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Effects of an APN-Led Amiodarone Clinic on Adherence to Recommended Monitoring Guidelines

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EFFECTS OF AN APN-LED AMIODARONE CLINIC ON ADHERENCE TO RECOMMENDED MONITORING GUIDELINES

by

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DEDICATION

I would like to dedicate this evidence-based project report to my husband, Ed, and children, Joe and Liz, for supporting me throughout this three-year journey. Without their love and support, I would never have made it to the finish line.

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ABSTRACT

Evidence shows that patients receiving amiodarone therapy have not adhered to monitoring guidelines set forth by the Heart Rhythm Society. Uncertainty with responsibility for monitoring has led to the development of pharmacist-managed or multidisciplinary-managed outpatient amiodarone clinics. Some limitations have been identified in the pharmacist-managed outpatient clinics that may be overcome by advanced practice nurse (APN)-managed clinics. The purpose of this EBP project was to determine what effects an APN-led amiodarone clinic would have on adherence to amiodarone monitoring guidelines. Using the PICOT format, the clinical question was developed: Does enrollment in an amiodarone clinic compared with "usual care" change adherence to monitoring as recommended by best practice guidelines and allow for earlier recognition of adverse effects of amiodarone to decrease negative patient outcomes over a four month time period? Using King's theory of goal attainment and the ACE Star model, guidelines for monitoring patients newly started on amiodarone therapy were implemented at a northwest Indiana cardiology practice. Following enrollment, data were collected via chart reviews and compared to a usual care group which consisted of patients seen in the office during the previous year who did not receive care based on monitoring guidelines. When the two groups were compared using the chi-square of independence, a significant difference was found in the post-amiodarone group for baseline EKG (X^2 (1) = 4.56, p = .03). Although results were not statistically different for baseline TFT (X^2 (1) = 1.35, p = .25), LFT, (X^2 (1) = 2.55, p = .11), CXR (X^2 (1) = 3.32, p = .07), and PFT (X^2 (1) = 1.55, p = .21) diagnostics, those participants in the post-amiodarone clinic group were more likely to complete the recommended diagnostics. This small-scale APN-led amiodarone clinic improved amiodarone monitoring adherence leading to the possibility of future practice of APN-led therapeutic drug monitoring clinics.

Keywords: advanced practice nurse, amiodarone, cardiology, monitoring

CHAPTER 1

INTRODUCTION

Evidence shows that patients receiving amiodarone therapy for various arrhythmias have not adhered to monitoring guidelines set forth by the Heart Rhythm Society (HRS), formerly the North American Society for Pacing and Electrophysiology (NASPE) (Goldschlager et al., 2007). One reason for this lack of adherence may be the providers' uncertainty over responsibility for monitoring amiodarone adverse effects (Dixon, Thanavaro, Thais, & Lavin, 2013). The literature reviewed depicts various outpatient clinics dedicated to the monitoring of amiodarone according to HRS guidelines (Goldschlager et al., 2007) through pharmacist-managed practices as well as multidisciplinary practices. Some limitations have been identified in the pharmacist-managed outpatient clinics that may be overcome by advanced practice nurse (APN) managed clinics.

Background

Amiodarone is an effective treatment for patients with atrial and ventricular arrhythmias. Amiodarone is approved by the Food and Drug Administration (FDA) for the treatment of recurrent, hemodynamically unstable ventricular fibrillation or ventricular tachycardia especially in patients with structural heart disease, those with left ventricular dysfunction, and those with recurrent ventricular tachycardia or for the suppression/prophylaxis against atrial fibrillation with rapid ventricular rates (Goldschlager et al., 2007). Although amiodarone is not FDA-approved for the treatment of atrial fibrillation, studies have shown that amiodarone has higher rates of maintaining sinus rhythm at one year compared to other antiarrhythmic medications such as propafenone and sotalol (Goldschlager et al., 2007). However, amiodarone is not a benign medication. It has a half-life measured in weeks to months rather than hours and is highly lipid-soluble (Siddoway, 2003). Its lipophilic properties cause amiodarone to be stored in the lungs, liver, fat, skin, and other organs. Amiodarone also has effects on the gastrointestinal system, central nervous system, genitourinary system, and ocular system. Absorption from the

gastrointestinal tract is slow; therefore, it may be months before oral amiodarone reaches its full therapeutic effect (Dulak, 2005).

Due to its potential for serious adverse effects, the HRS has issued recommendations for baseline testing and follow-up for those patients on chronic amiodarone therapy (Goldschlager et al., 2007). Issues related to follow-up include:

- The continued assessment of drug efficacy
- Titration of drug dose after achieving a steady state; evaluation of adverse and toxic effects
- Appropriate management of toxic effects
- Attention to important drug-drug interactions
- Attention to important drug-device interactions (Goldschlager et al., 2007, p. 1253).

According to Goldschlager et al. (2007), adverse effects are common, affecting as many as 15% of patients in the first year of amiodarone therapy and as many as 50% of patients during chronic amiodarone use. The adverse effects identified by Goldschlager et al. (2007) include pulmonary reactions (cough, dyspnea), gastrointestinal tract reactions (nausea, loss of appetite, constipation), thyroid reactions (hypothyroidism, hyperthyroidism), skin reactions (blue discoloration, photosensitivity), central nervous system reactions (ataxia, paresthesias, peripheral neuropathy, insomnia, tremors, memory impairment), ocular reactions (halo vision, disturbance in night vision, photophobia, blurred vision, precipitate deposits), cardiac reactions (bradycardia, atrioventricular blocks, arrhythmias), and genitourinary reactions (epididymitis, erectile dysfunction). Due to its highly lipophilic nature and slow absorption through the gastrointestinal tract, adverse effects may take as long as six months to resolve, necessitating the duteous follow-up of patients on amiodarone for signs of adverse effects (Goldschlager et al., 2007).

Statement of the Problem

For proper care of the patient and minimization of adverse effects of amiodarone, providers must be aware of the multitude of adverse effects of amiodarone and the recommended guidelines for monitoring. Per HRS recommendations, patients on amiodarone should be initially assessed every 3 to 6 months for the first year for rhythm and adverse effects assessment and every 6 months after the first year (Goldschlager et al., 2007). Often times, healthcare providers are unsure of who should be following through with the recommended monitoring (Bickford & Spencer, 2006). An amiodarone clinic managed by an advanced practice nurse could be a solution to this identified gap in patient care by providing increased adherence to HRS guidelines for amiodarone monitoring (Goldschlager et al., 2007).

Data from the literature. More than 2 million prescriptions for amiodarone are written each year for patients (LiverTox, 2014). As many as 93% of these patients (over 1.8 million) develop some form of adverse reaction to amiodarone (Tafreshi, Chui, & Riley, 2009). These adverse reactions may be decreased through dose reduction, but as many at 2-26% of patients (40,000 to 520,000) require discontinuation of amiodarone due to the adverse effects (Tafreshi et al., 2009). Discontinuation of amiodarone then renders patients vulnerable to the arrhythmia that amiodarone was prescribed to control unless an alternative can be found. The most feared adverse drug event is pulmonary toxicity, causing death in about 10% of those diagnosed (Dulak, 2005).

Amiodarone interacts with multiple medications and multiple classes of medications. The most serious interactions are with QT prolonging medications, causing further QT prolongation; digoxin, causing increased and even toxic digoxin levels; and warfarin, causing decreased warfarin clearance and increased risk of bleeding (Dixon et al., 2013; Dulak, 2009; O'Donovan, 2012; Vassallo & Trohman, 2007).

Research has shown that the implementation of an outpatient drug monitoring clinic for amiodarone can decrease the severity of the adverse effects and offer earlier recognition and treatment of the adverse effects by stricter adherence to amiodarone monitoring guidelines

(Bickford & Spencer, 2006; Snider, Kalbfleisch, & Carnes, 2009; Spence et al., 2011). Adherence to monitoring guidelines may allow for the continuation of amiodarone therapy, and research has shown that patient morbidity from such problems as hypothyroidism, loss of vision, and ataxia and mortality from such problems as pulmonary toxicity have decreased through earlier recognition and treatment of adverse effects (Sanoski et al., 1998; Snider et al., 2009). Major adverse amiodarone effects and incidence rates identified in the literature are discussed.

Adverse effects. Patients may experience a variety of adverse events. As many as 93% of patients on amiodarone therapy develop an adverse drug event (Sanoski et al., 1998; Tafreshi et al., 2009). These events may be merely problematic such as nausea, difficulty sleeping, or constipation requiring only amiodarone dose adjustments, to life threatening events including irreversible pulmonary damage requiring immediate discontinuation of amiodarone (Sanoski et al, 1998; Tafreshi et al, 2009).

Gastrointestinal. Gastrointestinal adverse drug events include hepatitis, cirrhosis, nausea, anorexia, and constipation. Clinical findings may include fatigue, weight loss, nausea, vomiting, hepatomegaly, or the patient may be completely asymptomatic. Incidence rates range from less than 3% to as much as 30%. (Dulak, 2005; Mackenzie, Syed, Pollak, & Koren, 2011; Vassallo & Trohman, 2007).

Dermatologic. Dermatological findings may include bluish discoloration to the skin or photosensitivity. These clinical findings are seen with sun-exposed skin and occur in less than 10% of patients to as many as 75% of patients (Dulak, 2005; Mackenzie et al., 2011; Vassallo & Trohman, 2007).

Ocular. Corneal deposits can occur in as many as 90% of patients. Patients may also experience halo vision (less than 5%), poor visual acuity, or less often, changes in peripheral vision due to optic neuropathy (Dulak, 2005; Mackenzie et al., 2011; Vassallo & Trohman, 2007).

Central nervous system. Peripheral neuropathy is experienced in 0.3% of patients whereas 3-30% of patients may experience ataxia, tremors, and sleep disturbances such as insomnia (Dulak, 2005; Mackenzie et al., 2011; Vassallo & Trohman, 2007).

Thyroid. Around 3% of amiodarone is comprised of iodine, leading to thyroid dysfunction in some patients caused by the inhibition of the de-iodination of T4 to T3 (O'Donovan, 2012; Vassallo & Trohman, 2007). Hyperthyroidism and hypothyroidism may occur in over 30% of patients taking amiodarone with hypothyroidism being more common. Symptoms may include weight loss, malaise, goiter, tremors, cold intolerance, hair loss, bradycardia, and tachycardia (Dulak, 2005; Mackenzie et al., 2011).

Cardiac. Around 5% of patients may experience bradycardia when taking amiodarone manifested by fatigue or syncope (Dulak, 2005; Mackenzie et al., 2011). Rarely patients may experience arrhythmias related to amiodarone use such as torsades de pointes or atrioventricular block (Dulak, 2005; Mackenzie et al., 2011).

Pulmonary. A potentially life-threatening complication of amiodarone therapy is amiodarone-induced pulmonary toxicity. Incidence rates range from 5-13% and mortality rates range from 10-23% (Ernawati, Stafford, & Hughes, 2008). Clinical findings may include acute onset of shortness of breath, nonproductive cough, chest pain, weight loss, and fever (Dulak, 2005; Mackenzie et al., 2011). Patchy infiltrates may be present on chest x-ray (O'Donovan, 2012).

Drug/food interactions. Amiodarone is metabolized by the cytochrome P450 system in the liver (Mackenzie et al., 2011) and may interact with multiple medications including warfarin; digoxin; beta-blockers; calcium channel blockers; cyclosporine; antidepressants including selective serotonin reuptake inhibitors and tricyclics; antimicrobials such as macrolides, azole antifungals, fluoroquinolones; other antiarrhythmics such as quinidine, disopyramide, procainamide, flecainide, and sotalol; and statins (Dulak, 2005; Mackenzie et al., 2011; O'Donovan, 2012; Vassallo & Trohman, 2007). Patients should also be instructed to avoid

grapefruit juice due to its inhibition of the cytochrome P450 pathway leading to increased levels of amiodarone in the blood (O'Donovan, 2012).

Research identification of adherence to amiodarone monitoring. Monitoring for amiodarone therapy is essential for early recognition and treatment of adverse effects. Bickford and Spencer (2006) conducted a study to assess baseline amiodarone monitoring adherence on hospital inpatients and adherence to continued amiodarone monitoring adherence as outpatients. Baseline monitoring for liver function tests, thyroid function tests, and chest x-rays was 87%, 82%, and 87% respectively. However, only 24% of the patients received baseline pulmonary function testing with only half of those including the diffusion capacity (Bickford & Spencer, 2006). As outpatients, only 35% of patients received liver function testing every six months, only 20% of patients received thyroid function testing every six months, and only 50% of patients received yearly chest x-rays (Bickford & Spencer, 2006).

Stelfox et al. (2004) conducted a similar study to assess baseline amiodarone monitoring adherence. The researchers found that 52% of patients had baseline pulmonary function testing completed, 42% had baseline liver function testing, 40% had baseline thyroid function testing, 85% had baseline electrocardiograms, and 60% had baseline chest x-rays (Stelfox et al., 2004). Amiodarone adverse drug events were identified in 8% of the patients during this monitoring period with approximately one-third of the adverse drug events deemed to be preventable with greater adherence to amiodarone monitoring guidelines (Stelfox et al., 2004).

