

# EXPLORING INDIVIDUAL PERSPECTIVES WITH AN INSERTABLE CARDIAC MONITOR

by

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Cardiovascular disease (CVD) is the leading cause of death for men and women in the United States. Individuals with syncope, cardiac arrhythmias and cryptogenic stroke are at risk for CVD because of a suspected arrhythmia. These individuals may choose to have an insertable cardiac monitor (ICM) inserted to detect cardiac arrhythmia's such as atrial fibrillation (AF). Little is known about self-care, quality of life (QOL) and the experiences of those with an ICM. The purposes of this dissertation were to understand the experiences of individuals who have an ICM inserted and to describe the effect on their self-care and QOL. In this qualitative descriptive study, maximum variety sampling was used to recruit a diverse sample. Participants ( $N = 12$ ) ranged in age from 41-95, with half ( $n = 6$ ) having the device because of syncope, infrequent AF ( $n = 1$ ), and others ( $n = 5$ ) for device insertion due to having a cryptogenic stroke. Manuscript 1 examined the decision-making process for ICM insertion in those with suspected arrhythmias. Understanding the influences that occur early in this process are important for the clinician when discussing options with this population. The purpose of this study was to describe how individuals make a decision to have an ICM inserted. The decision-making process to have an ICM inserted varied among participants. Three global categories emerged with data analyses: (a) pre-decision, (b) definitive decision, and (c) deliberated decision. Event symptoms, including physical, cognitive and emotional symptoms, and trust emerged as factors

in the decision-making process. Findings from this study indicate that clinicians should explore loss and emotional symptoms when caring for those making the decision to have an ICM. Because the timing of the decision varied and was related to trust, further research is needed to address the qualities that are important in interactions between the individual and their clinician that influence trust. Manuscript 2 focused on understanding the experiences of those with an ICM to improve health outcomes and QOL. The purpose of this study was to describe the experiences of those with undiagnosed cardiac symptoms or post-cryptogenic stroke living with an ICM. Data analyses resulted in three global categories: (a) influences on self-care, (b) managing, and (c) monitoring. Findings indicate that communication by the remote monitoring staff is an important aspect for those with an ICM. Future studies are warranted to determine the type and frequency of communication needed. Future studies are also needed to address fatigue and the importance of spiritual wellness in this population.



EXPLORING INDIVIDUAL PERSPECTIVES WITH AN INSERTABLE CARDIAC  
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by

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## **DEDICATION**

This dissertation is dedicated in memory of my grandmother, Fannie Gray Floyd, who left us way too soon. You were always one of my biggest cheerleaders and always believed in me. Though you are not here in person, you are always here in spirit. To my parents, Grayling and Mary Floyd, for instilling in me that any goal is within reach with hard work and determination. To my husband, Brandon, for his love and support throughout this entire process. I could not have finished without you.

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## CHAPTER 1: BACKGROUND

Arrhythmias are the most common cause for syncope when the etiology is cardiac related (Moya et al., 2009). The European Society of Cardiology (ESC) updated guidelines for diagnosing and managing syncope in 2009 (Moya et al., 2009) to include: identifying the basis for syncopal episodes to provide specific treatment as well as helping in understanding future individual risk. However, symptoms of cardiac arrhythmias and syncopal episodes occur infrequently and unpredictably. External short-term monitoring devices, such as the Holter monitor and external loop recorders, may not capture the episode in the short time they are worn; therefore, not always leading to diagnosis (Seidl et al., 2000; Solbiati et al., 2016). Recent advances in technology have led to the development of devices such as the insertable cardiac monitor (ICM) that offers long-term monitoring ability.

The ICM is a device that can assist clinicians with diagnosing cardiac arrhythmias associated with episodes of syncope (Edvardsson et al., 2011; Hong & Sulke, 2013; Ruwald & Zareba, 2013). The ICM is a device that can remain implanted for up to three years, increasing the chances of capturing the heart rhythm at the time of the episode. Individuals choosing the ICM are continuously monitored 24 hours per day. Although there is strong evidence to support use of the ICM in diagnosing cardiac arrhythmias and syncope, limited studies have examined the patient's perspective of having an implanted device that monitors heart rate and rhythm (Deaton, Dunbar, Moloney, Sears & Ujhelyi, 2003; Ricci et al., 2010).

Arrhythmias occur when there is an issue with the rate or rhythm of the heart. Symptoms of an arrhythmia vary and may include one or more of the following: bradycardia, tachycardia, irregular heartbeat, palpitations, anxiety, weakness, dizziness, syncope or near syncope, sweating, chest pain or dyspnea (National Heart, Lung, and Blood Institute [NHLBI],

2011). Atrial fibrillation (AF) is the most common arrhythmia experienced by individuals diagnosed with an arrhythmia (Lloyd-Jones et al., 2004).

It is estimated the cost of AF is approximately \$6 billion annually in the United States (US) (January et al., 2014; Mozaffarian et al., 2016). Globally, it is estimated AF affects 33.5 million individuals, and in the US the estimated 2010 prevalence of AF ranged from 2.7 million to 6.1 million and is expected to increase to over 12 million by the year 2030 (Mozaffarian et al., 2016). These increases may be due to the aging population or to pacemaker and cardiac defibrillator use resulting in an increase in diagnosis of AF. More importantly, individuals with AF are at increased risk for developing stroke, heart failure and sudden cardiac death (Mozaffarian et al., 2016). Approximately 795,000 individuals suffer from a new (77%) or recurrent stroke (23%) in the US each year with the vast majority (87%) classified as ischemic (Mozaffarian et al., 2016). Of concern is that approximately 25% to 40% of ischemic strokes are classified as having no definitive cause; cryptogenic stroke (Ritter et al., 2013; Yang et al., 2016). The presumed underlying mechanism for cryptogenic stroke is embolism secondary to AF.

Use of ICMs to capture arrhythmias and diagnose events can assist those diagnosed with AF to receive treatment and improve health outcomes related to heart disease. The signs and symptoms of AF can range from none at all to severe and may include: syncope, fatigue, irregular heartbeats, palpitations, dyspnea, hypotension or heart failure (American Heart Association [AHA], 2017a). These symptoms may interfere with an individual's ability to perform normal day-to-day self-care activities such as bathing and dressing as well as participating in social events and performing physical activity. With the prevalence of AF expected to increase significantly over the next decade, it is important to understand how devices

such as the ICM can assist individuals in managing their health. Managing health outcomes is important for this population due to their increased risk for diagnosis of stroke and heart failure and the significant costs associated with these chronic health conditions. Examining perceptions of those with an ICM will help with understanding the needs of this growing population and the perceived influence of ICMs assisting persons to manage their health outcomes.

### **Background and Significance**

Individuals experiencing symptoms of cardiac arrhythmias may undergo various diagnostic testing prior to choosing an ICM. An arrhythmia can only be confirmed when recorded by electrocardiogram (ECG) (January et al., 2014). With infrequent and unpredictable cardiac symptoms, an individual may have a normal ECG when examined in an emergency department or clinic setting. A Holter monitor may be considered if symptoms persist, but are undiagnosed with the basic ECG. The Holter monitor is typically used on a short-term basis (24 to 48 hours) and monitors the heart rhythm with a continuous recorder (AHA, 2015b).

Individuals keep a log of activities along with symptoms occurring with activity and submit the log to the clinician. The clinician reviews the log as well as any abnormalities in heart rhythm in an attempt to diagnose symptoms. When individuals have symptoms less often than daily or the Holter monitor is unable to diagnose symptoms, an external loop recorder (ELR) may be considered. The ELR may be used for up to one month and may be helpful to capture an event occurring frequently (Locati, Vecchi, Vargiu, Cattafi & Lunati, 2014). When individuals continue to experience cardiac symptoms that have been undiagnosed by one or more of the aforementioned diagnostic tests, the ICM may be considered due to its long-term monitoring ability.

Insertable cardiac monitors are often considered after other diagnostic tests have failed to

provide diagnosis due to higher costs associated with the device and their invasive nature. ICMs may also be considered after cryptogenic stroke due to the unknown etiology of the stroke (Sanna et al., 2014). It is imperative to identify the etiology to prevent recurrent stroke.

Research supports use of ICMs for diagnosing cardiac arrhythmias and episodes of syncope (Ashby, Cehic, Disney, Mahar & Young, 2002; Boersma, Mont, Sionis, Garcia & Brugada, 2004; Choe et al., 2015; Farwell, Freemantle & Sulke, 2004; Krahn, Klein, Yee & Skanes, 2001; Krahn, Klein, Skanes & Yee, 2004; Paruchuri, Adhaduk, Garikipati, Steinberg & Mittal, 2011; Podoleanu et al., 2014; Shanmugam & Liew, 2012; Solbiati et al., 2016). Studies have shown a higher rate of diagnosis than with the traditional methods of the Holter monitor and external loop recorders (Edvardsson et al., 2011). In fact, the diagnostic yield with an ICM in undiagnosed syncope is between 43 to 52% whereas non-invasive diagnostic testing has a diagnostic yield between 6 to 20% (Kanters et al., 2016). Research studies focusing on the use of ICMs after cryptogenic stroke have had good results with detecting arrhythmias in this population (Mittal et al., 2016; Ritter et al., 2013; Sanna et al., 2014). However, none of these studies have explored the perspective of the individual with an ICM.

As individuals continue to experience undiagnosed cardiac symptoms, they may also experience feelings of uncertainty. Uncertainty is described by Mishel (1984) as occurrences that are vague, ambiguous, unpredictable, unfamiliar, inconsistent, or lacking information. Symptoms that are infrequent and unpredictable lead to feelings of uncertainty. These feelings of uncertainty can cause increased anxiety and depression, affecting quality of life (QOL). Without a diagnosis, persons must alter their lives to accommodate this uncertainty to protect themselves. Uncertainty not only affects the individual experiencing symptoms, but the caregiver or significant other as well resulting in potential negative effects on the individual and

their social support system.

Those experiencing uncertainty due to undiagnosed cardiac symptoms may also experience anxiety (McCabe, Rhudy & DeVon, 2014) as well as fear (Deaton et al., 2003; McCabe, Rhudy, Chamberlain & DeVon, 2016; McCabe et al., 2014). Unresolved or continued feelings of anxiety and fear can lead to depression. Anxiety and depression also affect relationships with others. Depression affects relationships for a number of reasons: decreased activity, fatigue, isolation, withdrawal from social events and outings, and lack of self-care management to name a few (National Institute of Mental Health, 2016). This may lead to role reversal or role confusion in the relationship increasing the anxiety and depression. Thus, comorbid conditions of uncertainty are anxiety and depression affecting the individual and their relationships.

The negative effects from uncertainty in illness along with continued symptoms of cardiac arrhythmia affects QOL in these individuals (Moya et al., 2009; van Dijk et al., 2007). Because those diagnosed with AF often have impaired QOL related to their symptoms (Aliot, Botto, Crijns & Kirchhof, 2014; Deaton et al., 2003; Ong et al., 2006; Thrall, Lane, Carroll & Lip, 2006), we could presume that individuals having symptoms associated with AF without a diagnosis may also have impaired QOL. The impact of a diminished QOL includes decreased ability to perform normal self-care activities, decreased mobility, and increased depression and pain (Moya et al., 2009). Having a decreased QOL can influence both physical and mental well-being for the individual as well as their social support system. Understanding the cause of the symptoms as a means to mitigate or alleviate these unpredictable symptoms is imperative to their QOL.

Studies have largely focused on use of the ICM for diagnostic purposes. It is also

important to understand how these devices contribute to providing certainty when a diagnosis has not been reached. The percent of positive detection of arrhythmias when an ICM is implanted varies. In those with cryptogenic stroke, the rate of detection of AF varied from 10% to 30% (AHA, 2015c; Choe et al., 2015; Ritter et al., 2013; Sanna et al., 2014). In those with syncope, the rate of detection of AF was as high as 68% (Solbiati et al., 2016). However, there is no research on how this detection affected self-management. Solbiati and colleagues call for future research to focus on evaluating the ability of ICMs to change health outcomes instead of mainly focusing on diagnostic ability of the device (2016). This research addressed this gap in regards to the contributions of the ICM in managing health outcomes.

Individuals who are experiencing cardiac symptoms are already at risk for heart disease and stroke. The leading cause of death in the US for both men and women is heart disease; stroke ranks fifth for cause of death in men and women in the US (Mozaffarian et al., 2016). Because little is known about the ICM and self-care, QOL and health outcomes, exploring the perspectives of those with an ICM is important to inform the state of the science and influence how health care clinicians discuss use of technology with individuals experiencing undiagnosed cardiac symptoms.

### **Purpose of Study**

The purposes of this research study are to understand the experiences of individuals who have chosen to have an ICM inserted and to describe the effect on their health related self-care and QOL.

### **Theoretical Model**

The theoretical model guiding this research study is the model of perceived uncertainty in illness (Mishel, 1988). This model was selected for this research study due to the uncertainty of

diagnosis in individuals with unpredictable cardiac symptoms and after cryptogenic stroke. The model assisted the researcher by providing a framework for understanding how individuals process stimuli. This model was also selected to assist the researcher with exploring the antecedents of uncertainty in illness that could influence perspectives in those that have an ICM. See Appendix G for Mishel's model of perceived uncertainty in illness.

The first of three antecedents of uncertainty is the stimuli frame. The stimuli frame within Mishel's model of uncertainty includes symptom pattern, event familiarity and event congruency (1988). Symptom pattern, event familiarity and event congruency are all stimuli the individual perceives during illness. Symptom pattern refers to the consistency in which symptoms occur. If a symptom routinely occurs, there is less uncertainty during illness. An inconsistency with symptom pattern may lead to an increase in uncertainty regarding illness. Symptom pattern encompasses the number, frequency, location, intensity and duration of symptoms (Mishel & Braden, 1988). In those with cryptogenic stroke, individuals may not have experienced symptoms prior to the stroke and do not have a definitive etiology for the stroke. Having no symptoms prior to the stroke yields uncertainty.

The stimuli frame also includes event familiarity. Event familiarity occurs when the event is recurring (Mishel, 1988) and contributes to certainty. Those experiencing cardiac symptoms and cryptogenic stroke may have limited exposure for event familiarity due to acute illness and lack of diagnosis. This lack of recurring events may lead to feelings of uncertainty.

Lastly, the stimuli frame includes event congruence. Event congruence occurs when there is consistency in what is expected with the experience of the event (Mishel, 1988). Individuals may not be able to predict when a cardiac arrhythmia or syncopal episode may occur leading to uncertainty. All individuals who have syncope may not experience symptoms prior to

the event or they may experience symptoms, but not have a syncopal episode. This can also be true of those diagnosed with cryptogenic stroke. Not all persons who have experienced a stroke experienced symptoms prior to the stroke and not all persons who have cardiac symptoms experience a stroke. Individuals with cardiac symptoms may experience a negative stimuli frame leading to feelings of uncertainty because of the lack of event congruency with their symptoms, but they may also experience feelings of certainty if the event is congruent with their symptoms.

The second antecedent of uncertainty is cognitive capacity. Cognitive capacity refers to the ability to process information (Mishel, 1988). Processing information is important in recognizing symptom patterns, event familiarity and event congruence. Thus, memory is an important aspect of cognitive capacity.

The last antecedent in the model of uncertainty is structure providers. Structure providers include a credible authority, social support and education. These components may also positively influence the stimuli frame: symptom pattern, event familiarity and event congruence. Credible authority refers to the relationship individuals have with healthcare clinicians which includes trust and confidence in that relationship (Mishel, 1988). The health care clinicians working with those with cardiac symptoms and cryptogenic stroke can help to strengthen the stimuli frame by providing a positive connection. Having an open line of communication, trust and confidence in their health care clinicians can decrease feelings of uncertainty about health outcomes.

The second component of structure providers is social support. Social support can provide a positive effect on the components of the stimuli frame thus mitigating uncertainty. When individuals experiencing illness have increased social support, this in turn may influence their level of certainty (Mishel, 1988).

Lastly, education is a component of structure providers. While level of formal education is important, education can refer to understanding how symptoms affect their self-care and health outcomes. Education can come in the form of information received from healthcare clinicians and others including the media. Cognitive capacity and education are important antecedents that may impact the individual's perception of uncertainty and their ability to discuss how their health has been influenced by symptoms experienced.

While Mishel's model assisted the researcher in understanding how individuals process stimuli and adapt in times of uncertainty, it did not contribute to the understanding of influences on the physical occurrences of symptoms and the influence of those symptoms on self-care. Jurgens (2006) integrated Mishel's theory of uncertainty in illness with the theory of unpleasant symptoms by Lenz and Pugh to focus on the symptom experience, which informs individual response to physical and cognitive symptoms in self-care. Appendix H provides the model used by Jurgens that is the integration of the cognitive and physical symptom experience of self-care (Jurgens, 2006).

The theory of unpleasant symptoms notes physiological, psychological and situational factors affecting symptoms. Participants in this research study experienced physical symptoms such as cardiac arrhythmia, syncope and fatigue. They also experienced the psychological symptoms of fear, anxiety and depression related to physical symptoms. This model incorporates more definitive descriptions of patterns such as the timing, distress, intensity and quality of symptoms. Lastly, this model correlates the symptoms and factors with performance measures of self-care. This model assisted the researcher by providing a framework for understanding two important aspects to this research study; how cognitive symptoms influence uncertainty and how somatic awareness influences the physical symptom experience, and how

both affect self-care. This integrated theory provided a strong framework for exploring the experiences of those with undiagnosed cardiac symptoms and cryptogenic stroke.

### **Research Questions**

The research questions used to guide this research study include:

1. What are the experiences of individuals who have chosen to have an Insertable Cardiac Monitor (ICM) inserted?
2. How do participants who have an Insertable Cardiac Monitor (ICM) describe their health-related self-care?
3. How do participants who have an Insertable Cardiac Monitor (ICM) describe their QOL?

### **Definition of Terms**

Terms are defined and operationally defined as follows for this research study.

1. Heart Disease. According to the NHLBI (2013), the term heart disease includes diseases of the arteries, valves and also the efficiency of the pumping action of the heart. Disease of the arteries is termed coronary artery disease and is characterized by a buildup of plaque in the arteries. This buildup of plaque is the leading cause for myocardial infarction. The term heart disease also includes heart failure and hypertension.

Operationally defined as diagnosis of heart disease on medical record.

2. Cardiovascular Disease. Cardiovascular disease refers to conditions involving narrowed or blocked vessels that can result in a heart attack or stroke. Cardiovascular disease and heart disease are often used interchangeably (Mayo Clinic, 2014).

Operationally defined as diagnosis of cardiovascular disease on medical record.

3. Arrhythmia. The term arrhythmia refers to the rate and rhythm of the heartbeat.

According to the NHLBI (2011), an arrhythmia can occur if the heart rate is slower than normal or faster than normal or if there is an irregular rhythm. The normal resting heart rate is between 60 beats per minute and 100 beats per minute (AHA, 2015a). Not all arrhythmias are harmful or life threatening, but may create a lack of blood flow leading to damage in the body (NHLBI, 2011).

Operationally defined as diagnosis of arrhythmia on medical record.

4. Syncope. Syncope is “a transient loss of consciousness” (Strickberger et al., 2006, p. 1) and it is a common clinical problem. According to Strickberger et al., (2006) syncope has a common etiology that is cardiovascular in nature, which is associated with an increased mortality rate in those with underlying heart disease.

Operationally defined as self-reported episode(s) of syncope.

5. Cryptogenic stroke. A stroke with an unknown etiology. A stroke happens when there is an interruption of blood supply to the brain. This can occur from a clot obstructing the blood vessel, which is referred to as an ischemic stroke, or from a rupture of the blood vessel referred to as a hemorrhagic stroke (AHA, 2017b).

Operationally defined as ICD-10-CM diagnosis of I63.9 on medical record.

6. Uncertainty in Illness. Uncertainty in illness is “ambiguous and unpredictable symptoms, probable results of treatment, fluctuating course of symptom remissions and exacerbations, incomplete diagnosis, unclear explanations, lack of information, and unclear feedback concerning progress toward health” (Mishel, 1981, p. 258).

Operationally defined as self-reported uncertainty.

7. Cognition. Mishel describes cognitive capacity as “the information-processing abilities of persons” (1988, p. 227).

Operationally defined as no cognitive impairment noted in medical record

8. Social Support. Social support is defined as “the assistance and protection given to others” (Langford, Bowsher, Maloney & Lillis, 1997, p. 95). Social support may come in the way of a spouse or significant other, child, relative or friend.

Operationally defined as self-reported social support system.

9. Quality of Life. Quality of life is defined as “a concept that embraces a wide range of physical and psychological characteristics and limitations that describe an individual’s ability to function and derive satisfaction from doing so” (Padilla, Mishel & Grant, 1992, p. 155).

Operationally defined as self-reported ability to maintain physical and psychological functioning with satisfaction.

10. Self-care. Behaviors individuals implement for themselves in maintaining life, health and well-being in collaboration with a healthcare clinician (Self-care, 2017).

Operationally defined as self-reported behaviors.

11. Insertable cardiac monitors. Insertable cardiac monitors help health care clinicians diagnose those experiencing syncopal episodes or those with cardiac arrhythmias (Purerfellner et al., 2015). “Their utility and cost-effectiveness in the evaluation of syncope have been proven such that recent guidelines have advocated early use of these devices. ICMs are considered the reference standard in the analysis of syncope after the exclusion of high-risk patients. Current guidelines have also extended these indications to highlight their utility in the investigation of patients with infrequent, but recurrent

palpitations (Purerfellner et al., 2015, p. 1113). ICMs may also be referred to as an insertable loop recorder (ILR) (Medtronic, 2017).

Operationally defined as device (Medtronic Reveal LINQ™ ICM or Biotronik BioMonitor 2-AF® ICM) included on the medical record.

### **Assumptions**

In qualitative research truth and knowledge exists in the experiences and perception of the participants (Sandelowski, 1986). There are assumptions associated with the methods of truth and knowledge in this research study. It was the assumption of the researcher that participants would be able to accurately recall and describe their thoughts and feelings in choosing to have a device inserted that monitors the heart rhythm and subsequently describing how the device impacts their life. Specifically, describing how the device influences self-care, QOL and discussing the influence of a significant other on self-care behaviors. There was also the assumption that participants have experienced uncertainty of illness and are able to discuss their lives related to uncertainty.

### **Organization of Remaining Chapters**

Chapter one includes an introduction to this research study. In chapter two, a comprehensive review of the literature is provided. Chapter three includes the research design and methods for this study. With this dissertation, the manuscript option was selected. Two manuscripts were prepared for publication in lieu of the traditional chapters four and five. Manuscript one focuses on the experiences of individuals who have chosen to have an ICM, specifically on how these individuals make the decision to have an ICM inserted. Manuscript two focuses on how participants describe living with the device. Each manuscript includes an

introduction, sections on methods and results, and ends with a discussion section. References are included at the end of chapter three along with appendices.

### **Summary**

This research study explored the perspectives of those with an ICM and how this device affects QOL and self-care. This study adds to the current nursing science of how technology affects health outcomes in those with undiagnosed etiology of cardiac symptoms and stroke. The devices are costly, involve invasive procedure for insertion and assume a lengthy time of adopting. This technology is rapidly evolving. Further, this population is at high risk for injuring themselves and others and for stroke and recurrent stroke. By understanding how individuals with an ICM describe their health-related self-care and QOL, and how these individuals create meaning in the midst of uncertainty we can target interventions to enhance positive self-care in this high-risk population.

