Quality Improvement Project: Perioperative Care for Patients with Cardiac Implantable Electronic Devices

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Abstract

With the number of patients requiring implantable cardiac devices continuing to rise each year, the demand for anesthesia providers to be knowledgeable on proper management during the perioperative period has become critically essential. Improper perioperative cardioverter-defibrillator management by Certified Registered Nurse Anesthetists has the potential to result in patient harm and could be costly for both the patient and facility. The current process for anesthesia providers delivering perioperative care for patients with CIEDs lacks standardization and creates the potential for unexecuted safety measures related to their devices. The purpose of this quality improvement project was to assess anesthesia providers' perceptions of an AICD/PPM Handout as an educational tool to improve perioperative CIED management and patient safety. This quality improvement project was implemented in cardiovascular-designated operating rooms in a Level I trauma center in eastern North Carolina. Ten nurse anesthetists were sent an AICD/PPM Handout and introductory PowerPoint, along with pre- and post-intervention surveys. Respondents shared their perceptions on the inadequacy of awareness and utilization of current practice guidelines and hospital policy, the unnecessary time taken to attain patient device information, and the potential benefits educational guides could provide during the perioperative period. Survey results indicated that most CRNAs encounter problems in attaining pertinent device information, consuming unnecessary time, and that many CRNA's are unaware of or don't use the hospital's policy or current practice guidelines. Using data collected from these surveys could provide guidance for future improvements in perioperative AICD/PPM management.

Keywords: cardiac implanted electronic devices, nurse anesthetists, perioperative, device management

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Section I. Introduction

Background

Almost a third of a million patients receive cardiac implantable electronic devices (CIEDs) each year in the United States alone (Greenspon et al., 2011). With the increased incidence of dysrhythmia-associated diseases and improved life expectancy after implantation, the need for these devices is expected to continue (Neelankavil et al., 2013). As the abundance in implantations of CIEDs continues to rise, the demand for healthcare providers to be knowledgeable on how to properly manage them becomes critically essential. Among healthcare providers, anesthesia team members deliver crucial care to this population specific to the perioperative period, at a time when these patients may have elevated risk for poor outcomes related to their device. Without ensuring all safety measures are accomplished, anesthesia providers can exacerbate the risk to these patients associated with their devices before, during, and after surgery. These clinical risks include hypotension, arrhythmias, and myocardial tissue damage, which any may ultimately result in extended hospital stays, cancellation of surgery, readmission for device malfunction, and additional hospital resource utilization (Feldman & Stone, 2020).

The term CIEDs is an umbrella term that covers both cardioverter-defibrillators and pacemakers. These devices and their components are implanted around, inside, or superficial to a patient's heart according to the device's size, functionality, and purpose. A surgical procedure is required for the permanent placement of these devices. CIEDs are used for heart rate and heart rhythm management for individuals at risk for slow heart rate, known as bradycardia, and deleterious arrhythmias such as ventricular tachycardia or fibrillation. There are many disease processes and conditions that may put patients at risk for electrophysiological abnormalities. In

response to this risk, providers suggest CIED placement to their patients to mitigate risk and treat heart rate and rhythm issues. Pacemakers can stimulate the heart using electrical current to stimulate contractions at a desired rate. Pacemakers have many settings concerning which chambers of the heart they stimulate, when they intervene, and how the native heartbeat is detected. The cardioverter-defibrillator can use stronger electrical stimulation to pause the heart during lethal arrhythmias. This treatment attempts to reset normal electrical conduction in the heart. Today's CIED technology comes with a variety of settings and capabilities.

Improper perioperative CIED management by Certified Registered Nurse Anesthetists (CRNAs) has the potential to cause extensive patient harm. Most of the deleterious patient outcomes are related to the inability to limit electromagnetic interference (EMI) and failure to restore patients' pre-operative device settings if changes were made intra-operatively (Neelankavil et al., 2013). EMI is caused by several intra-operative instruments, but mainly by mono-polar electrocautery (Chia & Foo, 2015). Although bipolar electrocautery is a safer alternative, it is rarely preferred by surgeons due to its limited ability to cut and coagulate (Neelankavil et al., 2013). The harmful effects of EMI are due to the patient's device detecting this external electrical activity as intrinsic activity, leading to the triggering of unnecessary events such as pacing and defibrillation. The use of magnets intra-operatively is a method used to prevent inappropriate interventions delivered from the CIED. This is completed by placing the device in an asynchronous mode which limits external interference. Another common preventative measure can be to limit known sources of EMI in proximity to the CIED to 6 inches (>15 cm) as recommended by the Heart Rhythm Society (HRS) and the American Society of Anesthesiologists (ASA; Arora & Inampudi, 2017).