Success of amiodarone clinics. One of the best methods of decreasing potential adverse effects of amiodarone therapy is the use of a dedicated clinic. Sanoski et al. (1998) completed a study comparing amiodarone monitoring in patients before and after referral to a multidisciplinary amiodarone clinic. This multidisciplinary team consisted of an electrophysiologist, a clinical pharmacist, a cardiovascular pharmacy fellow, and electrophysiology nurse. The electrophysiologist's responsibilities included acting as medical director and overseeing the other team members and authorizing amiodarone dose

adjustments. The responsibilities of the clinical pharmacist, cardiovascular pharmacy fellow, and electrophysiology nurse included objective and subjective patient assessment, amiodarone drug interaction screening, patient/staff education, and scheduling/interpretation of diagnostic testing (Sanoski et al., 1998). Before enrollment in the amiodarone clinic, only 23% of the patients had the appropriate laboratory tests performed by primary physicians with improvement to 90% once the patients were enrolled into the multidisciplinary amiodarone clinic (Sanoski et al, 1998).

In 2004, Graham and colleagues conducted a similar study assessing amiodarone adherence rates in patients enrolled in an amiodarone monitoring clinic. This clinic was pharmacist-managed, rather than managed by a multidisciplinary team. Adherence to baseline monitoring improved for thyroid function testing, liver function testing, eye exams, and electrocardiograms, but not for pulmonary function testing and chest x-rays (Graham et al., 2004).

Snider et al. (2009) conducted a study comparing a pharmacist-led antiarrhythmic monitoring service with usual care. Before referral to the antiarrhythmic monitoring service, the researchers found that only 59% of patients had completed all the recommended diagnostic testing, but after enrollment into the antiarrhythmic service, 98.5% of patients had completed all of the recommended diagnostic testing (Snider et al., 2009).

Johnson and colleagues (2010) conducted a similar study comparing a pharmacist-led amiodarone monitoring service to usual care. After enrollment into the amiodarone monitoring service, percentage of adherence both at baseline and for continuing monitoring increased in all areas of diagnostics except for chest x-rays (Johnson et al., 2010). Spence et al. (2011) organized a similar study examining amiodarone monitoring adherence between those enrolled in the pharmacist-managed amiodarone monitoring clinic and those in usual care. Adherence was higher in the pharmacist-managed amiodarone clinic group for baseline and continued liver function testing, thyroid function testing, chest x-rays, and pulmonary function testing (Spence et al., 2011).

Spence et al. (2011) organized a study examining amiodarone monitoring adherence between those enrolled in the pharmacist-managed amiodarone monitoring clinic and those in usual care. Adherence was higher in the pharmacist-managed amiodarone clinic group for baseline and continued liver function testing, thyroid function testing, chest x-rays, and pulmonary function testing (Spence et al., 2011).

APN-led clinics. To date, no APN-led amiodarone/antiarrhythmic clinics were documented in the literature. However, other APN-led clinics for chronic disease/medication management have been successful. Chandler (2007) explored the use of a nurse-led clinic to reduce readmission rates for asthma. Readmission rate decreased from 22% to about 6% after enrollment into the nurse-led asthma clinic post hospital discharge. Hatchett (2005) outlined eight roles of a nurse-led clinic. These roles include “educating patients, providing psychological support and explanation, monitoring the patient’s condition, conducting physical assessments, ordering appropriated diagnostic investigations and interpretation, creating treatment plans, often involving other members of the multidisciplinary teams, such as GPs or primary care colleagues, managing medicines, empowering the patient or carer to achieve greater self-monitoring and/or care” (Hatchett, 2005, p. 50). Patients with heart failure have also been successfully managed by nurses (Grange, 2005). Evaluation of nurse-led heart failure clinics demonstrated an improved quality of life, individualized care, appropriate medication management, and improved patient education as well as reduced readmission rates (Grange, 2005). A nurse-led acute coronary syndromes clinic was found to have a significantly lower six-month readmission rates (Alfakih et al., 2009).

Nurses have also been used in medication management. In a 2012 study, Levine, Shao, and Klein compared a nurse-led warfarin monitoring service to the usual care of monitoring by a family physician. They found that nurse-led monitoring of warfarin was just as effective as physician monitoring (Levine et al., 2012). Aziz, Corder, Wolffe, and Comerota (2011) found that

a lower percentage of patients monitored by the anticoagulation service that was nurse-led required hospitalization and provided a significant cost savings.

Data from the clinical agency. The clinical agency for this EBP project was a cardiology practice in northwest Indiana. The electrophysiologist employed by the practice expressed concern that adherence to amiodarone monitoring could use significant improvement (N. Nasser, personal communication, June, 2013). Currently, approximately sixty patients within the electrophysiology practice are on amiodarone therapy. At the clinic, all patients newly initiated on amiodarone receive baseline thyroid/liver function testing, a baseline electrocardiogram, a baseline chest x-ray, a baseline pulmonary function test, and a baseline eye exam. Patients on chronic amiodarone therapy receive biannual liver/thyroid function testing, a yearly electrocardiogram, and a yearly chest x-ray. Some patients lost to proper amiodarone follow-up were identified by the project manager and the electrophysiologist as having adverse effects of amiodarone including liver toxicity demonstrated by severely elevated liver function tests, pulmonary toxicity demonstrated by abnormal chest CT scans and abnormal pulmonary function tests, and hypothyroidism as demonstrated by elevated TSH levels. It was decided by the electrophysiologist that implementing an amiodarone clinic would increase adherence to amiodarone monitoring guidelines and allow for increased use of amiodarone in the practice for treatment of arrhythmias (N. Nasser, personal communication, June, 2013).

A small-scale amiodarone monitoring clinic was initiated in August, 2013 to explore the benefit of an APN-led amiodarone clinic within the cardiology practice. A protocol for amiodarone monitoring was developed by the electrophysiologist using HRS guidelines (Goldschlager et al., 2007). Patients were educated on the risks and benefits of amiodarone use as well as the amiodarone monitoring schedule by the electrophysiologist and electrophysiology nurse, also serving as the EBP project manager. A patient education sheet was created educating patients about common adverse effects of amiodarone and the more dangerous effects including pulmonary toxicity. Also included on the patient education sheet was the

amiodarone monitoring schedule and the office number to call if any adverse effects were observed by patients. A more intense follow-up was conducted by the electrophysiology nurse to observe for both subjective and objective signs and symptoms of adverse amiodarone effects.

Purpose of the EBP Project

The purpose of this evidence-based practice (EBP) project was to assess if enrollment in an APN-led amiodarone clinic would change adherence to amiodarone monitoring recommended by best practice guidelines. Furthermore, it was hoped any adverse effects would be recognized in a timely manner to allow for earlier intervention to prevent patient morbidity and mortality from amiodarone adverse effects.

Identification of the compelling clinical question. The compelling clinical question that was hoped to be answered by this EBP project is: Does enrollment in an amiodarone clinic compared with “usual care” change adherence to monitoring as recommended by best practice guidelines and allow for earlier recognition of adverse effects of amiodarone to decrease negative patient outcomes over a four month time period?

PICOT format. This EBP project used the PICOT format to formulate the compelling clinical question (Melnyk & Fineout-Overholt, 2011). This format included the components of:

- (P)atient population or disease of interest. In this project, the population of interest is those patients with newly initiated amiodarone therapy who are 18 years of age or older.
- (I)ntervention or issue of interest. The patients enrolled in the amiodarone clinic based on HRS guidelines (Goldschlager et al., 2007) for the monitoring of amiodarone is the intervention of interest.
- (C)omparison intervention or issue of interest. Those patients identified by chart review as the “usual care” group will be the comparison group.

- (O)utcome. The outcomes of monitoring adherence, identification of adverse drug events, and decreased negative outcomes are of interest.
- (T)ime. The time period proposed was from September 1, 2013 to December 31, 2013.

Significance of the Project

Outpatient medication management clinics can be useful in monitoring those patients on medications which require more intense monitoring (Tafreshi et al., 2009). Subjective patient data can be gathered at each visit and added to the objective assessment to develop an assessment and plan of action to promote the best patient outcome for patients on amiodarone therapy (Earl & Reinhold, 2014). In order to build a strong outpatient medication management clinic, a strong therapeutic relationship must be built, patient health knowledge must be ascertained, and medication adherence must be evaluated (Earl & Reinhold, 2014). These are all practices that an APN is more than qualified to perform as depicted within the role components of clinician, consultant, educator, leader, and researcher which promote change, communication, critical thinking, and lifelong learning.

Nurse-led clinics are not new to healthcare, with nurse-led clinics already established in the care of patients with congestive heart failure (Grange, 2005), patients with heart disease (Hatchett, 2005), and patients with liver disease (McAfee, 2012), just to name a few. APNs can provide valuable care through clinical skills that offer symptom relief, facilitation of interdisciplinary referrals (McAfee, 2012), as well as provide improved outcomes for patients as demonstrated by fewer hospital readmissions (Grange, 2005). These tasks are completed by the APN through the education of patients regarding their chronic conditions (Grange, 2005; McAfee, 2012).

The design of this EBP project was created to show that enrollment into a nurse-led amiodarone clinic would enhance patient care within a specific cardiology practice and result in increased adherence to monitoring guidelines. Through adherence to recommended monitoring

guidelines, earlier recognition and treatment of adverse drug events of amiodarone would take place to decrease negative outcomes that may be experienced if otherwise left untreated.

CHAPTER 2

THEORETICAL FRAMEWORK, EBP MODEL, AND REVIEW OF LITERATURE

This chapter includes the theoretical framework, evidence-based practice model, and review of literature used for guidance of the project. This project uses Imogene King's Theory of Goal Attainment (King, 1971) as a theoretical framework and the ACE Star Model of Knowledge Transformation (Stevens, 2004) for the Evidence-Based practice model. The search engines used as well as the keywords and inclusion/exclusion criteria will also be discussed in this chapter. Once the review of literature was completed, the sources of evidence chosen were critically appraised to provide sustenance to the EBP project and provide guidelines for the use of an APN-led amiodarone clinic in the outpatient setting.

Theoretical Framework

Description and application of the model. In her book, *Toward a Theory for Nursing: General Concepts of Human Behavior*, Dr. King (1971) expressed the need for the establishment of a conceptual framework for nursing. With the explosion of evidence-based practice, the organization of key concepts became important, both in the advancement of clinical practice and in the education of future nurses. Some sort of harmony was needed between those responsible for patient care and those responsible for advancing research for clinical practice. From this, Dr. King developed her conceptual framework for nursing (King, 1971). This framework consists of three dynamic systems (individual, group, and society) interacting with one another. The center of Dr. King's conceptual framework consists of the personal system. This would be the individual, or patient, that the nurse interacts with. The patient is oriented toward achievement of goals in a dynamic manner through the guidance of nursing (King, 1971; King, 1981). For the purposes of this EBP project, the personal system will consist of the individual patient needing therapy in an APN-led clinic.

The individual interacts with others to form the interpersonal system. This part of the conceptual framework focuses on interactions that take place between the patient and those

assisting with goal attainment. The patient participating in the EBP project will interact with the EBP project manager to achieve a common goal.

The social system includes those individuals who share common goals and interests (Sieloff-Evans, 1991). Examples include families, religious groups, educational organizations, or governments (King, 1999). The social groups that patients are a part of often influence the patient's perceptions. For the purposes of the EBP project, the social system might include whomever the patient will bring with them to the follow-up appointments with the EBP project manager. This might include family members or friends.

The personal system encompasses the individual. Individuals interact with one other to form small groups called interpersonal systems. Groups with similar interests and goals come together to form organized structures, such as families and societies, called social systems (King, 1981). Several assumptions exist within this conceptual framework. First, human beings are considered to be dynamic, open systems. This allows for constant action within the environment and reaction to the environment. Nursing's focus is the interaction of patients within their individual environment, taking into account the perceptions each individual has of the environment in which they live. The common goal between nursing and the individual is to obtain or maintain health (Frey et al., 2002; King, 1971; King, 1981). Once individuals attain health, individuals have the ability to function appropriately within their societal role (Whelton, 1999).

In this nursing theory, nurses and patients come together, communicate information, set mutual goals, and take appropriate actions to attain the mutual goals. A new definition for nursing was created during the construction of the theory stating "nursing is a process of human interactions between nurse and client whereby each perceives the other and the situation; and through communication, they set goals, explore means, and agree on means to achieve goals" (King, 1981, p. 144). This new definition allowed for further expansion of patient-involvement in the development of treatment plans taking into account patient-individualized stressors and

obstacles to optimal health. In summary, the nurses and patients interact and move toward a common goal through the nursing process taking into account different perceptions (views) of the environment around them, different roles (position within the patient's social system), and stress (exchange of energy between the patient and their environment) through communication (trade of information) and transaction (series of negotiations) (King, 1981). King purposefully included patients in the treatment process and encouraged them to become a part of the treatment plan process. Goal attainment is useful in nursing as it allows for easy validation of the nursing process. Goal attainment is an easily measured outcome that provides evidence of the usefulness of the nursing process and nursing interventions through completion of the mutually agreed upon goal between nurses and patients. Both patients and nurses interact and form a relationship to better understand one another, develop mutual goals, and develop a process to obtain the set goals. Both parties within the dynamic interpersonal relationship contribute to goal attainment and processes to obtain mutual goals.

Application of the theoretical framework to EBP project. In this EBP project, improvement in amiodarone monitoring became the common goal for achievement by patients and the EBP project manager. Patients were the personal system. Once patients attended the first appointment with the EBP project manager, an interpersonal system was established. Through transactions as well as education of amiodarone adverse effects, the EBP project manager and patients decided on the mutually agreed upon goal of adherence to amiodarone monitoring guidelines to promote the best possible outcome of patients. Those participating in the patients' care, such as family members or friends, became part of the social system, influencing the process to achieve goal attainment.

