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The Creation of a Pacemaker Clinic at a Federally-Funded Patient-Centered Medical Home: A Quality Improvement Project

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Abstract

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MSN, Washburn University, 2008

BSN, Fort Hays State University, 1990

Project Submitted in Partial Fulfillment

Of the Requirements for the Degree of

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Abstract

It is common for clinicians to implant medical devices, such as permanent pacemakers and implantable defibrillators, for cardiac diseases. These medical devices require follow-up care at regular intervals to ensure proper device function and optimal outcomes. Currently, many individuals without insurance or financial resources lack access to recommended follow-up care after implantation of a cardiac device. The purpose of this project was to determine the number of individuals who have had a medical device implanted without insurance coverage over a 3-year period, and then to establish a clinic that provides this service. The standard of care and operating procedure for the pacemaker clinic was established using evidence-based guidelines from the Heart Rhythm Society and the American Heart Association. Complexity science was the theoretical model used to guide this project's design and implementation. This quality improvement initiative was non-experimental, descriptive, and quantitative. Data were extracted from the ICD Registry and United States Census Bureau to determine the number of residents, insurance status, and number of implants over a 3-year period. These data were used to estimate the number of individuals with devices. The data revealed that 40 individuals with low power cardiac devices and 15 individuals with high power devices lacked access to care. The model developed estimates a growth rate of 7 to 10% annually. The pacemaker clinic will provide access to over 70 individuals lacking care for their pacemakers, thereby resulting in improved healthcare outcomes, fewer preventable complications, and optimal device performance.

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Section 1: The Pacemaker Clinic

Introduction

Since the 1950s, use of cardiac implantable electronic devices (CIEDs) has gained acceptance in the cardiology discipline as routine therapy. CIEDs are the standard of care for many cardiac diseases, including sick sinus syndrome and advanced atrial-nodal heart block, as well the standard of care as primary or secondary prevention for sudden cardiac death (Modi, Krahn, & Yee, 2011). Technology has advanced rapidly over the past 20 years, allowing for dramatic reductions in mortality and morbidity for individuals with chronic cardiac conditions; technology evolved to include defibrillators for the treatment and prevention of sudden cardiac death (Crozier & Smith, 2012). Cardiac resynchronization provided hope and extended the lives of countless individuals with systolic heart failure and other cardiac pacing problems (Modi et al., 2011).

The increased use of CIEDs decreased hospital readmissions for heart failure, thus providing a financial incentive for their adoption (Noyes et al., 2013). This advanced therapy has helped control health care cost and promote population health. In addition, technological advances in the microprocessor industry resulted in cardiac devices with expanded memory, giving clinicians the information they need to improve patient care.

Expenditures for hospital implantable medical devices increased from $16.1 billion in 2004 to $19.8 billion in 2009 (U.S. Government Accountability Office, 2012). The implantable device market is growing at a rate comparable to Medicare and represents a significant portion of total Medicare expenditures (U.S. Government Accountability Office, 2012). The government payer, the Centers for Medicare, and Medicare Services (CMS) benefit when CIEDs are monitored after implantation, as

monitoring reduces the number of unnecessary hospital admissions (Abraham & Hayes, 2003).

Problem Statement

The standard of care requires regular monitoring of CIEDs with in-office programming or remote follow-up at regular intervals, as recommended by the Heart Rhythm Society (Tracy et al., 2012; Wilkoff et al., 2008). However, in some locations, including the area in which this project was conducted, cardiology practices only provide care for individuals who can pay or have insurance coverage (J. Wesco, personal communication, March 23, 2014). This policy creates a lack of critical access to care. Many individuals who received CIEDs urgently through the emergency room or who lost insurance coverage after implantation cannot obtain the recommended follow-up care, which often leads to severe complications (Ramsdale & Rao, 2012).

Individuals with high-voltage devices are at greater risk of experiencing complications from inappropriate shocks from their device, thereby raising mortality rates by up to 30% (van Rees et al., 2011). The exact cause of the increase in mortality is not fully understood, but inappropriate events, such as receiving an unnecessary shock, occur more frequently when follow-up care is lacking (Kleemann et al., 2012). Complications related to CIEDs are largely avoidable with proper follow-up and care (Kleemann et al., 2012).

The Heart Rhythm Society recommends regular follow-up for individuals who have an implantable device (Wilkoff et al., 2008). Most recipients of a pacemaker should have the device interrogated (the process of acquiring data from the device with radiofrequency telemetry) at least every 6 months (Wilkoff et al., 2008). For high-voltage

single-chamber, dual-chamber, or bi-ventricular devices, the recommendation for follow-up care is every 3 months (Wilkoff et al., 2008). Face-to-face follow-up is essential to the overall well-being of individuals with implantable devices (Malm & Sandgren, 2014).

Gaps in specialized follow-up care are caused by a lack of financial resources allocated to individuals with implantable devices who lack private insurance or government aid (J. Wesco, personal communication, March 23, 2014). All of the cardiology services in the Kansas City metropolitan area are subsidiaries of hospital-based organizations. This organizational structure allows cardiology practices to function in a manner similar to a for-profit corporation, resulting in limited access to individuals who do not have the ability to pay for their care via third-party or direct reimbursement (J. Wesco, personal communication, March 23, 2014).

If an individual receives a CIED on an emergent basis, lacks insurance coverage, or moves into the area with an implantable device, there is no place to obtain needed follow-up care other than the emergency department (ED). This method is inefficient and prevents continuity of care. As a result, patients have poor outcomes.