## CHAPTER 2: REVIEW OF THE LITERATURE

Cardiovascular disease (CVD), which encompasses high blood pressure, myocardial infarction, heart failure and stroke, is the leading cause of death in the United States (US) for both men and women (Mozaffarian et al., 2016). According to the Mayo Clinic (2014), the terms heart disease and cardiovascular disease are often used interchangeably, thus, the term CVD will be used for the remainder of this research study to include both AF and stroke. In 2011, the American Heart Association (AHA) projected that over 40% of the US population would be diagnosed with some type of CVD by the year 2030 (Khavjou, Phelps & Leib, 2016). Unfortunately, this percentage was achieved in 2015 with 41.5% of the US population diagnosed with at least one type of CVD. It is now predicted that by the year 2035, 45% of the US population will be diagnosed with CVD (Khavjou, Phelps & Leib, 2016). Cardiovascular disease is also the leading cause of death globally for both men and women, accounting for 31% of deaths in 2013 with the number of deaths worldwide expected to increase by the year 2030 (Mozaffarian et al., 2016). In North Carolina (NC), heart disease is the second leading cause of death and stroke ranks fourth. When combined, heart disease and stroke represent the leading cause of death for North Carolinians. In contrast to the state of NC, in Pitt County these statistics are worse with heart disease as the leading cause of death and stroke as the third leading cause for Pitt County residents (North Carolina Department of Health & Human Services [NCDHHS], 2016).

In addition to mortality, CVD also contributes to disability. There are approximately 45 million Americans with functional disabilities in the US, with heart disease, stroke, and high blood pressure included in the 15 leading illnesses contributing to those disabilities (Mozaffarian et al., 2016). These disabilities include difficulties with activities of daily living (ADL) and

limited ability in completing housework or employment. Currently, CVD costs the US \$555 billion per year with costs expected to increase to \$1.1 trillion per year by 2035 (Khavjou et al., 2016). The projected costs include medical care as well as indirect costs related to lost productivity at work and home. Therefore, further investigation for management in this population is warranted. This research study focuses on those with insertable cardiac monitors (ICM) due to: (a) undiagnosed cardiac symptoms or (b) with cryptogenic stroke: stroke due to unknown pathology. Individuals with undiagnosed cardiac symptoms are at risk for injury and other poor outcomes, such as myocardial infarction and stroke, and those with cryptogenic stroke are at high risk for recurrent stroke.

This chapter includes a comprehensive review of the literature. Because limited research has been conducted on individuals with undiagnosed cardiac symptoms, this review begins with an overview of CVD, specifically atrial fibrillation (AF) and stroke, and syncope. The concepts of cardiac illness and disease, uncertainty in illness, quality of life (QOL), ICMs and Jurgen's model on integration of the cognitive and physical symptoms of self-care (2006) was also explored.

### **Cardiovascular Disease**

In 2013, one in every three deaths that occurred in the US was related to CVD (Mozaffarian et al., 2016). More than 2200 Americans die each day from CVD which equates to one death every 40 seconds. Although there is a high mortality rate related to CVD, individuals are also surviving cardiac events, such as heart attack and stroke, due to advancements in research and health care (Mozaffarian et al., 2016). These individuals require assistance in managing their disease to increase their lifespan as well as improve or maintain their health related self-care and QOL.

## **Atrial Fibrillation**

Atrial fibrillation is a supraventricular tachyarrhythmia characterized by uncoordinated atrial activation and ineffective contraction of the atrium (January et al., 2014). Atrial fibrillation can only be diagnosed by electrocardiogram (ECG), however with the irregular and often inconsistent presence of AF, it may not be easily diagnosed in the clinic setting. Individuals often require prolonged monitoring to diagnose AF. This may include the Holter monitor, event loop recorders (ELR) and even ICMs. The symptom experience with AF varies as individuals may report irregular heartbeats, fatigue, shortness of breath, syncope and even heart failure. Atrial fibrillation is a major risk factor for the development of stroke. A stroke resulting from AF is often more severe than a stroke in those without AF (Lin et al., 1996). Individuals diagnosed with AF are twice as likely to be hospitalized than those without AF, and they often experience multiple hospitalizations (January et al., 2014).

Atrial fibrillation is the most common cardiac arrhythmia. The incidence of AF increases with age, therefore as the US population ages, the incidence of AF will continue to increase. Results of the Framingham Heart Study's Lifetime Risk for Development of AF, found that both men and women have a risk of developing AF at a rate of 1 in 4 when 40 years of age and older (Lloyd-Jones et al., 2004). Once diagnosed with AF, this study found a significant increase in risk for death in study participants.

It is estimated AF affects approximately 33.5 million individuals worldwide and approximately 2.7 million to 6.1 million individuals in the US. Those living with AF are expected to increase to over 12 million by the year 2030 for Americans (Mozaffarian et al., 2016). Annually, AF costs the US \$6 billion (January et al., 2014; Mozaffarian et al., 2016). In

2010, 13,383 NC residents were hospitalized because of AF. Atrial fibrillation was listed as the underlying cause of death for 574 North Carolinians in 2010 and was listed as a contributing cause of death for 294 of the nearly 4,300 North Carolinians who died from stroke (Tchwenko, 2012). Those diagnosed with AF are five times more likely to experience a stroke (Mozaffarian et al., 2016; Tchwenko, 2012). Because those diagnosed with AF are at increased risk for stroke, improving the management of AF is critical in decreasing the number of individuals that could possibly experience a stroke.

### **Syncope**

Syncope, defined as a transient loss of consciousness, can be a symptom leading to morbidity and mortality. There are several classifications of syncope, which includes: reflex, orthostatic hypotensive and cardiac. Syncope often occurs as a single event, but is recurrent approximately 20% of the time. More importantly, cardiac related syncope has the highest rate of recurrence (Saklani, Krahn & Klein, 2013). Syncope that is cardiac related is also associated with an increased mortality rate in those with underlying heart disease (Strickberger et al., 2006). The main goal when evaluating the individual with syncopal episodes is to ascertain the person's risk of death. Determining the cause for the syncopal episodes is important because those that are cardiovascular related increases the individuals risk of death or development of heart disease. Even though there are several classifications of syncope, these episodes often occur infrequently, unpredictably and causal mechanisms are undiagnosed in 40% of the cases (Strickberger et al., 2006).

Syncope accounts for approximately 1% to 3% of visits to the emergency department (ED) and up to 6% of all annual hospital admissions in the US (Goyal & Maurer, 2016; Moya et

al., 2009). Because a goal when evaluating syncope is to determine the cause of the syncopal episodes, some individuals require hospital admission. Approximately 40% of those presenting to the ED are admitted for further evaluation. According to data from Medicare, the cost for managing syncope is estimated at approximately \$2.4 billion annually in the US (Saklani et al., 2013). Initial evaluation for these individuals may include: a thorough health history, echocardiogram, ECG monitoring if the episode is suspected to be cardiac related, orthostatic assessment and serum blood tests to name a few (Moya et al., 2009). If hospitalization does not yield a diagnosis, individuals may be asked to use a form of ambulatory ECG monitoring. The type of monitor selected is dependent upon the frequency and duration of syncopal episodes (Strickberger et al., 2006). For episodes occurring on a daily basis, the Holter monitor may be the best choice in ECG monitoring. With episodes that occur routinely but not daily, the ELR may be optimal. Because the Holter monitor and ELR are used when symptoms occur frequently, neither would be recommended for those individuals with infrequent episodes of syncope. The ICM allows for long-term monitoring in those with infrequent episodes (Seidl et al., 2000; Solbiati et al., 2016; Strickberger et al., 2006).

Authors Probst, Kanzaria, Gbedemah, Richardson and Sun (2015) focused on describing trends in ED visits, diagnostic testing, and rates of admission from 2001 through 2010. They found approximately 1% of all ED visits were related to syncopal episodes and the rates of admission ranged from 27% to 35%. The proportion of ED visits related to syncopal episodes remained constant over this time period; however, the overall admission rate increased from 27.4% in 2001 to almost 32% in 2010. They also found an increased use in diagnostic imaging, computed tomography (CT), and magnetic resonance imaging (MRI) with an increase in use from 20.9% in 2001 to 44.6% in 2010. This increase in diagnostic testing leads to increased

hospitalization costs related to syncope and provides further support for long term monitoring with ICMs in this population.

## **Stroke**

Globally, stroke was the second leading cause of death in 2013 accounting for 6.5 million deaths. In that same year, ischemic heart disease was the leading cause of death worldwide. In the US, there are approximately 795,000 strokes annually. Startlingly, this equates to one person in the US experiencing a stroke every 40 seconds, and every 4 minutes someone dies from a stroke (Benjamin et al., 2017). In NC, stroke is the fourth leading cause of death, and heart disease ranks second; moreover, NC has the tenth highest stroke rate in the US. For perspective, this equates to one North Carolinian experiencing a stroke every two hours (NCDHHS, 2013). With the high prevalence of stroke worldwide, in the US, and in NC, this leads to increased costs. In the US, costs associated with stroke were approximately \$36.7 billion in 2015. By the year 2035, costs associated with stroke are expected to increase to approximately \$94.3 billion annually (Khavjou et al., 2016). In 2012, there were approximately \$931.5 million in charges associated with stroke hospitalizations in NC (NCDHHS, 2013).

North Carolina is part of the stroke belt, which consists of eight states with high stroke mortality (Karp et al., 2016; Tchwenko, 2012). The states included in this designation of the stroke belt are Alabama, Arkansas, Georgia, Louisiana, Mississippi, NC, South Carolina, and Tennessee. In some instances, the states included in the stroke belt expands to 12 states to include Florida, Indiana, Kentucky, Virginia, and Washington, DC. The buckle of the stroke belt consists of parts of Georgia, South Carolina and NC, to include the eastern counties of NC. These areas comprising the stroke buckle have the highest death rates caused by stroke in the US

and have held this status consistently for 30 years (Tchwenko, 2012). In fact, for those aged 35 to 54 years old in the stroke buckle, the death rates are more than double the rates for the US, and those aged 55 to 74 years old, the rates are 1.7 times greater than the rest of the US. In addition to high rates of mortality, stroke also contributes to high rates of morbidity and disability. Stroke is a primary reason for long-term disability in the US (Tchwenko, 2012). A secondary effect from stroke can include physical limitations, alterations in cognitive functioning and self-care deficits resulting in role change or role limitations.

Kim, Cahill and Cheng (2015) offer insight into the global stroke belt. Although rates of stroke remain significant worldwide and in the US, trends of morbidity and mortality with stroke are decreasing in developed countries. The global stroke belt is described as those countries with an increased stroke burden when compared with other countries. Eastern Europe, East and Southeast Asia, Central Africa, and Oceania are included in the global stroke belt as a result of increased incidence in mortality and morbidity. The countries identified in the global stroke belt experience death from stroke at a rate 10 times greater than those in countries with the lowest mortality rates. For example, in 2010 Qatar had the lowest age-standardized stroke mortality rates at 22.4 per 100,000 compared to Afghanistan, which is ranked at 187, with the highest age-standardized stroke mortality rates at 263.9 per 100,000. These developing countries also experience losses due to disability at a rate 10 times greater than developed countries. Globally by the year 2030, it is estimated there will be approximately 70 million survivors from stroke and more than 200 million disability-adjusted life years (DALY) lost. The DALY is a measurement of the overall burden of disease and is expressed as the number of years that are lost from poor health, disability or death. This is of particular interest to this research study due to the effects

on QOL after stroke as well as the number of individuals remaining at high risk for recurrent stroke.

A stroke can be classified as either ischemic or hemorrhagic with approximately 87% of strokes classified as ischemic and the remaining 13% as hemorrhagic. Roughly one-third of ischemic strokes are cryptogenic, having no definitive cause (Yaghi, Berstein, Passman, Okin & Furie, 2017). Yaghi and colleagues (2017) completed a narrative nonsystematic review of the literature on cryptogenic stroke. The results include discussion of the possible causes of cryptogenic stroke, including AF. Importantly, when AF is the cause of stroke, individuals are in need of anticoagulation therapy to prevent embolism and recurrent stroke. Diagnostic testing for these individuals may include computerized tomography scan, magnetic resonant imaging, transthoracic echocardiography, transesophageal echocardiography, and cardiac monitoring to name a few. Cardiac monitoring has become a standard in diagnostic testing for this population if an arrhythmia is suspected.

### **Uncertainty in Illness Model**

Uncertainty in illness was defined by Mishel (1981) as “ambiguous and unpredictable symptoms, probable results of treatment, fluctuating course of symptom remissions and exacerbations, incomplete diagnosis, unclear explanations, lack of information, and unclear feedback concerning progress toward health” (p. 258). Mishel’s uncertainty model helps to explain how those experiencing illness processes and understand the events (1988). Individuals who experience undiagnosed cardiac symptoms and stroke with an unknown etiology may have a cardiac monitor inserted. These individuals experience uncertainty due to a lack of diagnosis for the problems they are exhibiting. Mishel’s uncertainty in illness model has been used extensively in the cancer population (Hagen et al., 2015; Mishel & Sorenson, 1991; Sharif, 2017;

Wong & Bramwell, 1992), but not used as extensively in the cardiovascular population (Dudas et al., 2013; Winters, 1999).

Few studies have used the uncertainty in illness model to explore the AF population. Kang, Daly and Kim (2004) explored Mishel's model of uncertainty in illness in those with AF with a descriptive correlational, cross-sectional survey research design. The aim of this research study was to examine the associations between uncertainty and its antecedents in those with AF, as well as examine the perceived seriousness of their illness. The sample size of 81 was recruited via convenience sampling. Uncertainty was measured using the Mishel Uncertainty in Illness Scale – Community Form (MUIS-C), which consists of 23 items on a 5-point likert scale with ranges of strongly agree (5) to strongly disagree (1) for a total score range of 23 to 115. With this scale the higher the score, the greater the perceived uncertainty. Kang and colleagues reported moderately high levels of uncertainty in those with AF with a mean of 62.6 when comparing to means of other research studies using Mishel's uncertainty scale, such as myocardial infarction (52.3), breast cancer (33.7), and cardiac arrest (72.6). This is important to this study because if those diagnosed with AF experience feelings of uncertainty, then we can presume those with undiagnosed cardiac symptoms also experience feelings of uncertainty.

From the same study, Kang (2005) reports on the effects of uncertainty on perceived health status in those with AF. In addition to collecting data using the MUIS-C to measure uncertainty, Kang also collected data using Version 3 of the Symptom Checklist-Frequency and Severity (SCL) to measure severity of symptoms, the 15-item appraisal scale to measure perceived danger verses opportunity, and the Short Form-36 Health Survey (SF-36) of the Medical Outcomes Study questionnaire to measure perceived health status. Individuals experiencing an increased severity in symptoms also experienced a greater increase in

uncertainty. Although there were no significant findings in relation to physical symptoms and appraisal of danger, researchers concluded that mental health ( $r = -0.68$ ) and general health ( $r = -0.39$ ) both significantly correlated with the individuals perceived uncertainty as a danger. This is important for this research study because individuals have already chosen to have a cardiac monitoring device inserted. Thus, we can presume they have uncertainty from a lack of diagnosis for symptoms. We seek to determine if this uncertainty influences QOL and self-care in this population.

In another study, Kang (2011) examined the associations between uncertainty and its antecedents with AF in Korean individuals ( $N = 109$ ). Participants were recruited from three academic medical facilities in Korea. Social support was found to significantly impact uncertainty with individuals with good social support experiencing less uncertainty. Again, Kang utilized Mishel's uncertainty in illness scale to measure uncertainty, as well as the Multidimensional Scale of Perceived Social Support to measure social support and Version 3 of the SCLs to measure symptom frequency. In this study, social support, an antecedent in Mishel's uncertainty in illness model, was significantly associated with less uncertainty ( $\beta = -0.26$ ); however, those with increased frequency of symptoms reported greater uncertainty ( $\beta = 0.21$ ). According to the author, findings from this study may be helpful for nurses in understanding the need to assess the psychosocial and emotional needs in those with AF. These findings are important for this study. First, uncertainty crosses cultural boundaries and can be examined in diverse cultural samples. Second, it supports the exploration of the psychosocial perspective of those with undiagnosed cardiac symptoms that have an ICM implanted on the influence QOL and self-care.

Mishel's model of uncertainty in illness provides understanding in how individuals process and adapt to stimuli in times of illness, but it does not help in understanding how individuals process the physical and cognitive characteristics of the symptoms. Jurgens (2006) integrated Mishel's theory of uncertainty in illness with the theory of unpleasant symptoms by Lenz and Pugh. The theory of unpleasant symptoms is multifaceted and addresses the physical and cognitive symptoms an individual is experiencing, factors that influence the symptom experience, and the consequences of the symptom experience to include ADL's, social activities, role performance, and concentrating to name a few (Lenz, Pugh, Milligan, Gift & Suppe, 1997). By integrating these two theories, the new model developed by Jurgens addresses both the physical and cognitive aspects of the symptom experience and helps to understand how individuals respond to symptoms. This integrated model supports this research study because individuals with undiagnosed cardiac symptoms experience both physical symptoms as well as cognitive symptoms, which can lead to uncertainty. Uncertainty in illness can negatively influence mental health leading to anxiety and depression, which may impair QOL, thus effecting self-care.

In the only study found to use this integrated model, Jurgens (2006) conducted an exploratory, descriptive study in individuals with heart failure admitted to the hospital. This study ( $N = 201$ ) included participants from three different hospitals, including an urban facility, a suburban tertiary facility and a suburban community hospital. Questionnaires were utilized to collect data on general somatic awareness, heart failure-specific somatic awareness, and uncertainty. According to the author, individuals may be aware of symptoms, but will delay treatment until the symptoms interfere with activities of daily living. Jurgens hypothesized that symptom monitoring is negatively influenced by reduced somatic awareness. Jurgens found that

somatic awareness, specific to heart failure, along with symptom pattern was a predictor for delay in treatment; however, while uncertainty correlated with somatic awareness it did not predict delay.

While this population of heart failure patients does not directly reflect the population of participants of this research study, it does offer an understanding in how potential participants process and adapt to stimuli in times of illness and how this affects self-care. According to Jurgens (2006), both symptom monitoring and symptom awareness are important for self-care. Therefore, this integrated model assisted the researcher by providing a framework for understanding two important aspects to this study: how cognitive symptoms influence uncertainty and how somatic awareness influences the physical symptom experience, and how both affect self-care. This integrated model provided a strong framework to explore the experiences of those with undiagnosed cardiac symptoms and cryptogenic stroke. Understanding how the physical and mental characteristics of symptoms affects self-care and QOL is essential in understanding how to best assist these individuals with managing their own health outcomes.

### **Quality of Life**

There is strong evidence to support that QOL is affected in those diagnosed with AF, and those experiencing cardiac symptoms, such as syncope. In a systematic review of the literature on QOL and AF with rate and rhythm control, Thrall et al. (2006) found that those diagnosed with AF have poorer QOL outcomes compared to healthy control groups and the general population, but that QOL improves when rate and rhythm are controlled after intervention. In 2010, a review on the current state of the science regarding psychological distress in those diagnosed with AF found that depression and anxiety are present in those with AF, and this psychological distress results in impaired QOL. However, results from the 10 studies reviewed

were inconsistent due to various aims and study designs, as well as a variety of instruments used (McCabe, 2010).

Another study ( $N = 207$ ) examining the illness beliefs in those with AF found that individuals perceived the cause of AF to be psychological factors, age and heredity, and that AF provoked worry, anxiety and depression (McCabe, Barnason & Houfek, 2011). In addition to describing the illness beliefs in those with AF, this study also sought to describe the relationships of the various illness beliefs to determine implications for self-management. Participants that perceived AF as a chronic, unpredictable disorder ( $r = .30$ ) with major consequences ( $r = .58$ ), invoking worry, anxiety and depression ( $r = .36$ ) expressed a negative emotion associated with AF. Those reporting a good understanding of AF, expressed fewer negative emotions related to AF ( $r = -0.38$ ). Individuals differ in their illness beliefs concerning AF; therefore, clinicians should explore individual illness beliefs for improved self-management. These findings were consistent with another study concerning illness perceptions ( $N = 70$ ), where researchers examined how health-related QOL, depression and anxiety change after diagnosis of AF during the first year (Lane, Langman, Lip & Nouwen, 2009). In this study, anxiety was the predominant response after diagnosis of AF and researchers found that anxiety at baseline (38.5%) was the greatest predictor of reported anxiety at both six (30.9%) and 12 months (35.7%).

Recurrent syncope is related to significant morbidity with the adverse influence on QOL comparable with other chronic diseases (Saklani et al., 2013). Because treatment for syncope focuses on decreasing mortality, injury and recurrent syncopal episodes, determining the underlying cause for syncope is a priority in treatment. We know that those individuals who experience syncope also have a high risk for impaired QOL. In addition to determining the

underlying cause of syncope, it is also important to understand how QOL affects this population. In an early study, Rose, Koshman, Spreng and Sheldon (2000) evaluated the relationship of QOL with the frequency of syncopal episodes. In this cross-sectional study, participants ( $N = 136$ ) with a history of six or more syncopal events experienced a significant ( $p < 0.001$ ) negative relationship between the frequency of events to perceived overall health. Those with less than six syncopal events did not experience a negative relationship with perceived overall health. Although this study reports on the frequency of syncopal episodes compared to their perceived overall health, it is also important to understand other influences of perceived health status, such as safety in this population. This study seeks to expand the understanding of how symptom experiences influence QOL and self-care.

Another reason it is important to evaluate QOL in those with syncopal episodes is because of the affect syncope can have on their daily lives. People who experience syncope are at increased risk for injury as well as injuring others. By definition, syncope is a loss of consciousness. With this loss of consciousness, individuals have no control over their actions. This is problematic for those who work in hazardous conditions, drive as part of their job requirements, or for those who live or work alone. If these individuals were experiencing unpredictable syncopal events, then they would be limited in their work. For the year 2015, the Bureau of Labor Statistics reported the incidence of nonfatal occupational injuries or illnesses that required days away from work was 104.0 cases per 10,000 full-time employees. Falls, trip or slips accounted for 27% (309,060 cases) of the total reported injuries or illnesses. Heavy and tractor-trailer truck drivers (298.7 cases per 10,000), laborers and freight, stock, and material movers (289.4 cases per 10,000) were among the occupations with the highest rates for days away from work (Bureau of Labor Statistics, 2016). Those who experience syncopal events

while working could contribute to work related accidents. With the possibility of having work restrictions and being unable to perform duties, a lack of income would negatively affect QOL and health outcomes for this population. With people spending a significant amount of time driving and working each day, limitations related to syncope could affect the daily lives of these individuals as well as impact their employer and significant others (Barbic et al., 2014).