Theoretical framework strengths and weaknesses. The strengths of this framework include its ease in adaptability to a broad range of interpersonal relationships encompassing a wide range of disciplines throughout the patient care process. The APN can utilize goal attainment in the care of a multitude of chronic and acute conditions such as heart failure, liver

disease, and cardiac disease. The major limitation of this framework is the dependence on the interpersonal relationship. A strong therapeutic relationship must be built to establish the trust needed by patients to facilitate mutually agreed upon goals. The successful outcome of goal attainment must be mutually agreed upon by each party in the interpersonal relationship. Without agreement and participation, goal attainment will not be achieved. In the case of the amiodarone clinic, the mutual goal is improved adherence to amiodarone monitoring guidelines. Improved monitoring adherence is achieved through patient compliance with monitoring. Patient compliance with diagnostic monitoring is accomplished through patient education on the importance of amiodarone monitoring adherence. The common goal of increased adherence to amiodarone monitoring allows for early identification of potential adverse drug events.

Evidence-Based Practice Model

Description and application of the EBP model. The ACE Star Model was chosen to guide this evidence-based practice project. The model originated at the University of Texas Academic Center for Evidence-Based Practice (ACE) (Stevens, 2004). The goals of this university-based program include improving patient outcomes, improving patient care, and improving patient safety. The objectives of ACE are to (a) advance nursing roles in the synthesis of evidence, translation, incorporation, and improvement science; (b) furnish a location for interdisciplinary evidence-based practice; (c) simplify transfer of health care knowledge to nursing and health care practice; (d) inspire, enable, organize, and conduct research and interdisciplinary inquiries in the field of evidence-based practice and quality improvement; (e) and offer education in evidence-based practice through the entire spectrum of collegiate programs as well as continuing education programs (Stevens, 2004). The ACE framework organizes evidence-based practice processes into a five-point star which illustrates the five stages of the models including discovery of research, evidence summary, translation to guidelines, practice integration, and evaluation (Stevens, 2004).

Stage 1: Discovery of research. In this stage of the ACE Star Model, original knowledge is exposed through research and scientific inquiry (Stevens, 2004). Results are generated through single studies which can range from descriptive to correlational to causal and from randomized control trials to qualitative studies. The purpose of this stage is to build the mass of research regarding clinical activities.

Many patients on amiodarone have not adhered to recommended monitoring guidelines (Bickford & Spencer, 2006; Graham et al., 2004; Johnson et al., 2010; Raebel et al., 2006; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011; Tafreshi et al, 2009). Several studies were identified through a review of literature documenting the success of amiodarone clinics to improve adherence to monitoring guidelines (Graham et al., 2004; Johnson et al., 2010; Raebel et al., 2006; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011; Tafreshi et al., 2009). By using discovery of research, knowledge regarding the usefulness of amiodarone clinics in adherence to monitoring guidelines was obtained.

Stage 2: Evidence summary. The mass of research is combined into a single, significant statement. Systematic reviews are often developed in this stage as well as the identification of bias and effects of chance (Stevens, 2004). Evidence summary also allows for the recurrent update of knowledge with fresh evidence.

Within the current evidence, the use of outpatient amiodarone clinics has shown improvement in adherence to monitoring guidelines (Graham et al., 2004; Johnson et al., 2010; Raebel et al., 2006; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011; Tafreshi et al, 2009) and the earlier discovery of adverse effects of amiodarone (Johnson et al., 2010; Sanoski et al., 1998; Snider et al., 2009; Tafreshi et al., 2009). Most of the current research utilizes outpatient clinics run by pharmacists. Some amiodarone clinics were run by a multidisciplinary team including pharmacists, physicians, and nurses. The use of an APN-led clinic was designed to overcome barriers reported by the pharmacist-led amiodarone clinics.

Stage 3: Translation to guidelines. Translation permits evidence delivery into a summary of useful, relevant information termed clinical practice guidelines. This evidence may be located in care standards, clinical pathways, organizational protocols, and organizational algorithms. These guidelines represent evidence-based practices to support clinical decision-making. Evidence is coupled with clinical expertise and theory to allow for the application of the evidence across a multitude of patient populations and settings (Stevens, 2004).

Many large healthcare organizations (Johnson et al., 2010; Raebel et al., 2006; Snider et al., 2009; Spence et al, 2011) have instituted outpatient drug monitoring programs to increase adherence to monitoring guidelines and increase the identification of adverse drug effects. These monitoring programs have provided data that show increased adherence to monitoring guidelines and the early identification of adverse drug effects. By having a monitoring program dedicated to amiodarone monitoring by HRS guidelines, the confusion regarding who was responsible for monitoring these patients was negated and allowed for the early identification of adverse drug effects requiring dose adjustments or possibly discontinuation of amiodarone (Goldschlager et al., 2007). Multidisciplinary amiodarone clinics as well as pharmacist-led clinics have been documented in the literature.

Stage 4: Practice integration. Society expects healthcare professionals to remain up-to-date on current best practices. In order to complete this task, healthcare professionals and organizations must be willing to accept new guidelines for practice if the evidence is supportive of the change (Stevens, 2004).

This EBP project utilized a chart review of patients prior to institution of an amiodarone clinic in a small northwestern Indiana cardiology practice and then another chart review of patients after implantation of an amiodarone clinic. Baseline monitoring as well as continuation of monitoring for those on chronic amiodarone therapy was compared between these two cohorts.

Stage 5: Evaluation. Evaluation is the final step in the ACE Star Model (Stevens, 2004). The influence of evidence-based practice on patient outcomes, healthcare professional/patient satisfaction, efficacy/efficiency of care, economic analysis, and health status impact were evaluated. For this EPB project, outcomes evaluated included the number of participants that completed baseline diagnostic monitoring for those newly initiated on amiodarone and the number of participants that completed continuation of monitoring for those on chronic amiodarone therapy.

Previous studies and reviews have suggested an increase in the adherence to monitoring guidelines (Graham et al., 2004; Johnson et al., 2010; Raebel et al., 2006; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011; Tafreshi et al., 2009) and the identification of adverse effects of amiodarone allowing for early treatment to reduce morbidity and mortality from the adverse effects of amiodarone (Johnson et al., 2010; Sanoski et al., 1998; Snider et al., 2009; Tafreshi et al., 2009). It was hoped that these results would be duplicated in this EBP project.

Strengths and limitations of the EBP model. Strengths of the ACE Star model include the step-by-step progression of the EBP process outlined in five-points that flows logically from the start of EBP in the review of literature to the end where evaluation of the EBP process occurs. As movement occurs through the ACE Star model, the applicability of research to nursing practice strengthens. Research that has accumulated in an area has been reviewed, summarized, and transmitted to practice with evaluation of the implementation of the EBP. A more succinct summary along with consistent research that is summarized allows for a more meaningful research review and permits the research to be applicable to many different areas of nursing. A limitation of the ACE Star model includes the dependence on the availability of research literature regarding the proposed EBP project. Without available research, the EBP process becomes stalled at Stage 1 (Discovery of research). A lack of research pertaining to

APN-led amiodarone clinics was observed, requiring the expansion of the literature search to include any form of nurse leadership of amiodarone clinics for this EBP project.

Review of Literature

Literature review. Multiple sites were used in this literature review including the Cumulative Index of Nursing and Allied Health Literature (CINAHL), Medline, ProQuest, the Joanna Briggs Institute, the Cochrane Library, Academic Search Premier, the Virginia Henderson International Nursing Library, and GoogleScholar (see Table 2.1). A review of the literature was completed using the keywords of “amiodarone, monitoring, and toxicity” which yielded 6 results in a CINAHL search. Medline was searched using the limiters of publication dates from 1995-2013, English language and the keywords of “amiodarone and monitoring” which yielded 286 results. Adding the limiter of toxicity yielded 42 results. A ProQuest search using the limiters of publications dates from 2000-2013, English language, peer reviewed, and the keywords of “amiodarone, toxicity, and monitoring” yielded 445 articles. A search of the Cochrane Library using amiodarone yielded 3 results, antiarrhythmic yielded 2 results, and antiarrhythmic clinic yielded 13 results. A search of the Joanna Briggs Institute using the keyword of amiodarone yielded no results, antiarrhythmic yielded no results, and outpatient yielded 3 results. One article was found using a hand search of journal publications available in the clinic where the project manager is employed. A search using GoogleScholar using the keywords of amiodarone, monitoring, toxicity, ambulatory, clinic, and multidisciplinary using the limiter of publication dates from 2003-2013 yielded over 600 results, 15 of which were applicable to this EBP project using the inclusion criteria listed below and were duplicates from the above search engines. Two additional articles were found through a reference list search of applicable articles included in this EBP project. The limiters used were expanded and narrowed depending on the number of results received to allow for more specificity in the review of literature pertaining to the EBP project.

Table 2.1

Review of Literature

Database	Keywords Used	Limiters Used	Total Results	Relevant to Project	Duplicates	Included in Project
CINAHL	amiodarone, monitoring, toxicity	English language, Scholarly Journals	6	2	1	1
Medline	amiodarone, monitoring	English Language, Publication dates from 1995-2013	286	13	13	13
	Added the keyword toxicity		42	9	9	0
ProQuest	amiodarone, monitoring, toxicity	English language, publication dates from 2000-2013, peer reviewed	445	1	1	0
Joanna Briggs Institute	amiodarone		0			0
	antiarrhythmic		0			0
	outpatient clinic		3	0		0
Cochrane Library	amiodarone		3	0	0	0
	antiarrhythmic		2	0	0	0
	antiarrhythmic clinic		13	0	0	0
Academic Search Premier	amiodarone, monitoring, toxicity	English language, Scholarly Journals	18	5	5	0
Virginia Henderson International Nursing Library	amiodarone		3	0	0	0
	antiarrhythmic		9	0	0	0
	ambulatory care		9	0	0	0
Articles found through reference list search						2
GoogleScholar	amiodarone, monitoring, toxicity, ambulatory, clinic, multidisciplinary	published from 2003-2013	617	15	14	1

Abstract review. The abstracts of the articles were reviewed during the literature search for inclusion and exclusion criteria. The inclusion criteria included (a) overall scientific value, (b) adult subjects, (c) relevance to the EBP project, (d) publication after 2003, (e) studied amiodarone/drug monitoring, (f) written in English, and (g) utilized HRS amiodarone monitoring guidelines (Goldschlager et al., 2007). After review of several studies that adhered to the inclusion criteria, the publication date limiter was extended to include articles from 1995-2003 to allow for the inclusion of some of the first studies of amiodarone clinics. The study by Sanoski and colleagues (1998) included laid the foundation for amiodarone clinics, incorporating a multidisciplinary team in the structure of the amiodarone clinic. Factors that excluded studies from inclusion in the EBP project included (a) poor data quality, (b) written in a foreign language, (c) did not use amiodarone within the study, (d) used subjects under the age of 18, and (e) did not use HRS guidelines in the monitoring protocol (Goldschlager et al., 2007). After reviewing the full text of the articles that met inclusion criteria and removing the duplicates, 17 articles were identified for use in this EBP project. The 17 sources included 7 research studies, an expert committee practice guideline for amiodarone monitoring, and 9 articles discussing background amiodarone information including mechanism of action, use, adverse effects, and interactions. Nine additional articles were added to solidify the usefulness of APN-led clinics.

Describe levels of evidence. Polit and Beck's (2012) Evidence Hierarchy was used for this EBP project (see Table 2.2). This hierarchy describes seven levels of evidence based on the strength of evidence provided. At the top of the hierarchy representing Level I evidence are systematic reviews of randomized control trials (RCTs) and systematic reviews of nonrandomized trials. Level II evidence includes single randomized control trials (RCTs) and single non-randomized trials. Systematic reviews of correlational/observational studies comprise Level III evidence. Single correlational or observational studies represent Level IV evidence. Level V evidence includes systematic reviews of descriptive, qualitative, or physiologic studies.

Single descriptive, qualitative, or physiologic studies signify Level VI evidence. At the bottom of this hierarchy are expert opinions of evidence representing Level VII evidence.

Table 2.2

Hierarchy of Evidence

Hierarchy of evidence (Polit & Beck, 2012)	Articles included in project
Level I: a. Systematic review of randomized controlled trials (RCTs) b. Systematic review of non-randomized trials	0
Level II: a. Single RCT b. Single nonrandomized trial	1(a)
Level III: Systematic review of correlational/observational studies	0
Level IV: Single correlational/observational study	5
Level V: Systematic review of descriptive/qualitative/physiologic studies	0
Level VI: Single descriptive/qualitative/physiologic study	1
Level VII: Opinions of authorities, expert committees	1

Appraise relevant evidence. Once the review of literature was obtained and articles were chosen that met inclusion criteria, a thorough appraisal was completed on each source of evidence used for the EBP project. These appraisals were completed utilizing guidelines as outlined by Melnyk and Fineout-Overholt (2011). The appraisal tools included the *Rapid Critical Appraisal Checklist for Randomized Clinical Trials,* the *Rapid Critical Appraisal Checklist for Cohort Studies,* the *Rapid Critical Appraisal Checklist for Qualitative Evidence*, and the *Rapid Critical Appraisal Checklist for Evidence-Based Clinical Practice Guidelines* (Melnyk & Fineout-Overholt, 2011) (see Table 2.3).