Project Objectives

The primary goal of the pacemaker clinic at the Health Partnership Clinic is to provide care for all individuals with a CIED, regardless of their ability to pay. The goal of this project was to identify individuals with devices nearing elective replacement intervals before the device exhibits end-of-life behavior. Devices nearing the end of their useable life can trigger symptoms consistent with pre-implantation behavior, including syncope, chest pain, or in the case of pacemaker-dependent individuals, sudden cardiac death (Wilkoff et al., 2008).

Significance/Relevance to Practice

This change project originated in the ED of a local hospital after several encounters with patients (a) who had pacemakers with preventable complications due to lack of routine follow-up and (b) who lacked financial means or insurance coverage. In other cases, individuals received a CIED when they presented for urgent care or they received a device but did not receive follow-up care due to financial reasons.

The quality improvement plan for a pacemaker clinic was conceived after conversations with the chief executive officer of the Health Partnership Clinic (HPC). The HPC is a local clinic that provides services to individuals who have limited or no ability to pay for services, or who are on Medicaid, which local providers will not accept for payment. Without sharing patient details that would have compromised confidentiality, we determined that the HPC had some patients with CIEDs who were receiving only primary care. They were not receiving follow-up care for their cardiac needs. Therefore, we decided to assess the need for an extension of services at the HPC that would include a CIED clinic.

Project Question

Evidence-Based Significance of the Project

Two models were used in this project: the evidence-based practice model (EBPM) and the Iowa model. The EBPM is a tool for organizing a change project (Gawlinski & Rutledge, 2008). The Iowa model provides a structured process that assists the project manager throughout the project (Schaffer, Sandau, & Diedrick, 2013). The Iowa model incorporates feedback into the evolution of the project and allows for adaptation of ideas and concepts. Furthermore, the Iowa model is an excellent choice for this highly

technical subject, CIEDs, which present complex concepts that are difficult to relate to patient care, even for cardiac specialists unless they have expertise in electrophysiology (Schaffer et al., 2013). Both models were used to guide all phases of the project, including decision points.

Implications for Social Change in Practice

Initially, it was estimated that 10–20 individuals would not have insurance or the financial means to pay for care needed at a pacemaker clinic. Less than 20 people would be a small number for a full-time clinic. However, initial data revealed a substantial need in the geographic area for a pacemaker clinic that served individuals with no alternative for care.

The establishment of a pacemaker clinic designed to serve a vulnerable population was expected to reduce a gap in care and decrease a significant health disparity that exists due to financial reasons. By creating this change project and instituting the Heart Rhythm Society's standards for care of CIEDs, individuals would have access to a critical component of care that was currently unavailable (Lampert et al., 2010). A continuous quality improvement plan was implemented to ensure that quality care, as measured by the recognized standards, was provided. The priority was to provide safe care and to improve outcomes.

Definitions of Terms

Cardiac implantable electronic device (CIED): An electronic device that is self-contained and implantable in a human body (Ellenbogen & Wood, 2008).

Cardiac resynchronization device: A CIED that provides pacing therapy to the right and left ventricles, either simultaneously or with offset timing, to treat electrical and mechanical synchrony in the heart (Ellenbogen & Wood, 2008).

Device interrogation: A process that uses telemetry to retrieve programmed parameters and data stored in the memory of the device. A dedicated programmer or a remote server may obtain data (Ellenbogen & Wood, 2008).

Device programming: A non-invasive, stable, reversible change in some of the operating parameters that enable the provider to select settings to assess and optimize the system performance and longevity of the CIED (Hays & Friedman, 2008).

Heart failure with preserved ejection fraction: A state of cardiac failure in which the systolic function is normal or above normal (Hays & Friedman, 2008).

Implantable loop recorder (*ILR*): A device that stores recordings of the heart rhythm and data derived from the cardiac rhythm in memory (Ellenbogen & Wood, 2008).

Internal cardiovertor defibrillator: A device that provides therapy, such as high-rate pacing or high-energy shock, to either chamber of the heart (Ellenbogen & Wood, 2008).

Pacemaker: A device that provides sensing, pacing, and a response to either sensing or pacing to the atrium, right ventricle, or left ventricle of the heart (Ellenbogen & Wood, 2008).

Programmer: A device designed to receive telemetry from a family of devices made by a specific manufacturer of the CIED. The programmer allows the clinician to temporarily or permanently adjust CIED programs (Hays & Friedman, 2008).

Remote follow-up transmitter: A device that transmits information stored in the CIED to a remote server to which a clinician has electronic access, thereby allowing the clinician to assess device settings and diagnostics (Ellenbogen & Wood, 2008).

Assumptions and Limitations

Assumptions

It was assumed that data collected from the public domain, the United States Census Bureau, was accurate. It was necessary to use data in the public domain for this quality improvement project. Generalizations were assumed based upon this data, as specific implant data was unavailable.

Limitations

A limitation of the data collected for this quality improvement project was that all individuals were identified with data available in the public domain; this data may underestimate the need. Some individuals cared for by the HPC are undocumented immigrants and they may not have been represented in the census data.

There was no inherent bias in this project. The project was implemented without the influence of individual device companies, thus there was no commercial influence. Or conflict of interest. No financial assistance was solicited or accepted from third parties.

Section 2: Review of Scholarly Evidence

Introduction

The past decade has seen advances in therapies for individuals with cardiac disease, especially for heart failure and management of arrhythmias. This review of the literature will focus on the current treatment of heart failure and arrhythmias using CIEDs. The indications for use and postoperative management of the devices will be the focus of this review.

