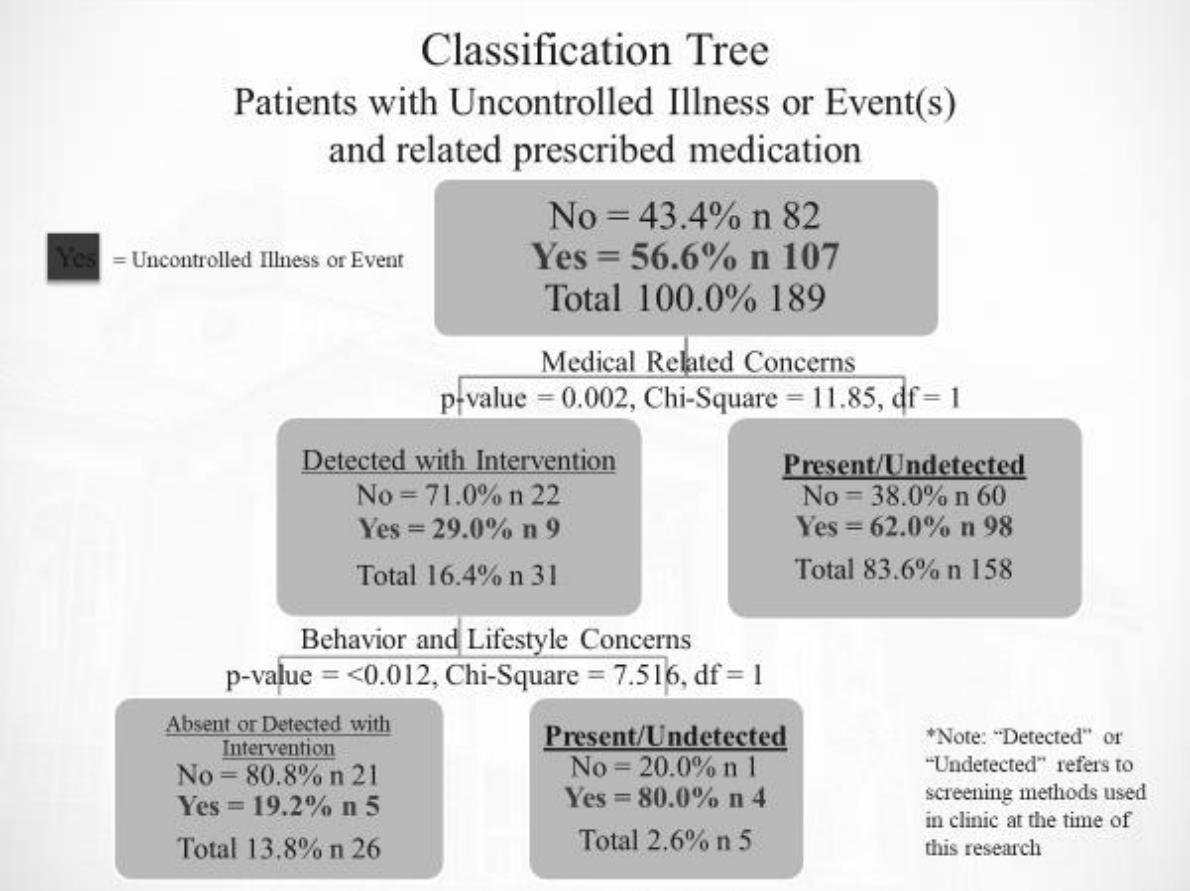


*Figure 3*. Classification tree: Patients with uncontrolled illness or event(s) and related prescribed medication.

The data in the classification trees described above contains some very positive information of note. In several cases, the data shows the impact made by the oncology healthcare staff. When oncology service nurse navigators, social workers, or others intervened to address barriers, there was a clear reduction in uncontrolled illness or events. For example, in the first classification tree, Figure 2, when medical or behavior/lifestyle concerns were detected and addressed by these individuals, there was no uncontrolled illness or events 66.0% and 100.0% of the time respectively. Likewise, in the second classification tree, Figure 3, for the same barriers, patients with related medications who maintained controlled and out of the emergency room and hospital were 71.0% and approximately 80.8% respectively.

# SECTION FIVE: DISCUSSION

## Implication for Practice

Currently there are many published toolkits available for use in healthcare settings. In addition, one can search literature and find a multitude of research on barriers to adherence, and interventions proven to have an impact on adherence and illness control. However, what is not found, is a comprehensive evidence-based instrument to screen for the most common, impactful barriers to medication adherence. Introducing the use of a comprehensive risk assessment tool such as the W-BMA instrument into practice is a first step in developing a comprehensive program to remove medication adherence barriers. Removing barriers to medication adherence may result in better controlled illness and reduced healthcare costs.

This research study included a pilot, or test-run, of the W-BMA screening instrument in retrospective data of OCM cancer patients. Despite the use of retrospective data, the new evidence-based instrument was found to be a more sensitive detector of potentially impactful and actionable barriers than the combined use of the PHQ-9 depression and NCCN distress screening instruments alone. This was an important question to answer, because although depression and distress impact many facets of a person's life, nonadherence can be complex, multifaceted, and require intervention of more than one form. Healthcare professionals may have erroneous notions that nonadherence is rare, misunderstand the barriers that make a patient nonadherent, and misunderstand the typical profile of a nonadherent patient. This may result in overlooking many nonadherent patients daily.

One lesson learned in this research involved observation of a high percentage of patients with uncontrolled illness. Nonadherence to medication regimens due primarily to the barriers listed in the screening tool may be a primary reason for these observances. Any question about

how common nonadherence is in the general population can be answered with the evidence from the aforementioned literature estimating that 50% to 70% of prescriptions make it to the pharmacy, 48% to 66% come out of a pharmacy, 25% to 30% are taken properly, and only 15% to 20% are refilled as prescribed (AMA, 2018; CDC, 2017a; Million Hearts, 2017). The findings of this study and incidence of uncontrolled illness in the sample, combined with the evidence from literature, creates a strong argument that nonadherence to medication regimens in these patients is likely related to the uncontrolled illness.

The SPSS frequencies analysis was conducted to compare the W-BMA screen with the current screens alone. The results suggest that the W-BMA really does identify a significantly larger number of patients with barriers than the current screens alone. The null hypothesis "Current screening methods alone identify a similar number of "at-risk" patients as the W-BMA screening method", however, the W-BMA screen identified more at-risk patients, allowing rejection of this null hypothesis. A significant number of patients in the sample size had barriers that went undetected by the healthcare clinic probably due to a lack of screening methods for these barriers. The significance of this finding was revealed in the classification tree produced in consultation with a statistician. The classification tree and sensitivity test shows evidence that first, the barriers found by the W-BMA screening instrument are strongly related to uncontrolled illness and second, illustrates how barriers can be complex and multi-layered so that even if one barrier is addressed, there may be others that significantly impact adherence and the health of the patient.

The use of retrospective data aided in accomplishing this pilot study without risk to the population to which it was applied. This researcher gained valuable insight into the potential use of the instrument in practice, especially as part of a disease or population specific intervention

program. Patient navigators, social workers, case managers, clinical nurse specialists, nurse practitioners, and patient educators working with populations at risk may find benefit in implementing this comprehensive screening instrument. The information derived from this pilot test did not in itself validate the instrument. Much of the validation has been derived from the copious amounts of fine work done by hundreds of individuals to resolve this very complex issue as demonstrated in the existing literature. Much of this available literature is outlined in Appendix A and discussed in the literature review.

A benefit of a pilot study is the ability for researchers to make improvements in the design of the study through lessons learned. Many ideas look great on paper, but seeing them in action allows researchers to gain a realistic perspective and identify the limitations and design flaws. This helps ensure success and efficiency of the larger study. Much of the validity of this instrument comes from the literature, but validity and feasibility of application of the instrument for practice must be assessed as evidence-based practice studies in each unique setting for which application is desired. The W-BMA instrument was developed with the structure and resources of the local cancer center in mind. The cancer center and associated healthcare system employs navigators and other staff who have the expertise and resources to intervene for some of the most vulnerable of the population as a part of a comprehensive navigation program. This research did not focus specifically on the impact of navigation or social work; however, the results of this study, especially as seen in the classification trees, indicate that these services do play an important role in promoting the well-being of vulnerable patient populations. Having this instrument available as a resource to help detect more impactful barriers may result in a lower rate of uncontrolled illness and adverse events.

**Limitations**

This research study had several limitations, many of those are intrinsic to pilot studies involving untested processes or procedures. However, there are those that warrant discussion to inform for future research on this instrument and warn those who may be tempted to use the instrument in practice without further study. Following are some of the limitations most impactful to this research study and worthwhile noting for future research using this instrument.

One limitation of this study involved the availability of data due to the retrospective design. The statistical tests used combined both categories of current, and all five categories of the W-BMA screening instruments, into one variable. However, not all warning signs, or even all categories of the W-BMA, could be assessed on retrospective data. Many of the individual data points in each category are not typically assessed and recorded in a normal clinic setting. This limited the ability to test for specificity of the instrument. The education barrier category and clinic visit category were both difficult to assess with confidence due to available documentation. There were not enough results from those single categories to report any meaningful findings as an independent variable. However, leaving education in the barrier assessment category is supported by literature and leaving clinic visits in the assessment for adverse events may be useful for future testing for financial impact. Prospective studies that include purposeful collection of all data points would help provide a robust evaluation of the W-BMA instrument.

Subject demographics aside from general population information, were limited to gender and age. Race was not recorded and is an important consideration in future analysis of this instrument. In the population studied, the race most common to the population is known to be Caucasian, which mirrors the population treated as a whole at the cancer center. It may be beneficial to include race in the demographics of future studies, especially in locations where there is a more diverse mix of patient race. Additional demographics may be helpful including

income level, zip code, transportation, employment, and specific social support (marital status) available to the patient.

Uncontrolled illness was used to test sensitivity; however, this assumes that the uncontrolled illnesses were caused by medication nonadherence or were somehow directly related. The classification tree arranges specific W-BMA barriers according to prevalence in the subset of patients with uncontrolled illness. However, there may be additional barriers, undetected in the data that would be more impactful to the patients' ability to adhere to their medication regimen. A prospective study in which each barrier category is thoroughly assessed would help eliminate this limitation. In addition, a prospective study may also help correlate medication nonadherence to the barriers and uncontrolled illnesses, although the literature makes a strong case to prove a hypothesis of that nature.

Another limitation is that the W-BMA instrument is a new screening instrument only tested by this single pilot study in a very specific population rife with medical comorbidities. Uncontrolled illness in this population may be much more common than in other populations, making the sensitivity testing for this group not applicable to other groups of patients. More testing is needed to validate the screening instrument in other populations to evaluate effectiveness at detecting preventable barriers and improving adherence. As noted in the introduction, research shows that people who are already adherent are very likely to stay adherent. This helps to conclude that future research may best be focused on populations that tend to have difficulty with medication adherence, multiple comorbidities, and uncontrolled illness. Although the screening instrument was created from research that proved there is a significant association of these barriers to uncontrolled illness, it is still an assumption that likely requires further testing.

Finally, the sample was selected in a manner to eliminate sample bias; however, the researcher then collected, coded, and entered the data into SPSS. Having an independent person code the data for preparation of entry into SPSS is normally recommended to help ensure good coding practices are used, and researcher bias is avoided. This researcher hopes to further explore the use of this instrument in additional vulnerable populations, avoiding some of the limitations discussed here.