Table 2.3

Evidence Appraisal

Citation	Purpose	Sample	Design	Measurement	Results/Findings	Evidence Level and Appraisal
Bickford, C. L. & Spencer, A. P. (2006).	Quantification of adherence to published recommendations for baseline monitoring when initiating inpatient amiodarone therapy at a university teaching hospital and determine whether appropriate serial monitoring of chronic amiodarone therapy is occurring in the outpatient setting.	45 patients admitted as inpatients at the Medical University of South Carolina (MUSC) who received amiodarone between November 1, 2003 and March 31, 2004. 20 patients with an MUSC outpatient provider who had received amiodarone therapy for at least 6 months.	Retrospective review of medical records	45 inpatients had their medical record reviewed to identify whether baseline liver function tests (LFTs), thyroid function tests (TFTs), chest x-ray (CXR), and pulmonary function tests (PFTs) were completed. 20 outpatients had medical records reviewed to evaluate if baseline LFTs, TFTs, CXR, and PFTs were completed and the number of patients who had received LFTs and TFTs every 6 months, and yearly CXRs.	Inpatients- 87% received baseline LFTs, 82% received baseline TFTs, 87% received baseline CXRs, and 24% received PFTs. Outpatients - 95% had received baseline LFTs, 75% had received baseline TFTs, 75% had received baseline CXRs, and 30% had received baseline PFTs. Only 35% of patients had LFTs every 6 months, 20% of patients had TFTs every 6 months, and 50% of patients had yearly CXRs.	*Level VI* Data review was limited to available files and did not include outside records. Descriptive statistics were applied to obtain adherence to monitoring and results collected are similar to other studies, indicating a need for dedicated amiodarone clinics.

Goldschlager, N., Epstein, A. E., Naccarelli, G. V., Olshansky, B., Singh, B., Collard. H. R., & Murphy, E. (2007).	Recommendation for amiodarone diagnostic monitoring		Clinical practice guideline with approval by the HRS Board of Trustees			*Level VII* Based on evidence-based data/clinical experience. Research funding not reported. Literature is included within one year of publication. Levels of evidence were not identified. Amiodarone monitoring guidelines are discussed with treatment of adverse events and need for referral allowing for easy completion by providers.

Graham, M. R., Wright, M. A., & Manley, H. J. (2004).	To determine whether adherence to monitoring guidelines improved as a result of the development and implementation of an amiodarone monitoring clinic (AMC).	225 patients were included in this study - 154 in the intervention group and 71 in the control group.	Retrospective cohort study	Those patients in the intervention (pharmacist-managed program) cohort and the usual care cohort were compared for adherence to testing during the 12 months after the initiation of the AMC.	For baseline diagnostics, the AMC improved compliance for some of the diagnostics. **AMC** - PFT - 12% - CXR - 18% - TFT - 36% - LFT - 40% - Eye Exam - 30% - EKG - 41% **Usual Care** - PFT - 15% - CXR - 24% - TFT - 32% - LFT - 31% - Eye Exam - 15% - EKG - 32% The AMC improved compliance with 2 of the 3 continued monitoring guidelines. **AMC** - TFTs - 66% - LFTs - 69%3. **Usual care** - TFTs - 37% - LFTs - 38% - EKG monitoring was not shown to be significantly improved by the AMC	*Level IV* Follow-up was sufficient to give data for the amiodarone clinic cohort and a specific timeline is discussed. The diagnostics completed were objective to remove bias, leading to valid study results. Statistical testing was completed to compare demographic data and adherence to baseline as well as continued amiodarone monitoring.

Johnson, S. G., Canty, K., Billups, S., & Schimmer, J. (2010).	To determine whether patients enrolled in a centralized amiodarone monitoring service (AMS) were more adherent to amiodarone monitoring guidelines and To determine if the incidence of amiodarone-related toxicity differed for patients enrolled in the AMS.	905 patients were included in the study - 518 in the control cohort and 387 in the AMS cohort.	Retrospective longitudinal cohort design	Control and AMS cohorts were compared in regards to baseline liver function tests (LFTs), thyroid function tests (TFTs), chest x-ray (CXR), and electrocardiogram (EKG) and appropriate follow-up interval testing	Baseline testing **Control cohort** LFTs 44%, TFTs 49%,CXR 56%, EKG 58% **AMS cohort** LFTs 69%, TFTs 55%,CXR 45%, EKG 76% 6 month follow-up testing **Control cohort** LFTs 76%, TFTs 70% **AMS cohort** LFTs 86%, TFTs 74% 1 year follow-up testing **Control cohort** LFTs 69%, TFTs 64%,CXR 71%, EKG 75% **AMS cohort** LFTs 84%, TFTs 68%, CXR 53%, EKG 89%. Statistical significance was found in LFT and EKG monitoring only.	*Level IV* Follow-up was sufficient to give data for the amiodarone clinic cohort and a specific timeline is discussed. Objective diagnostics removed bias, Statistical testing was completed to compare demographic data and adherence to baseline as well as continued amiodarone monitoring.

Raebel, M. A., Chester, E. A., Newsom, E. E., Lyons, E. E., Kelleher, J. A…Magid, D. J. (2006).	To determine if using an electronic tool effectively increases the percentage of patients receiving laboratory monitoring during ongoing drug therapy.	All adult members of the outpatient Kaiser-Permanente Colorado medical offices were eligible for the study. Patients were included in the study if taking at least one of the study medications. A total of 9139 patients were included.	Randomized trial	Usual-care group (control group) was compared to the intervention group. The intervention consisted of an electronic alert to pharmacists that a lab result was missing based on established guidelines. Pharmacists then ordered missing lab tests, reminded patients to undergo tests, reviewed lab results and managed any abnormal results.	For amiodarone, 71% of patients in the intervention group versus 55% of patients in the control group were appropriately monitored according to guidelines representing significant improvement in amiodarone adherence.	*Level IIa* Participants were randomly assigned, random assignment was concealed to participants and providers, and groups were similar based on statistical testing. It was not reported whether or not all participants completed the study.

Sanoski, C. A., Schoen, M. D., Gonzalez, R. C., Avitall, B., & Bauman, J. L. (1998).	Review the rationale and development of a multidisciplinary amiodarone clinic Document the clinical outcomes resulting from implementation of the amiodarone clinic.	60 patients were enrolled in the amiodarone clinic and adherence to monitoring guidelines was compared before enrollment into the amiodarone clinic and after enrollment.	Retrospective chart review	In a sample of 60 patients, adherence to monitoring guidelines was compared before and after enrollment in the amiodarone clinic	Before enrollment into the amiodarone clinic, 23% of the patients were adherent to monitoring guidelines. After enrollment, 90% were adherent to monitoring guidelines. Previously unrecognized adverse events were detected in 35% of the patients enrolled into the amiodarone clinic.	*Level IV* Follow-up was sufficient to give data for the amiodarone clinic cohort, the diagnostics completed were objective, and statistical testing was used to compare adherence to monitoring guidelines before and after referral to the amiodarone clinic.

Snider, M., Kalbfleisch, S., & Carnes, C. A. (2009).	To monitor antiarrhythmic drug therapy to improve the continuity and consistency of care for patients receiving class I or class III antiarrhythmic drugs.	134 patients receiving amiodarone, sotalol, dofetilide, and propafenone who were referred to an arrhythmic medications clinic in Columbus, Ohio between July 2007 and April 2008.	Retrospective chart review	Patient's diagnostic testing completion before enrollment was compared to post enrollment adherence to diagnostic testing according to monitoring protocols.	Pharmacist monitoring appeared to improve patient adherence to recommended testing protocols (98.5% compliance versus 59% before enrollment in the clinic). Pharmacist monitoring of outpatient antiarrhythmic medication therapy appeared to help identify adverse events and clinically significant drug interactions.	*Level IV* Inspected the same group of patients before and after enrollment into an antiarrhythmic monitoring clinic over a ten month period. Data were analyzed using the Fisher exact test or chi square testing to remove bias and led to valid study results. Since the same group of participants comprised the two cohorts, demographics bias was eliminated.

Spence, M. M., Polzin, J. K., Weisberger, C. L., Martin, J. P., Rho, J. P, & Willick, G. H. (2011).	To assess rates of lab monitoring of liver, thyroid, and pulmonary function and adverse events in a pharmacist-managed amiodarone monitoring program compared with usual care To estimate the return on investment from this intervention	2292 patients who received at least 100 days of amiodarone from June 1, 2007 through May 31, 2009. 181 patients were in the intervention cohort and 2111 were in the usual care cohort.	Retrospective cohort study	Those patients in the intervention (pharmacist-managed program) cohort and the usual care cohort were compared for adherence to testing at any time during the year after the initiation of amiodarone	Amiodarone program - LFT Baseline - 84% 6 months - 84.5% 1 year - 75.7% - TFT Baseline - 70.2% 6 months - 81.8% 1 year - 77.3% - PFT Baseline - 6.6% Within 1 year - 51.9% Usual care -LFT Baseline - 76.3% 6 months - 69.7% 1 year - 61.5% - TFT Baseline - 62.7% 6 months - 50.2% 1 year - 46.8% -PFT Baseline - 3.6% within 1 year - 14% A 200% return investment was demonstrated with the pharmacist-managed program.	*Level IV* Follow-up was sufficient to give data for the amiodarone clinic cohort and a specific timeline is discussed. Objective diagnostics removed bias and statistical testing was completed to compare demographic data and adherence to baseline as well as continued amiodarone monitoring. Randomization did not occur.

Critical appraisal of the RCT. Several questions were utilized as identified by Melnyk and Fineout-Overholt (2011) when critically appraising RCTs. These questions included assessment of (a) the validity of the study results, (b) the results including intervention/treatment effect, and (c) the applicability of the results to clinical practice.

Raebel and colleagues (2006) completed a study using an electronic tool to alert pharmacists to missing laboratory testing of patients on medications requiring routine laboratory monitoring based on published guidelines established by pharmacists and physicians. The percentage of patients who completed the laboratory testing was compared between the intervention and usual care groups using the x^2 test. Out of 160 patients in the intervention group, 114 (71%) completed the recommended testing compared to 161 patients in the usual care group, 89 (55%) of whom completed the recommended testing ($p < .01$). The analyses were completed using SAS software. The electronic tool used to remind pharmacists to order recommended testing increased the percentage of patients who received laboratory monitoring. This computerized tool may be a useful addition to an amiodarone clinic as exemplified by the increased number of patients on amiodarone who received recommended testing.

This RCT represents Level IIa evidence (Raebel et al., 2006). The study results were valid since (a) the study participants were randomly assigned to the experimental and control groups, (b) the random assignment was concealed from those enrolling participants into the study, (c) the participants and providers were blinded to the study group, (d) the study was completed over a year time period, (e) the participants were analyzed in their respective group, and (f) the participants in each group were similar based on statistical testing. It was not reported whether or not all participants completed the study.

Critical appraisal for the cohort studies. The questions identified by Melnyk and Fineout-Overholt (2011) in the critical appraisal of cohort studies include (a) the validity of the study results, (b) the results including the strength of association between the exposure and

outcome, and (c) the applicability of the results to clinical practice. These Level IV studies are discussed below in chronological order of publication date.

Sanoski, Schoen, Gonzalez, Avitall, and Bauman (1998) developed the first documented multidisciplinary amiodarone monitoring clinic. Sixty patients were referred to the amiodarone clinic. Comparison was made in adherence to monitoring guidelines before and after enrollment into the amiodarone clinic. Before enrollment in the amiodarone clinic, only 14 (23%) of the patients received appropriate monitoring as compared to 54 (90%) after enrollment in the amiodarone clinic. The authors also reported that previously undiagnosed adverse events were found in 21 (35%) of the patients enrolled in the amiodarone clinic. The researchers concluded that a multidisciplinary amiodarone clinic improves patient outcomes by monitoring for early recognition of medication-related toxicities and modifying medication dosage as indicated.

Participants were evaluated before and after referral to the amiodarone clinic (Sanoski et al., 1998). Follow-up was sufficient to give data for the amiodarone clinic cohort, although a specific timeline was not discussed within the report. The diagnostics completed were objective to remove bias, leading to valid study results. Chi-square testing was used to compare adherence to monitoring guidelines before and after referral to the amiodarone clinic. Not only did appropriate monitoring increase, but also the diagnosis of previously unrecognized adverse effects and amiodarone dose decreased or were discontinued depending on the severity of the adverse effects.

Graham, Wright, and Manley (2004) hypothesized that an amiodarone management clinic would improve adherence to published monitoring guidelines. In a retrospective chart review, the authors compared those patients enrolled in the amiodarone management clinic with those receiving usual care. Data obtained from the two cohorts (154 patients in the amiodarone management clinic group and 71 patients in the standard medical care group) were compared using x^2 or Fisher's exact test. No statistically significant differences were found in baseline monitoring adherence, but those patients enrolled in the amiodarone clinic were more likely to

adhere to monitoring guidelines for follow-up thyroid and liver function tests, eye examinations, and electrocardiograms. The authors also identified those patients taking interacting medications and compared adverse effects of these medications with amiodarone in both groups. The only significant finding was those patients taking warfarin were monitored more closely in the amiodarone management clinic group. It was hoped by the authors that the amiodarone management clinic would prove to identify adverse effects earlier to allow for prompter treatment of adverse effects, but differences between the groups did not allow for significant results. The standard medical care group took amiodarone for an average of one year where those enrolled in the amiodarone management clinic took amiodarone for an average of two years.

This study included two groups of participants, one group was evaluated as a “usual care” group and another group was those enrolled in the amiodarone clinic (Graham et al., 2004). Follow-up was sufficient to give data for the amiodarone clinic cohort; a specific timeline of one year post implementation of the amiodarone clinic was discussed. The diagnostics completed were objective to remove bias, leading to valid study results. Statistical testing was completed to compare demographic data and adherence to baseline as well as continued amiodarone monitoring.

Snider, Kalbfleisch, and Carnes (2009) compared compliance of antiarrhythmic laboratory monitoring before and after enrollment into a pharmacist-led antiarrhythmic monitoring clinic. In a retrospective chart review, the authors found that 59% of the patients were compliant with all recommended laboratory and diagnostic testing before enrollment into the clinic and compliance increased to 98.5% after the initial clinic visit. Amiodarone was reported to have the highest rate of detected adverse events that were previously unrecognized. The conclusion was reached that implementation of a pharmacist-led antiarrhythmic monitoring clinic was associated with an improvement in patient adherence to monitoring guidelines and earlier recognition of adverse drug events.