Literature Search Strategy

The literature search was conducted using a combined CINAHAL Plus with Full Text and MEDLINE with Full Text. In addition, the Cochrane Database of Systematic Reviews was used for meta-analysis. Keywords included: pacemakers, internal defibrillators, cardiac resynchronization, follow-up, remote, in-clinic, and complications. This initial search resulted in 3,458 studies. Next, the query was narrowed to the previous 15 years, which left 881 studies. This total was narrowed to studies most relevant, resulting in 103 articles. Thirty eight studies were most relevant to this quality improvement project.

General Review of Literature

CIEDs have been around since the 1950s; they are considered the standard of care for many cardiac diseases (Modi et al., 2011). Technology has improved considerably in the last two decades and dramatically reduced mortality and morbidity for individuals with chronic conditions (Crozier & Smith, 2012). From the early pacemakers to the new defibrillators, CIEDs are used to treat and prevent sudden cardiac death. For example, cardiac resynchronization has extended the lives of those suffering from systolic heart

failure (Modi et al., 2011). Some CIEDs provide several kinds of therapy: bradycardia support, ventricular arrhythmia therapy, heart failure monitoring, arrhythmia monitoring, and heart failure therapy—all in a single device (Wilkoff et al., 2008).

Expenditures for hospital implantable medical devices, by the Centers for Medicare and Medicaid Services (CMS) and private insurers, increased substantially in recent years, from $16.1 billion in 2004 to $19.8 billion in 2009 (U.S. Government Accountability Office, 2012). These expenditures represent a growth rate in excess of 20%.

After the initial implantation of a CIED, significant follow-up is required to prevent complications and maximize device function. Udo et al. (2011) conducted a multicenter randomized cohort study from 2003 to 2007 with 1,517 patients who had received a CIED. They found that 12.4% of these patients developed complications over the first 2 months. Thereafter, 9.2% of patients developed long-term complications (Udo et al., 2012). The researchers were unable to predict who would develop complications.

Follow-up is critical to the proper functioning of a device. However, there remains considerable debate in the cardiology community about the frequency and type of follow-up care required for patients with CIEDs (Van Eck et al., 2008). Van Eck et al. (2008) conducted secondary data analysis to determine the frequency of visits, the parameters measured during the follow-up, and the training of the personnel involved in this care. They found that (a) non-physicians perform the majority of these checks and (b) that crucial parameters were monitored, and appropriate parameter changes made to prevent device complications.

The result of pacemaker complications can be severe and dramatic. Ellenbogen, Wood, and Shephard (2002) found one potential complication. Delayed perforation of the chamber receiving the pacemaker lead may occur days to weeks after the initial implantation. If left untreated this can result in the death of the patient. However, this condition is readily assessable with a routine follow-up and examination by a provider.

Specific Review of Literature

The specific review will focus on the management of individuals postoperatively after implantation of a CIED. The device specific requirements will be addressed including pacemakers, defibrillators, and cardiac resynchronization devices. The indications and required care of these devices along with the training required to provide this care will be addressed.

Other than patients and their families, who are primary stakeholders in the success of CIEDs, three organizations are major stakeholders. These organizations monitor and govern the usage of CIEDs: the American College of Cardiology, the American Heart Association, and the Heart Rhythm Society. These organizations work with the Food and Drug Administration and the CMS to approve and monitor devices and set payment parameters. Members of these organizations conduct research studies and the results of the studies are published in peer-reviewed journals. Professionals from many disciplines work together to provide guidelines for device usage that help clinicians care for cardiac patients needing CIEDs.

General Follow-Up Considerations

All CIEDs, regardless of the type, have follow-up requirements. The four objectives in follow-up are patient-related considerations, device-related considerations,

disease-related considerations, and communication-related considerations (Wilkoff et al., 2008).

Patient-related issues. The primary objective of CIED follow-up is to optimize individuals' quality of life and to minimize the impact the device has on individuals' daily life activities. This goal is accomplished ensuring the system functions to meet each individual's needs. Time spent during the follow-up interaction also gives the clinician an opportunity to identify other health issues that may need attention.

Device-related issues. This goal includes the documentation of device function. When device function is abnormal, clinicians take corrective action. Monitoring the device is documented throughout the lifespan and planning for device succession occurs before failure of the device.

Disease-related issues. Diagnostics collected by the device provide insight into disease progression and the specifics needed to provide optimal care. Device follow-up sessions provide the clinician with access to this information. Clinicians can access and share this information with multidisciplinary team members.

Communication issues. CIEDs require a line of communication remain in place between manufacturer, clinician, and patient. Issues might arise with specific models from the device manufacturer, necessitating the sharing of information. Patients need access to their clinician, clinicians need access to the manufacturer, and the manufacturer needs access to patients via clinicians.

Indications for Implantation

The American College of Cardiology, American Heart Association, and the Heart Rhythm Society adopted the following guidelines for CIED implantation based upon

evidence class (Epstein et al., 2013): Class I conditions are those for which pacing treatment is definitely beneficial and necessary to prolong life. Examples of Class I conditions include heart blockage, asystole, or bradycardia that is hemodynamically compromising to an individual. Class II conditions are those in which pacing may be indicated, but there is some conflicting evidence or divergence of opinion. Class III conditions are those for which pacing may or may not be useful and may be potentially harmful.

Low-Powered CIED

Indications. Indications for low-powered devices or pacemakers include rhythm-related reasons, high-degree atria-nodal blockage, and symptomology. Symptoms related to heart rate include dizziness, lightheadedness, syncope, fatigue, poor exercise tolerance, and chest pain (Modi et al., 2011). Pacemakers may be dual-chamber devices with a lead into the right atrium and left ventricle, or single-chamber pacemakers with one lead into either the atrium or ventricle (Modi et al., 2011).