**Sustainability**

Adherence to a medication regimen is often a complex issue that requires thoughtful consideration and sustained intervention at the micro, mezzo, and macro levels. The use of the W-BMA screening instrument will be sustained if properly used and integrated into a larger comprehensive program. The micro level will be sustained through thoughtful use and interpretation of the instrument by the health professionals working with the patient. At the mezzo level, the health professional must engage with local, organizational groups such as palliative care teams, and resources such as navigators, social work, educators, advanced practice nurses, pharmacists, and others to develop a team approach to address barriers for each patient. The macro level requires that the entire community become engaged in supporting patients with adherence issues on a long-term basis. Examples of community programs that can help sustain interventions include community paramedic programs and reduced medication cost programs. Sustainability for the W-BMA screening instrument will require that it be used as a part of a comprehensive program at all three levels for identification of, and intervention for barriers.

The environment in which this study took place is a very supportive environment in which innovative improvements in practice are encouraged. Healthcare professionals and administration work tirelessly to improve the entire oncology populations' healthcare outcomes

and quality of life. The cancer center employs a team of healthcare professionals that include disease and population specific navigators, including an OCM navigator, as well as other integral support professionals such as social workers and educators. These individuals may utilize the W-BMA instrument for a full evaluation of patients in this population. Clinic physicians, nurses and staff simply do not have the time to complete the full evaluation required for best use of the instrument. Any attempt to integrate full screening at this level is not sustainable. However, a referral may be quickly made to a navigator when any number of barriers are identified by clinic staff. In certain populations, such as the one studied here, patients are automatically referred to a navigator at which time the instrument can be fully utilized.

Attempts to implement the instrument into an EMR for use on a wider patient population is something that could be examined in the future after further refining and study. This could be implemented in such a way that identification of a warning sign such as uncontrolled illness, or a high distress screening score would trigger a referral for further evaluation. Future use of the tool may include referral of additional populations of patients in the practice, generated from inpatient, or outpatient physicians, nurses and other healthcare professionals by simply identifying warning signs in one of the barriers.

The instrument studied in this project requires additional analysis and refinement before full implementation; however, the healthcare professionals involved with the population studied are very open to change and adoption of new methods or technology. It appears that addition of this screening may enhance the excellent services provided to the patients under their care. The key to sustainability for this screening instrument is in the methods used to glean the needed information from the patients, and then identifying, prioritizing, and adopting the appropriate interventions for each of the barriers found.

An important aspect of sustainability is correct use and interpretation of the instrument. One must be able to prioritize the barriers with consideration that resolving one barrier may also help resolve other dependent barriers, because attempting resolution of a barrier that is dependent on resolution of a more impactful barrier could be futile. Such futility would create an illusion of instrument ineffectiveness and discourage continued use. Continued use of the instrument may be influenced by measurable improvements in adherence to prescribed medications with reduced incidence of uncontrolled illness. Healthcare professionals utilizing this instrument will need to have access to the resources required, use critical thinking to prioritize the interventions needed, and implement them in a way that is sustainable for these patients who often have very complex barriers.

**Dissemination Plan**

The bible provided much of the inspiration for this researcher when developing and researching the W-BMA instrument and planning for dissemination. Isaiah 43:19 states, "Behold, I will do a new thing; now it shall spring forth; shall ye not know it? I will even make a way in the wilderness, *and* rivers in the desert" (King James Version). Healthcare professionals' (this researcher included) begin to raise their threshold of what is acceptable in the way of nonadherent behavior and uncontrolled illness, as it becomes more and more prevalent. Perhaps this happens very slowly over a period of several years in a healthcare system serving patients with increasingly complex intertwining factors, including more pressing healthcare issues such as cancer. Another contributing factor may also be that comorbid illnesses are often managed by multiple, loosely connected healthcare teams.

After nine years of work in oncology clinical research, this author learned that evaluating medication adherence, working closely with all healthcare teams involved in the care of the

patient's comorbid conditions, and intervening to remove barriers to adherence, increases a patient's likelihood of adherence to their medication regimens and lowers their likelihood of uncontrolled illness and resulting adverse events. This researcher also observed the effectiveness of a navigation program for patients with complex illnesses managed by multiple systems and teams. With this background in mind and with support from oncology clinic administration and support team, this project was undertaken to develop an instrument that might help improve OCM patients' adherence and lower incidence of uncontrolled illness. Dissemination of the knowledge learned in this research will be accompanied by a word of caution that it was a pilot project requiring more study, but with great hope that it will eventually improve the health and welfare of some of the most vulnerable cancer patients, and eventually other populations as well. The Iowa Model provides a practical step-by-step model to guide implementation of evidence-based projects from identifying the trigger to disseminating the results. Dissemination will take place in multiple formats following the Iowa Model "Implementation Strategies for Evidence-Based Practice" (Cullen & Adams, 2012).

Although patients are the focus of this evidence-based screening intervention, the target of dissemination will be the healthcare professionals and administration who will integrate this instrument into a comprehensive medication adherence program for their patient population. Methods to disseminate this information will include poster presentations, podium presentations, and publication of a manuscript based on this project, preferably to a journal of nursing specific to oncology nursing. Organizational support will be guided by the Iowa Implementation Model beginning with education about these research findings and recommendations for further research on the use of this instrument in a prospective manner. This researcher will also upload

this project to Liberty University Scholars Crossing where it can be accessed through the world-wide web.

This evidence-based research study invites a plethora of new collaborative research by nursing and other healthcare team members. The use of the instrument requires study to further assess feasibility of use in busy cancer centers. Can this instrument also be used in at-risk clinics for other acute or chronic disease states, or even the patient who returns repeatedly to the emergency room for treatment of uncontrolled chronic illness like diabetes? Evidence-based practice requires input and agreement from three sources for success: literature, healthcare providers, and patients. This study presents a resource that is validated with literature, pilot tested in one local population, and now needs to be tested and critiqued by healthcare providers in other communities and populations. Patients need to be approached with this screening in a manner that encourages open and honest participation, a challenge when working with people who often do not feel well and move quickly through their clinic visits.

In addition, there is a need to evaluate the impact of barriers and prioritization of interventions. The research found in this project was very informative for addressing individual barriers, but how is this applied to complex patients with multi-layered barriers? As indicated by the classification trees, individuals are still at risk when there are underlying issues. How does the healthcare community come together to ensure a sustainable practice of identifying these vulnerable patients and interceding to remove all impactful barriers, improve adherence, and measure resulting impact to the healthcare system? As a healthcare system, effort must be made to improve adherence to medication regimens and reduce the incidence of uncontrolled illness in our most vulnerable patient populations.

"And let us not be weary in well doing for in due season we shall reap, if we faint not."

Galatians 6:9 (KJV)

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## APPENDIX A: Evidence Table

**Name:** Addressing Barriers to Medication Adherence: An Evidence-Based Screening Instrument Validation Study

**Clinical Question:** In a one-year retrospective review of CMS eligible outpatient records, does the use of a new evidence-based screening instrument developed from literature, compared to current screening methods, increase identification of patients with barriers to medication adherence?