This retrospective chart review inspected the same group of patients before and after enrollment into an antiarrhythmic monitoring clinic over a ten month period (Snider et al., 2009). Data were analyzed using the Fisher exact test or x^2 testing to remove bias and led to valid study results. Since the same group of participants comprised the two cohorts, demographics bias was eliminated.

Johnson, Canty, Billups, and Schimmer (2010) compared those patients receiving usual care to those patients enrolled in a pharmacist-led amiodarone management service using a retrospective cohort design. Adherence was defined as completing baseline, six month, and 12 month monitoring per recommended guidelines for liver and thyroid function test as well as baseline and yearly chest x-rays and electrocardiograms (EKGs). Monitoring adherence rates between the two groups were compared using x^2 testing. The amiodarone monitoring service group had better adherence rates for liver/thyroid function monitoring and EKG monitoring but was statistically significant for liver function monitoring and EKG monitoring only. The authors also identified that the amiodarone monitoring service group had significantly lower adverse drug events (21 events in the amiodarone monitoring service group as compared to 48 events in the usual care group).

Two groups of participants were included in the study design (Johnson et al., 2010); one group was evaluated before the amiodarone clinic was implemented and the other group included those enrolled in the amiodarone clinic. Follow-up of four years for each group was sufficient to give data for each cohort. Objective diagnostics removed bias, x^2 statistical testing was completed to compare demographic data and adherence to baseline as well as continued amiodarone monitoring.

The most recent amiodarone monitoring clinic found in the literature search was a study conducted by Spence et al. (2011). This study's objective was to compare rates of laboratory monitoring of liver, thyroid, and pulmonary function as well as adverse drug events in a pharmacist-led amiodarone clinic as compared to usual care using a retrospective cohort study

design. Monitoring rates were compared using x^2 tests. Results showed that monitoring rates for liver and thyroid function at baseline and follow-up were significantly higher in the pharmacist-led amiodarone group as well as the obtainment of baseline chest x-rays. It was also shown that patients in the amiodarone clinic were less likely to be hospitalized for adverse drug events as compared to the usual care group leading the authors to hypothesize that a positive return on investment may be experienced from implementation of an amiodarone clinic.

This study also included two groups of participants; one group consisted of those participants who were seen in the medical centers without the amiodarone clinic and the other group consisted of those participants who were seen in the medical centers with the amiodarone clinic (Spence et al., 2011). Follow-up was conducted over a two year period, which was sufficient to give data for the amiodarone clinic cohort. Objective diagnostics removed bias and x^2 statistical testing was completed to compare demographic data and adherence to baseline as well as continued amiodarone monitoring. Randomization of participants did not occur as selection for the groups was based on which medical center participants used.

All of these studies included in the review of literature utilized retrospective chart reviews of non-randomized subjects leading to a lower level of evidence and bias. Multiple factors included selection bias, inadequate sample size, and disproportionate cohort sizes. Nonetheless, the data included did show clinical significance and provided evidence of improved patient outcomes through implementation of a monitoring clinic for amiodarone.

Critical appraisal for the descriptive study. This study was included as evidence in order to provide additional literature regarding the inobservance of monitoring guidelines. Guidelines for critical appraisal of qualitative evidence were used to critically appraise this Level VI study (Melnyk & Fineout-Overholt, 2011) and included (a) the validity of the study results, (b) the quality of the description of the findings, and (c) the applicability of the results to clinical practice. A nonrandomized sample was included in this study; all patients meeting inclusion criteria were included.

In 2006, a study was published comparing institutional adherence to recommended guidelines for the monitoring of amiodarone therapy. Bickford and Spencer (2006) completed a retrospective chart review for both inpatients and outpatients at a medical university and found that of the 45 inpatients initiated on chronic amiodarone therapy, only 5 (11%) completed all of the recommended baseline diagnostic testing. Twenty outpatients were identified on chronic amiodarone therapy. The number of patients completing all of the recommended baseline diagnostic testing was not reported. Baseline liver function tests (LFTs) were completed in 95% of the patients, thyroid function tests (TFTs) were completed in 75% of the patients, chest x-rays (CXRs) were completed in 75% of the patients, and pulmonary function tests (PFTs) were completed in 30% of the patients. Only 35% of the patients completed a six month LFT, 20% completed TFTs, and 50% completed a CXR. The authors hypothesized that adherence to recommended amiodarone monitoring guidelines might be enhanced through electronic reminders to order appropriate diagnostic testing, the implementation of amiodarone protocols, or the implementation of multidisciplinary amiodarone monitoring clinics.

The convenience sample of patients was taken over a five month period to assess adherence to amiodarone diagnostic monitoring (Bickford & Spencer, 2006). The data review was limited to files available within the hospital database and did not include outside records. Descriptive statistics were applied to obtain adherence to monitoring. The results collected were similar to other studies included in the literature review, indicating a need for dedicated amiodarone clinics.

Critical appraisal for the clinical practice guideline. The HRS guidelines for amiodarone monitoring were chosen as the clinical practice guideline this EBP project (Goldschlager et al., 2007). These guidelines were developed based on evidence-based data and clinical experience of the writing committee in the care of patients taking amiodarone. According to Melnyk and Fineout-Overholt (2011), clinical practice guidelines should be appraised for credibility and applicability/generalizability. It is unknown whether the guidelines

developers were funded researchers of the reviewed studies for the clinical practice guidelines. Literature was included in the reference list within one year of publication of the updated clinical practice guidelines. Levels of evidence of the literature review were not identified within the guidelines. Amiodarone monitoring guidelines are discussed as well as recommendations for treatment of adverse events and referral recommendations. This guideline was approved by the HRS Board of Trustees. These amiodarone monitoring guidelines provide a schedule for amiodarone monitoring as well as a blueprint for follow-up of patients taking amiodarone, complete with subjective and objective signs and symptoms of amiodarone adverse effects. The diagnostic testing recommended for amiodarone monitoring can easily be completed by providers.

Construct EBP

Literature Synthesis. The literature documents that initiation of an amiodarone clinic not only increases adherence to monitoring guidelines (Graham et al., 2004; Johnson et al., 2010; Raebel et al., 2006; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011, Tafreshi et al., 2009) as recommended by the Heart Rhythm Society (Goldschlager et al., 2007), but also increases early recognition of adverse events (Johnson et al., 2010; Sanoski et al., 1998; Snider et al., 2009; Tafreshi et al., 2009) (see Table 2.3). The benefit of earlier recognition of adverse events is the extent of morbidity and mortality due to amiodarone toxicity can be lessened through dose reduction or discontinuation of amiodarone if needed (Johnson et al., 2010; Sanoski et al., 1998; Snider et al., 2009).

Description of best practice model recommendation. The amiodarone monitoring guidelines (see Table 2.4) used in this EBP project were modeled after the guidelines recommended by the HRS. According to HRS guidelines (Goldschlager et al., 2007), certain diagnostic testing is recommended before initiation of amiodarone and at certain intervals throughout amiodarone therapy. Testing includes baseline liver function tests (LFTs), thyroid function tests (TFTs), pulmonary function tests (PFTs) including D_LCO (diffusion capacity for

carbon monoxide), chest x-ray (CXR), electrocardiogram (EKG), and a thorough eye exam. Not only do these serve as a baseline data for the patient for comparison in the future, but these baseline diagnostics also aid in the identification of those at higher risk for development of adverse effects of amiodarone (Johnson et al., 2010; Sanoski et al., 1998; Snider et al., 2009). In addition, the clinic was led by an APN to assess the effectiveness of this type of clinic management for increasing adherence to monitoring guidelines and the reduction in adverse events. After discussion with the electrophysiologist who assisted with the development of the monitoring protocol, it was decided International Normalized Ratios (INRs) would be followed weekly for six weeks after initiation of amiodarone due to amiodarone's potentiation of warfarin. All of the participants in the study who were on warfarin in conjunction with amiodarone were followed in a Coumadin clinic, negating the necessity for the project manager to see the participants on a weekly basis.

Table 2.4

HRS Recommended Amiodarone Monitoring Protocol

Diagnostic test	When test is completed
Liver function test (AST, ALT)	Baseline and every 6 months
Thyroid function test (TSH, FT4 if indicated)	Baseline and every 6 months
Chest x-ray	Baseline and yearly
Pulmonary function test (with D_LCO)	Baseline and as needed for suspicion for pulmonary toxicity
Eye exam	Baseline and as needed for suspicion of eye impairments
Electrocardiogram	Baseline and yearly
Digoxin monitoring	After amiodarone loading and as needed for signs of digoxin toxicity
Warfarin monitoring	Weekly for six weeks then based on results

Note. AST = aspartate transaminase; ALT = alanine transaminase; TSH = thyroid stimulating hormone; FT4 = free thyroxine; D_LCO = diffusing capacity of the lungs for carbon monoxide

Adherence to monitoring guidelines. A review of the literature showed that those patients receiving amiodarone are not being monitored as recommended by Heart Rhythm Society guidelines (Bickford & Spencer, 2006; Graham et al., 2004; Johnson et al., 2010; Raebel et al., 2006; Sanoski et al., 1998; Snider et al., 2009; and Spence et al., 2011). Implementation of specialized clinics dedicated to the monitoring of amiodarone at appropriate intervals has been shown to increase compliance to guidelines (Graham et al., 2004; Johnson et al., 2010; Raebel et al., 2006; Sanoski et al., 1998; Snider et al., 2009; and Spence et al., 2011) as well as increase earlier recognition of adverse events otherwise unnoticed (Snider et al., 2009; Sanoski et al., 1998; and Spence et al, 2011).

Application of the APN role. Certain limitations have been identified in previous studies that would be inapplicable in the APN-led clinic. The limitations identified were found in the pharmacist-led amiodarone clinics and pertained to the ordering of EKGs and CXRs. Pharmacists are limited to the ordering of laboratory tests only and relied upon the patient's primary physician to order the other diagnostics needed for monitoring guidelines (Johnson et al., 2010; Spence et al., 2011). In Indiana, an APN has the ability to order not only the laboratory diagnostics, but also other diagnostics such as EKGs, CXRs, and PFTs (Phillips, 2005). Thus, the use of an APN-led clinic would resolve the issue of ordering diagnostic testing found in pharmacist-led amiodarone clinics. Naylor and Kurtzman (2010) discussed the use of nurse practitioners in delivering high quality care. They found that the care provided was comparable with care delivered by physicians and in some instances, better with regards to patient follow-up; patient satisfaction; and more improved screening, assessment, and counseling (Naylor & Kurtzman, 2010), qualities which provide for a successful amiodarone monitoring clinic.

Answering the clinical question. The clinical question put forth in this EBP project was constructed using the PICOT format outlined by Melnyk and Fineout-Overholt (2011). The clinical question addressed by this EBP project was: What effects will an APN-led outpatient

amiodarone clinic have on adherence to amiodarone monitoring guidelines in the adult population over four months? In order to answer this clinical question, a practice change was implemented within a cardiology practice which encompassed an amiodarone clinic managed by an APN using HRS guidelines (Goldschlager et al., 2007). A comparison of adherence to amiodarone monitoring guidelines was completed using a chart review of two cohorts, one before initiation of an amiodarone clinic, and one after the practice change of implementation of an amiodarone clinic.

CHAPTER 3

IMPLEMENTATION OF PRACTICE CHANGE

Participants and Setting

A northern Indiana cardiology practice was chosen as the site for the implementation of the evidence-based practice (EBP) project. The purpose of this project was to compare patient adherence to recommended HRS monitoring guidelines for amiodarone (Goldschlager et al., 2007). This practice serves two different sites in the area with monthly patient volumes of around 100 patients. Participants included a convenience sample of patients newly initiated on amiodarone therapy during a consultation with the electrophysiologist at either site during the EBP project. Information was gathered from a chart review completed by the EBP project manager after initiation of the APN-led clinic and was compared to data collected from a chart review of participants receiving amiodarone during the previous year.

Before beginning the EBP project, neither site had a drug-monitoring program. The cardiology staff would initiate recommended diagnostic testing prior to amiodarone initiation as well as maintenance diagnostic testing. According to HRS guidelines, maintenance diagnostic testing consisting of LFTs and TFTs should occur at least every six months and a CXR should be performed at least yearly in all patients taking amiodarone (Goldschlager et al., 2007). Often times, a stable patient may only be seen by this cardiology practice every one to two years, increasing the likelihood that adherence to monitoring guidelines would be lost.

Outcomes

The primary outcome of this EBP project was a comparison to adherence to recommended HRS monitoring guidelines of amiodarone before and after implementation of an amiodarone clinic in an effort to identify adverse drug events and decrease negative outcomes (Goldschlager et al., 2007). A chart review of patients participating in the amiodarone clinic was compared to a chart review of patients seen in the cardiology clinic in 2012. A secondary outcome was to identify decreased morbidity and mortality associated with amiodarone use due

to the projected increased of adherence to monitoring guidelines and early recognition of adverse effects after participation in the amiodarone clinic.

Planning

The foundation for the evidence-based practice project started with a discussion of the proposed amiodarone clinic with the electrophysiologist of the practice and the practice manager. Both welcomed the idea of the proposed amiodarone clinic as an enhancement of patient care. Collaboration with the electrophysiologist took place to construct a patient teaching information sheet (see Appendix A), establish a protocol for initial and maintenance amiodarone monitoring based on HRS guidelines (see Table 2.4), and develop a standard subjective/objective assessment protocol (see Appendix B) for use in the amiodarone clinic (Goldschlager et al., 2007). After discussion with the EBP academic advisor, it was decided that a chart review would be more appropriate for the project and the amiodarone clinic would be initiated by the cardiology practice staff.