Follow-up considerations. Low-powered devices require follow-up at regular intervals. The first in-person follow-up should be within 72 hours of device implantation (Wilkoff et al., 2008). Parameters to be assessed include battery status, lead performance, pacing and sensing thresholds, and the diagnostics of these primary indicators. After this initial contact, follow-up should occur between 2 and 12 weeks. After this contact, follow-up can be every 3 months if remote follow-up is activated. In-clinic follow-up should occur no less than every 12 months (Wilkoff et al., 2008). As device longevity approaches elective replacement levels, follow-up is necessary at monthly intervals until the device (or a component thereof) is replaced (Wilkoff et al., 2008).

High-Powered CIED

The role of the implantable defibrillator has increased over the last 20 years. Initially, these devices were implanted for survivors of two episodes of sudden cardiac death (Greenberg et al., 2004). During the 1990s, the indications were expanded to include primary prevention of sudden cardiac death (Greenberg et al., 2004). Large multicenter studies such as MADIT and MADIT II demonstrated superior survival rates compared to traditional medication therapy (Greenberg et al., 2004). Devices have become smaller, more efficient, and safer over the years.

Indications. Indications for high-voltage devices are either primary prevention based upon heart function and risk factors or secondary prevention for sudden cardiac death. The major risk factor for sudden death is structural heart disease, either from coronary artery disease (ischemic) or other forms of cardiomyopathy not related to coronary artery disease (non-ischemic) (Desai, Fang, Maisel, & Baughman, 2004). Researchers demonstrated a significant reduction in mortality from the use of ICDs in both forms of structural heart disease (Desai et al., 2004; Greenberg et al., 2004).

Follow-up considerations. High-powered device follow-up requirements are similar to follow-up requirements to low-powered devices, with additional requirements unique to these devices. Clinicians monitor battery status, lead performance, pacing and sensing thresholds, high-voltage capacitor functioning, and charge time. The high-voltage functioning feature is the most important function of a high-voltage device.

Cardiac Resynchronization CIED

As the burden of heart failure has increased for individuals and society, new methods to treat this progressive disease have been developed (Abraham & Hayes, 2003).

One such therapy is cardiac resynchronization therapy (CRT). The CRT CIED provides electrical stimulation in multiple areas of the ventricle for individuals experiencing mechanical problems; such problems often lead to severe complications (Ramsdale & Rao, 2012).

Indications. The indications for CRT are heart failure, New York III or IV class, systolic dysfunction, and prolonged ventricular depolarization (QRS greater than 140ms; Burkhardt & Wilkoff, 2007). These indications were revised over the past several years and have become more restrictive in response to the ongoing debate over the long-term benefit for some populations.

Follow-up considerations. In addition to the follow-up needed for both low- and high-powered CIEDs, CRT CIEDs are used to treat heart failure. These devices have additional diagnostics capabilities that help clinicians assess fluid volume. This CRT CIEDs feature requires nearly constant monitoring. To address the need for nearly constant monitoring, remote monitoring is active at all times in the devices; outside of the hospital, the device maintains communication with home units that have Internet access. An alert triggered in the device by a cardiac event is sent to a database and then forwarded to the individual's clinician for review.

Multidisciplinary Relationships

Given the complexity of CIEDs, it may be necessary to obtain technical support for an individual's care (Hayes, Juknavorian, & Maloney, 2001). Industry allied professionals are individuals with industry training that may be certified by the International Board of Heart Rhythm Examiners. The Heart Rhythm Society also recognizes allied professionals; these professionals provide patient care (Hayes et al.,

2001). It is important to maintain awareness of the conflict of interest that is inherent when a device manufacturer employs a care provider. Decisions regarding patient care should occur in the absence of conflicts of interest. While technical advice can be sought, healthcare providers tasked with caring for the patient best make decisions that affect patients.

Adverse Events

For patients who receive a CIED, the standard of care requires regular monitoring of these devices with in-office programming or remote follow-up at regular intervals, as recommend by the Heart Rhythm Society (Tracy et al., 2012; Wilkoff et al., 2008).

Remote Follow-Up

One of the most significant changes with regard to monitoring of CIEDs is remote follow-up using the Internet. This change occurred rapidly. While programming or changing settings is unavailable via the telephone or Internet, almost every piece of information stored in the device can be transmitted into a database accessible by clinicians in real time. It is important for patients with a CIED to be aware of negative information related to their CIED. In the case of individuals with atrial fibrillation at risk for stroke who cannot be anti-coagulated, remote follow-up can be used to detect this rhythm disorder and notify the healthcare provider about this abnormality (Gimbel, 2012). When an individual has a normal heart rhythm, there are no transmissions, thus indicating no need for intervention. Remote follow-up used in conjunction with traditional in-office follow-up also offers improved productivity for clinics that adopt this method (Cronin et al., 2012). More importantly, outcomes improve for patients who have remote capabilities and traditional office follow-up visits (Cronin et al., 2012).

Theoretical Framework

The way healthcare is provided in the United States works well for a few individuals, however there remain a substantial number of people without insurance or the ability to pay for healthcare. Since early 2014, the healthcare system has not been functioning as intended. As such, theory based upon a nonlinear worldview is best for research into a phenomenon as complex as the healthcare system. Traditional linear thinking, in which the input equals the output or the size of the input is equal to the size of the output, must be replaced with the understanding that small changes can create great change. Complexity science (CS) describes phenomena as they are rather than how they should be.