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
|---|---|---|---|---|---|---|---|
| Al-Batran, M. (2015). Evidence based practice: The effectiveness of group psychoeducation for medications adherence among inpatient adults with schizophrenia in psychiatric and mental health settings. *Middle East Journal of Nursing*, *9*(2), 25-30. | Examine effectiveness of group psycho-education for medication adherence in adults suffering from Schizophrenia | This is an analysis of systematic reviews and randomized controlled trials focusing on the effectiveness of group psychoeducation for Schizophrenic patients. | Studies were selected from CINAHL, Pub-med, and MEDLINE from the years between 2009 and 2013 | It was proven that group psychoeducation for medication adherence was proven effective. Rehospitalizations were decreased, as well as a reduction in length of hospitalization. It also increased quality of life, and self-esteem among other things. | Level 1: Systematic Review of controlled trials | Schizophrenia can be very challenging, there is a high rate of drop-out from these programs, and the education cannot change certain behaviors. In addition, fear of the treatment plan resulted in decreased medication adherence in some cases. | Yes, I would use to support the use of education and its potential effectiveness even in individuals with schizophrenia. |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
|---|---|---|---|---|---|---|---|
| Brewer, S., Whitten, S., & Dziodzio, J. (2016). Implementation of a COPD clinical pathway with a dedicated respiratory therapist team. TEAM. *Respiratory Care*, *61*(10), OF53. | To evaluate the effectiveness of a clinical pathway to reduce readmission of COPD patients | A convenience sample of 61 COPD patients admitted to a Maine hospital | A multidisciplinary task force created an inpatient COPD pathway which included standardized medication orders. Respiratory Therapists were trained to follow the program which included discharge teaching and patient materials. | The Respiratory Therapists found that the primary medical team was unwilling to order specialty service consults. The therapists also found that patients felt the reason they were readmitted is that they felt they had been discharged too early on the previous admission. More data was required to evaluate the effectiveness of their intervention. | Level 6: Single descriptive or qualitative study. | The study results speak more to the disadvantages of the protocol in that they had difficulty getting providers to order. Also, the average length of stay was slightly longer at 4 days as opposed to 3.76 in the control group. | This study is a lesson learned in evaluating culture of the organization carefully when implementing any type of intervention that requires multidisciplinary cooperation. |
| Duncan, P. W., Bushnell, C. D., Rosamond, W. D., Berkeley, S. J., Gesell, S. B., D'Agostino Jr, R. B., & ... Sissine, M. E. (2017). The Comprehensive Post-Acute | To assess the effectiveness of a comprehensive, evidence based, post-acute care model on patient-centered outcomes | 40 units in North Carolina with a recruitment goal of 6000 patients (3000 per arm) discharged home with a stroke or transient | Randomized control trial. Two days after discharge, patients in the experimental arm received a phone call and then a two-week follow up visit. The visit included | The study is ongoing. The primary outcome is patient reported functional status, but secondary includes medication adherence and use of community resources. | Level 2: Randomized Control Trial | The study has not completed as of yet. It began in 2015 and is ongoing which is an indication that the study is accruing and going as well as possible. It appears from | Yes, this study is important evidence that there is merit behind an instrument |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
|---|---|---|---|---|---|---|---|
| Stroke Services (COMPASS) study: Design and methods for a cluster-randomized pragmatic trial. *BMC Neurology*, *17*, (1-13). doi:10.1186/s12883-017-0907-1 | | ischemic attack. Patients are adults 18 years and older with stroke or transient ischemic attack who are discharged home from the hospital. | assessment of social and functional determinants of health and an individualized COMPASS Care Plan integrated with a community-specific resource data based. Follow up phone calls are made at 30 and 60 days post discharge to follow up on interventions. | | | another search that they may have lowered their total accrual goal to 5000 from the previous 6000 goal. (Found here: https://www.pcori.org/research-results/2015/comparing-ways-improve-daily-functioning-stroke-survivors-after-they-leave) | developed to help identify community resources and a structured plan to help patients at high risk for readmission. |
| Flink, M., & Ekstedt, M. (2016). Prerequisites for patient self-management learning at hospital discharge - an observational multiple case study. *International Journal of Integrated Care*, *16*(6), 1- | The study aim was" to explore how the hospital discharge process provides a learning environment for patients' understanding of their self-management." | Adult patients being discharged from three internal medicine "wards" and caregivers/nurses in three different hospitals in Sweden. | This was an observational case-study design. Nurses were provided with information of which much effort was put into developing, to facilitate patient understanding | Information given at discharge was driven by the needs of the staff, as opposed to the patient's level of understanding. Providing information alone does not promote adherence to medications. Patients must be given the time to learn in a patient centered way, however, due to time | Level 4: case study design | The findings of this study were not what had been hoped by the researchers who had spent a great amount of effort developing an instrument that they hoped would be used by nurses to improve discharge teaching and | The important takeaway here is that there must be care with developing teaching materials as a way to improve |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
|---|---|---|---|---|---|---|---|
| 2. doi:10.5334/ijic.2768 | | | | limitations, patients are not involved in planning their care. | | medication adherence. | adherence to prescribed regimens. Healthcare workers/ nurses have little time to educate patients. |
| Hanson, R. L., Habibi, M., Khamo, N., Abdou, S., & Stubbings, J. (2014). Integrated clinical and specialty pharmacy practice model for management of patients with multiple sclerosis. *American Journal of Health-System Pharmacy*, *71*(6 | Integrated clinical and specialty pharmacy practice model for management of patients with multiple sclerosis | This is a description of a specialty pharmacy model utilizing an interdisciplinary approach including physicians, nurses, and pharmacists. | High rates of non-adherence to expensive MS drugs was addressed by creating a model to incorporate a dedicated team to address barriers including a pharmacist, and direct interaction with the patient. | The model improves patient compliance | Level 7: Expert Opinion | The model may not be reproducible because it involves an investment of time and resources. Not all clinics have pharmacists available to help with medication teaching. | Yes, this model describes something similar to an interdisciplinary team model that is missing from some units in the hospital. These |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
|---|---|---|---|---|---|---|---|
| ), 463-469. doi:10.2146/ajhp130495 | | | | | | | teams can help address barriers that patients may have to successful adherence to home medications. |
| Lafeuille, M., Frois, C., Cloutier, M., Duh, M. S., Lefebvre, P., Pesa, J., & ... Durkin, M. (2016). Factors associated with adherence to the HEDIS quality measure in Medicaid patients with schizophrenia. *American Health & Drug* | To assess the impact of baseline schizophrenia patient characteristics on adherence to antipsychotic medications | 12,990 Patients with schizophrenia between the ages of 25-64 on at least one antipsychotic medication | Descriptive review of Medicaid healthcare claims data between 2008 and 2011 from five states - to identify | Patients who showed adherence as a baseline characteristic and on one particular medication showed continued adherence | Level 6: descriptive study | This is a review of information found in a database and is completely dependent on the accuracy of the database, | Yes, this helps to develop the assessment instrument in that if patients are already adherent they are likely to continue to be adherent. |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
|---|---|---|---|---|---|---|---|
| *Benefits*, *9*(7), 399-409 | | | | | | | |
| Patel, S. D., Phuoc Anh (Anne), N., Bachler, M., & Atkinson, B. (2017). Implementation of postdischarge follow-up telephone calls at a comprehensive cancer center. *American Journal of Health-System Pharmacy*, *74,* S42-S46. doi:10.2146/ajhp160805 | To reduce within 30 day readmissions by developing and implementing a pharmacy-driven postdischarge follow-up telephone call program to assess adherence to medications, educate, and address concerns | Convenience sample of pharmacists employed by MD Anderson Cancer Center and patients discharged during the study period | Pharmacists were trained in a transition-of-care telephone call program. Patients were called and asked the questions to determine adherence, answer questions, and address discrepancies. | Patients who received the phone calls were less likely to be rehospitalized within 30 days following discharge. Out of 206 calls completed, 87 patients were found to have discrepancies in their medication regimen. | Level 4 Cohort Study | Convenience sample using a pilot instrument for the phone interview. | Yes. Although it is not a strong study on its own, with additional similar evidence this could support the usefulness of pharmacist follow up and/or use of a specific instrument when calling patients after discharge. |
| Tomko, J. R., Ahmed, N., Mukherjee, K., | To evaluate a pharmacist-driven discharge | Adult patients discharged from a | Retrospective review of patient charts | 30 day hospital readmission rates were significantly | Level 6: Single descriptive | This may not be replicable in a facility that does | Yes. This study showed |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
|---|---|---|---|---|---|---|---|
| Roma, R. S., Dilucente, D., & Orchowski, K. (2013). Evaluation of a discharge medication service on an acute psychiatric unit. *Hospital Pharmacy*, *48*(4), 314-320. doi:10.1310/hpj4804-314.test | medication service for hospitalized psychiatric patients. Patients were provided with immediate access to their medications upon discharge. | behavioral health unit to home between October 2010 and November 2011who were prescribed psychiatric prescriptions for self-administration | | decreased in studied subjects compared to total readmissions the previous year | | not provide ambulatory prescription services. | that immediate availability of prescriptions upon discharge combined with development of support decreases readmissions of psychiatric patients. |
| Aikens, J. E., Trivedi, R., Aron, D. C., & Piette, J. D. (2015). Integrating support persons into diabetes telemonitoring to improve self-management and medication adherence. *Journal of General* | To investigate the potential benefits for medication adherence of integrating a patient-selected support person into an automated diabetes telemonitoring and self-management program, and to determine whether these benefits vary | 98 initially non-adherent adult patients | Quasi-experimental design in which patients chose their preference for telemonitoring vs. interactive voice response calls. This was a three to six month intervention in which the patient could choose a | Out of 98 patients, 42% opted to involve a support person. Those who opted for the additional support person demonstrated significantly greater improvement in long-term adherence than those who participated alone. Distress was a predictor that the | Level 4: Case control study | A weakness is that patients randomized themselves. | Yes, this study brings the idea of distress as predictors of adherence into the picture, but also indicates |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
|---|---|---|---|---|---|---|---|
| *Internal Medicine*, *30*(3), 319-326. doi:10.1007/s11606-014-3101-9 | by the patients baseline of distress. | | support person to receive updates along with guidance regarding patient assistance. Distress was measured at baseline. | support person would eventually become less effective over time, but not for those who participated alone. | | | that having a support person is important to help with adherence when combined with additional services such as telemonitoring. |
| Balling, L., Erstad, B. L., & Weibel, K. (2015). Impact of a transition-of-care pharmacist during hospital discharge. *Journal of The American Pharmacists Association: Japha*, *55*(4), 443-448. doi:10.1331/JA | To assess the impact of a transition-of-care pharmacist during hospital discharge | 1011 adult patients were educated and 452 interventions by a pharmacist when discharges were coordinated in two inpatient units in Southern Arizona August 2012 to July 2013. | This was a before and after comparison where a pharmacist provided education and medication reconciliation as well as intervening to prevent errors. | Readmission rate dropped and several interventions included starting an omitted medication, preventing multiple discharge problems such as duplication of therapy, improper dose or quantity, inappropriate prescription, preventing a drug interaction etc. | Level 3 Control trial - no randomization | Convenience sample. Not all patients benefited from the service. there is no account for possible changes in acuity, or census. | Yes. This article adds to the evidence that patients have barriers to home adherence that start in the hospital setting and that |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| PhA.2015.14087 | | | | | | | intervention can help improve adherence. |
| Kangovi, S., Grande, D., Meehan, P., Mitra, N., Shannon, R., & Long, J. A. (2012). Perceptions of readmitted patients on the transition from hospital to home. *Journal of Hospital Medicine*, *7*(9), 709-712. doi:10.1002/jhm.1966 | To collect patient reported challenges that they believe contribute to illness relapse | 1084 adult inpatients of U.Penn and Penn Presbyterian hospitals between Nov. 2010 to July 2011. | Cross-Sectional Survey | Issues reported included, feeling unprepared for discharge, difficulty with ADLS, trouble adhering or accessing to discharge medications, lack of social support. low socioeconomic status (Medicaid or uninsured) were more likely to report difficulty understanding and executing discharge instructions, adhering to medications, etc. | Level 6 single descriptive study | Convenience sample | Yes, this study provides additional confirmation that there are risk factors that may be included in an assessment instrument. |
| Vervloet, M., Spreeuwenberg, P., Bouvy, M. L., Heerdink, E. R., de Bakker, D. H., & van Dijk, L. (2013). Lazy Sunday afternoons: The | Investigate impact of deviations from prescribed regimen in type 2 diabetes patients can be explained by characteristics of the individual medication intake | 104 non-adherent type-2 diabetes adult patients from 37 community pharmacies | Observational study. Patients were monitored for 6 months to see whether intake occurred and whether or not intake occurred within the agreed- | Medications in evening and weekends and holidays are less likely to be correctly timed and also more likely to be completely missed. The worst day was | Level 6 single descriptive | Electronic monitoring devices do not guarantee that it is the patient accessing the medication nor that the | Yes, this provides a good basis for considering altering timing of medicati |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| negative impact of interruptions in patients' daily routine on adherence to oral antidiabetic medication. A multilevel analysis of electronic monitoring data. *European Journal of Clinical Pharmacology*, *69*(8), 1599-1606. | moments and the patient | | upon time period (correct time) | Sunday at 33% compliance. | | medication was actually taken. | on schedule for non-adherent patients. |
| Peeters, B., Van Tongelen, I., Duran, Z., Yüksel, G., Mehuys, E., Willems, S., & ... Boussery, K. (2015). Understanding medication adherence among patients of Turkish descent with type 2 diabetes: a qualitative | To explore perspectives of Turkish migrants with type 2 diabetes on adherence to oral hypoglycemic agents | 21 adult Turkish descent patients recruited from primary care and community sources. | In-depth interviews. Analysis was guided by a grounded theory approach. | Healthcare providers should explore patient perspectives of medication adherence with their patients due to several different beliefs about medications, as well as problems with forgetfulness, feelings of depression, and lack of social support. | Level 6 qualitative study | Small sample | Yes, combined with other evidence this article reminds of some of the many other aspects that can factor into non- |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
|---|---|---|---|---|---|---|---|
| study. *Ethnicity & Health*, *20*(1), 87-105. doi:10.1080/13557858.2014.890174 | | | | | | | adherence. |
| National Community Pharmacist's Association. (2013). *Medication Adherence in America: A national report card.* Retrieved from http://www.ncpa.co/adherence/AdherenceReportCard_Full.pdf | A national survey conducted to determine self-reported adherence while also assessing demographic, attitudinal and behavioral factors related to prescription drug compliance. | 1020 American adults aged 40 and older (median age of 60) prescribed ongoing medication (average of four prescribed medications) for a chronic condition (the group that uses prescription medication most regularly and therefore at greatest risk for nonadherence). | Independent random-sample telephone survey conducted by a research firm. Survey assessed nine nonadherant behaviors:, in the past 12 months, patients failed to fill or refill a prescription, missed a dose, took a lower or higher dose than prescribed, stopped a prescription early, took an old medication for a new problem, took someone else's medicine or forgot whether they'd taken a medication. | 48% earned a grade of A or B 36 percent a grade of C or D. 15 percent Predictors Regression modeling, identified the six key predictors of adherence. Those include – in order of magnitude: Patients' personal connection with a pharmacist or pharmacy staff; How easy it is for them to afford their medications; The level of continuity they have in their health care; How important patients feel it is to take their medication exactly as prescribed; | Level 6 descriptive study - random survey | A telephone survey is dependent on the honesty of the respondent. Respondents may be reluctant to admit undesirable behaviors. There are questions about connectedness for both doctors and pharmacists. The study emphasizes the connectedness with a pharmacist as a behavior related to adherence. The study was conducted for the National Community Pharmacy Association so | Yes, this research contains useful information to learn about reasons for non-adherence and methods that may help promote adherence. |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| | | | | How well informed they feel about their health; and<br>The extent to which their medication causes unpleasant side effects. | | may be somewhat biased in the questionnaire as this has not been found in other studies. | |