In a prospective randomized open-label multicenter study ( $N = 78$ ), Podoleanu and colleagues (2014) sought to compare traditional diagnostic testing for syncope with the early use of an ILR (Reveal<sup>®</sup> or Reveal<sup>®</sup> Plus ILR) in relation to diagnostic yield, cost and influence on QOL. Participants were randomized into two groups. One group ( $n = 39$ ) included low risk individuals that would be receiving an ILR and the second group (control group,  $n = 39$ ) included low risk individuals to receive treatment consisting of conventional methods. Quality of life was measured using the Short Form Health Survey 36 items (SF-36) at baseline, then at six months and finally at the end of study (at 14 months). The SF-36 measures eight multi-item dimensions, including functional status, well-being and overall description of health. Results from the SF-36 indicated that QOL was not negatively impacted by the ILR, and there was no difference noted between the two sample groups. The researchers note there were no differences in the number of syncopal episodes between the two groups; therefore, they were not surprised there were no differences in QOL between the two groups at any time point. Participants in this study were evaluated and treated under the French healthcare system. The French healthcare system offers universal health care with citizens reporting high satisfaction of the healthcare system (Rodwin, 2003). Perhaps the universal health system of France plays a role in QOL for its citizens, therefore influencing QOL in this study. However, this study provides support for collecting the number of syncopal episodes when examining symptoms.

Although there is strong literature to support the psychological effects from AF on QOL, little is known about the effects on QOL in individuals with ICMs experiencing undiagnosed cardiac symptoms and cryptogenic stroke. In a systematic review by Solbiati et al. (2016) on the implantable loop recorder (ILR) versus conventional diagnostic methods for syncope, QOL was measured in two of the four research studies included in the review. However, each of the studies measured QOL differently, and the researchers completing the systematic review could not support the findings from the two studies. One study measured QOL using the 12-item short form of the Medical Outcomes Questionnaire (SF-12), and a second study measured QOL using SF-36 (Podoleanu et al., 2014). In the study that used the SF-12, the researchers noticed a movement towards an improved QOL for those with an ILR compared to the control group at the 18-month evaluation. In this research study, QOL was examined qualitatively to determine the influence of the ICM on daily living for individuals experiencing cardiac symptoms or cryptogenic stroke. In addition, this research study also seeks to determine the influence of the ICM on perceived health outcomes of individuals with an ICM, which correlates with QOL. How an individual feels about their QOL can have significant impact on their self-care. Self-care is behavior individuals implement to maintain life, health and well-being.

To date, the majority of research studies regarding QOL and stroke have focused on the first six months post stroke (van Mierlo et al., 2015). In a multicenter prospective longitudinal cohort study ( $N = 368$ ), van Mierlo and colleagues sought to describe QOL from two months through two years post stroke. Data collection included the short stroke-specific Quality of Life Scale to measure QOL, the Hospital Anxiety and Depression scale to measure emotional function, the Utrecht Scale for Evaluation of Rehabilitation-Participation to measure participation, and life satisfaction. Results from this study conclude that the changes to health

related QOL, participation and life satisfaction occur within the first six months. During analysis, a significant difference ( $p \leq 0.001$ ) was noted between two groups, those that are dependent with ADL's and those independent with ADL's. Accordingly, these two groups were then analyzed separately. Those participants who were independent with ADL's showed improvement in their health related QOL scores ( $p = 0.002$ ), in participation scores ( $p < 0.001$ ), and with life satisfaction ( $p = 0.020$ ) between the two and six month data collection points, and then again in life satisfaction scores ( $p = 0.003$ ) between the six and 12 month data collection point. Those participants who were dependent with their ADL's showed improvement in health related QOL scores ( $p = 0.009$ ) and with participation scores ( $p = 0.001$ ) between the two and six month data collection points, and participation scores ( $p = 0.031$ ) between the two and six month data collection points. This study is significant to this research study because participants were included that have had the ICM implanted for at least two months and no more than two years. There have been no studies examining QOL post stroke in those with an ICM implanted.

In another cohort study ( $N = 144$ ) examining the long-term effect of stroke on QOL, Suenkeler and colleagues (2002) assessed QOL using the SF-36. Researchers found that 66% of participants reported worsened life satisfaction and decreased QOL at the three and six-month follow up, as well as at the one-year follow up after stroke or transient ischemic attack. Another study ( $N = 86$ ) examined QOL, using the Ferrans and Powers Quality of Life Index-Stroke Version (QLI), for long-term (one to three years) stroke survivors (King, 1996). Depression ( $\beta = -.53, p = .0001$ ) and perceived social support ( $\beta = .33, p = .0005$ ) were predictors for QOL. Those reporting increased depression and less social support, reported lower overall QOL. Depression and social support was explored in this research study.

## Cardiac Monitoring

Cardiac monitoring has significantly changed over the years. The Holter monitor was developed and used as a way to monitor cardiac rhythms and diagnose arrhythmias. The next monitoring device that was developed was the ELR. While this device was able to provide a longer monitoring period than the Holter monitor, it was still limited by time. The newest cardiac monitoring device used for detection of cardiac arrhythmias is the ICM.

Prior to the technology used today for cardiac monitoring, the Holter monitor was developed and first used in 1961. The Holter monitor is non-invasive. It provides recordings for 24 to 48 hours due to limited storage space, although there are more advanced Holter monitors used today that can record for up to two weeks (Miller et al., 2016). Individuals who used a Holter monitor kept a written diary and pressed a button if they experienced any cardiac abnormality. After 24 or 48-hour usage, the Holter was then returned, and the cardiac rhythms were analyzed. According to Miller et al., major drawbacks of the Holter monitor are limitations on duration for monitoring and the absence of real-time reporting of results (2016). In 90% of cases, the Holter monitor did not provide a diagnosis (Seidl et al., 2000). Therefore, this diagnostic tool may not be the best option for those with irregular and infrequent cardiac symptoms.

The ELR is an external device that can be used to detect and diagnose cardiac arrhythmias. Earlier versions of the ELR required the individual to activate and record at a time they were experiencing a symptom. These devices must also be returned for analysis. Limitations to the ELR include limited memory and problems with cardiac rhythms being recorded over due to limited memory space (Miller et al., 2016). With the sporadic occurrence of AF, the ELR may not be the best choice for diagnosing cardiac arrhythmias.

The ICM, which is also known as an implantable loop recorder, is the latest device in cardiac monitoring. In particular, the Reveal LINQ™ ICM, is inserted under the skin in the chest using the Reveal LINQ™ ICM incision tool and insertion tool, and allow for longer monitoring than the ELR (Medtronic, 2015). Some ICMs can remain inserted for up to three years, such as the Reveal LINQ™ ICM (Mittal et al., 2015) and the Biotronik BioMonitor 2-AF® ICM is designed to last for as long as four years (Lauschke et al., 2016). This long-term monitoring provides for a greater chance of detecting and diagnosing an arrhythmia or syncopal episode (Miller et al., 2016). Due to higher costs and the invasive nature for insertion, ICMs are often considered after other diagnostic options have been exhausted.

As previously discussed in this chapter, Podoleanu et al. (2014) conducted a prospective randomized open-label multicenter study ( $N = 78$ ) to compare conventional treatment with syncope to treatment with an ILR inserted. Quality of life results from this study were discussed in an earlier section. Participants were randomized into two groups, the ILR group ( $n = 39$ ) and the conventional treatment group ( $n = 39$ ). At the end of the study, the cause for syncope was identified in 18 (46.2%) of the participants with an ILR, but only two (5%) in the traditional treatment group ( $p < 0.001$ ). There were lower health care costs associated with the ILR group compared to the traditional diagnostic testing group.

A review by Tomson and Passman (2015) focused on use of the Reveal LINQ™ ICM, in general monitoring of cardiac rhythms long-term as well as potential future uses for ICMs. Tomson and Passman noted that ICMs provide a diagnosis of the cause of syncope in up to 88% of those who have recurrent syncope, importantly, this is a cost effective diagnostic tool. The Reveal LINQ™ ICM received Food and Drug Administration (FDA) approval in February 2014. This device is the smallest ICM currently on the market and is 87% smaller than the previous

device produced by Medtronic: Reveal XT™. It measures 7 millimeters by 45 millimeters by 4 millimeters, has a battery life lasting three years, and allows for 20% more data memory when compared to the Reveal XT™. Insertion is easier than before with an insertion tool used to insert the device subcutaneously, and the incision can be closed using surgical tape or glue. Conscious sedation is not required for this procedure further reducing the risk for negative side effects.

National organizations have provided support for use of ICMs including the European Society of Cardiology's 2009 guidelines (Moya et al., 2009), which includes use of the ICM for diagnosis and management of syncope. Also, the European Heart Rhythm Association has also included recommendations for use of the ICM in those with syncope in an effort to rule out arrhythmia and in those with palpitations when other monitoring devices have failed to provide diagnosis.

In those experiencing ischemic stroke, there are recommendations for ECG monitoring for at least 24 hours in an effort to rule out AF. Although these are the current guidelines, 24 hours is often not long enough to capture an arrhythmia and longer monitoring is required. Unfortunately, there are not specific guidelines for the amount of time recommended for monitoring. In a randomized controlled trial ( $N = 441$ ), researchers sought to determine if long-term monitoring with an ICM for identifying AF was more effective than traditional follow-up protocols (control group,  $n = 220$ ) (Sanna et al., 2014). Participants included individuals age 40 or older and those with no AF within 24 hours of diagnosis of stroke or transient ischemic attack that occurred during the preceding 90 days. For those individuals included in the ICM group ( $n = 221$ ), the ICM was inserted within 10 days from randomization. Follow up occurred for both groups at one, six, and 12 months, and then every six months until the end of the study. The ICM used in this study was the Reveal XT™ by Medtronic. Atrial fibrillation was detected in 8.9% of the participants in the ICM group at six months follow up compared to only 1.4% of

participants in the control group. At 12 months, AF was detected in 12.4% of those in the ICM group compared with only 2% of those in the control group. At three years, of the 48 participants completing the final follow up, AF was detected in 30% of the ICM group compared with 3% of the control group. These researchers concluded that use of the ICM in those with cryptogenic stroke was more beneficial ( $p < 0.001$ ) than traditional follow up care post undiagnosed stroke. Additionally, they found that AF was often asymptomatic after cryptogenic stroke, further supporting the use of the ICM in this high-risk population.

This research study focuses specifically on individuals that have an ICM. For example, the Reveal LINQ™ ICM is a miniature cardiac monitor that has wireless telemetry capabilities for remote monitoring in those with suspected arrhythmias (Mittal et al., 2016; Purerfellner et al., 2015). This device automatically transmits data at the end of the day with alerts occurring when any of the following are detected: episodes from a patient activation, tachycardia, asystole, bradycardia or device detected AF (Purerfellner et al., 2015). The Biotronik BioMonitor ICM is also a device with long-term monitoring abilities that transmits daily (Ciconte et al., 2017). Due to the long-term monitoring ability of the ICM, the devices are useful in diagnosing AF and other irregularities of the heart. Also, due to infrequent and irregular episodes of syncope, the ICM is useful for providing long-term monitoring in individuals with unexplained syncope (Seidl et al., 2000; Tomson & Passman, 2015).

In a recent study by Mittal et al. (2016), researchers sought to determine the real-world performance of the Reveal LINQ™ ICM in detecting AF in individuals experiencing syncope ( $n = 1604$ ), identified AF ( $n = 1049$ ) and cryptogenic stroke ( $n = 1106$ ) for a total of 3759 participants. All episodes stored at three months after implantation were noted and a random selection of 10% of all episodes where AF was detected were also examined. Among all

participants, there were 20,659 episodes of AF detected by the device in 1020 participants with those already diagnosed with AF accounting for 16,506 of those episodes. These researchers concluded that the Reveal LINQ™ ICM is an excellent option in those with episodes of AF lasting longer than one hour, but the performance of the device is linked to the incidence of AF in those being monitored. While it has been established that ICMs are effective tools to use for diagnosing AF, the personal perspective of those who have the device inserted needs to be explored.

Other recent studies specific to the Reveal LINQ™ ICM, include research related to the device insertion location. The location of device insertion has implications related to resource utilization for healthcare organizations as well as the costs passed on to the individual receiving the device. Insertable cardiac monitors are normally implanted in a sterile operating room or cardiac catheterization laboratory (Wong et al., 2016), which is costly for the healthcare facility as well as the individual. In a prospective, non-randomized observational experiment by Wong et al. ( $N = 178$ ), researchers sought to determine the feasibility and safety of inserting the Reveal LINQ™ ICM in a sterile procedure room versus the traditional electrophysiology laboratory (2016). Eighty participants had the Reveal LINQ™ ICM inserted in an electrophysiology laboratory while 98 participants had the device inserted in a sterile procedure room. This study concluded the Reveal LINQ™ ICM could safely be inserted in an area other than traditional locations as long as sterile technique and guidelines from the manufacturer are followed with insertion. While limitations for this study included use of a single healthcare center and an observational design, results were promising.

In another study related to device insertion ( $N = 482$ ), Rogers and colleagues sought to compare the insertion of the Reveal LINQ™ ICM in an office setting compared to a hospital

(2017). This study was the first randomized trial evaluating the safety of inserting an ICM in an office setting verses the traditional hospital setting. In this randomized, unblinded, multicenter, prospective, parallel group study, 251 participants were included in the group with insertion in an office setting and 231 participants were included in the group with insertion in the hospital setting. All 482 attempts for insertion of the device were successful despite the location and complications occurred in less than 1% of the sample, similar to both location sites. These authors concluded there is strong evidence to support safe insertion of the Reveal LINQ™ ICM in an office setting, significantly reducing the costs associated with insertion of this cardiac monitoring device.

Research completed by Wong et al. (2016) and Rogers et al. (2017) has implications for this research study because both healthcare organizations as well as individuals prefer to decrease costs without compromising outcomes. For instance, in this research study, participants were asked about the personal economic impact of having this device inserted along with their perspective on the cost of the device verses their perceived benefit. Although there is strong evidence to support use of the ICM in diagnosing cardiac arrhythmias and syncope, studies have mainly focused on the diagnostic ability of these devices and most recently the costs associated with insertion. There have been limited studies that examine the individual's perspective of having an implanted device that monitors heart rate and rhythm.

### **Patient Perspectives**

Although the use of ICMs has been studied for diagnostic ability, the patient perspective has not been widely explored. With an increased use of ICMs for diagnosing cardiac symptoms and in those with cryptogenic stroke, it is important to gain the perspective of those who have the device inserted. Understanding the perspective of the patient can inform the state of the science

assisting health care clinicians in managing care, and inform interventions to improve self-management and QOL in those with an ICM. It can also help health care clinicians identify the needs of this population in managing their own health outcomes. The following studies are included in this literature review because they have examined the patient perspective in either AF or device implantation. Both are important to this research study.

### **Atrial Fibrillation**

It has been discussed that individuals with AF report psychological distress, such as fear, depression and anxiety (Deaton et al., 2003; McCabe et al., 2016; McCabe et al., 2014). Results from a study by McCabe and Barnason (2012), discussing the relationship among illness perception, coping strategies and symptoms on psychological distress in those with AF was included in an earlier section in this chapter. Another study ( $N = 15$ ) describes living with AF. This study had similar findings to the other studies included in this literature review: understanding and managing symptoms that limit function was important and support systems are significant. These researchers described support for this population was poor beginning with initial symptom complaint because clinicians may not recognize the psychological distress associated with AF, such as fear, anxiety, and uncertainty. Also, the clinician's attitude regarding the importance of managing AF can affect when individuals seek treatment for AF. (McCabe, Schumacher & Barnason, 2011). Therefore, it is important to understand the influence of physical symptoms early in the disease trajectory and how these physical symptoms affect daily living.

In another study, McCabe et al. (2014) explored the patient experience from initial symptom presentation to initiation of treatment for AF. Although this study does not specifically

discuss the patient perspective with an ICM, it does offer insight for this researcher on perspective of the patient experiencing symptoms without a definitive diagnosis. These authors suggest that a better understanding of the patient experience from onset of symptoms to initial treatment is needed to develop appropriate interventions for this population for better self-management. The sample included 22 females and 21 males from an academic medical facility, who had a diagnosis of AF. Using a descriptive qualitative design, the authors identified the following four themes: “(1) misinterpreting symptoms; (2) discovering the meaning of atrial fibrillation; (3) facing fears, uncertainty, and moving to acceptance; and (4) receiving validation and reassurance” (p. 786). Findings from this study include the importance of the health care provider in discussing information about AF. The health care provider plays a vital role in ensuring that individuals are knowledgeable about their symptoms and in diagnosis of specific disease processes such as AF. This is essential to ensuring individuals have the knowledge to promote self-care and in managing their health outcomes. The individuals in this research study have experienced cardiac symptoms, including syncope and cryptogenic stroke, and have decided to have an ICM inserted in an effort to reach a definitive diagnosis for their symptoms. Further understanding of their perspective may help with development of interventions to promote improved QOL and self-care.

### **Cardiac Monitoring Devices**

Patient experiences were explored in a qualitative study where an implantable atrial defibrillator was used on individuals due to diagnosed AF (Deaton et al., 2003). The sample size included three women and eight men whose age ranged from 35 to 80 years old, and who had the Medtronic Jewel<sup>®</sup> AF 7250 ICD-AT device inserted. This study differs from this research study

in that this device is an atrial defibrillator that offers a shock when the device detects AF. These individuals have already been diagnosed with AF and this device offers an intervention instead of exclusively monitoring for an arrhythmia. This study explored patient perspectives on illness experiences, symptoms, and treatment for AF. Findings from this study include themes that focused on AF prior to device implantation as well as the themes after device implantation. Prior to device implantation, the themes that emerged included (a) poor treatment and misdiagnosis, (b) stress due to the symptoms of AF, (c) limit in activities of daily living, (d) stress from prior treatment modalities, and (e) desire to maintain a normal lifestyle. After the individuals had the ICD-AT implanted the themes that emerged were positive and included (a) symptom relief, (b) resumption of a normal lifestyle, (c) incorporating shock occurrences into everyday life, and (d) social support. Findings from this study support that QOL is negatively impacted in this population due to symptoms associated with AF. This is important for this research study because although the potential participants have not been diagnosed with AF, they are exhibiting cardiac symptoms or have experienced cryptogenic stroke and can experience the same physical and emotional experiences as those with diagnosed AF.

Patient acceptance of an insertable monitoring device is important because of the length of time devices can remain implanted. Inserted devices that are monitored remotely can offer reassurance for the patient that they are being continuously monitored, but may be perceived as a negative experience. Individuals no longer have to wait for an appointment with their health care provider to get results regarding cardiac rhythm because someone is monitoring these patients routinely, however some individuals may prefer to visit their provider in an office setting more frequently. In a study ( $N=119$ ) to evaluate acceptance and satisfaction of remote monitoring of inserted devices, the authors found there was a positive acceptance with participants (Ricci et al.,

2010). Participants in this study included those with home monitoring devices, specifically 95 participants had a pacemaker and 24 had an implantable cardioverter defibrillator. Although the participants in this study did not have AF, the purpose of the study was to examine patient acceptance of remote monitoring. Therefore, these findings inform this research study because individuals already have an ICM and are being monitored remotely.

In a scientific statement by the AHA the importance of measuring health status as reported by the individual is an important aspect for improving cardiovascular health (Rumsfeld et al., 2013). The Impact Goal set by the AHA says, by the year 2020, the cardiovascular health of Americans will improve by 20%, and that deaths related to CVD will be reduced by 20%. This statement also includes the expectation from the Institute of Medicine that clinicians practice patient-centered care to not only address the physical needs of the patient, but the emotional needs as well to maintain or enrich QOL for the individual. In this research study participants were asked to describe their health, their physical, mental and emotional well-being, and their QOL.

### **Summary**

This review of the literature explored the concepts of cardiac illness and disease, uncertainty in illness, anxiety, depression, quality of life and ICMs. The literature presented in this chapter helps support the need to better understand individual's experiences with undiagnosed symptoms that have a cardiac monitoring device inserted. Many individuals who experience cardiac symptoms and syncopal episodes learn they have AF. If left untreated, AF can lead to the increased risk of stroke. It is important to diagnose AF because if an individual has AF they will require anticoagulation therapy in an effort to decrease their stroke risk. Those with stroke not related to AF may require antiplatelet therapy as opposed to anticoagulation

therapy (Diamantopoulos et al., 2016; Lau et al., 2015). Currently, there are limited studies exploring the patient perspective with cardiac monitoring devices. Studies involving the implantable cardioverter-defibrillator (ICD) were excluded from this study due to these types of cardiac devices offer an intervention instead of monitoring only with the exception of the article discussed above by Ricci et al. The ICD is implanted after diagnosis of potentially life threatening cardiac arrhythmias or dysrhythmias. The uncertainty with potential shock occurrence, along with the fear and anxiety associated with a potential shock, is a different experience from the experiences of the potential participants in this study; therefore, these studies were excluded from this review of the literature. Exploring perspectives for those that have an ICM can strengthen support for early use of these devices in the illness trajectory as well as offer insight for clinicians and nurses in how to assist individuals in managing their health outcomes.



## CHAPTER 3: METHODOLOGY

This chapter describes the methodology for this research study. It begins with discussion on the design. In addition, the sample, site selection, data sources and data collection techniques are included. Protection of participants is discussed along with management of recorded data and data analysis procedures.

### **Purpose**

The purposes of this research study are to understand the experiences of individuals who have chosen to have an insertable cardiac monitor (ICM) inserted and to describe the effect on their health related self-care and quality of life (QOL).

The research questions are:

1. What are the experiences of individuals who have chosen to have an insertable cardiac monitor (ICM) inserted?
2. How do participants who have an insertable cardiac monitor (ICM) describe their health-related self-care?
3. How do participants who have an insertable cardiac monitor (ICM) describe their QOL?

### **Design**

A qualitative approach was used for this research study because little is known about how individuals make health related self-care decisions and their QOL when they have a cardiac monitoring device inserted. Using a qualitative descriptive approach provides insight into the perspective of those living with undiagnosed cardiac symptoms or post-cryptogenic stroke in understanding the reality of health-related self-care decision-making and QOL for those with an insertable cardiac monitor. Specifically, this study seeks to understand how individuals with an

ICM inserted due to undiagnosed cardiovascular symptoms or cryptogenic stroke make decisions related to self-care and how QOL is affected. This is important because they have made the decision to have the ICM implanted in hopes of gaining answers for their symptoms or occurrence of cryptogenic stroke as well as providing guidance for future treatments.

Through qualitative research, the reality of others is understood (Morse & Field, 1995). When little is known, a qualitative research approach is best to assist the researcher in understanding the experience. A qualitative descriptive study is the design of choice when the outcome of a study is to describe an experience (Milne & Oberle, 2005; Neergaard, Olsen, Andersen & Sondergaard, 2009; Sandelowski, 2000). The focus of qualitative description is to provide a rich description of a specific experience, but low-inference interpretation by the researcher is also present (Neergaard et al., 2009; Sandelowski, 2000). The focus of this study is from the personal or emic point of view of participants.

This study has an ontological philosophical assumption with the researcher seeking to understand the reality of the experience. The significance of the experience of an event may differ for each participant (Creswell, 2013). This study seeks to understand what the reality is for individuals with an ICM. Reality is subjective and perspectives will vary among the different participants, however, commonalities may exist. Therefore, the aim of this study is to gain rich description of this unique experience to inform clinicians and patients in the pre-insertion decision making process, and to gain new knowledge that will inform nurses and clinicians as they care for and support these individuals after insertion.

### **Sample**

The sampling method used for this research study is maximum variation sampling. This technique is used for purposely selecting a heterogenic population (Denzin & Lincoln, 1994;

Sandelowski, 2000). In an effort to understand the experience of a diverse population and to ensure maximum variation sampling, participants of various races, genders and ages were recruited, as well as those with various types of ICMs. In qualitative research studies, there are no specific rules regarding sample size. The quality of data received from participants can influence sample size. Sample size for a qualitative study generally ranges from as few as three to as many as 20 participants (Magilvy & Thomas, 2009). Qualitative researchers collect data until saturation has been attained and no new information is received (Munhall, 2012; Seidman, 2013).