Simple agents, or initiatives, that are basic units following simple rules can generate complex structures (Paley, 2007). The relationship between these simple agents defines CS. Paley (2007) used CS and the understanding of complex adaptive systems (CASs) to determine why a cardiac rehabilitation unit was not receiving referrals. Paley (2009) identified many individual elements that were not considered complex issues but that, in aggregate, formed a bottleneck for referrals to this service. Using complexity analysis, Paley developed a new system that satisfied the needs of all stakeholders.

For a project that is multidisciplinary, using facilities from primary to tertiary care, and crossing many specialty practices, the Iowa model is not sufficient as a stand-alone mode. It serves well as the model for data collection, however a more comprehensive theory must be used in conjunction to capture the complete theme of the project. CS provides a patient centered model that helps define chaos and translate to

meaningful change in organizations (Hast, DiGioia, Thompson, & Wolf, 2013). It is well suited for the development of a pacemaker clinic.

Definition of Complexity Science

CS is neither a single theory nor exclusively a nursing theory; it is an interdisciplinary field recognizing multiple theoretical frameworks (Zimmerman, Lindberg, & Plsek, 2001). Lindberg, Nash, and Lindberg (2008) defined CS as "examining systems comprised of multiple and diverse interacting agents and seeking to uncover the principles and dynamics that affect how such systems evolve and maintain order" (p. 78). Zimmerman et al. (2001) stated that CS gives "a description of the complex phenomena demonstrated in systems characterized by nonlinear components, emergent phenomena, continuous and discontinuous change, and unpredictable outcomes" (p. 112).

Concepts of Complexity Science

CS recognizes that individuals, businesses, hospitals, and all systems are CASs. The word *complex* implies diversity and a great number of connections between wide varieties of elements; *adaptive* refers to the capacity to alter or change and the ability to learn from experience; and *system* refers to a set of connected or interdependent things (Zimmerman et al., 2001). CASs have many interconnected, interdependent, adaptive, and diverse elements, each of which may be a CAS (Lindberg et al., 2008). Diversity is essential for CASs because diversity allows for adaptation when confronted with a challenge. The interdependent nature of CASs is evidence that an individual cannot survive in isolation.

The eight major properties of CASs include diversity, self-organization, embeddedness, distributive control, nonlinear dynamics, adaptable elements, emergence, and the coexistence of order and disorder (Lindberg et al., 2008). A definition of each property is provided below.

Diversity. CASs are composed of heterogeneous parts in the system. Diverse elements enable the system to function at a higher level and outperform homogeneous groups.

Self-organization. CASs are subject to influence from many forces within and outside of the CAS that may create novel patterns, structures, and processes. Simply put, there is no such thing as a static CAS.

Embeddedness. Each agent is itself a CAS, as well as a part of all CASs that, in turn, make up a larger CAS. There is no such thing as isolation in CS and there is no insignificant CASs. Every individual may have great, little, or no impact on the larger CAS.

Distributive control. The concept of individual control does not exist within a CAS. Many agents formally and informally share control. Diversity is at the center of control in a CAS.

Non linear dynamics. The effect of a change agent in a CAS is difficult to predict. This unpredictability is due to the non-linear behavior of a CAS. Small changes may have large effects in a CAS, but can have proportional effects or no change at all. This condition is in stark contrast to linear theories, which state the output is equal to the input.

Adaptable elements. For a CAS to survive, it must be adaptable and have elements within the global CAS that are able to adapt. Biological species have the ability to modify themselves to survive the evolutionary process. CASs possess the ability to survive as organizations.

Emergence. CASs are not static organizations creating new and unexpected structures, patterns, or processes within the overall system. Emergents can take on a life of their own and create their own rules.

The coexistence of order and disorder. It is not essential for a CAS to have order. Instead, a CAS can thrive with or without order because the normal state of a CAS includes order and disorder.

Complexity Science and Nursing

The embedded principles of CS are evident in nursing practice. A schism exists, however, between practice and nursing theory. Current nursing theory has been predominantly derived from a linear worldview rather than from a dynamic, unitary worldview. Lindberg et al. (2008) suggested linear theories are detrimental to nursing education and negatively influence all aspects of nursing. CS provides an alternative to linear thinking and theorizing. It is a complementary perspective to facilitate describing, understanding, and using nursing theories that are compatible with nursing concepts and constructs (Lindberg et al., 2008). Using the concepts of CS to guide nursing research is the next logical step.

Complexity science provides a comprehensive framework to understand and navigate complex adaptive systems. The healthcare system, which has many adaptive

parts, is dynamic and in a constant state of change. This framework defined and captured the complex themes that guided this project.

Section 3: Methodology

Introduction

This study was designed to provide the necessary information to quantify the scope of the problem facing individuals lacking access to care who have an implantable cardiac device. The methods used to document the need will be covered in detail. Data from the Centers for Medicaid and Medicare Services, the United States Census Bureau, and the Health Partnership Clinic were used to develop a historical and predictive model to predict need.

Approach

Project Design

This quality improvement project used a non-experimental, descriptive, quantitative research design. It involved the secondary analysis of archival data, data provided by the Health Partnership clinic without patient identifiers or proprietary data.

Population and Sampling

U.S. Census Bureau data included the number of individuals residing in the geographical area, individuals who lost access to health insurance coverage in any given year, and the total number of device implants as reported to the Centers for Medicaid and Medicare. Descriptive analysis was used to determine the number of patients who had implantable devices but lacked access to care.

Two types of data were collected: the actual number of implantable devices and the insurance status of residents in the area. No patient identifiers were associated with this data. Inclusion criteria were as follows: CIED implants in Johnson County, Kansas, for the years 2010, 2011, and 2012. Insurance status for the general population was

obtained from U.S. Census Bureau data and used as a baseline to estimate the number of uninsured with an implantable device.