| Cawthon, C., Mion, L., Willens, D., Roumie, C., & Kripalani, S. (2014). Implementing routine health literacy assessment in hospital and primary care patients. *The Joint Commission Journal on Quality and Patient Safety: Joint Commission Resources, 40*(2): 68-76. | Addressing health literacy is a national health priority. The purpose of this study was to measure the acceptability, adoption, appropriateness, feasibility, fidelity, and sustainability of a three-item measure called the Brief Health Literacy Screen (BHLS) | Data was collected between November 2010 and April 2012 on 55,611 adults primarily middle-aged and Caucasian. | Approximately 5000 inpatient and outpatient nursing staff were informed and educated about the instrument. The instrument was embedded into the electronic health record and asked at admission to the inpatient or outpatient setting: Questions included: " The BHLS consists of three questions asking about confidence filling out forms, if they ask others to help them read hospital materials, and difficulty learning | The study found that it was feasible and efficient to include the three-question assessment as part of the nursing assessment process. There are instruments that are lengthier to administer, but not feasible. This study | Level three controlled trial | This study was to test feasibility of implementing a three question assessment. Further study is needed to evaluate effectiveness of the instrument. Further development of appropriate patient resources as well as training for nurses to administer the test were identified. | Yes, the Joint Commission is an accrediting body of our hospital system and the statements made as well as the references to the importance of assessing patients' specific learning needs holds additional weight. |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| | | | about medical condition due to difficulty understanding written materials. | | | | |
| Mausbach, B. T., Schwab, R. B., & Irwin, S. A. (2015). Depression as a predictor of adherence to adjuvant endocrine therapy (AET) in women with breast cancer: a systematic review and meta-analysis. *Breast Cancer Research and Treatment*, *152*(2), 239-246. doi:10.1007/s10549-015-3471-7 | To analyze the available evidence concerning the effects of depression on non-adherence to adjuvant endocrine therapy. | Breast cancer patients taking endocrine therapy with a total population of 17,735 patients with breast cancer. The articles were published between 2004 to 2014. . | Systematic review and meta-analysis Level of Evidence: Level 1 systematic Review and meta-analysis Limitations: 1. Only 9 studies included, 2. all studies included participants with depression but only one study included this as a variable, 3. None of the studies focused exclusively on the effect of depression on adherence. | The review states that as much as 20% of breast cancer patients are depressed. Depressed patients tend to be less adherent to their therapy. Mortality may be increased due to nonadherence to oral therapy. Women who are depressed had greater financial burden, lower quality of life, and shorter time to recurrence of their cancer. | Level 1 systematic Review and meta-analysis | Limitations mentioned in the study included. all studies included participants with depression but only one study included this as a variable and none of the studies focused exclusively on the effect of depression on adherence. | Yes, study supports importance of treating depression to improve adherence |
| Verbrugghe, M., Verhaeghe, S., Lauwaert, K., Beeckman, D., & Van Hecke, | To gain insight into the determinants and associated factors of nonadherence in | 25 studies focusing on adherence to oral anti- | Systematic review of literature | The study found that older age, and younger age (not middle age) along with therapy related | Systematic review of literature. Level one evidence | Patient characteristics differed widely so difficult to generalize. | Yes Supports importance of controlli |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| A. (2013). Determinants and associated factors influencing medication adherence and persistence to oral anticancer drugs: A systematic review. *Cancer Treatment Reviews*, *39*(6), 610-621. doi:10.1016/j.ctrv.2012.12.014 | patients taking cancer therapy | cancer therapy drugs | | side effects were the predominant factors in non-adherence. Better attention to management of side effects may help patients adhere to their oral chemotherapy and continue to take it longer. | | Approaches may need to be taylored to each person to be effective (given a choice)<br>Only two studies used MEMS to detect when medication vials were accessed.<br>Patients need to be "well-informed" | ng side effects to promote adherence |
| Bender, C. M., Gentry, A. L., Brufsky, A. M., Casillo, F. E., | To assess patient illness or treatment factors that may predict | 91 women with early stage breast cancer | Repeated measure design to assess adherence continuously for | Found lower adherence for women with depression, anxiety, or symptoms | Level 6 repeated measure design | Sample size may have been a factor related to cognitive | |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| Cohen, S. M., Dailey, M. M., . . . Sereika, S. M. (2014). Influence of patient and treatment factors on adherence to adjuvant endocrine therapy in breast cancer. *Oncology Nursing Forum*, *41*(3), 274. doi:10.1188/14.ONF.274-285 | nonadherence to endocrine therapy | receiving endocrine therapy | the first 18 months of endocrine therapy. Assessments completed at four time points to measure adherence rates between beginning and 18 months. | of illness prior to starting therapy. Adherence to endocrine therapy was lower in first eight months for those with negative mood. Women with breasts cancer may be at risk for nonadherence if they experience depression or anxiety and symptoms prior to initiating therapy. | | function. More research is needed to clarify cognitive function in adherence. | |
| Greer, J. A., Amoyal, N., Nisotel, L., Fishbein, J. N., Macdonald, J., Stagl, J., . . . Pirl, W. F. (2016). A systematic review of adherence to oral antineoplastic therapies. *Oncologist*, | To determine causes of nonadherence and factors that may help promote adherence. | 63 studies of adults with cancer who are prescribed oral chemotherapy drugs. Studies published between Jaunary 1, 2003 to June 30, 2015. | Systematic literature review | Adherence to endocrine therapy decreased over time to about 50% adherence by the 5th year. Depression played a significant role in adherence, especially in younger adults. Asking patients about adherence in the affirmative such as "What percentage of the time did you | Level 1: Systematic Review | The researchers found very significant limitations in most of the studies they reviewed, mostly concerning bias. In fact all but three studies were felt to be very biased. Authors felt more study is needed to determine | Yes, I will use this for the information regarding the effect of depression on adherence partly because the same |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| *21*(3), 354-376. doi:10.1634/theoncologist.2015-0405 | | | | take your medications" or "How well did you take your medications last month" as opposed to "How many pills did you miss" may yield more reliable and accurate responses. Overall, adherence declines over time with varying reasons. | | effective promotion of adherence. | is substantiated by other studies as well, however, the questions asked in the individual studies to help determine individual adherence factors and adherence were felt to be biased by the researchers doing the literature review. |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| Kaiser Family Foundation. (2017). *Public opinion on prescription drugs and their prices.* [online slide presentation of a 2015-2017 tracking poll]. Retrieved from https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/ | A public opinion poll on prescription drugs and their prices | 1171 adults age 18 and older | Telephone survey - Adults were surveyed by telephone between April 17-23, 2017 weighted to balance the sample demographics to match estimates of the national population according to the 2015 census bureau (KFF.org, 2017) | One in five adults reported taking at least four prescription drugs with 55% taking at least one. 35% of patients taking four or more prescription pills reported taking lower dosage, or skipped doses (and if uninsured did not fill the prescription) compared to 25% of those taking three or fewer. Income of $40,000 a year or less was another predictive factor of lowering, skipping, or not filling a prescription. | Level 6 survey | Convenience sample that may include sampling error and bias based on adults willing to answer questions over the phone could misrepresent the population as a whole. | Yes, this is a useful survey to help determine warning signs and barriers |
| Parr, K. (2017). *Health literacy: Improving understanding of discharge instructions.* Unpublished manuscript, School of Nursing, Liberty | To improve patient satisfaction and understanding of discharge instructions by factoring in literacy into discharge instructions and using teach-back to | Adults aged 18 - 89 having outpatient surgery without cognitive impairments. | Instructions were provided to patient at a 5th to 6th grade reading level with pictures if needed. Patients were asked to teach-back what they learned. Data was collected one | OAS CAHPS survey showed positive results; however, the sample of surveys returned was insufficient to show statistical significance. The Likert survey did show that patients | Level 6 single descriptive pilot study | Returned surveys did not show a statistical difference in CAHPs survey partly due to limited time frame of study and limited | Yes, this speaks well to how literacy impacts patient education, as well as |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| University, Lynchburg, Va. | assess understanding. | | month for patients discharged and compared to previous satisfaction scores. A Likert scaled phone survey was also used to collect information. | felt better prepared and better educated for discharge home after surgery. | | sample of returned surveys. | supporting the teach-back method of patient education |
| Boucher, J., Lucca, J., Hooper, C., Pedulla, L., & Berry, D. L. (2015). A structured nursing intervention to address oral chemotherapy adherence in patients with non-small cell lung cancer. *Oncology Nursing Forum*, 42(4), 383. | To evaluate a nurse-led intervention to enhance mediation knowledge and adherence using the Multinational Association for Supportive Care in Cancer Oral Agent Teaching Instrument (MOATT) | 30 adult patients with lung cancer | Longitudinal descriptive feasibility study to assess a structured nurse-led education session using MOATT. A 72 hour phone follow up was provided after initiatial education of the participant. Participants completed a knowledge rating scale, adherence scale at the end of the first cycle of oral chemotherapy. | The structured MOATT program were feasible for the program, and the adherence and knowledge outcomes were encouraging. Additional studies are needed to measure objective adherence measures and strategies for delivering supportive care to patients in their homes. | Level 6 longitudinal descriptive feasibility study | The findings were applicable to a single drug, erlotinib. Due to the single arm study the article states that proof of improvement is not possible for this study despite encouraging results. | It adds to the knowledge however it is a small study. |
| Spoelstra, S. L., & Sansoucie, H. (2015). Putting | To develop a synthesis of the literature | Extensive review of literature on | Comprehensive review of literature | The literature supports using patient feedback and | Level 1 systematic review of | Information about technology becomes outdated | Yes, this is a helpful |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| evidence into practice: Evidence-based interventions for oral agents for cancer. *Clinical Journal of Oncology Nursing*, *19*(3), 60-72. doi:10.1188/15.S1.CJON.60-72 | surrounding the issue of adherence and identify effective interventions for the promotion, treatment, and management of adherence to oral agents for cancer. | the topic of medication adherence. Adult Patients with cancer as well as other populations were included. The review was conducted in 2014 and included data within a ten-year time-frame. | including a "weight of evidence classification schema to assess levels of evidence of each source. Limitation: technology has changed since review | multicomponent interventions. Literature also suggests that text messaging, automated voice response and treatment of depression are likely to be effective methods of promoting adherence to oral medications. Factors effecting adherence included decreased dosing to once a dya to improve adherence. | research combined with level 5 review of literature | quickly and there is a warning that this could be the case for any technology recommended in this article. | review with combined evidence to support various strategies to help with adherence. |
| Irwin, M., & Johnson, L. A. (2015). Factors influencing oral adherence: Qualitative metasummary and triangulation with quantitative evidence. *Clinical Journal of Oncology Nursing, 19*(3), | A review to synthesize evidence regarding factors that impact medication adherence and to identify implications for practice. | 159 research studies from PubMed and CINAHL: 83 Quantitative; 46 qualitative; 17 mixed-methods; 9 systematic reviews; 3 meta-analysis; and 1 integrated review. Study | Qualitative metasummary and triangulation with quantitative evidence. Evidence includes Systematic Reviews and Meta-analysis, quantitative studies, and mixed methods studies. | Forty-four factors were identified to have an influence on adherence. | Level 1 meta-analysis with triangulation | Qualitative studies may contain varied classification of themes and concepts. This was adjusted by secondary review to establish reliability. | Yes, this is very helpful for establishing a very reliable list of warning signs to barriers with multiple research studies |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| 6-30. http://dx.doi.org.ezproxy.liberty.edu/10.1188/15.S1.CJON.6-30 | | samples ranged from 10 to 101,028. Large studies utilized insurance and pharmacy databases for descriptive analysis. | | | | | supporting the prevalence and impact of each barrier. |
| Wooldridge, K., Schnipper, J. L., Goggins, K., Dittus, R. S., &Kripalani, S. (2016). Refractory primary medication nonadherence: Prevalence and predictors after pharmacist counseling at hospital discharge. *J. Hosp. Med.*, *11*, 48–51. doi:10.1002/jhm.2446 | To evaluate the prevalence and predictors of refractory primary nonadherence in patients hospitalized with acute cardiovascular conditions who received counseling from a pharmacist before discharge. | 341 patients who received discharge counseling during a previous pharmacist study and had new medications to be filled. Mean age was 61.3 years. | Data was obtained from medical record review and follow up phone calls. | The primary outcome was percentage of patients who reported not filling at least one discharge prescription. Patients were asked to provide a reason the medication was not filled. Single marital status, lower income, and having more than 10 medications were significantly associated with not filling medications. Reasons included cost by 23.5% of patients. Additional reasons include lack of time to go to the pharmacy, | Level 6 single descriptive study | No limitations were mentioned however, the study may be difficult to replicate for many institutions do not have pharmacy staff to support. | Yes, it adds to the knowledge of warning signs and barriers to adherence. |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| | | | | medication not delivered or dispensed, and inability to afford the medications. | | | |
| Barthélémy, P., Asmane-De la Porte, I., Meyer, N., Duclos, B., Serra, S., Dourthe, L.-M., . Kurtz, J.-E. (2014). Adherence and patients' attitudes to oral anticancer drugs: A prospective series of 201 patients focusing on targeted therapies. *Oncology, 88*(1), 1. doi:10.1159/000366226 | To see if patients who receive an education regarding importance of adherence to five full years of hormonal therapy felt better informed and adhered to their therapy longer | 201 women with various stages of breast cancer in Alsace, France between 2012 and 2013. | A 15-item survey was given to patients located on four oncology units. | The researchers concluded that better education, and education repeated at intervals throughout therapy could be beneficial to increasing adherence to oral therapies of all types. | Level 6 single descriptive study | The researchers did not ask if the patients had educated themselves in any way. | Yes, this supports the vast literature on the importance of education in the presence of some literature that implies a limit on its effectiveness. It may be more about the method and timing, than simply checking it off a |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| | | | | | | | list as a one-time task. |
| Moss, R. C., Lowe, G. C., Frampton, C. A., & Revell, P. (2014). A nurse-led randomised controlled trial of a structured educational programme for patients starting warfarin therapy. *Journal of Research in Nursing, 19*(5), 402-412. doi:10.1177/1744987113515261 | To see if a structured educational program at implementation of an oral medication improves knowledge, satisfaction and therapeutic benefits of the drug | A randomized controlled trial of 45 hospitalized patients being discharged on warfarin | divided into two groups, one receiving the "usual" care, and the other provided with structured counseling and an educational video. Both groups were administered questionnaires at discharge and again at 3 months. Both groups were also assessed for satisfaction and time in therapeutic INR. | Patients who received the intervention had significantly better knowledge of their therapy than the control group. In addition, they also reported improved satisfaction and better time in the target INR range. | Level 2 randomized controlled trial | A relatively small number of patients in one location limits generalization | Yes, it adds to the multitude of literature confirming that education provided in initial and concurrent time periods is beneficial |
| Murphy, C. C., Bartholomew, L. K., Carpentier, M. Y., Bluethmann, S. M., & Vernon, S. W. (2012). Adherence to adjuvant hormonal | To assess for barriers to adherence | This is a review of twenty-nine peer-reviewed, primary studies of female breast cancer survivors taking endocrine | Nonadherence rates were as high as 71% at five years. Factors that were attributed to improved adherence included taking more medications at baseline, referral to an | The study concludes that many of these factors are not modifiable and that further research is needed to identify potentially modifiable factors so that interventions can be developed to improve adherence | Level 1 systematic review of primary research studies | Data was collected up to 2012 which limits to certain types of therapies taken. New therapies have been developed which may have impacted the rates of nonadherence | Yes, this is a good study helping to identify some of the most common barriers |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| therapy among breast cancer survivors in clinical practice: a systematic review. *Breast Cancer Research and Treatment, 134*(2), 459-478. doi:10.1007/s10549-012-2114-5 | | therapy published between 1998 and 2012. | oncologist and earlier year of diagnoses. The factors attributed to worse adherence included older age, increased out-of-pocket costs, switching therapies and side effects. | and decrease mortality related to non-adherence. | | in women on endocrine therapy. | |
| Roop, J. C., & Wu, H.-S. (2014). Current practice patterns for oral chemotherapy: results of a national survey. *Oncology Nursing Forum, 41*(2), 185-A110. doi:10.1188/14.ONF.41-02AP | The three-phase study purpose was to develop, validate and implement a national online survey regarding current practice patterns in nursing when caring for patients prescribed oral chemotherapy treatments. The survey was developed to explore and describe current nursing practices especially regarding challenges related to caring for | The survey was sent to 5000 nurses who were members of the oncology nursing society. 577 nurses responded. 51% of the nurses worked in practices that had developed specific policies and procedures and resources for | This is a survey study. The survey contained 17 force-choiced items and one free-text item. | The most frequently identified barriers to adherence were cost and adverse effects of the medication. The free-text column responses have an interesting common theme regarding erratic procedures and inadequate interdisciplinary communication. | Level 6 survey study | This study has the limitations of an online survey in which a convenience sample is included which may represent a select group of nurses who have time and are willing to complete a survey. | Yes, this survey free text information confirms inadequate interdisciplinary communication is identified as a factor that may contribute to lower |