The study sample includes individuals who have an ICM inserted because of undiagnosed cardiac symptoms or cryptogenic stroke for at least two months but not more than two years, and those without a diagnosis of cognitive impairment as noted on the medical record. Because up to one-third of individuals who experience a stroke also experience cognitive impairment (Eskes et al., 2015) and participants are asked to reflect on their lived experience, we only included those without cognitive impairment that are able to describe their experience.

Study participants were recruited from the East Carolina Heart Institute (ECHI) affiliated with East Carolina University (ECU). This site was selected because (a) this Electrophysiology Lab added 29 individuals who had the Reveal LINQ™ ICM inserted in 2016, (b) their dedication to improving the health status of North Carolinians, and (c) the large number of individuals served who have heart disease. North Carolina (NC) is part of the stroke belt, which includes eight to 12 southern states where the death rate of stroke is greater than the rest of the country (Mozaffarian et al., 2016; North Carolina Stroke Association, n.d.). Stroke is the fourth leading cause of death for North Carolinians and heart disease ranks second. In fact, NC has the tenth highest stroke rate in the US (NCDHHS, 2013).

Through directed research experience, the researcher completed appropriate paperwork to access the ECHI clinicians and nurses. These approvals did not give the researcher direct access to the patients or their medical record. Therefore, the employees of ECHI were identified as the initial contact to recruit for this study. The ECHI Electrophysiology Lab provides care for a diverse group of individuals with ICMs and this worked well for a purposive sampling method.

The inclusion criteria for this study includes: adults aged 18 and older without cognitive impairment, and individuals that already have a cardiac monitor implanted within the last two years, but not less than two months. Exclusion criteria includes: anyone under the age of 18, those that are non-English speaking, individuals that have had the device less than two months or greater than two years, and those that are cognitively impaired. This device is not being used in children at this time; therefore, children were excluded from this research study. Non-English-speaking individuals were excluded because translator services was not available, and the researcher only speaks English. Because were asking participants to recall their life prior to having the device inserted, those with cognitive impairments were excluded.

### **Setting**

Recruitment for participants began with personal contact or telephone calls from the nurse or person designated by the nurse in the Electrophysiology Lab. The data collection took place in a naturalistic setting in the field. Participants were able to indicate where they wanted to complete the interviews. Thus, the researcher offered to go into the homes of the participants or to another setting of their choice with the ability for privacy. It is important for the individuals participating in this study to feel comfortable when being interviewed to facilitate in depth communication.

## **Recruitment Methods**

The researcher met with the nurse and other ECHI Electrophysiology Lab staff to discuss the purposes of this study, the inclusion and exclusion criteria of study participants, and the recruitment methods. A script was provided for the nurse to follow when recruiting individuals who meet the inclusion criteria for the research study (see Appendix A). The nurse in the Electrophysiology Lab making the initial contact with potential participants begins to create trust that is needed for the researcher. If the individuals trust the nurse, then this helps with establishing trust for the researcher as well. Also, these processes decrease the likelihood of potential participants feeling coerced by the researcher.

The ECHI nurse contacted individuals from a master list of those who have a device implanted for more than two months and less than two years, and that do not have a diagnosis of cognitive impairment as reflected in their medical record. The nurse read the script. If the individual agreed to hear more about the study and agreed to release their name and contact information to the researcher, the nurse provided the contact information to the researcher. To avoid potential coercion, individuals were informed of the incentive of a \$20 Walmart gift card only after they agreed for the nurse in the Electrophysiology Lab to share their contact information. Then, the researcher contacted the potential participant to explain the study, answer questions, and set up a time and location for consent and data collection.

## **Protection of Human Subjects**

This study was submitted to the University Medical Center Institutional Review Board (UMCIRB) at East Carolina University for approval. The researcher obtained Informed Consent (IC) at the time of the interview. A copy of the approval letter from the UMCIRB is included (see Appendix B). The consent form was read word for word to each potential participant. If a

participant declined participation, they were thanked for their time and were not asked again to participate.

The UMCIRB requires all researchers to identify how they will protect the rights and welfare for all participants in a research study. All conversations occurred in a private place that was selected by each individual participant, such as their home. There was only one researcher conducting interviews with each participant. The IC documents are located in a secure location in the College of Nursing, specifically in the Office of the Associate Dean of Research and Scholarship. Pseudonyms were used on all transcripts and in dissemination of research findings. Data is secured on a firewall-protected computer, and data will be stored for six years after dissemination. After six years, electronic files will be deleted according to ECU protocols, and all transcripts will be shredded.

### **Data Collection**

Data collection for this study began once IRB approval was obtained. To ensure a full description, data collection continued until data saturation was reached and no new information was received (Munhall, 2012; Seidman, 2013). Once a list of those agreeing to be contacted was received, the researcher contacted each potential participant to explain the study, answer questions, and set up a time and location for consent and data collection. Data collection includes eliciting rich, detailed descriptions through interviewing those with an ICM. At the beginning of each interview, the Principal Investigator (PI) reviewed the research study in its entirety and consent was obtained. Each participant was informed the interview would be recorded with an audio recorder and assured there would not be any identifiable information on the recording.

If a potential participant was found to have any cognitive impairment at the time of the interview, the researcher would have continued with the interview and the data collected would have been excluded from data analysis. There were no participants with cognitive impairment at the time of the interview. Prior to the qualitative interviews, participants were asked to complete a demographic questionnaire to answer general questions about themselves such as age and educational level (see Appendix C), the Patient Health Questionnaire – 8 (PHQ-8) (see Appendix D), and the Generalized Anxiety Scale (GAD-7) (see Appendix E). The demographic questionnaire, PHQ-8 and GAD-7 are discussed later in this chapter in the section related to instruments.

After completing the questionnaires, the PI used formal, semi-structured interviews to elicit vivid descriptions of participant experiences with an ICM. A semi-structured interview is where the researcher prepares a guide or list of open-ended questions or statements intended to be covered with each participant (Neergaard et al., 2009). Probe questions/statements helped to elicit communication rich enough to answer the research questions and to gather rich data. The questions/statements were presented so that each participant could freely talk about each question/statement. The researcher was cognizant that participants may cover multiple questions/statements while responding to one question or statement. It was also important for the researcher to ask for further information or clarification, such as “Could you explain further”, when something was not understood (Seidman, 2013). It was helpful to ask the participant to provide an example, if needed, for clarification.

Once the researcher and participant were ready to begin, the audio recorder was placed between both individuals, and the participant was reminded that the interview was being audio recorded. The researcher began each interview with an opening statement or question, called a

grand tour question, a broad statement or question that relates to the research topic (Polit & Beck, 2012). For this study, the researcher began with the following statement: *Tell me about your health before having the ICM device inserted.* If participants requested additional instruction on what was meant by the opening statement, the researcher asked: *What symptoms were you experiencing before getting the ICM device put in?* A list of probe questions was developed that was used to elicit information important to answer the research questions (see Appendix F).

Once the interview was complete and the researcher left the interview location, the researcher took field notes. Field notes help to describe the participant and the setting to provide context to the interview. These notes included things observed during the interview, such as reflections that occurred during the interview, or it included the researchers own feelings about the experience. These personal feelings could alter or inform the assumptions of the researcher (Polit & Beck, 2012). It is important to write these observations or feelings down to reflect on their meaning and potential impact with the analysis of research data.

Methodological field notes are used during data collection to assist the researcher in formulating further plans for data collection as the study advances and in data analysis to describe how the study was conducted. For example, if a question was asked during data collection that did not elicit an in-depth response, then the researcher revised that question for future interviews. Theoretical field notes are used in data analysis to look for patterns and associations among participants once transcripts have been coded (Munhall, 2012).

## **Instruments**

Demographic data was collected on each participant using the demographic questionnaire. Each participant completed a questionnaire to include: (a) length of time device

has been inserted, (b) type of device, (c) age, (d) sex, (e) race, (f) education level, (g) employment status, (h) marital status, (i) symptoms experienced, (j) list of comorbidities, and (k) medications. Demographic data was used to describe the sample.

Participants also completed a questionnaire related to depression and anxiety to describe the study sample. The PHQ-8 is an eight-item depression scale derived from the PHQ-9 scale. Individuals with increased depressive symptoms are at higher risk for health related self-care issues and impaired QOL. Kroenke, Spitzer and Williams (2001) found as the PHQ-9 score increased, functional status decreased, consequently affecting QOL. The PHQ-8 was found to be useful in measuring depression (Kroenke et al., 2009). The GAD-7 is a seven-item self-reported scale that measures anxiety. Higher scores on the GAD-7 are also related to impaired functional ability (Spitzer, Kroenke, Williams & Lowe, 2006), which may affect the lived experiences of health-related self-care and QOL. Both instruments, the PHQ-9 and GAD-7, have strong reliability, 0.89 and 0.92 respectively (Kroenke et al., 2001; Spitzer et al., 2006). The PHQ-8 has a reliability of 0.82 (Pressler, et al., 2011).

Both the PHQ-8 and the GAD-7 were verbally administered to each participant. Participants selected from the options of not at all sure (0), several days (1), over half the days (2) and nearly every day (3) for each question asked from each instrument. Each question was marked with the respective numeric value. For example, the first question on the PHQ-8 asks: *Over the last two weeks, how often have you been bothered by any of the following problems? 1. Little interest of pleasure in doing things.* If the participant responded with several days, then a value of one was listed. All points were totaled at the end of the questionnaire with a range from 0 to 24, and a depression severity was assigned based on the total score. With the PHQ-8, scores ranging from 0 to 4 represents no symptoms of depression, 5 to 9 represents mild symptoms of

depression, 10 to 14 represents moderate symptoms of depression, 15 to 19 represents moderately severe symptoms of depression and 20 to 24 represents severe symptoms of depression. On the GAD-7, scores ranging from 0-5 represent mild anxiety, 6 to 10 represent moderate anxiety, 11 to 15 represent moderately severe anxiety and 16 to 20 represent severe anxiety. With a score measuring severe on either scale, PHQ-8 or GAD-7, the PI would have contacted the nurse in the Electrophysiology Lab. These instruments were used to guide probe questions/statements, to frame data analysis of the described experience, and to describe the sample.

### **Data Analysis Plan**

Each interview was transcribed verbatim into a Word document for analysis. A secure, online transcription service was used in the transcription process. In an effort to reduce error with transcription, a cross-check of the audio recorded interviews to the transcripts was completed to ensure accuracy. Polit and Beck (2012) recommend listening to the audio recording while completing the cross-check to confirm accuracy. To remain immersed in the data, the researcher completed the cross-check process independently by listening to the audio recording of each interview while comparing the recording to the transcribed document.

The data were analyzed using qualitative content analysis and focused on intraparticipant analysis, interparticipant analysis and interrelationships (Morse & Field, 1995). According to Sandelowski (2000), qualitative content analysis is used to analyze the data that is focused on summarizing the contents important to that data. In qualitative research studies, data collection and analysis may be an ongoing process occurring at the same time. The first interview was transcribed and analyzed, and field notes were considered to determine if different or additional questions needed to be asked in future interviews. Content analysis was used to examine the raw

data in each interview (Morse & Field, 1995). With constant comparison, data are compared with other data to explore similarities and differences.

In intraparticipant analysis, data analysis begins with immersion into the data. To achieve this, the researcher listened to the audio recording and read and reread the transcripts while reflecting on the data in their entirety for each research question. Each sentence was reflected upon in an effort to understand each research question. Sentences and phrases were highlighted that were revealing to both the meaning of health related self-care and QOL in search of categories central to the overall experience of having an ICM. Commonalities may not be apparent when first reading the transcript; therefore, reading and rereading of the transcripts was needed in an effort to fully understand and reflect upon what the participant has experienced. After transcripts were read and reread, codes and categories were created. Codes are repeated phrases or words within each interview. The codes or categories characterize the core of qualitative data analysis (Creswell, 2013). Coding allows the researcher to place the data in groups that are similar. A codebook was created and refined to analyze raw interview data.

In interparticipant analysis, the researcher examined the transcripts for commonalities among participants to formulate full, rich description of their experience. There were categories that were not common among participants. These differences help to enrich the research study, capturing the unique experiences of a diverse sample. Each transcript was analyzed and compared for commonalities as well as differences related to understanding the meaning of health related self-care and QOL in those with an ICM.

The final phase of analysis is interrelationships between categories. In this final phase, the relationship between categories and descriptions was analyzed. Quotes were selected from the interviews that captured the description of the experience of the participants. Through

writing and rewriting, reflection of the data occurred in a continual process allowing for understanding and interpretation of their experiences in answering each research question.

Once all transcripts were coded for common categories, NVivo 10 was used to assist with organizing the data. NVivo is software to aid the qualitative researcher in organizing and analyzing data. The demographic data sheets, PHQ-8 and GAD-7 scales were analyzed using SPSS 22. Descriptive statistics such as proportions, means and frequencies were used to describe the sample.

### **Trustworthiness and Integrity**

To maintain trustworthiness and integrity for this research study, the standards for the trustworthiness as suggested by Lincoln and Guba were utilized. There are four criteria described for maintaining trustworthiness with a qualitative study and they include: credibility, dependability, confirmability and transferability (Lincoln & Guba, 1985; Munhall, 2012; Neergaard et al., 2009).

Credibility refers to reliable findings and understandings of the data (Lincoln & Guba, 1985). Credibility was addressed through member checking and reflexive journaling. Member checking is a technique used for establishing validity in the researcher's interpretation of data from interviews (Sandelowski, 1993). In this study, the researcher met with each participant only once so the participant did not have the opportunity to read the transcripts to ensure what was written was how they intended to describe their experience. The researcher informally implemented member checking in this study by seeking clarification, when needed, on statements made by participants during the interview. Furthermore, credibility was addressed through reflexive journaling throughout the data collection and analysis process. This was also addressed through the audio recording of interviews along with verbatim transcription of each

interview, continuation of recruiting subjects until data saturation was reached, and the creation of a codebook with data analysis.

Dependability is the consistency of data collected (Lincoln & Guba, 1985). To address dependability, an audit trail was established. The audit trail consists of the availability of field notes, transcribed interviews and coded transcriptions to the dissertation committee for review (Munhall, 2012). A list of probe questions was utilized with each interview to maintain stability and consistency. However, the researcher also maintained flexibility with issues or responses initiated by participants. Interviews were carefully transcribed to maintain careful documentation. The overall design of the research study was derived from the pilot study. The pilot study is discussed in a later section in this chapter. The methodology of the study was updated to reflect findings from the pilot study.

Confirmability is the congruency of two or more independent examiners with ensuring the data are accurate (Lincoln & Guba, 1985). To meet confirmability, the researcher and designated dissertation committee members reviewed the findings as data analysis evolved. Finally, data were presented to the dissertation committee, which includes a scientist with long-term experiences working with this population.

Transferability refers to findings that can be transferred or applied in other populations or groups (Lincoln & Guba, 1985; Munhall, 2012). Field notes and a reflexive journal were utilized to attain transferability. Transcripts were coded for commonalities within each transcript and then compared among transcripts of all participants to enhance transferability.

In an effort to remain as objective as possible, reflexivity was utilized to put aside personal feelings about all aspects of this research study. A reflexive journal was used as a bracketing technique. Ahern identifies 10 tips to help qualitative researchers with bracketing in

research studies (Ahern, 1999). Assumptions were identified in chapter one of this study. The researcher recognizes that potential conflicts may arise in regards to role conflict. The researcher is also a registered nurse with experience working with individuals with cardiovascular disease. The researcher understands that the roles of being a registered nurse and researcher are two different roles for this research study. The researcher prepared a list of questions to help maintain consistency between interviews (See Appendix F). The nurse in the Electrophysiology Lab was recognized as the gatekeeper for this population. Trust was established by meeting with the nurse. A reflexive journal was maintained to describe findings or other items of interest during the data collection and analysis process.

### **Results of Pilot Study**

A pilot study was conducted in the spring of 2016 to inform this research study and determine if recruitment methods, research design, sampling method, setting and instruments were satisfactory. During the pilot study, it was determined that recruitment may be an issue in the planned research study. Three names of those who had a Reveal LINQ™ ICM and were experiencing syncopal episodes or cardiac arrhythmias were initially provided to the researcher for the pilot study. Of the three individuals who agreed to be contacted by the researcher, only one agreed to meet the researcher for an interview. The nurse in the Electrophysiology Lab then had to contact another individual with the device. With potential difficulty in recruiting participants, recruitment was extended to include those who have experienced cryptogenic stroke and have an ICM inserted, without regards to manufacturer of the device. These individuals may experience uncertainty with the unknown etiology of their stroke and may also experience symptoms such as fear, anxiety and depression just as those who have undiagnosed cardiac

symptoms. Fear, anxiety and depression may affect self-care issues and QOL for these individuals, therefore this population can help to inform this research study.

When asked if the device affects their health, participant 001 stated “no”, but participant 002 stated, “It’s probably caused me more anxiety than it has peace mainly because I’m so aggravated. If it did what I thought it was going to do I think it would give me reassurance and give me peace.” This population has the potential to experience anxiety and depression. One participant in the pilot study reported that the device increased anxiety; therefore, two scales were added to the research study to capture anxiety and depression in each participant. Specifically, the PHQ-8 and GAD-7 scales were to capture depression and anxiety respectively and to assist the researcher in data collection and analyses.

Of the two individuals interviewed in the pilot study, one participant spoke about their spouse throughout the interview. It was decided to include a probe question concerning the significant other in the research study to understand the influence of this person on self-care and QOL for the individual with an ICM.

Both interviews with the pilot study took place in the homes of the individuals. This naturalistic setting was determined to be sufficient for this research study. A naturalistic setting allows the individual to feel comfortable during the interview. During analysis of the interviews and demographic questionnaires, it was determined that educational level should be added to the questionnaires to compare each participant.

In summary, this pilot study provided support for expanding the population to include those individuals who have an ICM implanted after experiencing cryptogenic stroke. The pilot study also supports including the PHQ-8 and GAD-7 instruments, including a probe question in

regards to the significant other, adding educational level and including participants with an ICM regardless of manufacturer.

### **Limitations**

This research study is limited to one site in Eastern North Carolina and may not be generalizable to the general population. Another limitation is this study is based on a participant's perception and self-reporting of those perceptions. The assumption is that these two populations, those experiencing cardiac symptoms and those with cryptogenic stroke, have similar experiences. A limitation of this study is that it may not capture the diagnosis specific experience.

### **Summary**

This chapter provides detailed information regarding the methodology for this research study. The qualitative descriptive study is described along with the sample, sampling method, site selection, recruitment methods, protection of human subjects, data collection and instruments to be used in this study. Trustworthiness and integrity were addressed with detailed discussion on credibility, dependability, confirmability, transferability, and bracketing. Results of the completed pilot study were also discussed with explanations on changes that occurred to the study based on findings from the pilot study. Finally, limitations were addressed.

## CHAPTER 4: EXPLORING THE EXPERIENCES OF INDIVIDUALS WITH AN INSERTABLE CARDIAC MONITOR: MAKING THE DECISION

### **Abstract**

Little is known about the decision-making process for insertable cardiac monitor (ICM) insertion in those with suspected arrhythmias. Understanding the influences that occur early in this process are important for the clinician when discussing options with this population.

The purpose of this study was to describe how individuals make a decision to have an ICM inserted. The research question guiding this qualitative descriptive study was: What are the experiences of individuals who have chosen to have an ICM inserted? Using a sample with maximum variation, participants ( $N = 12$ ) ranged in age from 41-95, with most ( $n = 7$ ) having the device inserted because of syncope or infrequent atrial fibrillation (AF), and others ( $n = 5$ ) for device insertion due to having a cryptogenic stroke. The decision-making process to have an ICM inserted varied among participants. Using content analysis and constant comparison, three global categories emerged: (a) pre-decision, (b) definitive decision, and (c) deliberated decision. Event symptoms, including physical, cognitive and emotional symptoms, and trust emerged as factors in the decision-making process. Clinicians should explore loss and emotional symptoms when caring for those making the decision to have an ICM. Because the timing of the decision varied and was related to trust, further research is needed to address the qualities that are important in interactions between the individual and their clinician that influence trust.

## Background

Arrhythmias are the most common cause for syncope when the etiology is cardiac related (Moya et al., 2009). The European Society of Cardiology (ESC) updated guidelines for diagnosing and managing syncope in 2009 (Moya et al., 2009). These guidelines noted the importance of identifying the basis for syncopal episodes to provide specific treatment as well as helping in understanding future individual risk. However, symptoms of cardiac arrhythmias and syncopal episodes occur infrequently and unpredictably. External short-term monitoring devices, such as the Holter monitor and external loop recorders, may not capture the episode in the short time they are worn; thus, not always leading to diagnosis (Seidl et al., 2000; Solbiati et al., 2016). Advances in technology have led to the development of the insertable cardiac monitor (ICM) that offers long-term continuous monitoring ability.

The ICM, a device that can assist clinicians with diagnosing cardiac arrhythmias associated with episodes of syncope (Edvardsson et al., 2011; Hong & Sulke, 2013; Ruwald & Zareba, 2013) and cryptogenic stroke (Yaghi, Bernstein, Passman, Okin & Furie, 2017), can remain implanted for up to three years. Individuals choosing the ICM are continuously monitored 24 hours per day increasing the chances of capturing the heart rhythm at the time of the episode. Although there is strong evidence to support use of the ICM in diagnosing cardiac arrhythmias and syncope, limited studies have examined the patient's perspective of having an implanted device that monitors heart rate and rhythm (Deaton, Dunbar, Moloney, Sears & Ujhelyi, 2003; Ricci et al., 2010).

Symptoms of an arrhythmia vary and may include one or more of the following: bradycardia, tachycardia, irregular heartbeat, palpitations, anxiety, weakness, dizziness, syncope or near syncope, sweating, chest pain or dyspnea (National Heart, Lung and Blood Institute

[NHLBI], 2013). Atrial fibrillation (AF), the most common arrhythmia experienced by individuals (Lloyd-Jones et al., 2004), is a major risk factor for the development of stroke. A stroke resulting from AF is often more severe than a stroke in those without AF (Lin et al., 1996). Individuals diagnosed with AF are twice as likely to be hospitalized as those without AF, and they often experience multiple hospitalizations (January et al., 2014). These hospitalizations contribute to the estimated annual \$6 billion cost of AF in the United States (US) (January et al., 2014; Mozaffarian et al., 2016).

Globally, it is estimated AF affects 33.5 million individuals, and in the US the estimated 2010 prevalence of AF ranged from 2.7 million to 6.1 million and is expected to increase to over 12 million by the year 2030 (Mozaffarian et al., 2016). These increases may be due to the aging population or to pacemaker and cardiac defibrillator use resulting in an increase in diagnosis of AF. More importantly, individuals with AF are at increased risk for stroke, heart failure and sudden cardiac death (Mozaffarian et al., 2016). Approximately 795,000 individuals have a new (77%) or recurrent stroke (23%) in the US each year with the vast majority (87%) classified as ischemic (Mozaffarian et al., 2016). Of concern is that approximately 25% to 40% of ischemic strokes are classified as having no definitive cause: cryptogenic stroke (Ritter et al., 2013; Yang et al., 2016). The presumed underlying mechanism for cryptogenic stroke is embolism secondary to AF.