Methods for Safeguarding Human Subjects

Data were obtained after approval from the Walden University Institutional Review Board (12-01-14-0307415). Because no patient identifiers were included in the data, there was no risk associated with unauthorized use of the data or violations of confidentiality. No human subjects were involved in the collection of this data.

Ethical Issues

The concept of autonomy is one of the guiding principles of ethical care (American Nurses Association, 2001). Autonomy allows all competent individuals to refuse any or all treatment provided. Refusal of treatment can be a difficult situation when the device is implanted improperly and cannot be easily removed from the individual's body (Kobza & Erne, 2007). Cultural and religious beliefs may influence individuals' healthcare decisions. Ethical issues are relevant for individuals with implantable devices and these devices often provide therapy needed to live (Kobza & Erne, 2007). For some individuals, withdrawal of therapy results in immediate death. Withdrawal of basic support is controversial and can be considered euthanasia. The individual ultimately controls his or her own destiny and others should respect the autonomy of this right.

At end of life, a patient may wish to terminate therapies provided by the device. When this situation occurs, the provider must have a thorough discussion with the patient and family. The provider must not project his or her values when a patient decides to cease therapy.

There are no human subjects in this quality improvement project. There are no patient identifiers associated with any data collection. The archival data collected was anonymous and was stored on the investigators computer. The raw data will be destroyed at the conclusion and publication of this project. The project was undertaken at a clinical site and no incentives were associated with this project.

Data Analysis Strategies

The total numbers of CIEDs were tallied along with the likely number of individuals with CIEDs who might lack access to care, based upon implant numbers from the ICD registry. Patient-specific indicators including age and gender were obtained. The analyses included comparisons of means and the total number of identified individuals.

Project Evaluation Plan

Evaluation Strategies

The first step in this study was to review the literature on an ongoing basis to compare actual performance of the clinic with evidence-based studies and consensus practice. This information was used to ensure that, in the rapidly changing environment of clinical care, the clinic will follow and maintain best practices. A systematic quality-monitoring plan was created as an addition to the ongoing quality program in place at the HPC to monitor a random sample of patient encounters to ensure that standards are followed.

New Practice Guidelines

Guidelines for practice fall into three categories: pacemakers, defibrillators, and CRT devices. A set of protocols was established for each implantable device. The standard format is similar, in that remote monitoring is used whenever possible, given the

technical and communication limitations some individuals face. Patient checks are scheduled every 90 days for all types of devices, with remote checks being allowed for 3 of 4 annual checks for pacemakers. For high-voltage devices, remote checks can be used biannually, with one in-clinic check performed every 6 months.

For individuals on antiarrhythmic medication, more frequent follow-up may be recommended on an individual basis (Wong, Yu, & Holbrook, 2010). For individuals receiving high-voltage therapy, consultation with a local electrophysiologist or cardiologist specializing in the care of patients with these devices is needed to ensure optimal medical management (Lampert et al., 2010).

For clinic patients taking antiarrhythmic medication, an alert was built into the electronic record. This alert will make primary care providers and staff aware of the potential serious drug interactions that some medications, especially antibiotics, might have on the conduction system of the heart when an ADD is being used.

New Standards of Care at the HPC

Patients visiting the HPC for medical device follow-up can expect to receive care provided at traditional pacemaker clinics. The Heart Rhythm Society is the organization that guides private and public payers' treatment of heart rhythm disorders. This organization works closely with the U.S. Food and Drug Administration and the suppliers of medical devices to monitor and report potential adverse outcomes related to devices already implanted. The Heart Rhythm Society sets the care and follow-up standards for care of CIEDs.

The Heart Rhythm Society recognized the role of the non-physician provider in the care of CIEDs and issued a policy statement to detail the qualifications and standards

of care (Gura et al., 2003). The core knowledge and skills are detailed in this position statement including: Core Knowledge, Core Standards and Elements, Rhythm Management, and Follow-up (Gura et al., 2003). The International Board of Heart Rhythm Examiners (IBHRE) offers certification as a Cardiac Electronic Device Specialist (CEDS) to eligible candidates to document their knowledge (Gura et al., 2003). The staff performing follow-up interrogations at the Health Partnership Clinic will be required to have this CEDS certification.

Project Strengths and Limitations

Analysis of Self

The role assumed by the project manager/student was comprehensive: scholar, manager, practitioner, administrative and cheerleader. The most significant contribution made was to create an atmosphere where the need for this service was appreciated and with resulting social change. The easy part was to provide the service. The development of the project required patience and extensive management of resources. It was very gratifying to make multiple presentations to the board of directors with a positive outcome.

Summary

This project, when fully implemented will provide evidence base care to a vulnerable population with cardiac devices. This specialized care is not available to residents in the geographical area at this time. Thus, a critical need will be filled as a result of this project, resulting in positive and meaningful social change.

Section 4: Findings, Discussion and Implications

Findings

Johnson County, Kansas, experienced a decline in the population from 2011 to 2012; however, the population grew in 2013 to 417,507 individulals (United States Census Bureau, 2014). Given this variability, the poplulation of adults over the age of 18 for 2001-2013 was used for this study: 407,669 (United States Census Bureau, 2014).

Table 1

Number of Adults in Johnson County, Kansas by Age

Year	18– 65 years of age	Over 65 years of age	Total population
2011	344,936	59,743	404,679
2012	341,501	59,322	400,823
2013	350,577	66,930	417,507
2014	345,671	61,998	407,669

Number of CIED Implants in Johnson County, Kansas

The number of total implants was obtained from St. Jude Medical's marketing department (C. Peltz, personal communication, December 08, 2014). This information is available via request and is acquired from industry data and publically reported financial reports. The total number of low power implants averaged 728 per year for the years 2011 to 2013. The total number of high power implants for the same time period was 718, averaging 239 per year. There was a slight contraction in implants during this time period, so the average of the 3 years was used for this study.