| Article Title, Author | Study Purpose | Sample | Methods | Study Results | Level of Evidence | Study Limitations | Would Use as Evidence to Support a Change? |
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| | patients taking oral chemotherapy, and to identify common barriers to treatment adherence in patients. | patients taking oral therapy. | | | | | adherence of medication in patients. It also supports cost and adverse effects as two common barriers to adherence. |

## APPENDIX B: Permission to use The Iowa Model Revised and Implementation Strategies for Evidence-Based Practice

### Permission to Use the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care

[redacted] - University of Iowa Hospitals and Clinics <noreply@qualtrics-survey.com>

Sun 12/10/2017 9:40 PM

To: Washburn, Donna (Nursing) <djwashburn@liberty.edu>;

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**Citation:** Iowa Model Collaborative. (2017). Iowa model of evidence-based practice: Revisions and validation. *Worldviews on Evidence-Based Nursing, 14(3), 175-182. doi:10.1111/wvn.12223*

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### Permission to use Implementation Strategies for EBP

[redacted] - University of Iowa Hospitals and Clinics <noreply@qualtrics-survey.com>

Reply

Sun 12/10/2017, 9:40 PM

Washburn, Donna (Nursing)

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Implementation Strategies for Evidence-Based Practice

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**Citation:** Cullen, L., & Adams, S. L. (2012). Planning for implementation of evidence-based practice. *Journal of Nursing Administration, 42*(4), 222-230. doi:10.1097/NNA.0b013e31824ccd0a

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## APPENDIX C: CITI Training Completion Certificate

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT COURSEWORK TRANSCRIPT

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS*

NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

**Name:** Donna Washburn (ID: 1645501)

**Email:** Djwashburn@liberty.edu

**Institution Affiliation:** Liberty University (ID: 2446)

**Institution Unit:** Nursing

**Curriculum Group:** Biomedical Research - Basic/Refresher

**Course Learner Group:** Biomedical & Health Science Researchers

**Stage:** Stage 1 - Basic Course

**Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.

**Report ID:** 20817799

**Completion Date:** 10-Sep-2016

**Expiration Date:** 10-Sep-2019

Minimum Passing: 80

**Reported Score*:** 98

| REQUIRED AND ELECTIVE MODULES ONLY | DATE COMPLETED | SCORE |
|---|---|---|

| | | |
|---|---|---|
| Belmont Report and CITI Course Introduction (ID: 1127) | 04-Mar-2010 | 3/3 (100%) |
| History and Ethics of Human Subjects Research (ID: 498) | 17-Mar-2010 | 7/7 (100%) |
| Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2) | 17-Mar-2010 | 4/5 (80%) |
| Informed Consent (ID: 3) | 17-Mar-2010 | 4/4 (100%) |
| Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4) | 18-Mar-2010 | 4/4 (100%) |
| Records-Based Research (ID: 5) | 18-Mar-2010 | 2/2 (100%) |
| Genetic Research in Human Populations (ID: 6) | 18-Mar-2010 | 2/2 (100%) |
| Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680) | 10-Sep-2016 | 5/5 (100%) |
| FDA-Regulated Research (ID: 12) | 18-Mar-2010 | 5/5 (100%) |
| Research and HIPAA Privacy Protections (ID: 14) | 28-Sep-2015 | 5/5 (100%) |
| Vulnerable Subjects - Research Involving Workers/Employees (ID: 483) | 28-Sep-2015 | 4/4 (100%) |
| Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777) | 10-Sep-2016 | 5/5 (100%) |
| Conflicts of Interest in Research Involving Human Subjects (ID: 488) | 18-Mar-2010 | 2/2 (100%) |
| Liberty University (ID: 15111) | 10-Sep-2016 | No Quiz |

**For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.**

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2 COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.



**Name:** Donna Washburn (ID: 1645501)

**Email:** Djwashburn@liberty.edu

**Institution Affiliation:** Liberty University (ID: 2446)

**Institution Unit:** Nursing

**Curriculum Group:** Biomedical Research - Basic/Refresher

**Course Learner Group:** Biomedical & Health Science Researchers

**Stage:** Stage 1 - Basic Course

**Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.

**Report ID:** 20817799

**Report Date:** 13-Sep-2016

Current Score**: 100

| REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES | MOST RECENT | SCORE |
|---|---|---|
| History and Ethics of Human Subjects Research (ID: 498) | 13-Sep-2016 | 7/7 (100%) |
| Students in Research (ID: 1321) | 13-Sep-2016 | 5/5 (100%) |
| Liberty University (ID: 15111) | 10-Sep-2016 | No Quiz |
| Informed Consent (ID: 3) | 13-Sep-2016 | 5/5 (100%) |
| Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4) | 13-Sep-2016 | 4/4 (100%) |
| Belmont Report and CITI Course Introduction (ID: 1127) | 13-Sep-2016 | 3/3 (100%) |
| Records-Based Research (ID: 5) | 13-Sep-2016 | 3/3 (100%) |
| Genetic Research in Human Populations (ID: 6) | 13-Sep-2016 | 5/5 (100%) |
| Vulnerable Subjects - Research Involving Prisoners (ID: 8) | 13-Sep-2016 | 4/4 (100%) |

| | | |
|---|---|---|
| Vulnerable Subjects - Research Involving Children (ID: 9) | 13-Sep-2016 | 3/3 (100%) |
| Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10) | 13-Sep-2016 | 3/3 (100%) |
| FDA-Regulated Research (ID: 12) | 13-Sep-2016 | 5/5 (100%) |
| Research and HIPAA Privacy Protections (ID: 14) | 28-Sep-2015 | 5/5 (100%) |
| Vulnerable Subjects - Research Involving Workers/Employees (ID: 483) | 28-Sep-2015 | 4/4 (100%) |
| Hot Topics (ID: 487) | 13-Sep-2016 | No Quiz |
| Conflicts of Interest in Research Involving Human Subjects (ID: 488) | 13-Sep-2016 | 5/5 (100%) |
| Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2) | 13-Sep-2016 | 5/5 (100%) |
| Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777) | 10-Sep-2016 | 5/5 (100%) |
| Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680) | 10-Sep-2016 | 5/5 (100%) |