Use of ICMs to capture arrhythmias and diagnose events can assist in identifying those who should receive treatment and improving health outcomes related to heart disease. With the prevalence of AF expected to increase significantly over the next decade (Mozaffarian et al., 2016), it is important to understand how devices such as the ICM can assist individuals in managing their health. Managing health outcomes is important for this population due to their

increased risk for diagnosis of stroke and heart failure and the significant costs associated with these chronic health conditions. Because insertion of an ICM is invasive and requires long-term commitment, examining the perceptions of those early in the decision-making process can help with understanding their needs. Therefore, the purpose of this study was to describe, from the individual's perspective, the decision-making process for an ICM.

### **Theory**

The theoretical framework used to guide this study was Jurgens' integration of the cognitive and physical symptom experience of self-care (Jurgens, 2006). Jurgens integrated Mishel's model of perceived uncertainty in illness with Lenz and Pugh's theory of unpleasant symptoms to focus on the individual's response to physical and cognitive symptom experience. See Figure 1. The theory of unpleasant symptoms notes physiological, psychological and situational factors affecting symptoms. This integrated theory provided a comprehensive framework to explore the experiences of those with undiagnosed cardiac symptoms and cryptogenic stroke.

### **Methods**

A qualitative descriptive research design was used to address the research question: What are the experiences of individuals who have chosen to have an ICM inserted? Using a sample with maximum variation, the sample included: (a) adults aged 18 and older without cognitive impairment, and (b) individuals that already have an ICM implanted within the last two years but not less than two months for either syncope, cryptogenic stroke, or other cardiac event. This study was approved by the Institutional Review Board (IRB).

An electrophysiology lab employee contacted individuals who met inclusion criteria to describe the study and obtain consent for release of their name and contact information to the

principal investigator (PI). Then, the PI contacted each potential participant to further explain the study, answer questions, and set up a time and location for consent and data collection for willing participants. The electrophysiology lab employee and the PI used a script when contacting participants to maintain consistency. To avoid potential coercion, potential participants were not informed of an incentive until after they agreed for the electrophysiology lab employee to share their contact information with the PI.

From a potential 85 participants, three were excluded because of participation in a pilot study, 37 were excluded due to date of device insertion, and 24 were excluded because of refusal to allow their contact information to be shared with the PI. Of the 21 potential participants contacted, two refused to participate after speaking with the PI, two were excluded due to cognitive impairment, and five individuals did not return a telephone call to the PI. The remaining 12 individuals participated in this research study ( $N = 12$ ).

### **Setting**

To facilitate in depth communication and to offer comfort, privacy, and security for participants, data collection took place in a naturalistic setting of choice by the individual. Most participants (92%) chose their own homes as the setting for data collection.

At the beginning of each interview, the PI reviewed the study in its entirety and obtained consent. To describe the sample, a demographic questionnaire was completed and included: (a) length of time device has been inserted, (b) type of device, (c) age, (d) sex, (e) race, (f) education level, (g) employment status, (h) marital status, (i) symptoms experienced, (j) list of comorbidities, and (k) current medications. After completing the questionnaire, formal, semi-structured interviews were completed. All interviews were audio recorded and lasted approximately 0.5 to 1.5 hours. Probe questions/statements were used to glean rich data to

answer the research question. See Table 1 for sample probe questions. The PI began each interview with the grand tour statement, “Tell me about your health before having the ICM device inserted”. This statement allowed participants to recall their health prior to having the device inserted and offered insight into the symptoms they were experiencing. At the end of the interview each participant was given a \$20 gift card to thank them for their participation.

### **Data Analyses**

The demographic data to describe the sample were analyzed using SPSS 22. Qualitative data were analyzed by transcribing each interview verbatim into a Word document. Each transcript was compared to each audio recording for accuracy. These qualitative data were analyzed by using qualitative content analysis and constant comparison (Morse & Field, 1995). Content analysis assisted with examining the raw data from each transcript and constant comparison was used to explore the similarities and differences between interviews. Transcripts were initially read, common discussions were noted, and a codebook developed. Using these codes, each participant’s data were coded for these common categories. Data analyses continued with the PI reading and reexamining each transcript and comparing each transcript to other transcripts and the codebook. Data emerged from this process and the codebook was refined and included categories such as event symptoms and trust. These categories were placed into related groups called clusters and clusters with similar meanings were combined into global categories. A second reviewer, a doctorally prepared nurse researcher, validated coding. Global categories, clusters, and examples of raw data are included in Table 3. NVivo 10 was used to organize the data.

## Results

The participants in this study ( $N = 12$ ) ranged in age from 41-95. Of those with device insertion because of syncope or cardiac symptoms ( $n = 7$ ), the majority were male (86%) and White (86%). In those with device insertion because of cryptogenic stroke ( $n = 5$ ), the sample was mostly female (80%) and White (67%). See Table 2 for demographic information.

The decision-making process to have the ICM inserted varied among participants. Three global categories emerged in data analyses: (a) pre-decision, (b) definitive decision, and (c) deliberated decision. Figure 2 describes the process of making the decision for ICM insertion in individuals experiencing an arrhythmia, syncopal episode or from cryptogenic stroke. These global categories along with clusters and examples of raw data are presented in Table 3.

### Pre-Decision Making

Pre-decision, the first global category identified, is the event and/or experiences that led to the decision for ICM insertion. Symptoms associated with the experiences or the event comprised pre-decision. Event symptoms are defined as the physical, cognitive or emotional symptoms associated with the experience/event leading to ICM insertion. Participant symptoms varied prior to device insertion, therefore, the clusters were also examined related to the type of event: cryptogenic stroke, syncope or AF.

**Physical event symptoms.** A physical symptom is an objective or subjective sensation experienced by the individual that is different from their normal state. Physical event symptoms were identified as relating to the diagnosis or rationale for ICM insertion.

Participants ( $n = 5$ ) that experienced a stroke described various physical symptoms that led them to seek care. Only two of these individuals described noticing the stroke symptoms

themselves. The following quote is from a 50-year-old White female describing the moment she realized she had a stroke.

I never knew I had the stroke until I woke up . . . I got up for work, first thing I do, I make my bed. I noticed that morning, though, that I had the stroke, I went to make my bed, and I no mobility of my right hand. I thought, hmm. So I kept trying to make the bed, still not realizing that my hand, I'm not, it's not doing it. I'm moving it, but it's not doing anything . . . And I looked in the mirror and I saw my face. My face had drooped. My face was droopy on the same side as my arm.

Another 50-year-old Black female could only recall the symptom of having high blood pressure at the time of her stroke. However, she reported asking her sister to take her to the emergency department stating, "I asked my sister because she had one [stroke] and she told me I needed to go to the emergency room, and I went to the emergency room and they told me that I was going through one [stroke]."

Three individuals had a family member identify the need for them to seek care because of a change in their normal status. Of these three participants, only one described a change in physical status leading a family member to encourage them to seek care. The following quote is from a 73-year-old Black male describing how his niece informed him that he was going to the emergency department.

I was just feeling weak and sickly . . . So then the same day, my niece came over and she said, "Well, I don't like the way you look and she said get dressed." So she took me to [Level 1 Trauma Center], and that's where they kept me.

All participants with stroke described varying physical signs leading them to seek care at the time of their event.

Of the six participants describing physical symptoms related to syncope, four individuals (67%) described experiencing multiple syncopal episodes with three of these individuals describing other physical signs in addition to syncope. A 95-year-old White male described his three syncopal events prior to ICM insertion.

I had fallen once in the home and twice in the road . . . I mean the second time in the highway I don't remember nothing. Don't remember, won't dizzy, won't nothing. All I knew is I woke up, somebody had gotten me into the house . . . I cracked my nose and got the skin off my nose and forehead, and I was messed up a right good while and I don't know why.

He did not experience any prodromal symptoms to syncope, but only experienced the syncopal event. No prodromal symptoms prior to syncope is contrary to a 41-year-old man who experienced multiple episodes of syncope. He described the physical signs he experienced at the time of the syncopal episodes: “Everything would go fuzzy” and then seeing “Sparks in front of my eyes and then I would just break away to a tunnel, almost like tunnel vision.” Then, he described the syncopal episode saying that if he did not sit down quickly, “I’d go out.” Others experienced symptoms such as heart palpitations, sweating, and “feeling awful”, “lightheaded”, and “dizzy” along with multiple syncopal episodes.

Two participants described experiencing a single syncopal event without associated symptoms. A 74-year-old White male described his daily routine of going out to a local fast food restaurant for breakfast and then, “I passed out and busted my head open.” Another participant, a 65-year-old White male stated he was at the barbershop and “passed out in the barber chair.” These two individuals did not describe any other physical signs leading to the single syncopal episode or at the time of the event.

One participant in this study did not experience a syncopal event or a stroke. He described working in the heat all day and then coming home to check his blood pressure on an automatic machine he used at home on a regular basis. He stated, “I came home to check my blood pressure . . . and my pulse was over a 180. That's when I found out that I was in an erratic heart rate.” This participant was a retired healthcare first responder, and he listened to his heart with his stethoscope after checking his blood pressure and noting the pulse rate. He recognized that his heart rate was not in a regular rhythm. He did not experience any other physical signs other than an increased irregular heart rate.

**Cognitive event symptoms.** A cognitive symptom is a perception, memory, or mental status that is abnormal from the individual’s normal state. While these symptoms may be prodromes to the event, they were part of the pre-decision phase of having an ICM inserted.

Those who had a diagnosis of stroke experienced cognitive signs prior to having their ICM inserted. Three out of five (60%) individuals who experienced a stroke described memory deficits at the time of the event or leading up to the event. The following quote is from a 70-year-old White female describing her experience with forgetfulness.

My husband did say . . . I didn't see it, he said that right before I had the stroke . . . he could tell that I didn't remember things as well as I did at one time . . . he said he saw where I was getting more forgetful and having to ask more questions than normal.

Another participant, a 69-year-old White female, described not being able to remember how to use the microwave. A 50-year-old Black female, stated, “I didn’t know what was going on” at the time of the event.

Individuals with syncopal events also described experiencing cognitive symptoms associated with the event. Two out of the six participants described not remembering the syncopal event or events prior to the syncope event. A 74-year-old White male stated, “I got up to come home, but I don’t remember nothing after that.” He could remember going to the fast food restaurant and getting up to leave, but could not recall any events after getting up to leave. Another participant, a 95-year-old White male, stated, “I don’t remember nothing.” This individual had three syncopal episodes and could not recall the events leading up to the actual syncopal event. Another individual described feeling disoriented with some of the syncopal events. The remaining participants who experienced syncopal events and the one participant with AF did not describe any cognitive symptoms associated with their event.

**Emotional event symptoms.** Individuals also described emotional symptoms they experienced with a syncopal event or a stroke. An emotional symptom is the state of mind, feeling, or mood of an individual associated with an event. An emotional symptom can be either positive or negative and is based on the perception of the individual.

Two of the five participants that experienced a stroke described emotional signs associated with the event. A 69-year-old White female stated, “I would be crying a lot for really no reason.” The following quote is from a 50-year-old White female who described the emotional distress she experienced after waking up and realizing she had a stroke: “When I went in the bathroom . . . I looked in the mirror and I saw my face. And then, I panicked.” She described the feeling of panic as she realized that she could not use her arm, her face was drooping and her speech was garbled. She explained not wanting to speak for fear of how she sounded and that her speech was incomprehensible.

Two out of the six individuals with syncope described emotional symptoms associated with multiple events. One participant, a 78-year-old White female, described a feeling of relief after being informed that she was experiencing syncope.

Just putting a name to it was nice, because it seemed like before then, everybody thought I was little cuckoo. You know, I think they thought I was being over-dramatic. I always felt like, oh for crying out loud, will you find something here and tell me what it is? So it was a relief, really.

While this same participant described a feeling of relief with having a name to call her events, she also expressed her frustration associated with experiencing recurrent events. She stated, “It’s hell, for crying out loud. I mean, is it all in my mind or something?” and “It’s a little embarrassing, to a certain extent.”

Other participants described being scared. One man described being awakened from his sleep on his birthday with symptoms he had not experienced before: “I’ve had it my whole life [heart irregularity] and never thought about it, but that one scared me.” He described the fear of thinking he was having a heart attack and how that fear caused him to seek treatment in the middle of the night.

### **Definitive Decision**

All participants in this study made a decision to have an ICM inserted, however, the decision process varied among participants. The second global category is definitive decision. A definitive decision is a final decision that is reached decisively and is based on a reliable authority. The cluster, blind trust, comprised the definitive decision category.

**Blind Trust.** Blind trust is confidence placed in an authority figure by an individual. Blind trust for device insertion occurred with seven of the 12 (58%) individuals in this study and

was not limited to only one diagnostic group of participants. Each of these seven individuals made the decision for device insertion while hospitalized after an event and reported they agreed immediately based on their clinician's authority and expertise. Of the seven individuals making a decision based on blind trust, five experienced a stroke and two experienced a single syncopal event.

A 73-year-old Black male that experienced a stroke stated, "Well I didn't know what to expect cause I really didn't know why they were putting it in until the doctor came in, told me they were going to put it in there." Another participant, a 50-year-old Black female, said "When I was in the hospital for my stroke, they told me then that's what they was going to do. They was going to put one [ICM] in my chest." She also expressed that she had doubts with insertion, but the thought of having a heart attack led her to not question the clinician's choice of insertion. Another participant, a 70-year-old White female described how she made the decision for device insertion while hospitalized for a stroke.

They told me they'd like for me to have the device put in so that they could monitor me and that was fine with me. I wasn't gonna ask a lot questions 'cause I mean I just did what they wanted me to do.

A 50-year-old White female described feeling confident about her decision for device insertion because, "I felt confident if that's what they thought and they recommended, who am I to say; He suggested it, and I agreed with it."

Two participants that experienced a single syncopal episode requiring hospitalization described their agreement for device insertion based on the blind trust of their clinician. A 74-year-old White male stated, "He [clinician] said well you know, it ain't going to cost you nothing and I forgot what he said, anyway, I agreed to it." Another participant, a 65-year-old White

male, who also experienced a single syncopal episode said, “I was just ready to put in anything they could do, because with my heart, they’re the expert so, I’ll try all of their advice. They told me I needed it. I said put it in.”

### **Deliberated Decision**

The third global category to emerge from data analyses is deliberated decision. A deliberated decision is defined as a choice made after careful thought and consideration. Participants that made a deliberated decision explored their options prior to consenting to an ICM insertion. The three clusters that comprise this global category are seeking to understand, experiencing loss, and relational trust. Five out of the 12 participants made a deliberated decision for device insertion. Four out of the five individuals experienced syncopal events and one experienced atrial fibrillation.

**Exploring options.** Individuals described experiencing different diagnostic or treatment options after having symptoms and prior to device insertion. Three of the five individuals described exploring their options after recurrent events and prior to device insertion. Of the three participants who described other diagnostic testing, all described wearing a Holter monitor.

One man completed a sleep study. He described heart rate readings up to 156 beats per minute when wearing the external monitor, and it was determined he was asleep when the monitor captured some of the increased readings. From the sleep study, he reported that he stopped breathing 70 times during his sleep study session. He was diagnosed with sleep apnea and now uses a BiPaP machine when he sleeps. However, he continued experiencing physical symptoms. He tried different medications to help with symptom management stating, “We kept going back and forth for probably months trying to find the right medicine.” He continued

discussing how his clinician wanted him to try an external monitor for three months. The following quote captures his decision for seeking a different option.

I think it was pretty much at that point, it was just either that [ICM] or the Holter monitor for three to four months. There's no way I could wear a Holter monitor for three months. And the one that I did have on, it drove me almost at a point of insanity after six days. I was ripping wires off in the middle of the night. I was replacing more of the adhesive contacts more than I even had. I ran through all my extra contacts in three days. So I was reusing the ones that wouldn't stick with tape and everything I could to keep them on. And then finally, I just called the office and I said, I can't do this. I can't keep it on. It won't stay on. I need to find another option.

In addition to using a Holter monitor on two different occasions, a woman with multiple episodes of syncope discussed the diagnostic testing undergone in an attempt to diagnose her symptoms. She stated, "I've had about three stress tests. I had a heart catheterization where they found small blockages . . . and numerous cardiograms . . . And, that didn't show them anything definitive, so that's why we kept on try this, try that." She went on to say, "I consented to the device because I thought maybe it would give us more answers . . . It was gonna be the defining moment."

**Experiencing Loss.** A second cluster that comprised the global category deliberated decision was experiencing loss. Individuals described the process of physically losing something, such as their job, and also described losing a sense of independence or security. The following quote exemplifies loss.

I've always been the one to take care of everybody and then when it started to get to the point where I couldn't work, I couldn't do my day-to-day stuff . . . Well, it's like why? .

. . . If I can't work and I can't take care of people and I can't do what I normally do, what's the point? . . . I like to hunt but I can't. I can't go walking through the woods for half a mile any more.

He also described quitting his job as a tractor-trailer truck driver because of his symptoms.

Another participant, a 78-year-old White female, described a loss of physical function: not being able to stand for more than 15 minutes at a time. She stated, "We were watching a parade . . . I can't stand there, I have to sit down." She adapted to her difficulty with standing by bringing a fold-up stool with her. A third participant also described a loss because of physical signs associated with his event. A 57-year-old White male stated, "I don't go out of town anyway unless I have somebody else that can drive with me; I used to love to travel, but now it's like, Mm-hmm (negative)." A fourth participant described a loss of independence because of multiple syncopal events. The following quote is from a 95-year-old White male.

Last year before I fell the last time, I'd get out there and walk that dog a half a mile every morning . . . When I take her I just walk her on the lawn, that ain't much exercise . . . I used to drive the car all over town . . . We were in the middle of my birthday and it came up that I had to renew my license. I never went up there to do it.

**Relational Trust.** Relational trust is defined as a confidence developed between individuals. Participants in this study described a decision made for device insertion based on collaboration with their clinician or family and used the terms "we" and "us" to describe that interaction. For example, a 68-year-old White male, described his reason for choosing to get the device and expressed that it was a shared decision between himself and his clinician.

The doctor felt that it was a good progressive thing to do since I like to be progressive with my health. Then the best way to try to monitor this [infrequent episodes of atrial

fibrillation]. So, he suggested that would be the ideal way to do it and especially since I was in good health anyway, it would hopefully prolong and take the guesswork out of putting me on the medication that maybe I did not need to be on. And that's the reason why we decided to put the device in.

Another participant, a 57-year-old White male, also described being part of the decision-making process regarding device insertion.

They explained to me in detail what this [device] was for and what it was not for, that's why we opted for this for now. I feel like they [cardiologists in hospital setting] work as a team with my personal physical physician here and decided what was best for me. I could've said no just as quick as I said yes. This was a good thing for me, this is an option and I opted to have it.

One male described his inability to wear the external Holter monitor for the planned three months because of difficulty with keeping the electrodes in place. He described contacting his physician asking for a different option and his physician discussed the ICM with him.

### **Discussion**

Although the use of ICMs has been studied for diagnostic ability, the individual perspective has not been widely explored. With increased use of ICMs for diagnosing cardiac symptoms in those with syncope and cryptogenic stroke, it is important to gain the perspective of decision-making from those who have the device inserted. This study examined the experiences of those with an ICM to include exploration of the event leading to ICM insertion and the physical, cognitive and emotional symptoms experienced by each participant prior to device insertion. In this study, individual symptom experiences varied among the participants related to their etiology. However, symptoms reported in our study, such as rapid heart rate and fear, were

consistent with previous studies in those with known AF (Deaton et al., 2003; McCabe, Rhudy, Chamberlain & DeVon, 2016; McCabe, Schumacher & Barnason, 2011).

The Impact Goal set by the AHA states that by the year 2020, the cardiovascular health of Americans will improve by 20%. Included in this scientific statement is the expectation from the Institute of Medicine that clinicians practice patient-centered care addressing both the physical and emotional needs of patients (Rumsfeld et al., 2013). The emotional symptom experience has not been well studied in the AF population (McCabe & Barnason, 2012; McCabe, Rhudy & DeVon, 2014). Interestingly, individuals in this study described their emotional symptoms, such as anxiety and fear, in relation to their overall symptom experience. Although insertion of an ICM addresses the physical symptom experience of individuals, findings from this study highlight the need to address the emotional symptom experience in this population. Understanding how emotional symptoms influence the decision-making process for ICM insertion would assist clinicians developing targeted interventions to promote health in this population.

To date, studies have focused on the performance of the ICM in diagnosing AF in those with syncope and cryptogenic stroke (Choe et al., 2015; Mittal et al., 2016; Podoleanu et al., 2014); however, this study explored how individuals make the decision to have the device inserted. The decision-making process for choosing ICM insertion varied among participants and was based on their presentation of symptoms. Those with symptoms or diagnosis of a stroke were more apt to make a decisive decision during their hospitalization. Further, they desired to prevent another stroke or event. Two others who experienced a single syncopal event also made a decisive decision while hospitalized. A commonality shared between these two groups was blind trust in their clinician to make the decision for device insertion in the acute phase of their

event. This finding is consistent with a study examining patient preferences in the decision-making process when hospitalized. Researchers found the desire to participate in a decision was greater when the symptom was less severe and that patients relied more on the clinician recommendation when symptoms were more severe (Goggins et al., 2014).

Hospitalization post stroke or syncopal episode is a vulnerable time period resulting in high stress. During high stress, decision-making capabilities are diminished (Visvanathan et al., 2017). Thus, individuals may rely more on the expertise of the clinician. This situation results in a power shift and may place the individual at risk for making an informed consent. Further, those experiencing stroke may not have the cognitive capacity to make a decision for insertion of this device while in the acute phase (Visvanathan et al., 2017). An ICM is primarily used to monitor and detect cardiac arrhythmias and as such, assists in providing diagnostic information to guide the clinician in determining the appropriate antithrombotic therapy, antiplatelet or anticoagulant for AF (Brachmann et al., 2016). An ICM does not offer an intervention if an arrhythmia is detected as an internal defibrillator. Because ICM insertion is invasive and is an elective diagnostic tool that does not offer a life-saving intervention, the risk versus benefit of device insertion should be carefully discussed with the individual. Additionally, the use of a simple form with information provided at their level of comprehension should be used when obtaining informed consent (Lipworth, Ankeny & Kerridge, 2006). Further exploration of the ethical issues associated with ICM decision-making in the acute setting is warranted.

In this study other participants made a deliberated decision for device insertion after multiple events. These individuals discussed options and many explored other treatment choices such as medication management or external monitors to diagnose the cause of their symptoms prior to ICM insertion. In contrast to the definitive decision group, those deliberating the

decision were not hospitalized while making a decision. They had time to explore their options prior to device insertion. While exploring their options, these individuals not only continued to experience symptoms, but they also experienced loss. The losses described were similar to those experienced by individuals with seizures (Wirrell, 2006) or those with an implantable cardioverter defibrillator (Ferrick & Ferrick, 2017) such as loss of safety, security, employment or independence. Thus, care for those during the deliberated decision phase should focus on the assessment of loss and how they are coping with these losses. Further, clinician assessment should also include screening for comorbidities, such as depression and anxiety, to understand psychological health during this period.