Table 2

Number of Low and High Powered Medical Device Implants for Johnson County, Kansas

Year	Number of Low Voltage Implants	Number of High Voltage Implants
2011	732	263
2012	762	253
2013	679	202
Total	2,183	718

Number of Uninsured Johnson County Residents

The number of uninsured residents in Johnson County remained steady during the years 2011 to 2013 and averaged 21,730 uninsured adults between the ages of 18 and 65 (United States Census Bureau, 2014). Very few of the individuals over 65 had minimal insurance through Medicare. What is not known is the number of individuals lacking Medicare Part D and the number unable to afford physician visits. The researcher assumed that they were represented in this number with an average of 85 individuals annually.

Table 3

Number of Uninsured Residents in Johnson County

Year	Between 18 – 65 Years of Age	Over 65 Years of Age
2011	22,225	175
2012	21,607	39
2013	21,358	42
Average	21,730	85

Implant Demographics

The number of CIED implants increases significantly with age. The exact number of non-Medicare implants is unavailable in the public domain and local hospitals consider this information proprietary and will not disclose the exact numbers. The largest study that tracks medical device implants by age is the ICD registry sponsored by the Heart Rhythm Society and the American College of Cardiology Foundation (Kremers et al., 2013). This registry has over 850,000 participants and represents the most comprehensive database for CIED implants in the United States (Kremers et al., 2013). This database represents hospitals' voluntary reporting, which has the possibility to not accurately represent the data. The data from this registry demonstrated that 35% of CIED implants occur in the under 65 age group, thus this number was used given the assumption that individuals in the under 65 age group receive CIED implants.

Table 4

CIED Implants per Thousand of Total Population

Year	Low Voltage	High Voltage
2011	1.809	0.650
2012	1.901	0.631
2013	1.626	0.484
Average	1.779	0.588

Estimated Number of Noninsured Individuals Receiving CIEDs

Using the assumption of the ICD registry, that 35% of CIED implants occur in the under 65 age group and no hospital in the county provides pediatric services, the number of implants per 1000 individuals was applied to the 18 to 65 population with the assumption that 35% of the total implants in the county occurred in this group. This was

then applied to the uninsured group to estimate the total number of implants for both low- and high-voltage devices.

Table 5

Number of Potential Individuals with CIEDs Lacking Access to Care Over the Past 3 Years Based Upon 35% for Age 18-65 and 65% Over Age 65

Year	Between ages 18 – 65 years		Over 65 Years of age	
	Low Voltage	High Voltage	Low Voltage	High Voltage
2011	14	5	<1	<1
2012	13	5	<1	<1
2013	13	5	<1	<1
Total	40	15	<1	<1

It is estimated that 13 low-voltage implants, along with 5 high-voltage implants, occur in the uninsured population annually in Johnson County. The number of implants in the over 65-age group is less than one annually. This finding is consistent with information provided by the Health Partnership patient database. Given that the average life of a CIED is 5 years and the average length of patient relationships at the Health Partnership Clinic, it is likely that there are currently 40 individuals with low-power devices and 15 individuals with high-power devices lacking recommended care. This number is likely to grow as Kansas has elected not to extend Medicaid benefits to this group of patients.

Discussion

The total population lacking medical care for their implanted devices in Johnson County, Kansas, is substantial. Using the assumptions from the United States Census Bureau and the ICD registry, it can be accurately predicted the number of individuals

lacking care is a significant and stable size. The recent implementation of the Affordable Care Act is not likely to change this need, as Kansas has not expanded Medicaid eligibility.

Implications

For individuals lacking access to care with an implantable CIED the ramifications can be catastrophic. Seniors complications can and often occur without proper follow up care. For local institutions the financial implications can be considerable. With the average emergency department visit for a CIED complication costing $12,000, it only takes a few preventable complications to have a significant impact (S. Elsey, personal communication, December 6, 2014). The availability of care will enhance individuals' lives and provide a place for medical care. This will result in positive social change for over 50 residents of Johnson County within the first few months of this clinic's formation.

Summary and Conclusions

There is a definite need for social change in Johnson County Kansas to provide access to care to uninsured, undocumented, and individuals without the ability to pay for specialty cardiac care. Many individuals that have implantable cardiac devices cannot achieve full health without access to care. This project identified this need and provided a workable solution. Using skills learned in the terminal degree program for the Doctor of Nurse Practice, a program to address this need was successfully developed, funded, and implemented. Many individuals will now have access to this care that previously did not.

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Section 5: Scholarly Product

The Creation of a Pacemaker Clinic at a Federally Funded Patient Centered Medical Home: A Quality Improvement Project

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The Creation of a Pacemaker Clinic at a Federally Funded Patient Centered Medical Home as a Quality Improvement Project

Since the 1950s, use of cardiac implantable electronic devices (CIEDs) gained acceptance in the cardiology realm as routine therapy. CIEDs are the standard of care for many cardiac diseases, including sick sinus syndrome, advanced atrial-nodal heart block, and as primary or secondary prevention for sudden cardiac death (Modi et al., 2011). Technology has advanced rapidly, allowing for dramatic reductions in mortality and morbidity for individuals with chronic cardiac conditions (Crozier & Smith, 2012). From the humble pacemaker, technology evolved to include defibrillators for the treatment and prevention of sudden cardiac death.