Intervention

Participants in the amiodarone clinic completed initial diagnostic testing based on HRS guidelines at the time of amiodarone initiation (Goldschlager et al., 2007). Baseline testing consisted of LFTs and TFTs as well as a chest x-ray that were often times completed the day of consultation. The participant was then scheduled for a PFT at the participant's earliest possible convenience. A follow-up visit was scheduled with the cardiology staff shortly after completion of the diagnostic testing to discuss the results of the initial diagnostic testing, perform further participant teaching regarding the use of amiodarone and its potential adverse effects, evaluate for compliance of amiodarone loading if applicable and ensure maintenance dose was started, and answer any questions the participant may have regarding amiodarone use and side effects. More intensive monitoring of known medication interactions was discussed with the participant if needed. Based on HRS guidelines, weekly monitoring of INRs for the first 4-6 weeks post amiodarone initiation is recommended to assess for interactions between amiodarone and

warfarin and allow for warfarin dose modification (Goldschlager et al., 2007). HRS guidelines also recommend more frequent digoxin levels during the concomitant use of amiodarone and digoxin (Goldschlager et al., 2007). Another visit was scheduled one month after the initial visit with the cardiology staff to evaluate the participant for adverse effects and evaluate for compliance of amiodarone therapy and adherence to monitoring guidelines. Participants were encouraged to call as needed for suspicion of adverse effects of amiodarone for cardiology evaluation.

Recruitment

Data for the EBP project were collected by a retrospective chart reviews. Participants in the cardiology practice's amiodarone clinic were compared to those participants seen by the cardiology practice in 2012 on amiodarone. Inclusion criteria included those participants over 18 years of age newly initiated on amiodarone during the specified time period. Exclusion criteria included participants under the age of 18 and those not on amiodarone.

Data

Measures and their reliability and validity. Lack of any previous formal drug monitoring program identified the necessity of the evidence-based practice project. Literature found in the first three steps of the ACE Star model supported the need for the amiodarone clinic to enhance adherence to monitoring guidelines for the use of amiodarone. In the first stage of discovery of research, it was recognized that patients on amiodarone therapy have adverse effects not recognized in a timely manner and new ways to improve recognition were identified through the use of an amiodarone clinic protocol. The second stage of evidence summary showed the use of outpatient amiodarone clinics improved the discovery of the adverse effects of amiodarone through adherence to monitoring guidelines. Translation to Guidelines in the third step utilized HRS guidelines for amiodarone monitoring through the use of amiodarone clinics to evaluate patients for early signs of adverse effects of amiodarone (Goldschlager et al., 2007).

A data collection tool (see Appendix C) was developed to collect demographic data including age, height, weight, gender, and race as well as length of amiodarone use, concurrent use of warfarin or digoxin, and a current medication list. This information was used to compare the two cohorts during the chart review to assess for bias in the data collected. Statistical comparisons were made between the groups in order to increase the reliability that the adherence to monitoring results was due to the amiodarone clinic. Consistency of data collection was maintained by the use of the same data collection tool for each participant with the same person collecting and recording the data. Validity was maintained by the use of data measures from the electronic medical record.

Collection. A variety of data were collected during this project. A demographic sheet was completed by the project manager consisting of the participant's age, height, weight, gender, race, current medical problems, and current medication list. At the bottom of the demographic sheet was a flow sheet to record completion of diagnostic testing. This data collection sheet was used both for the usual care cohort as well as the amiodarone clinic cohort. Data were coded using a code key (see Appendix D) that was secured in a locked cabinet separately from the data collection sheets to maintain confidentiality of the participants.

Management and analysis. Adherence to guidelines at the initiation of the amiodarone clinic was compared to those not enrolled in the amiodarone clinic. The data for those participants not enrolled in the amiodarone clinic were obtained from a retrospective chart review of the participants on amiodarone in the previous year at the cardiology practice where the project took place. Independent *t*-tests were used to compare age, weight, and height of the participants and x^2 tests were used to compare adherence to guidelines between the participants enrolled in the amiodarone clinic and those not enrolled in the amiodarone clinic as well as participant gender, use of warfarin, and use of digoxin.

The data collection tool created for use during this EBP project was based on data collected in other comparisons of amiodarone clinics included in this EBP project report

(Bickford & Spencer, 2006; Graham et al., 2004; Johnson et al., 2010; Raebel et al., 2006; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011; Tafreshi et al., 2009). The data collected were used to compare the two groups included in this EBP project using SPSS software.

Protection of Human Subjects

Several methods were employed to protect the participants and their rights during the evidence-based practice project. In the early stages of the project, the project manager completed training through the National Institute of Health geared towards the protection of human subjects. Institutional Review Board approval through Valparaiso University was obtained as well as approval through the cardiology practice facility. All data were coded and the code key and data were kept separately in a locked cabinet accessible only by the project manager.

CHAPTER 4

FINDINGS

The purpose of this EBP project was to evaluate if the implementation of a nurse-led amiodarone clinic would increase monitoring according to HRS-recommended monitoring guidelines. The question was answered using descriptive statistics to analyze data collected prior to the implementation of the amiodarone clinic and after through retrospective chart reviews. Statistical and descriptive analyses of the data collected before and after initiation of the amiodarone clinic were performed to answer the clinical question. Implications regarding the results identified will be discussed at more length in Chapter 5.

Participant Characteristics

Data for the baseline cohort were obtained through a retrospective chart review of all patients seen in the electrophysiology clinic in the year 2012. A total of ten participants (seven males and three females) were identified and included in this baseline cohort. The amiodarone clinic was initiated at the cardiology clinic in August of 2013. Nine participants (seven males and three females) were identified in the amiodarone clinic cohort for inclusion. Data abstracted from the charts included demographic data consisting of age, height, weight, gender, and race, along with date of amiodarone initiation, length of amiodarone use, use of warfarin, use of digoxin, medical history, and a current medication list.

Demographic data (see Tables 4.1 and 4.2) consisting of age, height, weight, race, and gender was compared between the two cohorts. An independent samples *t* test that compared the mean height, weight, and age of the two cohorts was conducted (see Table 4.3). No significant difference was found between the two groups in age ($t(17) = -.03$, $p = .97$), height ($t(17) = -1.57$, $p = .13$), and weight ($t(17) = .82$, $p = .43$). A chi-square test of independence was calculated comparing the race and gender between the two groups. No significant difference was found for race ($X^2(1) = 2.01$, $p = .16$) or gender ($X^2(1) = 3.21$, $p = .07$).

Table 4.1

Group Statistics for Demographics (age, height, weight)

	Pre-amio clinic (n = 10)	Post-amio clinic (n = 9)
	M (*SD*)	
Age (in years)	74.50 (10.63)	74.67 (10.97)
Height (in inches)	69.40 (2.41)	71.22 (2.64)
Weight (in pounds)	215.50 (56.42)	195.22 (51.14)

Table 4.2

Group Statistics for Demographics (race, gender)

	Race		Gender	
	Caucasian	African-American	Male	Female
Pre-Amio Clinic n (percentage)	8 (80%)	2 (20%)	7 (70%)	3 (30%)
Post-Amio Clinic n (percentage)	9 (100%)	0 (0%)	9 (100%)	0 (0%)

Table 4.3

Independent Samples Test for Demographics (age, height, weight)

	Levene's Test for Equality of Variances		*t*-test for Equality of Means						
								95% CI	
	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Age	.05	.84	-.03	17	.97	-.17	4.96	-10.62	10.29
Height	.06	.81	-1.57	17	.13	-1.82	1.16	-4.27	.62
Weight	.27	.61	.82	17	.43	20.28	24.81	-32.07	72.62

Changes in Outcomes

Prior to the initiation of the amiodarone clinic, it was found that adherence to HRS monitoring guidelines needed improvement. All nine participants included in the amiodarone cohort completed the educational session. In the pre-amiodarone clinic cohort (n = 10), baseline diagnostic monitoring adherence for EKG, TFT, LFT, CXR, and PFT were at 60%, 40%, 30%, 50%, and 10% respectively (see Table 4.4). After initiation of the amiodarone clinic (n = 9), the percentage of adherence increased to 100%, 66.7%, 66.7%, 88.9%, and 33.3% respectively (see Table 4.4). Adherence to the baseline eye exam was at 0% for the pre-amiodarone clinic cohort and did not change after initiation of the amiodarone clinic.

Table 4.4

Adherence to Baseline Monitoring Pre and Post Amiodarone Clinic

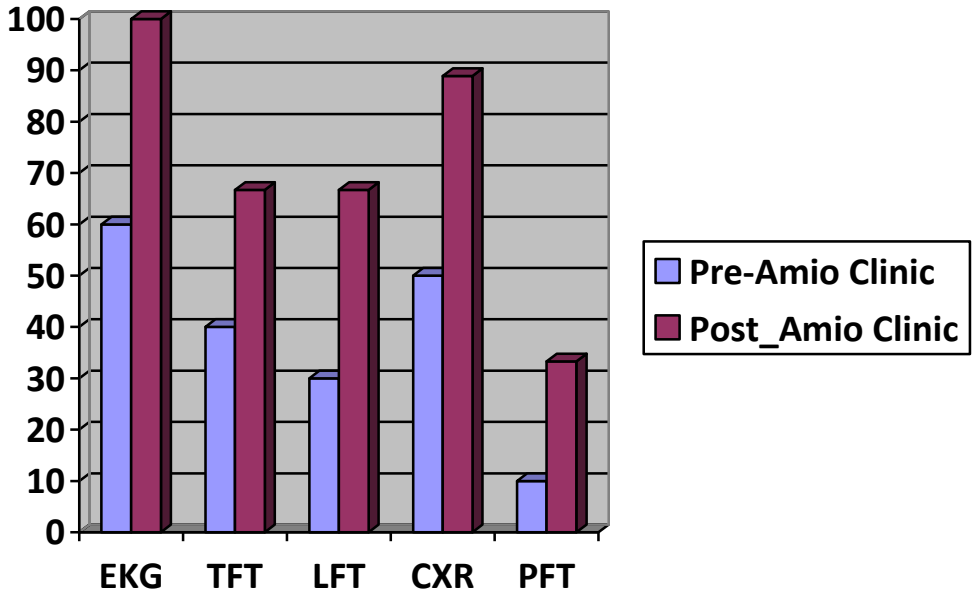
Diagnostics	Number Completed	
	Pre-Amio Clinic (n = 10)	Post-Amio Clinic (n = 9)
EKG	6 (60%)	9 (100%)
TFT	4 (40%)	6 (66.7%)
LFT	3 (30%)	6 (66.7%)
CXR	5 (50%)	8 (88.9%)
PFT	1 (10%)	3 (33.3%)
Eye Exam	0	0

Statistical testing. Participants in the pre-amiodarone clinic cohort were compared to the post-amiodarone clinic cohort with respect to adherence to HRS monitoring guidelines for baseline diagnostics (see Table 4.4). When the two groups were compared using the chi-square of independence for baseline diagnostics, a significant difference was found in the post-amiodarone group for baseline EKG (X^2 (1) = 4.56, p = .03). Although the results were not significantly different, baseline TFT (X^2 (1) = 1.35, p = .25), baseline LFT, (X^2 (1) = 2.55, p = .11), CXR (X^2 (1) = 3.32, p = .07), and PFT (X^2 (1) = 1.55, p = .21) diagnostics all improved; those participants in the post-amiodarone clinic group were more likely to complete the recommended diagnostics.

Significance. Based on the data collected and analyzed for this EBP project, a nurse-led amiodarone clinic increased adherence to amiodarone monitoring using HRS guidelines (see Figure 4.1). Although not all the results were statistically significant, adherence to amiodarone monitoring increased in all diagnostic studies except for eye exams after the amiodarone clinic was implemented. Seven (77.8%) of the nine amiodarone clinic participants remained on amiodarone during the EBP project.

Figure 4.1

Percent Adherence to Monitoring Pre-Post Amiodarone Clinic



Drug interactions. Out of the nine participants in the amiodarone clinic, six (66.7%) of them were concurrently taking warfarin. All six of these patients were followed through a Coumadin clinic not part of the amiodarone clinic. Each respective Coumadin clinic was alerted to patient initiation of amiodarone and weekly INRs were completed on all six patients for six weeks and then weekly until two consecutive INRs were within range per the Coumadin clinic protocol. None of the participants in the amiodarone clinic were concurrently taking digoxin.

Past medical history. All nine (100%) of the participants in the amiodarone clinic were prescribed amiodarone for the treatment of atrial-based arrhythmias. Three (33.3%) of the participants had concurrent coronary artery disease. Four (44.4%) of the participants had concurrent hyperlipidemia, receiving statin therapy and/or fenofibrate therapy.

Amiodarone morbidity. Two (22.2%) of the participants in the amiodarone clinic had their amiodarone discontinued during this EBP project. One of the patients was admitted for pneumonia towards the end of the EBP project which led to the immediate withholding of amiodarone until further diagnostics could be completed. A CT scan showed fibrotic changes consistent with early amiodarone pulmonary toxicity. The other participant had persistent nausea, dizziness, and insomnia after two months on amiodarone. No signs of liver, thyroid, or eye effects from amiodarone were observed on either participant during the EBP project.

Amiodarone mortality. None of the participants died during the EBP project due to amiodarone adverse effects or otherwise.