During the deliberated decision period, participants noted exploring options for diagnosis and treatment with others. These processes resulted in developing a trusting relationship. Participants felt that the decisions were collaborative. This is similar to the findings in a study describing the patient experience from the onset of symptoms to the initial treatment of AF. The researchers found that study participants were reassured when the clinician took quick action in treating their AF, expressed concern for their condition and provided explanations (McCabe et al., 2014).

Future studies should address the qualities that are important in the interaction between the individual and their clinician on the decision-making process for ICM insertion. Because some participants also described the importance of a family member with the recognition of symptoms or in the decision for device insertion, the influence of the individual's support system should also be explored.

All individuals in this study experienced an event with physical, cognitive and/or emotional symptoms. Understanding the perspective of how persons make the decision for ICM

insertion is important in identifying needs early in the decision-making process. This knowledge enables clinicians to intervene in facilitating informed decisions to improve the health in those with undiagnosed cardiac symptoms and cryptogenic stroke.

### **Implications to Professional Practice**

Future studies are needed to understand how emotional symptoms influence self-care in those at risk for CVD. Studies should include assessment strategies and interventions to promote healthy behaviors.

Figure 1

Jurgens' Integration of the Cognitive and Physical Symptom Experience of Self-care

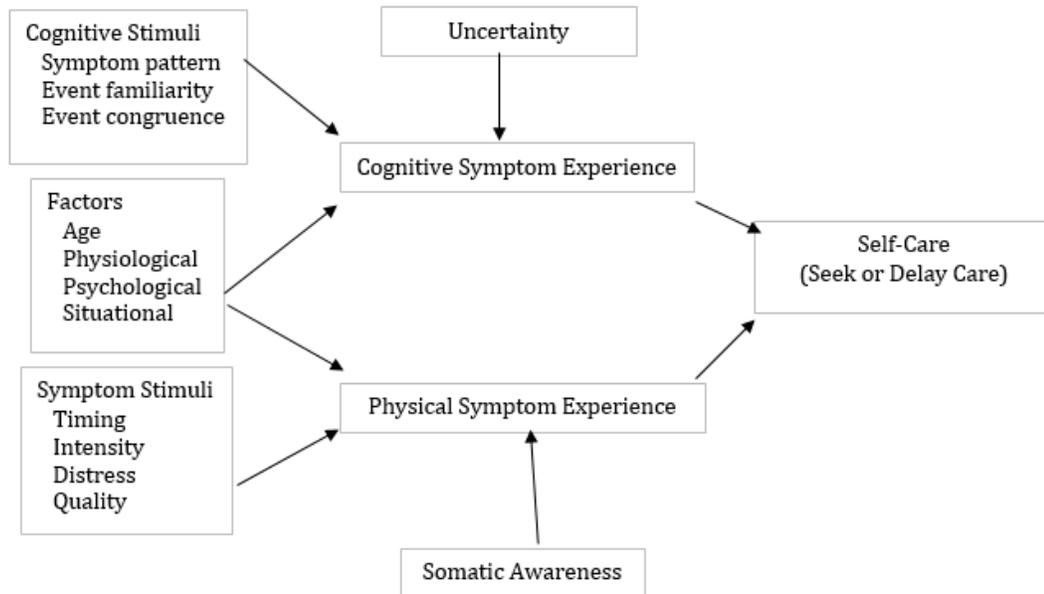


Table 1

*Example of Probe Questions*

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Sample Probe Questions

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What were the things that you considered before choosing to receive the implanted device?

What was the length of time from when you experienced the initial symptoms to the time you sought treatment?

What are the reasons for you to get this implanted device?

What were your influences (for or against) when considering an implanted device?

---

Table 2

*Demographic Data (N = 12)*

	<i>M (SD)</i>	<i>Range</i>	<i>N (%)</i>
Syncope			5 (42%)
Length of time of device insertion (months)	14 (7)	4-22	
Age	67 (20)	41-95	
Sex			
Male			4 (80%)
Female			1 (20%)
Race			
White			4 (80%)
Native American			1 (20%)
Highest level of education completed			
High school graduate			3 (60%)
Bachelor degree			2 (40%)
Atrial fibrillation			1 (8%)
Length of time of device insertion (months)	N/A	10	
Age	N/A	68	
Sex			
Male			1 (100%)
Female			0
Race			
White			1 (100%)
Highest level of education completed			
Some college			1 (8%)
Cryptogenic Stroke			6 (50%)
Length of time of device insertion (months)	5 (4)	2-13	
Age	64 (11)	50-74	
Sex			
Male			2 (33%)
Female			4 (67%)
Race			
White			4 (67%)
Black			2 (33%)
Highest level of education completed			
Less than high school			2 (33%)
High school graduate			3 (50%)
Associate degree			1 (17%)

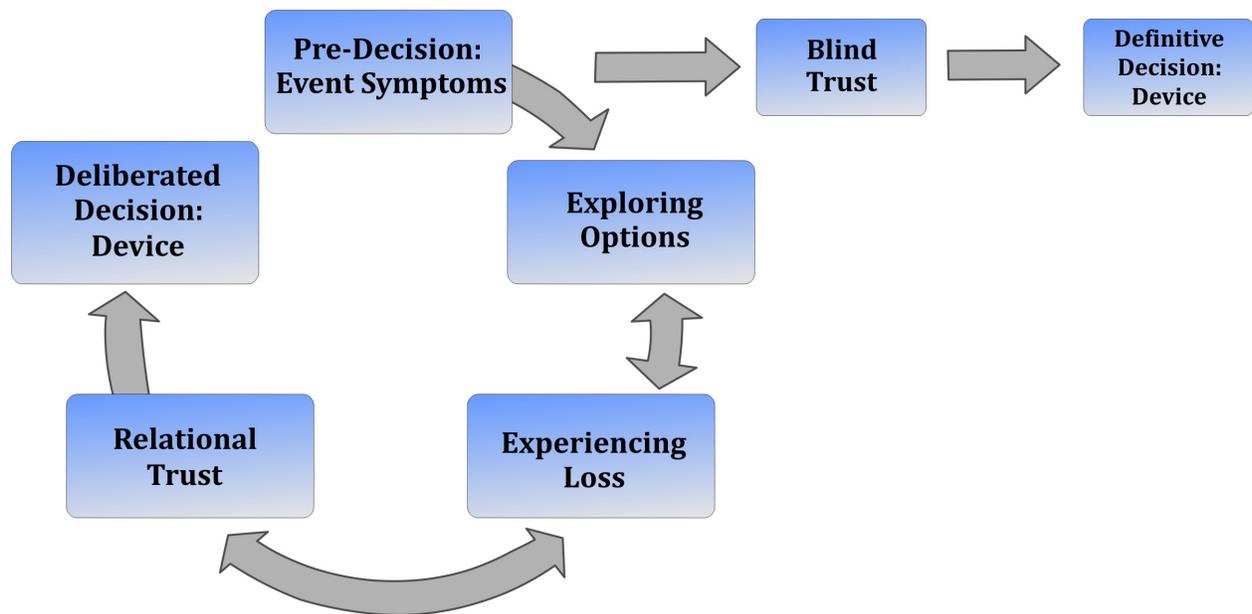
Table 3

*Data Analyses - Making the Decision*

Global Categories	Clusters	Initial Raw Data
Pre-Decision	Physical Event Symptoms	Blood pressure was high; I got to feeling weak and sickly; My face had drooped; I passed out; you just drop; heart palpitations; feel like you're gonna faint; heart was racing; my chest hurt; erratic heart rate; little pinch or little stab; garbled speech
	Cognitive Event Symptoms	Couldn't use the microwave; didn't know what was going on; getting more forgetful; disoriented
	Emotional Event Symptoms	I panicked; it's just annoying; very frustrated; it's a little embarrassing; that one scared me
Definitive Decision	Blind Trust	The only way to find out; I just did what they wanted me to do; they're the expert; told me they were go put it in there; if that's what they thought and they recommended, who am I to say; He suggested it, and I agreed
Deliberated Decision	Exploring Options	We kept going back and forth for probably months trying to find the right medicine; I need to find another option; that didn't show them anything definitive, so that's why we kept on try this, try that
	Experiencing Loss	I used to drive the car all over town; I ain't doing much of nothing; I'm just shut down; I can't follow my hobbies; I don't go out of town...unless I have somebody else that can drive with me; I used to love to travel; I like to hunt, but I can't
	Relational Trust	We opted for this for now; the doctor felt that it was a good progressive thing to do; we decided to put the device in

Figure 2

Making the Decision for ICM Insertion



## CHAPTER 5: LIVING WITH AN INSERTABLE CARDIAC MONITOR: INFLUENCES ON SELF-CARE AND QUALITY OF LIFE

### **Abstract**

This study focused on individuals with an insertable cardiac monitor (ICM) as a result of undiagnosed cardiac symptoms, syncope, or cryptogenic stroke. Little is known about the experiences of those with ICMs. Understanding the needs of this population can improve their health outcomes and quality of life (QOL). The purpose of this qualitative descriptive study was to describe the experiences of those with undiagnosed cardiac symptoms or post-cryptogenic stroke living with an ICM. The research questions used to guide this study are: (a) What are the experiences of individuals who have chosen to have an ICM inserted?; (b) How do participants who have an ICM describe their health related self-care?; and (c) How do participants who have an ICM describe their QOL? The maximum variation sample ( $N = 12$ ) included White (75%), African American (17%) and Native American (8%) adults ranging in age from 41-95. Content analysis and constant comparison were used to analyze the data, with a focus on intraparticipant analysis, interparticipant analysis and interrelationships. Data analysis resulted in three global categories: (a) influences on self-care, (b) managing, and (c) monitoring. To identify the needs of this population, we need to understand their experiences living with the device. Further research is needed to address the health care needs of those living with an ICM.

One in every three deaths that occurred in 2013 in the United States (US) was related to cardiovascular disease (CVD) (Mozaffarian et al., 2016). Cardiovascular disease is also the leading cause of death globally for both men and women, accounting for 31% of deaths in 2013 with the number of deaths worldwide expected to increase by the year 2030 (Mozaffarian et al., 2016). Although there is a high mortality rate related to CVD, individuals are also surviving cardiac events, such as heart attack and stroke, due to advancements in research and health care leading to the decline of mortality rates (Barnason et al., 2017; Mozaffarian et al., 2016). These individuals require assistance in managing their disease to increase lifespan and improve or maintain health related self-care and quality of life (QOL). The American Heart Association (AHA) projected in 2011 over 40% of the US population will be diagnosed with some type of CVD by the year 2030 (Khavjou, Phelps & Leib, 2016). Unfortunately, this percentage was achieved in 2015 with 41.5% of the US population diagnosed with CVD. Concerning is that by the year 2035 over 45% of the US population will be diagnosed with CVD (Khavjou et al., 2016). Thus, understanding the experiences of those living with CVD is important for promoting healthy behaviors and improving outcomes.

Cardiovascular disease contributes to disability. Approximately 45 million Americans have functional disabilities and heart disease, stroke, and high blood pressure are four of the 15 leading illnesses contributing to disabilities (Mozaffarian et al., 2016). Disabilities include difficulties with activities of daily living and limited ability in completing housework or employment. Secondary effects from stroke include physical limitations, alterations in cognitive functioning and self-care deficits resulting in role change or role limitations. Furthermore, symptoms associated with atrial fibrillation (AF), such as syncope, fatigue, irregular heartbeats, palpitations and dyspnea (American Heart Association, 2017b) interfere with activities. For

example, these symptoms may interfere with an individual's ability to perform normal day-to-day self-care activities, such as bathing and dressing, in addition to participating in social events and performing physical activity, thus affecting QOL. Currently, CVD costs the US \$555 billion per year with costs expected to increase to \$1.1 trillion per year by 2035 (Khavjou et al., 2016). These costs include medical care as well as indirect costs related to lost productivity at work and home due to illness or injury. To understand self-care needs and to lower the disability costs for CVD, further investigation in the management of those with CVD is warranted.

Individuals experiencing infrequent and unpredictable cardiac symptoms with suspected cardiac arrhythmia, such as syncope and cryptogenic stroke, may undergo various diagnostic testing to determine the cause of their symptoms. The insertable cardiac monitor (ICM) is one of the latest devices in long-term cardiac monitoring. Some ICMs can remain implanted for up to three years, such as the Reveal LINQ™ ICM (Mittal et al., 2015). Another is designed to remain implanted for approximately four years, the Biotronik BioMonitor 2-AF® ICM (Lauschke et al., 2016). This long-term monitoring provides a greater chance of detecting and diagnosing an arrhythmia like AF (Miller et al., 2016). Due to the higher costs and the invasive procedure for insertion, ICMs are considered only after other diagnostic options have been exhausted.

Research supports use of ICMs for diagnosing cardiac arrhythmias and episodes of syncope (Paruchuri, Adhaduk, Garikipati, Steinberg & Mittal, 2011; Podoleanu et al., 2014; Shanmugam & Liew, 2012; Solbiati et al., 2016). Studies have shown a higher rate of diagnosis compared to the traditional methods of the Holter monitor and external loop recorders (Edvardsson et al., 2011). In fact, the diagnostic yield with an ICM in undiagnosed syncope is between 43 to 52% whereas non-invasive diagnostic testing has a yield between 6 to 20% (Kanters et al., 2016). Research studies focusing on the use of ICMs after cryptogenic stroke

have also had good results with detecting arrhythmias (Mittal et al., 2016; Ritter et al., 2013; Sanna et al., 2014). However, none of these studies have explored the perspective of the individual with an ICM.

Individuals with CVD and undiagnosed cardiac symptoms are at risk for injury and other poor outcomes, such as myocardial infarction and stroke, or those with cryptogenic stroke are at high risk for recurrent stroke. This study focused on those with an ICM because of undiagnosed cardiac symptoms, syncope, or cryptogenic stroke. Exploring the perception of individuals living with an ICM will help the clinician in understanding the needs of this population to improve their health outcomes and QOL. Therefore, the purpose of this study was to describe the experiences of those with undiagnosed cardiac symptoms or post-cryptogenic stroke living with an ICM.

### **Methods**

The research questions used to guide this qualitative descriptive study are: (a) What are the experiences of individuals who have chosen to have an ICM inserted?; (b) How do participants who have an ICM describe their health related self-care?; and (c) How do participants who have an ICM describe their QOL? Sampling criteria included adults who had an ICM inserted for at least two months, but not more than two years, without a diagnosis of cognitive impairment as noted in the medical record, and were English speaking.

### **Subject Recruitment**

Subjects were recruited from an electrophysiology lab in eastern North Carolina (NC). Individuals meeting the inclusion criteria for this study were contacted by telephone from an employee in the electrophysiology lab to ascertain their interest in being contacted by the principal investigator (PI). The study was described to each potential participant using a script to

maintain consistency with each call. When an individual declined to have their contact information shared with the PI, they were thanked for their time. Only those who consented to release personal information to the PI were contacted. At that time, individuals were informed of the incentive to participate in the study. The PI used a standardized script to explain the study, and determined a time, date and location for data collection if they agreed to participate. See Figure 1.

### **Setting**

It was important for individuals participating in this study to feel comfortable, safe and secure when being interviewed to encourage in depth communication; therefore, data collection took place in a naturalistic setting determined by each participant. Most individuals (92%) chose their home as the setting for data collection with only one participant (8%) choosing to meet at the local library. The PI secured a room at the local library for privacy.

### **Data Collection**

Data collection for this study began after Institutional Review Board (IRB) approval was obtained. At the beginning of each interview, the PI reviewed the study in its entirety and consent was obtained. Each interview was audio-recorded with interviews lasting 0.5 to 1.5 hours. Prior to the qualitative interviews, participants were asked to complete a demographic questionnaire to answer general questions about themselves such as age, educational level and comorbidities. In addition, participants completed the Patient Health Questionnaire – 8 (PHQ-8), a screening tool for depression (Kroenke et al., 2009), and the Generalized Anxiety Scale (GAD-7), a tool used to screen for anxiety (Spitzer, Kroenke, Williams & Lowe, 2006), to describe the sample. Both instruments, the PHQ-8 and GAD-7, have strong reliability, 0.82 and 0.92 respectively (Pressler, et al., 2011; Spitzer et al., 2006).

After completing the questionnaires, the PI used formal, semi-structured interviews to elicit vivid descriptions of participant experiences with an ICM. Each interview began with the broad opening statement, “Tell me about your health before having the ICM device inserted,” to allow participants to recall their health prior to device insertion. Probe questions/statements, such as “Some people say it gives them security to have the device and others say it makes them nervous, how does it make you feel?” and “Self-care are behaviors that you implement for yourself to maintain your life, health and well-being. How do you promote self-care?”, were used to elicit communication to answer the research questions and to gather rich data. At the completion of the interview, each participant received a \$20 gift card to thank them for their time.

### **Data Analyses**

Data from the demographic questionnaire, PHQ-8 and GAD-7 scales were analyzed using descriptive statistics. Each qualitative interview was transcribed verbatim. To ensure accuracy and reduce error with transcription, a cross-check of the audio recorded interviews to the transcripts was completed (Polit & Beck, 2012). In addition to using content analysis and constant comparison with data analyses, the PI also focused on intraparticipant analysis, interparticipant analysis and interrelationships (Morse & Field, 1995). Qualitative data analyses began with immersion into the data, intraparticipant analysis. To achieve this, the PI listened to each audio recording and read and reread the transcripts while reflecting on the data in their entirety for each research question. Sentences and phrases were highlighted in search of categories central to the overall experience of living with an ICM. After transcripts were read and reread, codes and categories were created. The codes and categories characterize the core of qualitative data analysis (Creswell, 2013). A codebook was created and refined to organize raw

interview data. In interparticipant analysis, the PI examined the transcripts for commonalities among participants to formulate full, rich description of their experience. Each transcript was analyzed and compared for both commonalities and differences. In the final phase, interrelationships, the relationship between categories and descriptions was analyzed. Common categories were grouped together in clusters and clusters with similar meanings were combined into global categories. Then, quotes were selected from the interviews that captured the description of the experience of the participants. To validate coding, a doctorally prepared second reviewer reviewed all coding decisions.

### **Trustworthiness and Integrity**

To maintain trustworthiness and integrity for this research study, the standards for trustworthiness as suggested by Lincoln and Guba were utilized (1985). Credibility was addressed through reflexive journaling throughout the data collection and analysis process. This was achieved through the audio recording of interviews along with verbatim transcription of each interview, continuation of recruiting subjects until data saturation was reached, and the creation of a codebook with data analysis. To manage dependability, an audit trail was established to include: the availability of field notes, transcribed interviews, and coded transcriptions. A list of probe questions was utilized with each interview to maintain stability and consistency. However, the researcher also maintained flexibility with issues or responses initiated by participants. To meet confirmability, the PI and colleagues reviewed the findings as data analyses evolved. Transcripts were coded for commonalities within each transcript and then compared among transcripts of all participants to enhance transferability (Lincoln & Guba, 1985; Munhall, 2012).

## Results

To understand the experiences of a diverse population and to ensure maximum variation sampling, participants of various races, genders and ages were recruited in addition to those with various types of ICMs. The sample ( $N = 12$ ) was comprised of Caucasian (75%), African American (17%), and Native American (8%) adults ranging in age from 41-95 ( $M = 66$ ;  $SD = 15$ ). The majority of participants were male (58%). Half of all participants received the ICM because of cryptogenic stroke (50%), nearly half received the device because of syncope (42%), and one participant received the device because of unpredictable AF (8%). The majority had the Medtronic Reveal LINQ™ ICM (58%), and the remaining participants had the Biotronik BioMonitor 2-AF® ICM (42%) with length of device insertion ranging from 2 to 22 months ( $M = 9.5$ ,  $SD = 7$ ) for the total sample. The majority had a high school education or less (67%), were married (58%) and retired (84%). Participants self-reported comorbidities included hyperlipidemia, hypertension and diabetes. See Table 1 for comorbidities. Two (17%) participants self-reported heart disease as a comorbidity. Eight (67%) participants reported a reduced ability to exercise. Five of 12 individuals scored mild to moderately severe on the depression scale. Two of 12 participants scored moderate to severe on the anxiety scale. Total scores for both scales are listed in Table 2. In this study, the PHQ-8 scale had a reliability of 0.93 and the GAD-7 scale had a reliability of 0.97.

While the experiences of those living with an ICM varied among participants, they also shared similarities. The analysis resulted in three global categories: (a) influences on self-care, (b) managing, and (c) monitoring. See Table 3 for clusters and examples of raw data.

## **Influences on Self-Care**

The first global category to emerge was influences on self-care. Self-care is intentional behaviors individuals implement for themselves to maintain life, health and well-being in collaboration with a healthcare clinician. Self-care can be viewed on a continuum beginning with the individual and ending with the clinician. Clusters of the individual's perception of health, symptoms experienced, and influence of the clinician affected intentional behaviors for self-care.

**Perception of health.** Perception of health is a comprehensive view of one's health status considering the presence of symptoms and any impairment in physical functioning related to disease or disability. Because self-care can be viewed on a continuum that begins with the individual, participants were asked what health meant to them and how they viewed their health perception.

When participants were asked to identify what health meant to them, an older female described the meaning of health: "Health means life. Health means being able to have a good quality of life to do things that you like to do. That's what it means to me and that's why I'm trying to do better than I did years ago." An older male participant stated:

Health to me, would be taking care of yourself to be able to have a better quality of life.

That if you can take care of yourself and stay in good health and do the right things, then it only makes you, hopefully, live longer and not suffer as much.

A younger female participant, with functional limitations after stroke, described the meaning of health to her as, "Being able to do what I want to do. Having the mobility, having my brain work right, and my body." Participants related health with functional ability and good QOL to continue to do things they enjoy.

Participants used the terms good ( $n = 9$ ), not good ( $n = 1$ ), or poor ( $n = 1$ ) when describing the perception of their overall health. One participant, a middle-aged female who experienced a stroke, never stated that her overall health was good, nor bad, but discussed the negative aspects with health due to functional limitations, such as ambulation and physical activity. One older man who has the ICM because of syncope described his perception of health as poor when he considered his multiple comorbidities, but he continued to remain positive about his overall health and physical abilities. He stated, “Well, from all the things I have wrong with me, I guess it would be poor, but I'm blessed that I'm still able to do all what I can do.” A younger male participant with the ICM because of syncope also described his health as “not so good.” A commonality shared between these individuals is either continued symptoms, such as palpitations and syncope, or functional limitations due to physical deficits experienced after stroke. These symptoms or limitations contributed to their inability to continue doing things they enjoyed. Although those reporting a good perception of health continued to experience symptoms, such as fatigue and weakness, these symptoms did not interfere with their ability to continue doing things they enjoyed.

**Symptoms experienced.** Symptoms can be identified as physical, cognitive or emotional in nature that vary from the normal self. A physical symptom can be objective or subjective and is a feeling experienced that is an alteration from a person's baseline state. A cognitive symptom is a limitation with memory or change in mental status that is different from the individual's normal state. Emotional symptoms are changes in feelings or mood of an individual usually associated with an event. All of these symptoms influence the self-care continuum.