**For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.**

**Verify at**: https://www.citiprogram.org/verify/?694a5a80-3014-4f34-8e0a-31434f88ec20

Collaborative Institutional Training Initiative (CITI Program)

Email: support@citiprogram.org Phone: 888-529-5929

Web: https://www.citiprogram.org

## APPENDIX D: Medication Adherence Barrier Identification Instrument (Version used for data collection)

### Medication Adherence Barrier Identification Instrument

Instructions for use in practice: Place a check next to each warning sign, then mark associated potential barrier identified (Refer to an oncology navigator for further evaluation and coordination of interdisciplinary care)

For Data Collection: Gender:_____Year of Birth:_____ Unique ID:_____ OSS Following: y/n

| **Barrier:** | **Warning Signs:** | **Notes: (referrals/interventions)** |
|---|---|---|
| ☐ **Financial/Social Support** | ○ Age 65 or higher and one or more of the following:<br>○ Unmarried and/or absence of social support<br>○ Medicaid eligible<br>○ Income less than 50,000 dollars/year<br>○ Limited pharmacy access (location of residence related to pharmacy, resides outside of city, lack of transportation) | |
| ☐ **Depression/Distress/ Anxiety** | ○ **PHQ-9 Depression screen Score of = / > 15**<br>○ **NCCN Distress Score of = / > 4**<br>○ Diagnoses of anxiety, or on medication for anxiety | (PHQ-9, NCCN scores represent "Current screening") |
| ☐ **Medical Related Concerns**<br><br>*Related cues: Side effects/Effectiveness/Medication Reconciliation Issues/relationship with provider/multiple comorbidities/ Polypharmacy/ Poor Performance Score (ECOG)/cancer therapy last 6 months* | ○ More than 10 medications<br>○ Uncontrolled illness<br>○ Unexpected side effects and/or lack of expected side effects<br>○ Distressed about side effects<br>○ Prescription not filled or refilled at expected rate<br>○ Late stage of cancer<br>○ Poor physical status (ECOG 1 or over)<br>○ Provider relationship strained<br>○ No show for appointments and reluctance to reschedule/Requesting a different provider<br>○ Significant other concerns about not following treatment regimen | Greater than 10 prescribed medications?<br><br>Record # of meds here and consider consult:_____ |
| ☐ **Behavior/Lifestyle**<br><br>*Related cues: Forgetting/Don't think it's needed/Didn't "agree" to take it/Don't like taking it/ too busy/Away from home/no established routine* | ○ Prescription not refilled at expected intervals<br>○ Pill bottle contains more pills than it should based on fill date (If it is the original bottle)<br>○ Taking additional unprescribed herbal or "natural" substances<br>○ Tobacco, ETOH abuse, illegal drug use<br>○ Weekly/daily pill box contains unopened/unused pills<br>○ Reluctance to accept a change in regimen<br>○ Preference to be "prescription free" or "all natural" or other alternatives | |
| ☐ **Educational** | ○ English is not first language | |

| | | |
|---|---|---|
| *Related cues: Knowledge deficits including general knowledge/limited English proficiency/functional/Cognitive/Psychological/Health literacy/Untreated Vision or Hearing Impairment/Memory impairment/misconceptions /Distrust* | ○ Reluctance, difficulty, or inability to read and/or correctly explain written medication instructions (on pill bottle or med list)<br>○ Medication not taken correctly<br>○ Identifies medications by color, size, and shape but unable to explain what medications are, or what they are for.<br>○ Has not filled prescription/reluctant to answer questions about compliance with regimen<br>○ Significant other takes care of all paperwork<br>○ Known memory impairment | |

| **Uncontrolled Chronic Illness:** | **Signs/Symptoms:** | **Related Medication:** |
|---|---|---|
| ☐ **Diabetes** | | |
| ☐ **Hypertension/CVD** | | |
| ☐ **Renal Impairment** | | |
| ☐ **Sustained uncontrolled depression/Mental Illness** | | |
| ☐ **COPD** | | |
| **Unplanned Care:** | Sign/Symptom/Diagnoses | Related or possibly related med |
| ☐ **Clinic Visit** | | |
| ☐ **Emergency Room Visit** | | |
| ☐ **Hospitalization** | | |

**Talking points:**

- ✓ Over 300 billion dollars spent on prescription drugs in 2015 (DC, 2017)
- ✓ Mental health and non-communicable disease are expected to exceed 65% of the global burden of disease in 2020; however 50% to 60% of patients (especially those with chronic diseases) are nonadherant to the medicine prescribed (Lam & Fresco, 2015).
- ✓ 50% to 70% of prescriptions make it to the pharmacy, 48% to 66% come out of a pharmacy, 25% to 30% are taken properly, and only 15% to 20% are refilled as prescribed (Millionhearts.hhs.gov, 2017).
- ✓ Successful therapy with medication is key to combating challenges with public health in both developed and developing countries. Therefore health care professionals and researchers need to do everything possible to improve adherence to medication regimens (Lam & Fresco, 2015).
- ✓ Definition of adherence: The World Health Organization definition of adherence: "the extent to which the persons' behavior (including medication-taking) corresponds with agreed upon recommendations from a

healthcare provider" and includes the initiation, continuation and discontinuation of the therapy as directed (Lam & Fresco, 2015; WHO, 2003).

- ✓ The CMS (Centers for Medicare and Medicaid Services) posted new measure information forms such as the NQF 2468: Adherence to Oral Diabetes Agents for Individuals with Diabetes Mellitus. CMS will look at databases of individuals prescribed at least two oral diabetes agents in 12 months. Specifically they will look at adherence to the oral diabetes medications by checking if prescriptions are filled. In addition, this measure is paired with two additional measures to check adherence to statins and ACEIs and ARBs for individuals with diabetes (CMS, 2017).
- ✓ A qualitative metasummary and triangulation with quantitative evidence provided forty-four factors influencing adherence from 159 studies of patients with and without cancer. Factors included provider relations, side effects, forgetfulness, and beliefs about medication necessity, establishing routines for taking medication, social support, and ability to fit medications into lifestyle, cost, and medication knowledge. Depression and negative expectations of results also had a negative effect on adherence (Irwin, & Johnson, 2015). This study was the most helpful in identifying the most prevalent barriers to adherence with multiple studies confirming each one.

## Barrier References and Notes:

| | |
|---|---|
| 1.Finances/ Social support | Cost can be a deterrent to filling prescriptions; patients do not fill their prescriptions about a quarter of the time, and do not take them about half of the time (AMA, 2018).<br>Single marital status, lower income, and having more than 10 medications were significantly associated with not filling medications. Reasons included cost by 23.5% of patients. Additional reasons include lack of time to go to the pharmacy, medication not delivered or dispensed, and inability to afford the medications (Wooldridge, Schnipper, Goggins, Dittus, & Kripalani, 2016).<br>Hanson, Habibi, Khamo, Abdou & Stubbings (2014) conducted a pharmacy study to examine whether connecting patients with a team to help address the prohibitive expense of multiple sclerosis drugs would improve adherence. It was in fact proven helpful, although the team concept involving advanced providers was an expensive concept that would be difficult to reproduce and sustain. The cancer center employs financial navigators, social workers, and nurse navigators who may provide a more sustainable coordination of care.<br>Three major factors predict whether or not a patient can afford medication: 1. Insurance coverage, 2. overall health and 3. Income. In addition individuals who make under $50,000/year in income are more likely to skip doses or stop taking their medication than individuals with higher income (NCPA, 2013).<br>Geography can be a significant hindrance for patients who live in rural areas, especially without reliable internet service (Heath, 2017).<br>In a New York Times online journal article, Frakt (2017) cites systematic reviews and randomized control trials analyzing several methods to address adherence such as electronic reminders, pill organizers, and electronic reminder and feedback systems. The author concludes that reduced price, or free medications are the only consistent predictor that patients will take and refill medication as directed (Frakt, 2017). "For those with certain chronic conditions, extra help in affording medications can reduce adverse events and hospitalizations<br>- One in five adults reported taking at least four prescription drugs with 55% taking at least one. 35% of patients taking four or more prescription pills reported taking lower dosage or skipped doses (and if uninsured did not fill the prescription) compared to 25% of those taking three or fewer. Income of $40,000 a year or less was another predictive factor of lowering, skipping, or not filling a prescription (KFF, 2017).<br>- 1084 adult patients at University of Pennsylvania and Pennsylvania Presbyterian hospitals were surveyed to discover the issues they felt caused their readmission. Among the most common reasons included low socioeconomic status (Medicaid or uninsured) driven barriers of obtaining and adhering to medication regimens (Kangovi et al., 2012).<br>Irwin & Johnson (2015) cite cost or lack of insurance coverage was mentioned 26% of the time, and social support was a reported factor of nonadherence 32% of the time in their meta-analysis of qualitative research with triangulation to quantitative studies.<br>Single marital status is a significant predictor of nonadherence according to one study (Greer et al., 2016). |

| | |
|---|---|
| 2. Depression, Distress and/or Anxiety | Patients who are depressed or anxious are less likely to take their medications (AMA, 2018).<br>Patient fills out PHQ-2 followed (if indicated by PHQ-2 score) by the PHQ-9. A score of 15 or higher on PHQ-9 indicates a moderately severe depression barring other causes such as thyroid disorder (American Family Physician, 2012).<br>If a patient has a history of mental health disorders such as depression, anxiety, or addiction, he or she is less likely to adhere to their medication regimen (Millionhearts.hhs.gov, 2017).<br>Greer et al. (2016) in a systematic review of adherence to oral chemotherapy agents reported that depression played a significant role in nonadherence, with some rates dropping to about 50% at the five-year follow up.<br>Adjuvant endocrine therapy adherence was lower in women with depressive symptoms, especially in younger women just starting endocrine therapy. Individuals with depression have greater non-adherence than patients without depressive symptoms. In this study, women with lower adherence were also found to have a shorter time to recurrence of their cancer, increased medical costs and worse quality of life (Mausbach, Schwab & Irwin, 2015).<br>Long-term distress may be a predictor of non-adherence (Aikens, Trivedi, Aron, & Piette, 2015).<br>- The Oncology Nursing Society provides information gleaned from an extensive review of literature on medication adherence. Their resource states that treatment of depression is found to be an intervention that is likely to be effective (Spoelstra, & Sansoucie, 2015). |
| 3. Medical Concerns | The greater the number of different medications prescribed and the higher the frequency, the more likely that a patient will be nonadherant to their medication regimen (AMA, 2018). The relationship to the provider is also a predictive factor in adherence. Advertisements, news coverage and stories can have a negative effect and/or cause mistrust. Patients are less likely to fill their prescription if they do not trust the prescriber (AMA, 2018)<br>"Mutually respectful collaboration with providers" is one key to improving adherence (CDC, 2017a). A meta-analysis of qualitative research with triangulation to quantitative research revealed a 42% frequency of provider relationship as a predictor of adherence in the qualitative literature. A positive relationship facilitates adherence while a negative relationship does the opposite (Irwin, & Johnson, 2015).<br>Side effects were reason for stopping medication in 21% of self-reported reasons for nonadherence in a national telephone survey of 1020 adults with chronic illness and four or more medications (NCPA, 2013). Side effects were found 40% of the time in the qualitative literature in a meta-analysis of research regarding nonadherence (Irwin, & Johnson, 2015).<br>- A qualitative study of Turkish migrants with type 2 diabetes found that nonadherence may be impacted by different beliefs about medications (Peeters et al., 2015).<br>- Barriers to adherence can start in the clinic or hospital setting due to medication reconciliation discrepancies (Balling, Erstad, & Weibel, 2015).<br>-although questionnaires can be time prohibitive to administer there are some that can be effective for assessing nonadherence. However interviewing patients is an easy, low-cost method to assess patient's adherence. Although knowledge may not accurately reflect adherence, knowing that they will be asked about medications by their provider may encourage adherence (Lam & Fresco, 2015).<br>As mentioned in the financial and social category, single marital status, lower income, and having more than 10 medications were significantly associated with not filling medications. Reasons included cost by 23.5% of patients. Additional reasons include lack of time to go to the pharmacy, medication not delivered or dispensed, and inability to afford the medications (Wooldridge, Schnipper, Goggins, Dittus, & Kripalani, 2016). |
| 4. Behaviors/Lifestyle<br><br>4. Behavioral and Lifestyle Barriers<br>- Forgetting/Don't think it's needed/Didn't "agree" to take it/Don't like taking it/ too busy/Away from home/no established routine | Forgetting was the number one self-reported reason for nonadherence in a national telephone survey (NCPA, 2013). However, additional research reviews of studies comparing reminder methods to control groups revealed that this may not be as large of an impact as previously reported (Frakt, 2017).<br>Patients who express that they are tired of taking medications are showing a predicting sign that they are nonadherant (Millionhearts.hhs.gov, 2017).<br>Frequency of forgetfulness was 38% and doubting necessity was 35% in a meta-analysis of research with triangulation (Irwin, & Johnson, 2015). In the same study, pill burden is mentioned with 25% frequency and regimen complexity 22% of the time.<br>Methods to encourage patient adherence recommended by the Oncology Nursing Society include Reminder instruments such as calendars, pill diaries, pill boxes with compartments for time of day for each day of the week, electronic reminders such as alarms, timers, smart phone apps, glowing or electronic pill containers and medication dispensing machines (ONS, 2016).<br>As mentioned in the financial and social category, single marital status, lower income, and having more than 10 medications were significantly associated with not filling medications. Reasons included cost by 23.5% of patients. Additional reasons include lack of time to go to the pharmacy, medication not delivered or dispensed, and inability to afford the medications (Wooldridge, Schnipper, Goggins, Dittus, & Kripalani, 2016). |