CHAPTER 5

DISCUSSION

The purpose of this EBP project was to observe the effects of an APN-led amiodarone clinic on adherence to monitoring per HRS guidelines (Goldschlager et al., 2007). Based on other research findings in the literature, use of an amiodarone clinic increased adherence to monitoring (Graham et al., 2004; Johnson et al., 2010; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011). This EBP project supported those recommendations as adherence to amiodarone monitoring increased after enrollment into the amiodarone clinic.

Explanation of Findings

Data for this project were collected using a retrospective chart review pre and post amiodarone clinic. Demographic data were collected from each group and compared for significant differences between the two groups which would impact the validity of the findings. Baseline monitoring data including baseline EKG, TFT, LFT, CXR, and PFT were collected and compared in the pre and post amiodarone participants. Monitoring data were analyzed using SPSS software. An independent samples *t*-test was used to compare age, height, and weight of the participants in the pre and post amiodarone clinic participants. Chi-square testing was used to evaluate for significant differences in gender and race in the pre and post amiodarone clinic participants as well as the appraisal of adherence to diagnostic monitoring between the pre and post amiodarone clinic participants.

Answer to PICOT question. The original PICOT question was: Does enrollment in an amiodarone clinic compared with “usual care” change adherence to monitoring as recommended by best practice guidelines and allow for earlier recognition of adverse effects of amiodarone to decrease negative patient outcomes over a four month time period? Adherence to monitoring for baseline EKGs, TFTs, LFTs, CXRs, and PFTs increased over the four month period in the APN-led amiodarone clinic. Two patients were found to have significant adverse effects from amiodarone prompting discontinuation of amiodarone. Both of these patients

recovered after the early recognition of amiodarone adverse effects and discontinuation of amiodarone.

Pre-amiodarone clinic diagnostic adherence. Of the ten participants identified prior to the implementation of the amiodarone clinic, baseline EKG completion was 60%, baseline TFT completion was 40%, baseline LFT completion was 30%, baseline CXR completion was 50%, and baseline PFT completion was 10%. A review of the literature included studies evaluating adherence to baseline amiodarone monitoring in the absence of a dedicated amiodarone clinic (Bickford & Spencer, 2006; Graham et al., 2004; Johnson et al., 2010; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011; Stelfox et al., 2004). The EBP project results found in the retrospective chart review of participants not enrolled in the amiodarone clinic were similar to the results in the literature. Bickford and Spencer (2006) reported higher baseline TFT, LFT, CXR, and PFT results (82%, 87%, 87%, and 24% respectively). Stelfox and colleagues (2004) reported baseline adherence rates for LFT (42%), TFT (40%), and CXR (50%) which were similar to the baseline adherence rates in the pre-amiodarone clinic participants in the EBP project.

Post-amiodarone clinic diagnostic adherence. After implementation of the amiodarone clinic, baseline completion of EKG diagnostics rose from 60% to 100% and was statistically significant. When comparing the findings from this EBP project to the literature, mixed results were found. In a study by Graham and colleagues (2004), EKG adherence was not shown to be significantly improved (41% in the amiodarone clinic cohort as compared to 32% in the usual care cohort). In other studies, adherence to EKG monitoring in this EBP project was similar to those results reported in the literature post implementation of an amiodarone clinic (Graham et al., 2004; Johnson et al., 2010; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011). Snider and associates (2009) described increased adherence to amiodarone monitoring for baseline EKG adherence (from 80% to 100%).

Post amiodarone monitoring in this EBP project for TFT (66.7%) and LFT (66.7%) increased. In 2004, Graham and colleagues reported improved adherence for continued amiodarone monitoring for TFT (66%) and LFT (69%) in the amiodarone clinic cohort as compared to the usual care group with adherence rates of 37% for TFT and 38% for LFT. Johnson and colleagues (2010) found that baseline adherence rates increased for LFT (from 44% to 69%) and TFT (from 49% to 55%) after implementation of an amiodarone clinic.

Spence and associates (2011) found that PFT adherence rates rose from 3.6% to 6.6% after implementation of an amiodarone clinic. In this EBP project, similar baseline PFT results were document prior to the implementation of the amiodarone clinic (10%), but rose to 33.3% after implementation of the amiodarone clinic. Snider and colleagues (2009) reported improvement in baseline PFT adherence from 30% to 100% after initiation of an antiarrhythmic medications clinic.

In this EBP project, baseline CXR adherence increased post amiodarone clinic. However, in the literature, mixed results for baseline CXR adherence were reported. Snider and associates (2009) described increased adherence to amiodarone monitoring for CXR (from 70% to 100%) after implementation of antiarrhythmic medications clinic. Spence and colleagues (2011) revealed an increase for baseline CXR (from 49.3% to 59.1%) after initiation of an amiodarone clinic. Johnson and associates (2010) found that baseline adherence for CXR was reported as better in the usual care cohort (56%) as compared to those enrolled in the amiodarone clinic (45%).

The amiodarone clinic for this EBP project did not improve adherence to baseline eye exam completion. Only one study included in the literature review discussed baseline adherence to eye exams (Graham et al., 2004). In their study, baseline adherence to eye exams increased from 15% to 30% after implementation of an amiodarone clinic.

Post-amiodarone adverse events. Various amiodarone adverse events were documented in the literature. In this EBP project, 2 adverse events (22.2%) were documented.

One participant had evidence of early pulmonary toxicity and the other participant had musculoskeletal and gastrointestinal adverse effects that impacted activities of daily living. Adverse events were also reported in the literature. Spence and associates (2011) documented liver, thyroid, musculoskeletal, and pulmonary reactions to amiodarone as well as digoxin toxicity with concurrent amiodarone administration. When compared with the usual care group, the number of patients affected by adverse events was much less (8 reported adverse events in the amiodarone clinic group versus 81 in the usual care group). Johnson and researchers (2010) described fewer adverse events in the amiodarone clinic cohort (21 as opposed to 48 in the usual care cohort) with the top reported adverse event being thyroid-related. Sanoski and colleagues (1998) reported adverse effects of amiodarone in 21 (35%) of the 60 patients enrolled in the amiodarone clinic with the top reported adverse effect being hypothyroidism. Graham and associates (2004) also found similar adverse effects of amiodarone (the most common reported were TSH elevation and cough/dyspnea) with more adverse effects documented in the amiodarone clinic group.

Evaluation of the Applicability of the Theoretical and EBP Framework

Two frameworks led the development, implementation, and analysis of this EBP project: King's Theory of Goal Attainment as the nursing model and the ACE Star Model as the EBP framework.

King's Theory of Goal Attainment. King's Theory of Goal Attainment (King, 1971; King, 1981) functioned as the theoretical framework for this EBP project. Goal attainment was modified to describe the relationship between the project manager and the participants in the amiodarone clinic.

Concepts related to the project manager. In the Theory of Goal Attainment, nursing is responsible for assessing patients' needs to improve health, developing a trusting, therapeutic relationship with patients, and guiding patients to achievement of a mutual goal to improve health (King, 1971; King, 1981). In this case, it was the project manager's responsibility to

develop a treatment plan with the input of the amiodarone clinic participant. It was important to incorporate individualized stressors and barriers to goal attainment as well as deliver the education necessary to allow the amiodarone clinic participant to fully take part in the plan of care related to goal attainment.

Concepts related to the participants in the amiodarone clinic. The participants in the amiodarone clinic made up the interpersonal system that is the heart of King's Theory of Goal Attainment. The interpersonal system is made up of three parts: the personal system (the participant in the amiodarone clinic), the interpersonal system (the interaction between the project manager and the participant in the amiodarone clinic), and the social system (those individuals whom the participants chose to bring with them to follow-up appointments in the amiodarone clinic) (King, 1971; King, 1981). These individuals in the social system included family, friends, or caregivers.

Even though goals were mutually set, the amiodarone clinic participant was still responsible for completion of the recommended diagnostic monitoring. It was found after discussion with the participants that EKGs were easy to complete due to the fact that they were completed at the follow-up appointments with the project manager. Lab diagnostics and CXR were also similarly easy to complete as they could be done immediately after the appointments. PFTs and eye exams were the most difficult to complete as reported by the amiodarone clinic participants as these had to be scheduled at a later date and at another facility. Further education could be done stressing the importance of the necessity for baseline PFTs and eye exams. This way a more thorough discussion could be had with the patient in order to fully attain the mutual goal of completion of *all* baseline diagnostics upon the initiation of amiodarone.

Concepts shared by the project manager and the participants in the amiodarone clinic. The interactions that took place between the project manager and participants in the amiodarone clinic facilitated the mutual attainment of goals; in this case, improved adherence to amiodarone monitoring guidelines. These interactions included the initial educational session

with the participants. The project manager was sure to discuss any potential barriers to adherence of monitoring guidelines and any stressors that might be involved in scheduling the diagnostics required outside of the clinic. Barriers and stressors to completion of diagnostic testing could include financial complications, transportation complications, or simply lack of wanting to have the diagnostics completed. Some stressors were medication specific and related to drug-drug interactions between amiodarone and other medications the participants were taking. The drug-drug interactions included in this EBP project included warfarin and digoxin. None of the participants included in the EBP project were concurrently taking digoxin, but six of the nine participants included were taking warfarin. These participants were followed in a Coumadin clinic and teaching was done with the staff of the Coumadin clinics. Teaching included amiodarone's interaction with warfarin, the recommended dosage reduction by one-third to half when starting amiodarone, and weekly INRs for six weeks with dosage adjustments necessary to maintain therapeutic ranges, then per routine monitoring (Dulak, 2005; Goldschlager et al., 2007; Siddoway, 2003).

The implementation of the amiodarone clinic was well-received by the cardiology practice as well as the amiodarone clinic participants. In fact, the participants in the amiodarone clinic shared how pleased they were with the education delivered by the project manager and the close follow-up to monitor for adverse effects of amiodarone.

ACE Star Model. The ACE Star Model yielded a five step process to guide this EBP project (Stevens, 2004). The steps include knowledge discovery, evidence summary, translation, integration, and evaluation.

Stage 1: Discovery of research. In this stage, original knowledge is exposed through research and scientific inquiry (Stevens, 2004). In this EBP project, several studies were identified through a review of literature documenting the success of amiodarone clinics to improve adherence to monitoring guidelines (Graham et al., 2004; Johnson et al., 2010; Raebel et al., 2006; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011; Tafreshi et al., 2009).

By using discovery of research, knowledge regarding the usefulness of amiodarone clinics in adherence to monitoring guidelines was obtained.

Stage 2: Evidence summary. In this stage, the mass of research is combined into a single, significant statement, often in the form of systematic reviews, as well as the recurrent update of knowledge with new evidence (Stevens, 2004). Within the current evidence, the use of outpatient amiodarone clinics has shown improvement in adherence to monitoring guidelines (Graham et al., 2004; Johnson et al., 2010; Raebel et al., 2006; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011; Tafreshi et al, 2009) and the earlier discovery of adverse effects of amiodarone (Johnson et al., 2010; Sanoski et al., 1998; Snider et al., 2009; Tafreshi et al., 2009). A review of the literature did not reveal an APN-led amiodarone clinic, but other APN-led clinics for chronic disease/medication management were successful (Alfakih et al., 2009; Aziz et al., 2011; Chandler, 2007; Grange, 2005; Hatchett, 2005; Levine et al., 2012). Success was documented by patient-reported symptom relief, facilitation of interdisciplinary referrals, improved patient outcomes, fewer hospital readmissions, and better patient education regarding chronic condition management (Grange, 2005; Hatchett, 2005; McAfee, 2012). This evidence of APN-led clinics for other diseases and medication management were used to support the APN-led clinic in the EBP project.

Stage 3: Translation to guidelines. Translation allows for evidence delivery into a summary of useful, relevant information into clinical practice guidelines, care standards, clinical pathways, organizational protocols, or organizational algorithms through evidence-based practices and clinical expertise across many patient populations and settings (Stevens, 2004). Many large healthcare organizations (Johnson et al., 2010; Raebel et al., 2006; Snider et al., 2009; Spence et al, 2011) have instituted outpatient drug monitoring programs to increase adherence to monitoring guidelines and increase the identification of adverse drug effects. By having a monitoring program dedicated to amiodarone monitoring by HRS guidelines, the confusion regarding who was responsible for monitoring these patients was negated and

allowed for the early identification of adverse drug effects requiring dose adjustments or possibly discontinuation of amiodarone (Goldschlager et al., 2007). Multidisciplinary amiodarone clinics as well as pharmacist-led clinics have been documented in the literature. This EBP project was the first documented APN-led amiodarone clinic in the literature, and as described, the APN-led clinic had the potential to offer additional benefits not found in pharmacist-led amiodarone clinics including the ability to order all of the diagnostic testing recommended by guidelines including PFTs and CXRs which the pharmacist is not able to do as defined by pharmacist scope of practice without a collaborating physician (Johnson et al., 2010; Spence et al., 2011).

Stage 4: Practice integration. Society expects healthcare professionals to remain up-to-date on current best practices. In order to complete this task, healthcare professionals and organizations must be willing to accept new guidelines for practice if the evidence is supportive of the change (Stevens, 2004).

This EBP project utilized HRS guidelines for the monitoring of amiodarone in a dedicated amiodarone clinic (Goldschlager et al., 2007). Baseline monitoring was compared between a chart review of patients prior to initiation of an amiodarone clinic in a small northwestern Indiana cardiology practice and then another chart review of patients after implementation of an amiodarone clinic.