Participants identified their physical symptoms experienced over the previous year such as weakness ( $n = 8$ ) and palpitations ( $n = 7$ ). The frequency of symptoms experienced by the overall sample is listed in Table 1. The majority ( $n = 9$ ) of the sample identified fatigue as a symptom experienced over the previous year. Participants described fatigue with completing activities that did not previously cause fatigue. Two male individuals described fatigue when cutting the grass. One of the males expressed, “I mean I go out there and cut grass and it’s hot, that just zaps me; I mean it just feels like it drains me of all my strength. I just can’t take it.” An older woman included, “I just give out” when describing her attempts to walk for physical activity, but she was able to walk two miles in 30 minutes prior to her stroke seven months before. An older male individual remarked, “I get tired quicker” referring to how he tires easily since a stroke two months ago. All participants receiving the ICM because of syncope reported fatigue and almost half of those receiving the device because of stroke reported fatigue. Half of those reporting fatigue have comorbidities of hypertension and stroke.

Participants described other physical symptoms such as loss of balance and palpitations. A female participant, post cryptogenic stroke, described balance issues when walking compared with herself prior to the stroke. She stated:

I still was active, but I'm not as steady on my feet as I was at one time, that's getting better but, my balance is not as good as it was at one time . . . It's not as bad, it's not that bad, but it, I can tell a difference in it. I have to be more careful when I walk.

A younger male participant who experienced syncopal episodes described his experience with heart palpitations and dizziness stating:

My heart will pound real hard once every 15 or 20 minutes or so. But it's a . . . I'll get a sudden pound and I'll feel it like a pressure spike. I feel a hit through my head behind my eyes and then I'll get . . . Just like someone hit me, I'll be all dizzy and just disoriented. He also described feeling “anxious” when his “heart races up”. A female participant who also had the device inserted because of syncope described her symptoms as, “I can feel it. I can feel, I go . . . I can't breathe, and I, you feel like you're gonna faint.” A middle-aged woman described physical symptoms she felt approximately two months after experiencing a first-time stroke.

I had noticed that I had a tingling on my right side of my body. And it was like a faint tingle. It wasn't anything major. But it was enough to where it made me aware, especially after having the stroke. . . . I thought, well you know what and I gonna do? I'm just gonna wait it out a little bit. And I'm just gonna kinda see if maybe if it's just me panicking. 'Cause I thought I might be panicking. . . . the later the night went, the more tingling I felt. And then, not only was it in my arm and in my face, I started feeling my tongue. That same tingling in my tongue. And I thought, oh my God, now I'm gonna have another stroke.

Participants also identified cognitive symptoms experienced over the previous year such as confusion ( $n = 4$ ) and forgetfulness ( $n = 2$ ). One older female participant described forgetfulness after experiencing a stroke and an older male with syncope also described forgetfulness. One participant described feeling depressed because of memory deficits after the stroke:

Have I gotten depressed over it, oh yeah, but the depression is not that I had the stroke, the depression is that I used to remember so much stuff and didn't have a problem

remembering names and dates and I have a hard time now. I mean, it's coming back but it's slow. That bothers me 'cause I never had that, to depend on somebody else to tell me a date for something or anything 'cause I knew it. I mean, I don't mean I was brilliant, but I was, I was sharp on that.

**Influence of clinician.** On the continuum of self-care, the clinician is on the opposite end from the individual. The clinician includes any healthcare professional working directly with the patient, such as the physician, nurse practitioner or nurse who can influence decisions or actions made by the patient for their health. Participants described the influence or lack of influence of the clinician on their self-care behaviors.

When asked about the information received from their clinician on self-care strategies to prevent another stroke, an older woman added, “I guess keep my blood pressure under control. That’s the main thing.” When asked if she was provided any information on diet and activity, she added, “Well, they didn’t really tell me.” Another participant who was post cryptogenic stroke stated, “No, not really” when asked if he received teaching about diet and exercise from a clinician. When asked if he knew how to prevent another stroke he stated, “No, I don’t know. I hope I don’t have one.” Another female participant described the limited information she received about continuing her routine workouts post stroke, stating:

I would. You know, I think, hindsight being 20/20, at this point, I wished I had asked more questions as far as the workouts, the activities, the pros and the cons, and the do’s and the don'ts, and if my heart's really gonna spit out another blood clot, you know, things like that. But then, I think, also, it's your heart. I'm on blood thinners. What's the best thing for your body? Workout. So why would I think that they wouldn't want me to? So, I try to look at both sides of the spectrum and I use my own judgment. I wish I had

[the conversation with the clinician] . . . I wished I had to have the conversation, probably, and I didn't. But, what am I gonna do now? It's already been three months. Of the five individuals in this study because of stroke, three reported limited to no detailed information on diet and exercise to prevent another stroke or to improve their health. Another female participant post cryptogenic stroke described the influence by her clinician on her positive attitude with self-care.

Cause he [primary physician] told me that I'd get that much of my memory back and I wouldn't stay like I am. And that gave me a lot of hope and determination that I was gonna do all I could to make that happen, to help it happen, so, and he said that staying active, exercising would help a lot, so that's, that's what I'm doing.

She walks every morning and stays active during the day.

A man with the device because of infrequent episodes of AF described his physician as being “very open-minded” and further stated “he listens to what I have to say” and “he encourages me.” This participant described his daily routine as very active, physically, and that he makes healthy choices when it comes to his diet and nutrition. Two other participants, one female and one male, both described their physician as one that “encourages” them with their self-care. A younger male participant with syncopal episodes and a history of AF remarked, “no caffeine 'cause my doctor said that's bad for the AFib”, when asked about self-care behaviors. The participants with syncope did not report specifically that their clinician provided them with educational information to promote self-care; however, most of them reported positive self-care behaviors and knowledge regarding a healthy diet, such as low salt.

## **Managing**

Managing, the second global category identified, is the ability to function in everyday life despite difficult experiences. Continuing to experience infrequent and undiagnosed cardiac symptoms or living with the effects from stroke affects daily life and activity. The clusters living with loss, faith, and support system comprised this global category.

**Living with loss.** Participants described experiences that altered their normal state, resulting in a loss of physical function or cognitive ability. A female participant post stroke added, "I'm not as strong as I used to be . . . Like getting off a lid, I'm not as strong. Lifting up things, not as strong." She continued, "I think when I went to [clinician] before, he really let me push on his hands and I don't think he thought that was strong enough." An older man remarked, "I probably ain't been walking in so long it would probably wear me out right now." A middle-aged female participant provided details in the loss she has experienced because of physical deficits post stroke:

I was very active. I used to could cook and clean. I used to do everything that I can't do no more. I don't exercise as much as I used to either. I used to do sit ups, push-ups, and walk a lot.

When asked if she stopped doing those things because of limited physical ability she said, "I can't. I don't feel like I can. I think if I walked around the block, I might stumble and fall."

Another female participant who also experienced a stroke resulting in memory loss stated, "It bothers me to know that I don't know something that I used to know and it bothers me that I have to ask somebody else something about it when before I did not. It kinda makes you feel inadequate." She also described how the loss of memory left her feeling dependent on others

stating, “That bothers me because I've never been that type of person, knowing that I have to be dependent.”

Half of all participants described a loss of driving or driving independently because of syncope or deficits after stroke. An older woman post stroke said that she has not driven in nine months and described her dislike with depending on others for transportation. A middle-aged woman no longer able to drive remarked, “I got to rely on people to help me, to take me places and I hate it. I hate it. Cause I'm used to getting going where I want to go. I was just always independent.” An older man with syncope described his experience with the loss of driving: “My 95th birthday my license expired and I didn't want to go up there and try to get them. They tell me if the state knew about me falling out, I'd have to retire my license until I got straight.” He described his dependence on his children for transportation.

An older woman and an older man post stroke described their ability to drive in their small community, but an inability to drive long distances. A man experiencing syncopal episodes described the loss of security he feels when driving long distances. He said, “Most of the time if I go somewhere I want somebody to be with me, riding with me, or . . . I don't go out of town anyway unless I have somebody else that can drive with me.”

In addition to living with the losses of physical function, cognitive ability and driving, participants also described their losses with hobbies or things they enjoyed. Two older men with syncope described the loss of gardening. One of the men described how gardening was a lot of work, but how he missed it. The other man described how he managed by adapting his gardening skills to deal with his loss of function:

I don't plant anything in the ground anymore. I put my flowers in pots and I get some flower boxes on my front porch, I have raisings, and I tend to my flowers and stuff like, that way I won't have to get out and do a lot of digging.

He spoke about how his garden was smaller than in previous years, but how he continued to enjoy working with flowers. A middle-aged woman described a desire to attend sporting events as she did prior to a stroke, but was unable to due to her limited ability to ambulate. An older man with syncope described the loss of participating in hobbies he enjoyed:

I do woodworking just for a hobby more or less. And I just enjoy that shop [building in backyard], but my machinery is breaking down, and the electric drill give out and won't charge, and about half of everything out there worn out, needs to be thrown away, and I'm just shut down. I can't follow my hobbies . . . and I'm just here on shut down.

Most participants were retired and were no longer working prior to their event leading to ICM insertion. Two of the younger participants were forced to quit their job because of continued cardiac symptoms or stroke. A younger man with syncope and cardiac symptoms described how his inability to continue with his job made him feel inadequate in providing for his family.

I think a lot of it is frustration because . . . I've always been the breadwinner. I've always been the one to do the providing. I've worked my whole life since I was, well before 15. . . It started to get to the point where I couldn't work, I couldn't do my day-to-day stuff and I needed help doing things and then, well, it's like if I can't work and I can't take care of people and I can't do what I normally do, what's the point? Because now I'm being, I'm just here being taken care of.

Two participants described their loss in the ability to perform activities as they did previously, but they also spoke about how the loss affected them from a cultural perspective. A middle-aged woman described the loss she has experienced with the inability to comb her hair: “With my hands, it affected me, how I do my hair and I can’t comb it like I used to. I have to have someone else come over and comb it for me.” She described the ability to comb her hair as something she did with pride because hair care is an influential aspect of her culture. A younger man described his loss with the ability to go hunting:

I’m not able to do a lot of the things that make me happy that I find that I enjoy. I used to hunt a lot. I like to hunt but I can’t, I can’t go walking through the woods for half a mile any more. I get too winded . . . So a lot of the stuff I could do, I can’t now. And that does wear on me.

He spoke about hunting from a cultural aspect. “I don’t look at it as just killing an animal. The animal is giving you the ultimate sacrifice so that you can live. . . I actually get a little foggy-eyed thinking about it.”

**Faith.** Half of all participants ( $n = 6$ ) described faith in God as a strength when managing their emotional health. A woman included, “It gives me something to do. Like tomorrow night, we go to Bible study and we study the Word of God so that just empowers me to just do something and it gives me something to do.” She described this as giving her something to look forward to weekly. Some described how their faith in God contributed to less worry. One man described how his experience from a previous heart attack changed his outlook on life, contributing to his lack of worry about future health problems:

That’s the reason I said if the Lord don’t need me, then leave me here, but if He needs me I’m ready to go. And you know when I first had my heart attack and got out of the

hospital, it used to worry me and I told my wife one day, you know this used to worry me and I ain't going to worry about it no more and I ain't.

Another woman described the influence faith has on her life and how less worry allowed her to have a positive outlook.

I don't worry anything like I used to. . . . I mean, it is what it is and you make the best of it and that's not how I felt years ago, but I keep going back to the year 2000 . . . . We got a new minister and he came over and asked us to come back to church and we did and he started teaching Sunday school and, we just started going and everything changed. My whole life changed. My attitude about things changed. We were very active, more positive, and so I don't worry about things anymore because things I worried about I had no control over anyway. Why was I sitting and keep worrying on stuff that made me eat so much? I'd get so depressed. That's what caused me to eat so much and now I don't feel that, I don't feel depressed . . . . I feel like the Lord is gonna take care of me.

**Support system.** A support system is someone who provides support, both physical and emotional, to another person. Participants described their support system as an important part of managing their symptoms and functional limitations. In fact, this support was viewed as positive push. An older woman shared how her husband acts as her main support person.

That's why I walk. He pushes me. I get up early now, he's in bed sleeping, but I walk. I come back, take a shower and then I come, go to the cafe and he'll come in there and meet me or whatever, but if it wasn't for him, I probably wouldn't go walk in the mornings. I'm being really honest. He makes me want to do the stuff I do so I keep myself very busy, very active and I try to stay very positive because he does. And I

probably wouldn't be in as good a shape as I am right now and gotten along as well as I have if it hadn't been for him. He's a very good support system.

Support by participants was provided by different people, not necessarily from a spouse or significant other. A male participant, who is unmarried, described how his grandson supports him.

I have a grandson . . . And we'll go out to the park when it cools down and I'll walk.

We've got a place behind the hospital and I'll walk at least, one or two laps with him. He's my push person.

This same man discussed how his children push him to take better care of himself. He stated, "My support group pushes me." A married male described his wife as, "Very helpful. She's actually been the one that pushes me in the right direction."

Another unmarried man described how his brother plays a significant role in how he manages his life, but from the perspective of learning from his brother's poor health.

My brother . . . Is a very big influence on the reason why I do what I do because he doesn't take care of himself the way he should. So, it gives me more incentive to make sure I take care of myself because someday I may have to take care of him.

He is a caregiver to his brother and described their close relationship. He also discussed how his brother's poor health acts as his motivation because he wants to maintain a healthy lifestyle.

## **Monitoring**

The third global category to emerge from the data analyses is monitoring. Those that have an ICM are monitored from a remote location for alterations in heart rate or rhythm. Three

clusters comprise this global category including: (a) security, (b) knowing, and (c) communication. All participants ( $N = 12$ ) were monitored by the same electrophysiology lab.

**Security.** Security is feeling safe and free of worry when relying on someone or something. Nine participants indicated the ICM offered them security. In addition to describing the device as offering security, a man replied:

I feel like physically it's there to make sure that everything is going all right with my heart . . . I feel like it's doing the job they said it would do. I feel like it's helping me to, if something were to go wrong, at least I would know . . . I guess mentally making me have that confidence, the reassurance that it's gonna pick up [alteration with heart causing symptoms] and let me be aware of what's going on.

Another male participant shared how the device provides security:

I would lean more to the security. Just that I know something is keeping track and I don't have to think about it . . . It does help that I know something is checking on me. And it's diagnosing me as I go. So that way, it's one last thing to worry about. It does give me that feeling like something is watching all the time, like 24/7 diagnostic.

An older male described the device as a safeguard stating, “Because that device, to me, is a safeguard to my health and if something drastically goes wrong, then I know that I'm being looked after because that device will tell them that something is not doing right.” Another man described the feeling of security he has with the device stating, “Yeah, I feel like if something's going wrong, they can tell me before I guess.” A woman added, “I mean it's assurance that it's there and they could pick up on it if there was something.”

A woman who has the device because of syncopal episodes described that the device itself does not offer her security. Another woman who had the device inserted because of stroke

indicated that she does not think about the device offering security: “It’s gonna do what it’s supposed to do . . . It’s in there, it’s like, it’s part of me and it doesn’t worry me.”

In addition to the security of the device, participants described feeling secure with the process of being monitored. An older man described his trust with the staff monitoring him. “I mean I trust them. I do what I’m supposed to do and I hope that they’re doing what they’re supposed to do.” Another participant described his confidence of being contacted if an abnormality was detected during the monitoring process: “But I feel like if it was something really bad, they would let me know. They would call me immediately, 'cause they said they monitor these things constantly.” A middle-aged woman offered, “If there’s a problem, they’ll call me.” Another man described his feeling of security with the recording of an event.

It definitely gives me security because that little thing right there [transmitter], if something happens drastically, I’m going to push it cause, only thing you do, is right here, you push that button and it instantaneous records what is happening that second. And boom, it gets downloaded.

Two female participants that did not describe the device offering security, did describe the process of monitoring as security.

**Knowing.** The ICM monitors heart rate and rhythm, but certain devices can also generate data such as, levels of physical activity over a 24-hour period. Knowing is understanding what data are generated and transferred from the ICM.

When participants were asked if they had any concerns with the information transmitted from their device, the majority ( $n = 7$ ) said no. When asked if they knew what information was transmitted, again, the majority ( $n = 7$ ) said no. For example, an older woman said, “I don’t know too much about it” and a man added, “I don’t know the whole list, but I know it’s just

basically, it's like where the EKG shows up.” When asked if he would be concerned to know that his levels of physical activity could be monitored, a male participant remarked, “Yeah, it would, but I’m comfortable the way it is . . . It wouldn’t be a problem.”

One man with device insertion for 10 months described the desire to know findings from his device. With prior experience in healthcare, he expressed a desire to know more about the information being transmitted. He revealed:

It would be nice to have something that you . . . you would have a little bit of education about it, but part of that is probably my curiosity of being in the medical field to have something that you can help track the results of what it’s doing.

**Communication.** Communication is the act of exchanging information between individuals. Those with an ICM are being monitored remotely, thus relying on communication from the individuals evaluating their reports for information concerning the data received from their ICM. Four participants stated, “No news is good news” when asked if they would like to receive communication from the electrophysiology lab staff. In addition to saying, “No news is good news,” a middle-aged woman post stroke with device insertion for two months stated, “I think, call me if there's a problem. And if I don't hear from you, I know that I don't have a problem. If I hear from you, that means, hey, we need to check you out.”

A woman with the device for six months added, “They’ve not ever called me so I don’t think it showed anything.” An older man with the device inserted for 13 months, stated, “I don’t know what good it’s doing . . . They ain’t told me nothing.” When this same man was asked if this device affects his mental well-being he said, “It hasn’t. Cause they haven’t called to tell me something was wrong.”

Another woman post cryptogenic stroke and device insertion for five months responded that she has not been contacted by the staff monitoring her device. When asked if she was informed of how and when they would contact her, she recalled, "They said something about us contacting them and I forgot how they do it. It's been so long so I just don't remember." When asked if she had any concerns with no contact she stated, "No, once, for a minute there, I was, because, I was thinking no one was monitoring me and I thought it [the device] was just here on my chest." An older man with the ICM inserted for 14 months because of syncopal episodes stated, "I think they would call me, wouldn't they? You reckon they would?" When asked if he would feel better if they called on a routine basis he said, "Every two months would be fine because it has been a long time since I've been in touch. If they let me know every two or three months we haven't experienced anything different . . . ." A 78-year-old female with device insertion for 22 months because of syncope remarked, "I don't think anybody's looking at it. That's why they're not finding anything. So, we've said that a number of times. You'd think that you'd hear something. Well, no news is good news, isn't it?" This participant had the device inserted the longest. She recalled communication occurring when she initially had the device inserted:

He'd [monitor technician] call me once a month and he'd say, "Everything looks fine. Do you need to come in? Do you think you need to come in?" I'd say, "No, I don't." So, and then we wondered why the calls stopped. And then they sent a letter . . . And, then they changed the whole thing, and that's when the calls stopped. And I said, I don't think anything's happening. I don't feel as if anything's happening.

Another female participant who is post cryptogenic stroke that has had the device for four months said, "So far, I haven't gotten any feedback from them on any problems." She went on to say:

I like it if they don't call because they're not finding anything. I mean, if they wanted to call once every six months to say, "You know, everything so far is A-okay," that's fine, but I feel as long as I don't hear from them, I feel like I'm doing okay . . . So that's like a security blanket too, you know. But you know what? I can live with however they want to do it, they're the doctors, they probably know what's best and I can live with that. So, I don't worry. I used to worry all the time. I don't worry anymore.

A man with the device for four months because of syncope described a desire for more communication by the electrophysiology lab staff.

I really would, if it was just once in a while, you know, once a month even. You know, just to let me know, okay, things are looking fine . . . But, you know, I'm not pressured on doing that. But like the other day when everything happened, I knew I could call then. He described calling in to the clinic because of pain to his arm and feeling reassured because he was called back promptly. Another male participant also discussed a desire to hear from the staff.

They look at the data every single day. It downloads it during the night. They look at it. They log it and unless there is something that looks weird or something, with the EKGs and everything they gets downloaded, then I never hear anything. I've not heard from them since day one.

He continued:

The one thing I would like to see, I would like to see some kind of report that at least they would send to their patients periodically just to have information. I mean, I've been 10 months and I haven't had a single phone call and don't know anything other than when I go to the doctor every six months to tell me what it's doing. You know, them . . . you are being monitored every . . . every single day. . . Well, some form of feedback occasionally from it.

All participants reported keeping their scheduled appointments, but also reported limited communication with the electrophysiology lab staff outside of scheduled appointments.

### **Discussion**

Prior studies with ICMs have focused on diagnostic results, but understanding the perspective of those with these devices is important in managing outcomes for those experiencing undiagnosed cardiac symptoms and cryptogenic stroke. With the prevalence of AF expected to increase significantly over the next decade, it is important to understand the experiences of those with an ICM and how remote monitoring can assist individuals in managing their overall health. This study explored the experiences of those with an ICM to gain insight into influences on self-care and QOL.

In this study, participants generally described their health as good. The participants described their perception of health in comments equating health to life, doing the right things and caring for ones' self. Their perception of health was also related to quality of life and their ability to continue doing things they enjoyed even with continued symptoms or physical limitation. The individual's ability to adapt to symptoms or limitations is a factor in their overall perceived health. Similar associations were found in a study in those with AF (Blum et al., 2017). This study focused on the differences between men and women on symptom experienced

and health perception and they found that women with higher symptom burden reported lower health perception than men.

Participants reported symptoms of anxiety, depression, fatigue, palpitations and shortness of breath. These are consistent with those experienced by others prior to diagnosis of AF (McCabe, Chamberlain, Rhudy & DeVon, 2016) and those with known AF (AHA, 2017b; McCabe, Schumacher & Barnason, 2011). These symptoms interfered with an individual's ability to consistently perform normal day-to-day activities, mobility and participating in social events, thus influencing self-care. Depression affects individuals for a variety of reasons including: decreased activity, fatigue, isolation, withdrawal from social events, and lack of self-care management (Moya et al., 2009; National Institute of Mental Health, 2016). More importantly, it can diminish QOL (Moya et al., 2009). Depression is a common condition reported in individuals with CVD (Mills et al., 2015). In this study, those with physical deficits post stroke and individuals continuing to experience cardiac symptoms reported mild to moderate depression. Uncertainty in illness can negatively influence mental health leading to depression, which may impair QOL, thus effecting self-care. Understanding how depression influences self-care for individuals with an ICM will assist health care clinicians with tailoring interventions to meet the psychological needs of this population.

The majority of the participants in this study reported fatigue as a symptom. This is significant because half of the sample also reported a reduced ability to exercise. Physical activity is an important aspect in self-care management and reducing the risk of CVD. Having multiple chronic conditions (Koopmans & Lamers, 2000) and older age (Liao & Ferrell, 2000) have been associated with increased fatigue. The mean age of this study was 66 and participants self-reported multiple comorbidities including hypertension, diabetes, stroke, AF, and

myocardial infarction. Both age and the presence of comorbidities may have contributed to fatigue in this population. Fatigue may also influence depression (Crane, Efirid & Abel, 2016). Therefore, further evaluation of fatigue and depression in those living with ICMs is warranted to address interventions to alleviate these symptoms. Studies evaluating routine assessment of fatigue and depression in individuals with infrequent cardiac symptoms and cryptogenic stroke may improve self-care management.