| | |
|---|---|
| 5. Educational Barriers | - Predictors of nonadherence include limited English language proficiency, low literacy, don't believe in the benefits of medication or believe they are not necessary or even harmful (Millionhearts.hhs.gov, 2017).<br>- Patients who do not understand the purpose, side effects, or expected time before it is effective may result in nonadherence. This is true in patients with chronic illness because there is often no obvious result so the patient may think it is not doing anything for them and stop taking it (AMA, 2018).<br>- The Oncology Nursing Society review of literature recommendations suggest in 2014 there was not enough information to establish education as an effective means of promoting adherence (Spoelstra, & Sansoucie, 2015). However, an additional study published by the Oncology Nursing Society in 2015 cites medication knowledge was mentioned 25% of the time in an extensive meta-analysis of qualitative studies triangulated with quantitative studies (Irwin, & Johnson, 2015).<br>-A Joint Commission study assessing the feasibility of a three-question literacy instrument states that addressing health literacy is a national health priority and Standard PC.02.02.01 is cited "The hospital effectively communicates to patients when providing care, treatment, and services" "Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. It is a necessary skill for successful navigation of the health care system, communication with providers, and management of chronic conditions. However, an estimated 90 million adults in the United States have low health literacy,2 which is associated with lower rates of preventive .care, poorer disease control, and greater mortality, as well as increased health care utilization and costs.3,4 (Cawthon, Mion, Willens, Roumie & Kripalani, 2014). Inability to read and understand directions, pill bottle labels may be due to small print, confusing medical terms or abbreviations as well (CDC, 2017a).<br>-Patients with higher levels of education typically are correlated with better health, have had more health education, and can advocate better for themselves (Heath, 2017).<br>Using 5th to 6th grade reading level with pictures and "teach-back" methods may help patients feel better prepared for discharge and to care for themselves (Parr, 2017).<br>-A structured, nurse-led teaching program that included follow-up phone calls at set intervals had encouraging results in lung cancer patients taking an oral chemotherapy drug (Boucher, Lucca, Hooper, Pedulla, & Berry, 2015).<br>In a systematic review of randomized control trials it was proven that group psychoeducation was effective in improving medication adherence in adults suffering from schizophrenia (Al-Batran, 2015).<br>-A study conducted by pharmacists at MD Anderson Cancer Center in Texas showed reduced hospitalization when patients were contacted by a pharmacist within 30 days of discharge to have adherence assessed, questions answered, and any discrepancies addressed (Patel, Phuoc, Bachler & Atkinson, 2017).<br>- An additional pharmacist-driven study evaluated the impact of providing medications immediately upon discharge to patients admitted to a psychiatric unit and found that this improved adherence to the treatment regimen (Tomko et al., 2013). This is not feasible when a dispensing pharmacy is not readily available. However it may be helpful to utilize this method if available in the future.<br>- 1084 adult patients were surveyed to discover the issues they felt caused their readmission. The most common reasons included feeling unprepared for discharge and lack of social support. Low socioeconomic status (Medicaid or uninsured) were more likely to report difficulty understanding and executing discharge instructions (Kangovi et al., 2012). |

## APPENDIX E: Letters of Support

Mrs Washburn,

Thank you for your interest in this project. We are happy to grant you permission to work on this study and provide you any support you need. Please let me know how I can assist you further.

Thanks,

Director of Practice Operations
Lynchburg and Southside Hematology Oncology
(434) 200-1492
(434) 401-5167

**From:** Donna Washburn
**Sent:** Tuesday, March 20, 2018 11:46 AM

**Cc:** Washburn, Donna (Nursing) <djwashburn@liberty.edu>
**Subject:** PERMISSION NEEDED PLEASE
**Importance:** High

Managing Director
Centra Pearson Cancer Center
Administrative Suite
1701 Thomson Drive
Lynchburg, VA 24501

Director
Centra Medical Oncology Clinic
Suite 200
1701 Thomson Drive
Lynchburg, VA 24501

3/20/2018

Dear _____

As a graduate student in the department at Liberty University, I am conducting an evidence-based practice nursing research project as part of the requirements for a Doctorate of Nursing Practice. The title of my study is, "Addressing barriers to medication adherence: An evidence-based screening instrument validation study." The purpose of the research is to find out if an evidence-based screening instrument will help identify actionable barriers to successful medication adherence in patients who are Medicare/Medicaid eligible. If after a retrospective review of medical records, it is found that the screening instrument can in fact help identify actionable barriers. The screening instrument may then

help navigators intervene and prevent unnecessary clinic visits, emergency room visits, and hospitalizations, by connecting these individuals to available community resources, depending on the barriers identified.

I am writing to request your permission to conduct the project using retrospective medical record data from CMS/OCM patients who have received chemotherapy in the Centra Medical Oncology Clinic within a year prior to IRB approval of the project. For this study, there will be no interaction with patients, no consent or surveys of any kind, and no prospective data collection. I will require interaction with med-onc staff, navigator staff, and OCM staff for assistance identifying OCM patients who are eligible for review. This may be as simple as a printed report showing a list of potentially eligible patients for me to screen. I have been screened and provided with Centra student intern identification and computer access.

Following your written permission, I will be submitting the study to the Liberty University IRB, and Centra IRB for approval.

Thank you for considering my request. If you choose to grant permission, please provide a signed statement on Centra letterhead indicating your approval, or respond by e-mail to djwashburn@liberty.edu.

Thank you
Donna Washburn MSN, RN, CNS, ACNS-BC, AOCNS
434-426-1278
djwashburn@liberty.edu

Regards,
Donna

Donna Washburn MSN, RN, CNS, ACNS-BC, AOCNS
Clinical Nurse Specialist
Director Professional Clinical Practice
Centra Health
Office: 434-200-3296

**Our Mission**: Excellent Care for Life
**Our Vision**: To be the **Most Trusted** Provider of Innovative Healthcare
**Our Nurses**: Nurses have been ranked the **most trusted profession** 15 years in a row

You have my permission.
Please keep us updated.

Managing Director,
Alan B. Pearson Regional Cancer Center
Lynchburg, VA 24501

# APPENDIX F: Institutional Review Board Approvals

CENTRA HEALTH Institutional Review Board
EXEMPT RESEARCH CHECKLIST
*Version 5, 19DEC2017*

Centra IRB
Received (date): 5/25/18
Action:

**Date:** March 26, 2018
**Centra IRB #:** 0422e **IRB of Record** _____

EXEMPT
Date: 6-19-18

**Facility: Centra Pearson Cancer Center**

**Principal Investigator**: Donna Washburn MSN, RN, CNS, ACNS-BC, AOCNS

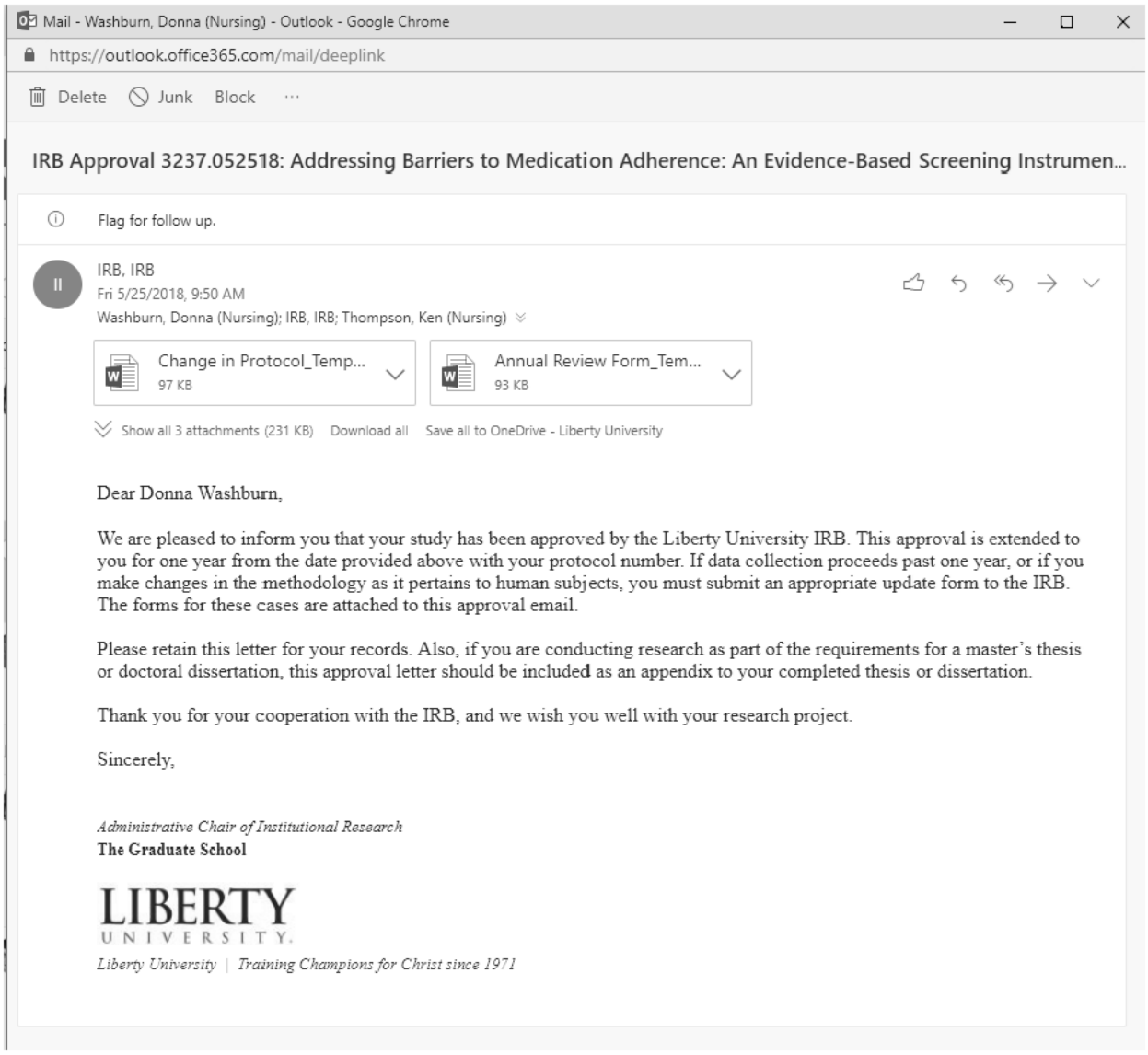
**Email address:** djwashburn@liberty.edu; donna.washburn@centrahealth.com