Stage 5: Evaluation. Evaluation is the final step in the ACE Star Model and consists of influences of evidence-based practice on patient outcomes, healthcare professional/patient satisfaction, efficacy/efficiency of care, economic analysis, and health status (Stevens, 2004). For this EPB project, outcomes evaluated included the number of participants that completed baseline diagnostic monitoring before and after initiation of an amiodarone clinic. Previous studies and reviews suggested an increase in the adherence to monitoring guidelines with the implementation of an amiodarone clinic and the early identification of adverse effects of amiodarone allow for early treatment to reduce morbidity and mortality from the use of

amiodarone (Graham et al., 2004; Johnson et al., 2010; Raebel et al., 2006; Sanoski et al., 1998; Snider et al., 2009; Spence et al., 2011; Tafreshi et al., 2009).

This EBP project demonstrated that the implementation of an APN-led amiodarone clinic increased adherence to monitoring guidelines. Furthermore, participants in the amiodarone clinic expressed increased satisfaction with the enhanced educational process and more frequent office visits to monitor for adverse effects of amiodarone. Two participants in the amiodarone clinic were found to have significant enough adverse effects of amiodarone to warrant discontinuation of amiodarone therapy, further adding to the usefulness of a dedicated amiodarone clinic and potential improved health status. An APN-led clinic would be more cost-effective than a physician-led amiodarone clinic due to the differences in salary requirements. Additionally, an APN-led clinic can overcome some of the ordering difficulties associated with the pharmacist-led amiodarone clinics. Pharmacist-led clinics are not able to order certain diagnostics such as PFTs, CXRs, and EKGs.

Strengths and Limitations of the EBP Project

Strengths. There were several strengths to this EBP project. First, the data collected supports the use of a dedicated amiodarone clinic to increase adherence to amiodarone per recommended guidelines. This additional data contributes to the current evidence of the usefulness of amiodarone clinics in improving adherence to amiodarone monitoring guidelines and also adds the new knowledge of an APN-led amiodarone clinic. Second was the utilization of APN skills. APNs can provide valuable care through clinical skills that offer symptom relief, facilitation of interdisciplinary referrals (McAfee, 2012), as well as provide improved outcomes for patients as demonstrated by fewer hospital readmissions (Grange, 2005). These tasks are completed by the APN through education of patients regarding their chronic conditions (Grange, 2005; McAfee, 2012), by more frequent office visits in the amiodarone clinic for earlier recognition of adverse effects, and by increased compliance with baseline diagnostic testing. Participants with adverse effects requiring treatment from a specialist (such as those

experiencing signs and symptoms of hypothyroidism) would be sent to an appropriate healthcare provider for treatment.

One of the ten participants in the usual care cohort required the discontinuation of amiodarone due to suspected pulmonary toxicity requiring hospitalization and aggressive treatment. Two of the nine participants in the amiodarone cohort required the discontinuation of amiodarone due to adverse effects. One of the two participants was hospitalized for pneumonia and a CT scan showed fibrotic areas in the lungs suspicious for amiodarone-induced pulmonary toxicity. The participant was treated and released after a few days and fully recovered. The other participant experienced GI symptoms and muscle tremors which have since resolved since stopping amiodarone due to early recognition of adverse effects.

Naylor and Kurtzman (2010) found that the care provided by APNs was comparable with care delivered by physicians and, in some instances, better with regards to patient follow-up; patient satisfaction; and more improved screening, assessment, and counseling, qualities which provide for a successful amiodarone monitoring clinic. Third, patients in this EBP project expressed their satisfaction with the involvement in and individualization of the treatment plan as guided by the Theory of Goal Attainment which added to patient accountability for treatment compliance.

Limitations. This EBP project only drew participants in a non-randomized fashion from one of the physicians within the cardiology practice over a short period of time. Also, only new patients to amiodarone were included in the project. Had the time been extended to one year and participants gathered from all four physicians, the number of participants would have been larger and more information regarding adherence to amiodarone monitoring per recommended guidelines in chronic users of amiodarone could have been compared before and after implementation of the amiodarone clinic. Due to the use of electronic medical records, only results found in the electronic medical record were included in this EBP project.

Improvements to adherence could have been made by using reminder letters if baseline diagnostic testing results were not received within one week of amiodarone initiation. Also, an alert embedded in the electronic medical record prompting the prescriber of amiodarone to assess and order baseline diagnostics as required upon initiation of amiodarone could have improved adherence.

Implications for the Future

Practice (APN role or professional nurse). In the state of Indiana, nurse practitioners are able to assess patients, order appropriate diagnostic testing, review the diagnostic testing, and make recommendations to the treatment plan based on diagnostic testing results. These are all skills needed in the implementation of an amiodarone clinic and negate some of the limitations found in pharmacist-managed amiodarone clinics. The usefulness of the APN in this type of role could be expanded to incorporate a multitude of medications that require diagnostic monitoring, leading to a new niche in healthcare for the APN. An example of another APN-led clinic may include an arrhythmia clinic dedicated to the monitoring of antiarrhythmic medications including amiodarone, sotalol, dofetilide, flecainide, and propafenone. In this role, the APN could provide the patient medication education including uses, side effects, adverse effects, monitoring protocols; ordering and monitoring of diagnostic testing related to each specific antiarrhythmic medication; assessment of adverse effects of the antiarrhythmic medication; dose titration as necessary; and referral as needed to other specialty healthcare providers for treatment of adverse effects.

Theory. King's Theory of Goal Attainment was a useful theory in the guidance of the implementation of the amiodarone clinic due to the incorporation of the patient in the treatment plan. Adherence to recommended amiodarone monitoring guidelines was improved through goal attainment by leading the EBP project manager and participants through a series of transactions to facilitate the decision on a mutual goal while taking into account each participant's unique barriers and stressors to goal attainment. Application of the Theory of Goal

Attainment would be suitable in future research requiring common goal attainment between researchers and research participants.

Research. An APN-led amiodarone clinic research study could not be found in the literature. Instead, other APN-led clinics were included in the literature review and applied to implementation of an amiodarone clinic. Hospital readmission rates decreased after enrollment into a nurse-led asthma clinic (Chandler, 2005); nurse-led heart failure clinics have demonstrated an improved quality of life, individualized care, and appropriate medication management (Grange, 2005); and nurse-led anticoagulation clinics were more cost effective and found that fewer patients in the nurse-led clinic required hospitalization (Aziz et al., 2011). This EBP projects starts to fill the knowledge gap found in this area and new research is needed regarding effects on amiodarone monitoring adherence, patient outcomes, and cost effectiveness of an APN-led amiodarone clinic to continue to fill the knowledge gap discovered. Research designs should include longitudinal designs to track the same groups of patients before and after enrollment into an APN-led amiodarone clinic while incorporating a cost analysis.

Education. Further education is necessary regarding the lack of adherence to amiodarone monitoring guidelines and the improved adherence to monitoring guidelines through the implementation of an amiodarone clinic. This EBP project provides useful information to cardiology and primary care nurses regarding lack of adherence to amiodarone monitoring and urges those in this specialty area to evaluate current monitoring protocols for adherence rates. Future clinics led by APNs might also incorporate other antiarrhythmic medications requiring diagnostic monitoring as well as other medications used in the treatment of chronic diseases. Not only can this provide another area of expertise for APNs to fulfill, but also improvement of patient outcomes through early awareness of drug adverse effects.

Conclusion

The evaluation of this EBP project suggests that implementation of an APN-led amiodarone clinic increases adherence to amiodarone monitoring guidelines. A review of the literature identified that other amiodarone clinics also improved adherence to amiodarone monitoring guidelines, but none were found that were APN-managed. Some of the research identified patients who had already suffered amiodarone adverse effects that had gone unnoticed by current healthcare providers, giving further indication for a dedicated amiodarone clinic. Through patient interactions, patient education, and assessment of barriers and stressors to adherence to diagnostic monitoring, improved awareness and early recognition of amiodarone adverse effects may be achieved through mutual goal attainment. Patient education skills and the ability to monitor health status in a holistic manner are already ingrained into the APN role, leading to the opportunity of a new function in healthcare.

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AUTOBIOGRAPHICAL STATEMENT

Melissa M. Bartoszewicz

Ms. Bartoszewicz graduated from Indiana University with a Bachelor of Science in Nursing Degree in 2000. She has worked in several hospitals and multispecialty clinics over the last fourteen years. Twelve of those years she has specialized in the area of cardiology. She currently is employed in a multispecialty clinic where she has spent the last five years with the cardiology department working with the clinic's only electrophysiologist. Her role has been the education of patients in the electrophysiology department; education has focused on medication management and ablative treatment of complex arrhythmias. This passion for education led to the development of her evidence-based practice project within the Doctorate of Nursing Practice program. Melissa will earn her Doctorate of Nursing Practice degree in 2014. Melissa was recently inducted into Sigma Theta Tau International, Zeta Epsilon Chapter, the national nursing honor society. She is interested in continuing her career as an advanced practice nurse in electrophysiology and hopes to start an arrhythmia clinic at her current place of employment.

ACRONYM LIST

ALT: alanine transaminase

APN: advanced practice nurse

AST: aspartate transaminase

CXR: chest x-ray

D_LCO: diffusing capacity of the lungs for carbon monoxide

EBP: evidence-based practice

FT4: free thyroxine

HRS: Heart Rhythm Society

INR: international normalized ratio

LFT: liver function test

TFT: thyroid function test

TSH: thyroid stimulating hormone

PFT: pulmonary function testing

Appendix A

AMIODARONE PATIENT EDUCATION

Guidelines for Therapy

Your doctor has prescribed amiodarone for you. This medicine is used to treat irregular heart rhythms. While you are taking this medication, you will need to complete testing before you start the medication and every six months while taking the medication. It is preferred that you take this medication with food at the same time every day. You should avoid drinking grapefruit juice or eating grapefruits. This may decrease the effects of the medication. Please report all medications you are taking to your cardiologist as well as any new medications you may start. Some medications may react with amiodarone. They may increase or decrease the effects.

Here are the lists of tests that must be completed at the start of your treatment and at certain intervals while on amiodarone. Any of these tests may be completed at any time in the future if side effects are suspected.

At Baseline	**Every 6 Months**	**Yearly**
Liver function test	Liver function test	Chest x-ray
Thyroid function test	Thyroid function test	Eye exam
Pulmonary function test		EKG
Chest x-ray		
Eye exam		
EKG		

Side Effects

Side effects are more likely to occur at higher doses during the loading period. Most side effects lessen or go away with a decrease in dose. Amiodarone stays in your body for a long period of time. If the medication is stopped, the effects may still remain in your body for several weeks or months. Please call your cardiology provider if you experience side effects, which may include:

Shortness of breath/cough	Sensitivity to the sun	Loss of appetite
Nausea and vomiting	Tiredness/fatigue	Constipation
Skin discoloration	Blurry or double vision	Muscle weakness/tremors

Lung problems

In a small number of patients taking amiodarone over a long period of time, lung damage can occur. This damage can be lessened or reversed completely if amiodarone is stopped early. If you develop shortness of breath or a cough, please tell your cardiology provider immediately.

Skin reactions

Your skin may develop a redder look. This may increase when exposed to sunlight. A bluish-gray discoloration may also be seen. These reactions are normal side effects. Sunscreen, hats, and long-sleeves/pants are recommended to help decrease these effects.

Eye problems

Amiodarone can sometimes deposit small particles in the eye. Sometimes blurry or double vision can occur. These deposits can be seen on a thorough eye exam by an ophthalmologist (eye doctor). If eye deposits are seen on exam and are causing vision loss, the amiodarone dose may have to be decreased or stopped completely.

Sleep Disturbances

While taking amiodarone, you may experience changes in sleep patterns. Insomnia is common, especially during the loading period. This will lessen as the dose is reduced. If insomnia is a problem, please discuss this with your cardiology provider for treatment options.

As with any medication, your doctor will determine if the benefits of amiodarone outweigh the risks or complications due to side effects. If you experience side effects, please contact your cardiology provider. A dose adjustment or further testing may be needed.

Appendix B

Amiodarone Clinic Patient Evaluation Protocol

I. At the initial visit:
   A. Basic history and physical
      1. Vital signs: BP, HR
      2. Lung exam
      3. Heart exam
      4. Review of current medication list to check for potential drug interactions with amiodarone
   B. Baseline tests if not obtained at cardiology consultation
      1. CXR
      2. EKG
      3. Pulmonary function test
      4. Ophthalmology exam
      5. CMP, Magnesium, TFT (and PT/INR and/or digoxin level if appropriate)
   C. Patient education on amiodarone use, side effects, interventions to decrease side effects

II. At the one month visit:
   A. Basic history and physical to elicit for adverse effects
      1. Fatigue
      2. Cough/shortness of breath
      3. Palpitations
      4. Syncope
      5. Blurry/double vision or loss of vision
      6. Skin changes
      7. Weight loss/nausea/vomiting
      8. Muscle weakness/tremors
      9. Sleep disturbances
      10. Changes in medications
   B. Discuss baseline testing
   C. Order further testing based on baseline testing results or patient complaints of side effects

Appendix C

Code # _____

Amiodarone Clinic Data Collection Tool

Patient Age: _____ Patient Height: _____ Patient Weight: _____

New to Amiodarone? _____ If no, length of amiodarone use: _____

Date of Initiation: _____ Warfarin? _____ Digoxin? _____

Past Medical History:

_____

_____

_____

Current Medications:

_____

_____

_____

	Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	3 Month	6 Month	1 Year
H & P										
EKG										
TFT										
LFT										
CXR										
PFT										
Eye Exam										
Digoxin Level										
INR										

*shaded boxes indicate when diagnostic study is needed (3 month testing optional)
*place date of exam in box

Recheck as Needed for Symptomatic Adverse Drug Reactions

EKG								
TFT								
LFT								
CXR								
PFT								
Eye Exam								
Digoxin Level								
INR								

*place date of exam in box

Appendix D

Amiodarone Clinic Code Key

Code Number	Patient Name	Date of Birth	Medical Record #