Influence by the clinician is a vital contribution on the self-care continuum. Educating the individual is an important role for the health care clinician, especially for the nurse (Dickson & Riegel, 2009). The health care clinician plays a vital role in ensuring individuals are knowledgeable about their symptoms and disease process, such as AF, (McCabe, Rhudy & DeVon, 2014) and prevention of further illness (Barnason et al., 2017). Information provided by the clinician is essential in ensuring individuals have the knowledge to promote self-care and manage their health outcomes. In a study by McCabe, Schad, Hampton and Holland (2008), researchers found that educational information provided during hospitalization was not retained two weeks post discharge. Individuals in this study were at least two months post hospital discharge for their event. The individuals in this research study continued to experience cardiac symptoms after ICM insertion. Individuals experiencing an alteration from their normal physical or mental self, such as those experiencing infrequent and unpredictable cardiac symptoms, often require recurrent or repeated educational sessions to retain information and implement positive health behaviors.

Up to one-third of individuals who experience a stroke also experience cognitive impairment (Eskes et al., 2015). Two participants in this study described forgetfulness as a symptom experienced further demonstrating the need for repeated teaching. Participants

described education sessions with clinicians as lacking specific information, such as the level of physical activity they can resume post stroke and ways to prevent future stroke. Managing health outcomes is important for this population because of their increased risk of stroke and heart failure and the costs associated with these chronic health conditions. Interventions should focus on continued teaching of the disease process at each encounter with the clinician, assessment in the ability of the individual to complete self-care activities and achievement of individualized interventions to improve self-care.

Participants described loss because of unpredictable symptoms and cryptogenic stroke, and their ability to manage loss in this study. Spiritual wellness was an important factor in those living with loss. Half of all participants described faith in God as important to their emotional health. In addition, these individuals described less worry. In a study with a similar group of individuals, increased spiritual wellbeing was associated with decreased depressive symptoms (Mills et al., 2015). Future research is needed to determine the long-term influence of spiritual wellness on QOL in those with unpredictable cardiac symptoms and stroke.

Social support to push them to improve self-care was also important to participants in this study for living with loss and managing health. Participants relied on their significant other or identified support person to manage unpredictable symptoms, encouragement and assistance with functional limitations, such as driving. Findings in this study are consistent with another study, indicating a support person is important in their daily lives (Kang, 2011). They found that individuals with good social support experienced less uncertainty. In another study, those with perceived less social support reported lower overall QOL (Suenkeler, et al., 2002). Individuals in this research study with good social support described a good QOL. Future studies should not only focus on the individual living with an ICM, but also the influence of the support person on

the individual's QOL.

Use of ICMs to capture potential arrhythmias and diagnose events can assist those with cardiac symptoms and cryptogenic stroke to seek treatment and improve outcomes related to CVD. The vast majority of the individuals in this study described the device as offering security. With only one participant describing the device as not offering security. This participant had the device for 22 months without a diagnosis explaining her symptoms. Findings from this study are consistent with findings from another study concerning remote monitoring (Ricci et al., 2010) that found 92% of their participants received a sense of security with the implanted device, implantable cardioverter defibrillator, or pacemaker. Security with an inserted monitoring device is important because of the length of time devices can remain implanted. Inserted devices that are monitored remotely may offer reassurance and decrease worry.

Although there was a sense of security, individuals in this study described limited communication from the electrophysiology lab staff in regard to findings from the device. Some found the lack of routine telephone calls reassuring because they felt this indicated the device was not detecting any abnormal information; no news is good news. Others described a desire for more frequent communication even if the communication was to inform them the device had not detected any abnormal rhythm. The individuals in this study do not see a clinician in the electrophysiology lab on a routine basis, but they did express a desire to hear from someone intermittently concerning the results from the device. This is consistent with findings from another study (Ricci et al., 2010), in which the contact by telephone with those being remotely monitored played an important role for participants. In another study, Petersen, Larsen, Nielsen, Kensing and Svenden (2012) noted patients wanted more feedback and communication on what their device was transmitting. Participants in our study did not know the type of data transmitted

from their device. Those with ICMs should receive scheduled contact from the monitoring lab. This communication would assist in maintaining clinician trust and offer reassurance. Future studies should address the amount and type of communication needed to offer reassurance for those with ICMs.

Additional studies are needed to examine the influence of the clinician on positive self-care management and outcomes for individuals living with an ICM. Having an open line of communication, trust and confidence in their health care clinician can decrease feelings of uncertainty about health outcomes and improve QOL. Finally, the role of the support person should be explored as the push for positive self-care.

### **Limitations**

This study was limited to one site in Eastern North Carolina and may not be transferrable to the general population. Another limitation is this study is based on the participant's perception and self-reporting of those perceptions. Therefore, participant responses may not be representative of those with undiagnosed cardiac symptoms and cryptogenic stroke.

### **Implications**

Studies are needed to determine the frequency and type of communication offered by the remote monitoring staff that offers reassurance to those with ICMs, keeping them informed of findings from their device. Future research evaluating the effects of fatigue on self-care in those with cardiac symptoms is important. Also, future studies should address the role of spiritual wellness on QOL in those with unpredictable cardiac symptoms and stroke. To promote positive health behaviors, it is essential to understand the psychological needs of those with ICMs and how psychological needs influence self-care. Finally, it is important for the clinician to utilize

every opportunity to teach about disease process and healthy behaviors that may decrease an individual's risk for development of chronic diseases, such as CVD.

### **Conclusion**

Understanding the experiences of those with an ICM, both the positive and negative influences on self-care, is important in identifying needs early in the disease trajectory. Health care clinicians need to be cognizant of the support needed by the individual, both in knowledge and support systems. This knowledge allows clinicians to develop targeted plans of care for these individuals in promoting healthy self-care behaviors and increasing QOL.

Figure 1

Flowchart of Subject Recruitment Process

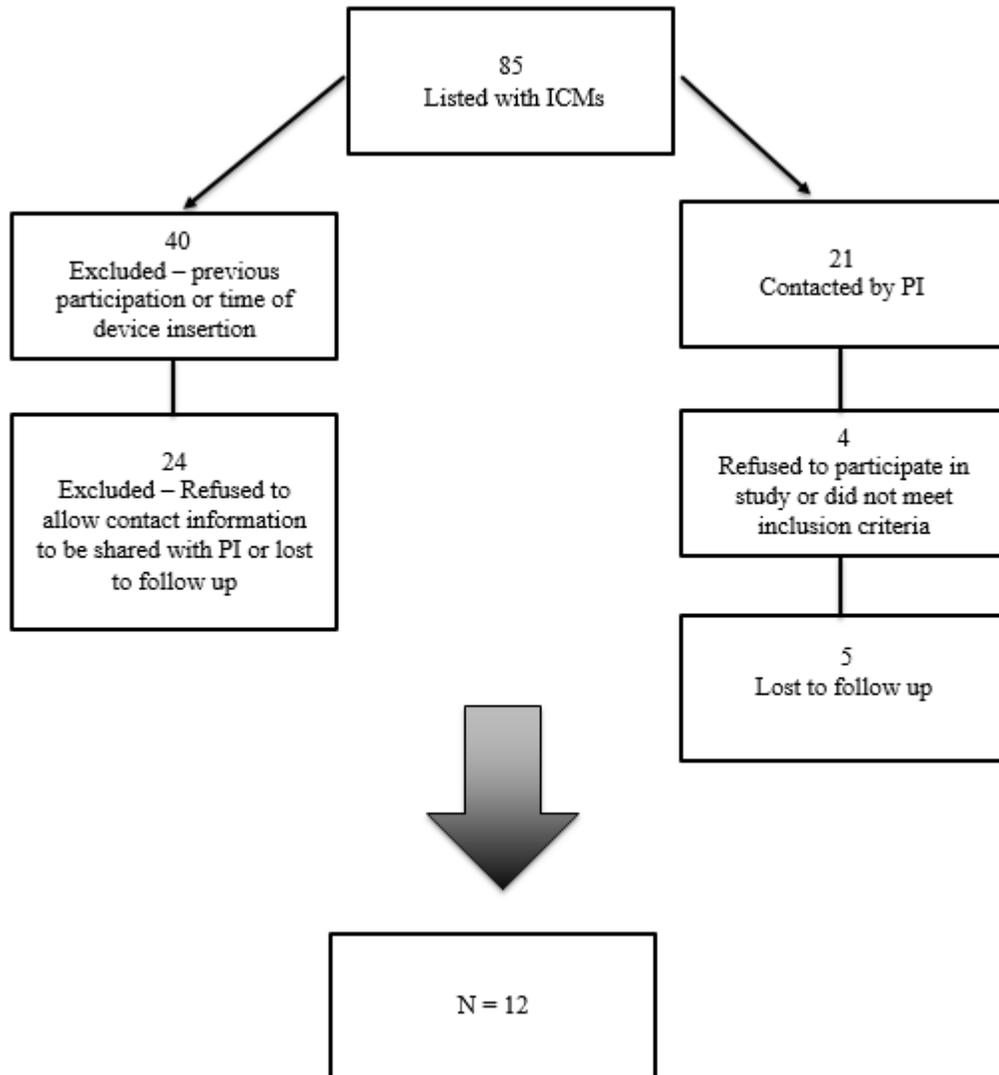


Table 1

*Comorbidities and Symptoms – Self-Reported (N = 12)*

	<i>N (%)</i>
<b>Comorbidities</b>	
Hyperlipidemia	8 (67)
Hypertension	7 (58)
Stroke	7 (58)
Diabetes Mellitus	4 (33)
Atrial fibrillation	2 (17)
Myocardial Infarction	2 (17)
Sleep apnea	2 (17)
<b>Symptoms (over previous year)</b>	
Fatigue	9 (75)
Weakness	8 (67)
Palpitations	7 (58)
Shortness of breath	7 (58)
Dizziness	5 (42)
Lightheaded	5 (42)
Chest pain	5 (42)
Confusion	4 (33)
Fainting	4 (33)
Near fainting	3 (25)
Forgetfulness	2 (17)

Table 2

*PHQ-8 Total Score and GAD-7 Total Score (N = 12)*

<i>Depression and Anxiety Screening Tools</i>	<i>Total Score N (%)</i>
<i>PHQ-8: Total Score/Depression Severity</i>	
0-4 = none to minimal	7 (58)
5-9 mild	2 (17)
10-14 = moderate	1 (8)
15-19 = moderately severe	2 (17)
20-24 = severe	N/A
<i>GAD-7: Total Score/Anxiety Severity</i>	
0-5 = mild anxiety	10 (83)
6-10 = moderate anxiety	1 (8)
11-15 = moderately severe anxiety	N/A
16-20 = severe anxiety	1 (8)

Table 3

*Data Analyses – Living with an ICM*

Global Categories	Clusters	Initial Raw Data
Influences on Self-Care	Perception of Health	Good; not so good; poor; healthy; taking care of yourself; able to have a good quality of life
	Symptoms Experienced	I just give out; my heart races up and skips; over anxious; I can't breathe; my heart starts beating real fast; I get tired
	Influence of Clinician	They didn't really tell me; I'll do whatever the doctors tell me and ask me to do; I wish I had the conversation; listens to what I have to say; encourages me
Managing	Living with loss	I quit gardening; can't work; I was driving until the end; I can't follow my hobbies; I was just always independent
	Faith	Study the Word of God; empowers me; the Lord is gonna take care of me
	Support system	He pushes me; you've got to have the right support system; pushes me in the right direction; my push person
Monitoring	Security	Sense of security; it's gonna do what it's supposed to do; it's a part of me; 24/7 diagnostic; safeguard to my health; it's there to make sure that everything is going all right with my heart
	Knowing	I don't know too much about it; I know just basic; Nice to have a little education about it
	Communication	No news is good news; they've not ever called me; they ain't told me nothing; if I don't hear, I know nothing is wrong

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APPENDIX A: IRB APPROVAL LETTER



EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board Office
4N-70 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office 252-744-2914 · Fax 252-744-2284 · www.ecu.edu/ORIC/irb

Notification of Amendment Approval

From: Social/Behavioral IRB
To: Aprel Ventura
CC: Patricia Crane
Date: 7/11/2017
Re: Ame3 UMCIRB 16-000222
UMCIRB 16-000222
ICM Individual Perspectives

Your Amendment has been reviewed and approved using expedited review for the period of 7/11/2017 to 3/6/2018. It was the determination of the UMCIRB Chairperson (or designee) that this revision does not impact the overall risk/benefit ratio of the study and is appropriate for the population and procedures proposed.

Please note that any further changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. A continuing or final review must be submitted to the UMCIRB prior to the date of study expiration. The investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

Table with 2 columns: Document, Description. Row 1: Aprel Ventura - Dissertation Proposal (0.02), Study Protocol or Grant Application

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

APPENDIX B: SCRIPT FOR EMPLOYEE IN THE ELECTROPHYSIOLOGY LAB

**Title of Research Study: Exploring individual perspectives with an Insertable Cardiac Monitor**

Script for employee in the Electrophysiology Lab

Hello, my name is \_\_\_\_\_, and I am a \_\_\_\_\_ working in the Electrophysiology Lab. There is a study going on exploring how a person decides to have an insertable cardiac monitor and to explore experiences they have had with the device. In this study a nurse would interview you. This study would only take about 1 hour of your time. You will be asked questions about your cardiac monitoring device. This study will better help us to take better care of people with this device.

Are you interested in speaking with someone about this research study?

Yes \_\_\_\_\_

No \_\_\_\_\_ (if no, thank them for their time)

If yes,

Ask if you may share their name and telephone number with the nurse working on the study. The nurse will call you to give you more information about the study.

To thank you for your time, you will be given a \$20 Walmart gift card.

APPENDIX C: DEMOGRAPHIC QUESTIONNAIRE

**Title of Research Study: Exploring Individual Perspectives with an Insertable Cardiac Monitor**

*Page 1 of 3*

**Demographic Questionnaire**

Participant # \_\_\_\_\_

1. Length of time (in months) device has been inserted \_\_\_\_\_ months
2. What is your type of device? Circle your response
  - (0) Medtronic REVEAL™ LINQ
  - (1) Biotronik
  - (2) Other \_\_\_\_\_
3. What is your current age? \_\_\_\_\_
4. What is your gender? Circle your response
  - (0) Male            (1) Female            (2) Other \_\_\_\_\_
5. How would you classify yourself? Circle your response
  - (1) White or Caucasian
  - (2) Black or African American
  - (3) Hispanic or Latino
  - (4) Asian
  - (5) Pacific Islander
  - (6) Native American
  - (7) Multiracial
  - Other (please write in your response) \_\_\_\_\_
6. What is your highest level of education completed? Circle your response
  - (1) Less than High School
  - (2) High School Graduate
  - (3) Some College
  - (4) Associate Degree
  - (5) Bachelor Degree
  - (6) Master's Degree
  - (7) Doctoral Degree
7. How would you describe yourself?
  - (0) Employed Full-time
  - (1) Employed Part-time
  - (2) Unemployed
  - (3) Retired

**Demographic Questionnaire**

8. How would you describe yourself? Circle your response

- (1) Single
- (2) Married
- (3) Divorced
- (4) Widowed
- (5) Cohabitate

9. What symptoms have you experienced?

Symptoms	Never	Over the last 2 weeks	Over the last 3 months	Over the last 3 to 6 months	Over the last 6 to 12 months
(0) No symptoms					
(1) Palpitations					
(2) Weakness					
(3) Reduced ability to exercise					
(4) Dizziness					
(5) Lightheadedness					
(6) Confusion					
(7) Fainting					
(8) Near fainting					
(9) Fatigue/tiredness					
(10) Shortness of breath					
(11) Chest pain					
(12) Other _____					
(12) Other _____					
(12) Other _____					
(12) Other _____					

**Demographic Questionnaire**

Participant # \_\_\_\_\_

10. Medical Diagnoses (List all medical diagnoses)

11. Medications (List all medicines you are currently taking)

APPENDIX D: PATIENT HEALTH QUESTIONNAIRE – 8 (PHQ-8)

**Title of Research Study: Exploring individual perspectives with an Insertable Cardiac Monitor**

Participant # \_\_\_\_\_

**Patient Health Questionnaire – 8 (PHQ-8)**

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
	+	+	+	
<i>Add the score for each column</i>				
Total Score ( <i>add your column scores</i> ) =				

Total Score/Depression Severity: **0-4 = none to minimal, 5-9 mild, 10-14 = moderate, 15-19 = moderately severe, 20-24 = severe**

A score of 10 or greater is considered major depression, 20 or more is severe major depression.

Retrieved from Stanford Patient Education Research Center. Reproduced with permission.

APPENDIX E: GENERALIZED ANXIETY DISORDER 7-ITEM (GAD-7) SCALE

**Title of Research Study: Exploring individual perspectives with an Insertable Cardiac Monitor**

Participant # \_\_\_\_\_

Generalized Anxiety Disorder 7-item (GAD-7) scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
<i>Add the score for each column</i>	+	+	+	
Total Score ( <i>add your column scores</i> ) =				

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all \_\_\_\_\_  
 Somewhat difficult \_\_\_\_\_  
 Very difficult \_\_\_\_\_  
 Extremely difficult \_\_\_\_\_

Total Score/Anxiety Severity: **0-5 = mild anxiety**, **6-10 = moderate anxiety**,  
**11-15 = moderately severe anxiety** and **16-20 = severe anxiety**

Source: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. *Arch Intern Med.* 2006;166:1092-1097.

## APPENDIX F: QUALITATIVE INTERVIEW PROBE STATEMENTS/QUESTIONS

### **Title of Research Study: Exploring individual perspectives with an Insertable Cardiac Monitor**

#### **Qualitative Interview Probe Statements/Questions:**

The grand tour statement for this research study is: *Tell me about your health before getting the ICM device.* If participants request additional instruction on what is meant by the opening statement, the researcher will ask: *What symptoms were you experiencing before getting the ICM device put in?*

#### **RQ 1: What are the experiences of individuals who have chosen to have an Insertable Cardiac Monitor (ICM) inserted?**

- What was the length of time from when you experienced the initial symptoms to the time you sought treatment?
- Has your clinician discussed a potential diagnosis with you?
- Tell me what you understand about your disease.
- What are the reasons for you to get this implanted device?
- How has uncertainty played a role in your choice to get this device implanted?
- What were the things that you considered before choosing to receive the implanted device?
- What other treatments did you experience prior to having this device implanted?
- How would you describe your satisfaction with remote monitoring of your heart?
- What are your expectations for having an implanted device?
- How has your life changed or been different since the device?
- How many times have you gone to the emergency department because of symptoms?
- What symptoms have you experienced since the device was implanted?
- How does your significant other influence decisions about how you take care of yourself (both helpful and nonhelpful)?
- How does your healthcare provider influence decisions about how you take care of yourself (both helpful and nonhelpful)?
- Some people say it gives them security to have the device and others say it makes them nervous, how does it make you feel?
- What are your concerns with the information that is transmitted from your device?
- What were your influences (for or against) when considering an implanted device?
- What instructions did you receive concerning the device and monitoring with the device?
- What has been your personal economic impact to having this device?
- What is your opinion about the cost of the device verses your perceived benefit?
- Thinking back to before you had the device implanted and up until this current time, what would have been helpful for you to know that you didn't know then?
- Is there anything that you would like to share about your health and your device that we haven't already discussed?
- If you had the opportunity to speak to others getting this device, what would you say?

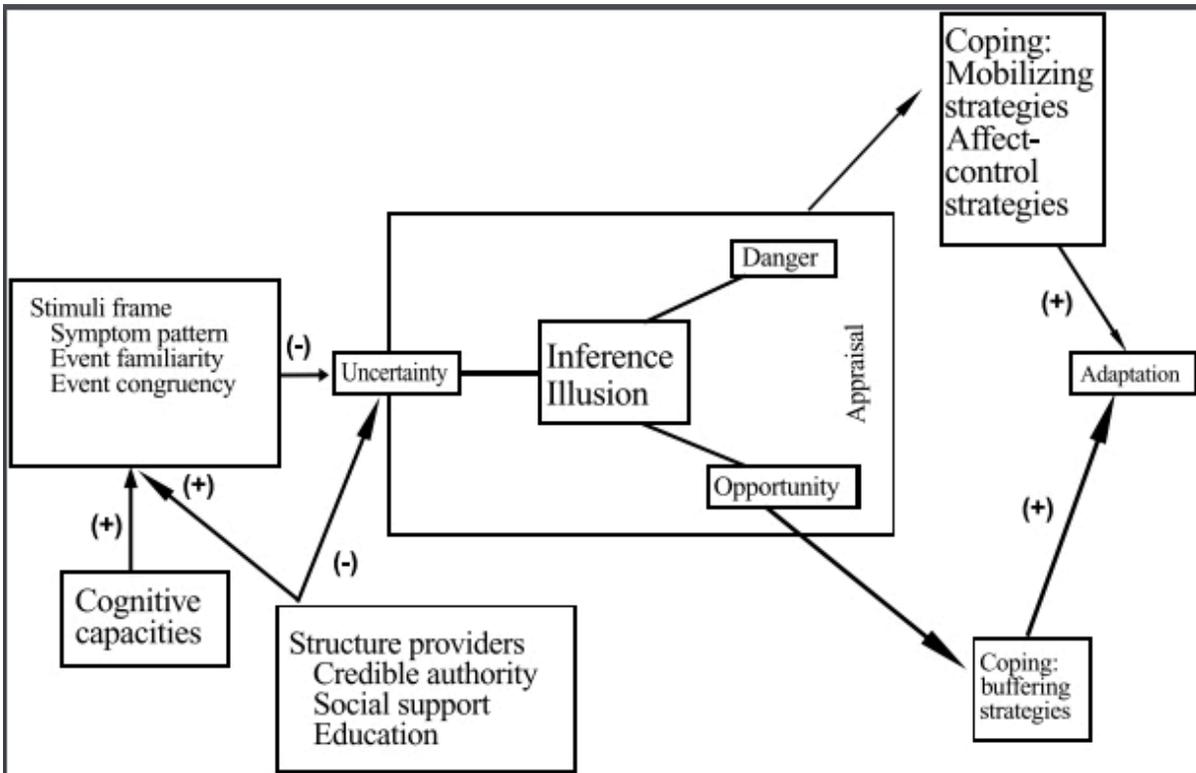
**RQ 2: How do participants who have an Insertable Cardiac Monitor (ICM) describe their health-related self-care?**

- Health has been defined as a state of complete physical, mental and social well-being and not just the absence of disease. What does health mean to you?
- How would you describe your overall health? Has this changed since having the device inserted?
- Self-care are behaviors that you implement for yourself to maintain your life, health and well-being. How do you promote self-care?
- How have these symptoms influenced your ability to care for yourself physically, mentally and emotionally?
- How has uncertainty played a role in your self-care?
- What else do you need to help with managing your care?

**RQ 3: How do participants who have an Insertable Cardiac Monitor (ICM) describe their QOL?**

- How have the symptoms you have experienced affected your QOL?
- What are the limitations with your health that decrease or affect your satisfaction with your overall well-being?
- What are the strengths with your health that increase or affect your satisfaction with your overall well-being?
- How does this device affect your physical well-being?
- How does this device affect your mental well-being?
- How does this device affect your emotional well-being?
- How have these symptoms affected your quality of life?
- How has uncertainty affected your QOL?
- How would you describe your quality of life prior to getting the device-inserted verses now having the device?
- How does your healthcare provider influence your overall QOL?

APPENDIX G: MISHEL'S MODEL OF PERCEIVED UNCERTAINTY IN ILLNESS



APPENDIX H: JURGENS' INTEGRATION OF THE COGNITIVE AND PHYSICAL SYMPTOM EXPERIENCE OF SELF-CARE