Expenditures for hospital implantable medical devices increased from $16.1 billion in 2004 to $19.8 billion in 2009 (U.S. Government Accountability Office, 2012). The implantable device market is growing at a rate comparable for Medicare and represents a significant portion of total Medicare expenditures. The government payer, the Centers for Medicare and Medicare Services (CMS), benefits when CIEDs are cared for after implantation by reducing unnecessary hospital admissions.

Cardiac resynchronization has provided hope and extended the lives of countless individuals with systolic heart failure and other cardiac pacing problems (Modi et al., 2011). The increased use of CIEDs also helped decrease readmissions for heart failure, thus providing a financial incentive for their adoption (Noyes et al., 2013).

Project Objectives

The goal of the pacemaker clinic at the Health Partnership Clinic is to provide access to care for all individuals with a CIED regardless of their ability to pay. This

change will result in an increased quality of care, as evidenced by complication rates consistent with the national average for individuals receiving care in traditional pacemaker clinics. The secondary goal of this project was to identify individuals with devices nearing elective replacement intervals before the device exhibits end-of-life behavior.

Significance/Relevance to Practice

On multiple occasions, individuals present to local Emergency Departments with preventable device complications from lack of routine follow-up. In some cases, individuals lost their insurance and could no longer afford clinic visits. In other cases, individuals receive a CIED when presenting for urgent care, yet do not receive follow-up care. The common thread is these individuals are unable to obtain follow-up care, primarily due to financial reasons.

A pacemaker clinic was conceptualized after conversations with the Chief Executive Officer of the Health Partnership Clinic (HPC), a local clinic that provides services to individuals with limited or no ability to pay for services, or Medicaid, which local providers will not accept for payment. Local practices have limited space for these patients to receive care (Health Care Partnership, 2014). Without sharing patient details that would have compromised confidentiality, we determined that the Health Care Partnership had some patients receiving primary care with CIEDs. These patients were not receiving follow up care for their cardiac needs. As such, we decided to assess the need for an extension of services at the HPC to include a CIED clinic.

New Standards of Care at the HPC

Patients visiting the HPC for medical device follow-up can expect to receive care provided at traditional pacemaker clinics. The Heart Rhythm Society is the organization that guides private and public payers' treatment of heart rhythm disorders. This organization works closely with the U.S. Food and Drug Administration and the suppliers of medical devices to monitor and report potential adverse outcomes related to devices already implanted. The Heart Rhythm Society sets the care and follow-up standards for care of CIEDs.

The Heart Rhythm Society has recognized the role of the non-physician provider in the care of CIEDs and issues a policy statement to detail the qualifications and standards of care (Gura et al., 2003). The core knowledge and skills are detailed in this position statement including: Core Knowledge, Core Standards and Elements, Rhythm Management, and Follow-up (Gura et al., 2003). The International Board of Heart Rhythm Examiners (IBHRE) offers certification as a Cardiac Electronic Device Specialist (CEDS) to eligible candidates to document their knowledge (Gura et al., 2003). The staff performing follow-up interrogations at the Health Partnership Clinic will be required to possess this certification.

Number of CIED Implants in Johnson County Kansas

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was a slight contraction in implants during this time period, so the average of the three years will be used for this study.

Number of Uninsured Johnson County Residents

The number of residents in Johnson County remained steady during the years 2011 to 2013 and averaged 21,730 for adults between the ages of 18 to 65 (United States Census Bureau, 2014). For individuals over 65 there were very few individuals not having minimal insurance through Medicare. What is not known is the number of individuals lacking Medicare Part D and not able to afford physician visits. The assumption will be made that they are represented in this number with an average on 85 individuals annually.

Implant Demographics

The number of CIED implants increases significantly with age. The exact number of Non-Medicare implants is not available in the public domain. Local hospitals consider this information proprietary and will not disclose the exact numbers. The largest study that tracks medical device implants by age is the ICD registry sponsored by the Heart Rhythm society (Kremers et al., 2013). This registry has over 850,000 participants and represents the most comprehensive database for CIED implants in the United States (Kremers et al., 2013). This registry demonstrated that 35% of CIED implants occur in the under 65 age group, thus this number will be used in the assumptions of individuals receiving CIED implants in this demographic.

Estimated Number of Non Insured Individuals Receiving CIEDs

Using the assumption of the ICD registry, that 35% of CIED implants occur in the under 65 age group, and no hospital in the county provides pediatric services, the number

of implants per 1000 individuals will be applied to the 18 to 65 population with the assumption that 35% of the total implants in the county occurred in this group. This will then be applied to the uninsured group to estimate the total number of implants for both low and high voltage devices.

It is estimated that 13 low voltage implants, along with 5 high voltage implants, occur in the uninsured population annually in Johnson County. The number of implants in the over 65-age group are less than one annually. This finding is consistent with information provided by the Health Partnership demographics. Given that the average life of a CIED is 5 years, and the average length of patient relationships at the Health Partnership Clinic, it is likely that there are currently 40 individuals with low power devices, and 15 high power devices lacking recommended care. This number is likely to grow as Kansas has elected not to extend Medicaid benefits to this group of patients.

Implications

For individuals lacking access to care with an implantable CIED the ramifications can be catastrophic. Serious complications can and often occur without proper follow-up care. Local institutions risk considerable financial implications of providing mandated care to the uninsured population. The average emergency department visit for a CIED complication costing $12,000 in this area. It only takes a few preventable complications to have a significant impact on local hospitals (S. Elsey, personal communication, December 6, 2014). For individuals, the availability of care will enhance their lives physically and provide the emotional security of a medical home. Positive social change resulted for over 50 residents of Johnson County within the first few months of this clinics formation.

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