**Phone number:** 434-426-1278

**Title of Research Project/Study Title:** Addressing Barriers to Medication Adherence: An Evidence-Based Screening Instrumen: Validation Study

Attach documents related to the study.

| **Checklist Statements** | **True** | **Not True** |
|---|---|---|
| **Category 1 – For Educational Settings** | | |
| 1. The research will only be conducted in established or commonly-accepted educational settings including but not limited to schools and colleges. (May include other sites where educational activities regularly occur.) | | |
| 2. The research will involve only normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. | | |
| 3. The research will not involve individuals as participants who are known to be prisoners. | | |
| 4. The research is not subject to FDA regulations. | | |
| **Category 2 – For Educational Tests, Surveys, Interviews, Public Behavior Observation:** | | |
| 5. The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. | | |
| ***Address statement 6 only if the research will involve children as participants. If children will NOT participate, state N/A and continue with statement 7.*** 6. The procedures will be limited to the use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior where the investigator will NOT participate in the activities being observed. | | |
| 7. The information obtained from educational tests, survey procedures, interview procedures or observation of public behavior will be recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects. ***"True" to either statement 7 or 8 will qualify for exemption provided that statements 9 and 10 are true.*** | | |
| 8. Any disclosure of the human subjects' responses outside the research could NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. | | |
| 9. The research will not involve individuals as participants who are known to be prisoners. | | |
| 10. The research is not subject to FDA regulations. | | |



Mail - Washburn, Donna (Nursing) - Outlook - Google Chrome

https://outlook.office365.com/mail/deeplink

Delete Junk Block ···

IRB Approval 3237.052518: Addressing Barriers to Medication Adherence: An Evidence-Based Screening Instrumen...

Flag for follow up.

IRB, IRB
Fri 5/25/2018, 9:50 AM
Washburn, Donna (Nursing); IRB, IRB; Thompson, Ken (Nursing)

Change in Protocol_Temp... 97 KB

Annual Review Form_Tem... 93 KB

Show all 3 attachments (231 KB) Download all Save all to OneDrive - Liberty University

Dear Donna Washburn,

We are pleased to inform you that your study has been approved by the Liberty University IRB. This approval is extended to you for one year from the date provided above with your protocol number. If data collection proceeds past one year, or if you make changes in the methodology as it pertains to human subjects, you must submit an appropriate update form to the IRB. The forms for these cases are attached to this approval email.

Please retain this letter for your records. Also, if you are conducting research as part of the requirements for a master's thesis or doctoral dissertation, this approval letter should be included as an appendix to your completed thesis or dissertation.

Thank you for your cooperation with the IRB, and we wish you well with your research project.

Sincerely,

*Administrative Chair of Institutional Research*
**The Graduate School**

LIBERTY UNIVERSITY.

*Liberty University | Training Champions for Christ since 1971*

# APPENDIX G: SPSS Coding Key and Comments

| SPSS Variables (expanded) | Definition and Scoring System | Notes |
|---|---|---|
| **ID** | Last three numbers of MRN, then subject number using four placeholders I.e. 0001 to 0300 | ie: 1230001 |
| **Gender** | 1 - male, 2 = female | |
| **BirthYear** | Year of birth | |
| **CurrentMC_MA** | Medicare/Medicaid Patient, 1 = negative, 2 = Positive with documented intervention, 3 = Positive without documented Intervention | Current intervention to provide insurance and financial counseling on initial visit prior to treatment |
| **CurrentPHQ9** (Independent variable: "Current Screening") | PHQ-9 Depression Score 15 or higher, 1 = negative, 2 = Positive with documented intervention, 3 = Positive without documented Intervention | Current Scoring Tool in use, also integrated into W-BMA Depression, Distress, and Anxiety category (Part of independent variable for study called: "Current Screening") |
| **CurrentNCCNDistress** (Independent variable: "Current Screening") | NCCN Distress Score 4 or higher, 1 = negative, 2 = Positive with documented intervention, 3 = Positive without documented Intervention | current Scoring Tool in use, also integrated into W-BMA Depression, Distress, and Anxiety category (Part of independent variable for study called: "Current Screening") |
| **WBMA1_Fin_Soc** (Independent variable "W-BMA Screen" or "W-BMA Instrument") | Category 1, Financial and Social Risk, 1 = negative, 2 = Positive with documented intervention, 3 = Positive without documented Intervention | Washburn Barriers to Medication Adherence Risk Assessment Tool - Risk Factors associated with financial and social barriers (Part of independent variable usually referred to as: "W-BMA Screen" or "W-BMA Instrument") |

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| **WBMA2_Dep_Dis_Anx** (Independent variable "W-BMA Screen" or "W-BMA Instrument") | Category 2, Depression, Distress, Anxiety Risk, 1 = negative, 2 = Positive with documented intervention, 3 = Positive without documented Intervention | Washburn Barriers to Medication Adherence Risk Assessment Tool - Risk Factors associated with depression, distress, and anxiety including PHQ-9 and NCCN Distress scores (Part of independent variable usually referred to as: "W-BMA Screen" or "W-BMA Instrument") |
| **WBMA3_MedRelCon** (Independent variable "W-BMA Screen" or "W-BMA Instrument") | Category 3, Medical Related Concerns, 1 = negative, 2 = Positive with documented intervention, 3 = Positive without documented Intervention | Washburn Barriers to Medication Adherence Risk Assessment Tool - Risk Factors associated with medical related barriers (Part of independent variable usually referred to as: "W-BMA Screen" or "W-BMA Instrument") |
| **WBMA4_Beh_Lifestyle** (Independent variable "W-BMA Screen" or "W-BMA Instrument") | Category 4, Behavioral and lifestyle, 1 = negative, 2 = Positive with documented intervention, 3 = Positive without documented Intervention | Washburn Barriers to Medication Adherence Risk Assessment Tool - Risk Factors associated with behavior and lifestyle barriers (Part of independent variable usually referred to as: "W-BMA Screen" or "W-BMA Instrument") |
| **WBMA5_Educ** (Independent variable "W-BMA Screen" or "W-BMA Instrument") | Category 5 Educational, 1 = negative, 2 = Positive with documented intervention, 3 = Positive without documented Intervention | Washburn Barriers to Medication Adherence Risk Assessment Tool - Risk Factors associated with educational barriers (Part of independent variable usually referred to as: "W-BMA Screen" or "W-BMA Instrument") |
| **Diabetes_uncontolled** | Uncontrolled Diabetes, Defined as blood glucose over 140 without a formal diabetes diagnoses, or glucose over 180 with DMII diagnoses or over 130 if documented fasting. 1 = Negative and no med, 2 = Negative and on associated med, 3 = Positive and no prescribed medication, 4 = Positive and has a prescribed medication | Uncontrolled chronic illness assessment for sensitivity testing. All uncontrolled illness grouped into one variable for primary statistical tests. |

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| **HTN_uncontrolled** | Uncontrolled Hypertension, Defined as BP greater than 140 systolic, or 90 diastolic in two or more visits without resolution to 130/80 or below. 1 = Negative and no med, 2 = Negative and on associated med, 3 = Positive and no prescribed medication, 4 = Positive and has a prescribed medication | Uncontrolled chronic illness assessment for sensitivity testing. All uncontrolled illness grouped into one variable for primary statistical tests. |
| **Renal_Imp_uncontrolled** | Uncontrolled Renal Illness defined as an abnormal GFR grade 2 or worse, or Creatinine Grade 2 or worse sustained over 2 or more consecutive visits, 1 = Negative and no med, 2 = Negative and on associated med, 3 = Positive and no prescribed medication, 4 = Positive and has a prescribed medication (Note: this is a common adverse event associated with cancer treatment) | Uncontrolled chronic illness assessment for sensitivity testing. All uncontrolled illness grouped into one variable for primary statistical tests. |
| **Dep_Mental_uncontrolled** | Uncontrolled depression or mental illness, defined as documented in chart, 1 = Negative and no med, 2 = Negative and on associated med, 3 = Positive and no prescribed medication, 4 = Positive and has a prescribed medication | Uncontrolled chronic illness assessment for sensitivity testing. All uncontrolled illness grouped into one variable for primary statistical tests. |
| **COPD_uncontrolled** | Uncontrolled COPD, 1 = Negative and no med, 2 = Negative and on associated med, 3 = Positive and no prescribed medication, 4 = Positive and has a prescribed medication | Uncontrolled chronic illness assessment for sensitivity testing. All uncontrolled illness grouped into one variable for primary statistical tests. |
| **Event_Unplanned_Clinic** | Unplanned Outpatient Clinical Visit, 1 = negative or visit was unrelated or probably unrelated to possible medication nonadherence or uncontrolled illness (# 1 or 2 negative in uncontrolled illness section), | Event Assessment for potential correlation with severity of uncontrolled illness and future measurable financial implications of non-adherence. |

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| | 2 = Positive and possibly or definitely related to possible medication nonadherence and/or uncontrolled illness (# 3 or 4 positive responses in uncontrolled illness section) | |
| **Event_ER** | Emergency Room Visit with or without hospitalization, 1 = negative or visit was unrelated or probably unrelated to possible medication nonadherence or uncontrolled illness (# 1 or 2 negative in uncontrolled illness section), 2 = Positive and possibly or definitely related to possible medication nonadherence and/or uncontrolled illness (# 3 or 4 positive responses in uncontrolled illness section) | Event Assessment for potential correlation with severity of uncontrolled illness and future measurable financial implications of non-adherence. |
| **Event_Hospital** | Hospitalization (including observation), 1 = negative or hospitalization was unrelated or probably unrelated to possible medication nonadherence or uncontrolled illness (# 1 or 2 negative in uncontrolled illness section), 2 = Positive and possibly or definitely related to possible medication nonadherence and/or uncontrolled illness (# 3 or 4 positive responses in uncontrolled illness section) | Event Assessment for potential correlation with severity of uncontrolled illness and future measurable financial implications of non-adherence. |
| **OSS_Full_Support** | Oncology Support Services providing full support. 1 = yes, 2 = no | Oncology Support Services providing full support throughout patient treatment to address known issues (not including "meet and greet" and initial pretreatment financial counseling) Full support focused on Navigator involvement, but includes Social Worker, Financial Support, Palliative Care. |

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| **NuprescribedMeds** | The number of prescribed meds - includes OTC meds recommended by provider | Excluded: Chemotherapy treatment and medications used to pretreat the patient in the clinic prior to chemo administration. Also excluded: OTC medications not recommended by provider including allergy and cold relief remedies, vitamins or herbal supplements, pain relief medications and sleep aides |
| **Free Text Comments** | | |