Adding to the difficulty of caring for these patients are the ongoing technological advancements in CIEDs, including their large variety of functionality and brand-specific features (Karuppiah et al., 2020). Constant changes leave anesthesia providers with uncertainty and ambiguity as they attempt to provide the best care practices specific to each patient. Although guidelines provided by various organizations, groups, and medical professionals exist (Chakravarthy & George, 2017), adopting a standardized tool may assist CRNAs in providing care for patients with CIEDs. Providing a standardized approach to patients with CIEDs attempts to address all aspects of the Quadruple AIM developed by the Institute for Healthcare Improvement (2022). Standardization of care could improve the delivery of care by anesthesia providers and also enhance the patient care experience by reducing the likelihood of harmful outcomes and increased healthcare costs specific to this patient population (Karuppiah et al., 2020).

The HRS and ASA are two examples of trusted organizations that aim to provide up-to-date guidelines on patient care interventions under specific circumstances (Feldman & Stone, 2020). Many providers throughout the country utilize their guidelines, which are mostly generated by an expert panel. These expert panels commonly use their clinical experience and expertise to develop recommendations, but statistical evidence is usually not provided as support (Solomon-Adenola, 2020). CIED guidelines that are produced typically include general device education, new technology, and common issues with suggested treatment. If hospital policies are not readily accessible to providers, it is inferred that CRNAs use similar and supported guidelines to direct their care. Although they are commonly used, recommendations may differ between organizations, are not commonly supported by statistical evidence, and may not have

the most current data to address newer technologies (Feldman & Stone, 2020). The AANA does not currently endorse nor address anything regarding CIED management for CRNAs.

Organizational Needs Statement

Our partnering organization is one of the largest hospitals in North Carolina. The facility provides care to eastern North Carolina, an area where many residents either currently have CIEDs or have a high incidence for the need for CIEDs related to comorbidities. Anesthesia team members, specifically CRNAs, must be knowledgeable regarding CIEDs to deliver safe care during the perioperative period. Eliminating variability and providing a consistent tool, such as a checklist, may assist nurse anesthetists within the organization in decision-making specific to perioperative care for patients with CIEDs. An important goal of nurse anesthetists near the time of surgery is to ensure all safety measures are implemented. Providing more uniformity in the CRNAs' approach to delivering care has the potential to improve their patient management skills and may be beneficial in a time of decision-making. As mentioned, this would support the organization in achieving the Quadruple AIM established by the Institute for Healthcare Improvement (IHI).

Problem Statement

The current process for anesthesia providers delivering perioperative care for patients with CIEDs lacks standardization and creates the potential for unexecuted safety measures that should be taken to avoid potentially dangerous or lethal outcomes for these patients related to their devices.

Purpose Statement

The purpose of this quality improvement project was to assess anesthesia providers' perceptions of an AID/PPM Handout as an educational tool to improve perioperative CIED management and patient safety.

Section II. Evidence

Description of Search Strategies

To gather sufficient information and evidence regarding both the problem and potential solution, a structured literature search was completed. For the search, PubMed, Google Scholar, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) were used to identify current evidence on nurse anesthetists' perceptions of their management of perioperative care for patients with AICDs. The following concepts were used in gathering evidence: *anesthesia, pacemaker, perioperative, and management* (See Appendix A). To narrow results for concise and credible material, search results were limited in the years they were published, from 2002 (PubMed and CINAHL) or 2017 (Google Scholar) to the time of the search (2022), and English language. Appendix B provides an overview of the search strategies used, which returned nearly 100 articles between PubMed and CINAHL, and a large number in Google Scholar with a review limited to 10 pages of results. From potential articles identified through the search, 18 were saved for their data regarding CRNAs' management of AICDs during the perioperative period. From references cited within these selected articles, additional articles and online sources were also identified and reviewed.

Initially, most of the material identified was directed toward appropriate and supported interventions and techniques to manage CIEDs, rather than the perceptions of CRNAs of that management. To identify evidence addressing the perceptions of nurse anesthetists, efforts were redirected toward extracting material from a larger volume of broadly defined articles and guidelines. Most articles pertinent to this project comprised of expert opinions endorsed by particular organizations and medical institutions. Upon full-text review and based on the levels of evidence as described by Melnyk and Fineout Overhol (2019), a single case report (Level VI), one qualitative study (Level VI), and five expert opinion papers (Level VII) were identified as

pertinent to this project. Most literature addressing CIED management by CRNAs is of low-level quality and was evident during research for this project. Solomon-Adenola (2020) also completed a project with a similar topic and reported that most literature addressing CIED management by CRNAs is of low-level quality. Pertinent resources used for data and evidence extraction are displayed in a Literature Matrix as Appendix C.

Selected Literature Synthesis

Within the literature, there is consensus that anesthesia providers' knowledge of CIEDs and their management is critical for patient safety during the perioperative period. Evidence also consistently supports the following themes: lack of sufficient statistical data on management techniques (Solomon-Adenola, 2020), guidelines vary over time and between professional organizations (Chia & Foo, 2015; see also Feldman & Stone, 2020), and advances in device technology may lead to complex management (Chakravarthy & George, 2017; see also Karuppiah et al., 2020). Source material differs in devices used, clinical settings, patient populations, and preferences of clinical guidelines. By improving their knowledge of CIED management, anesthesia providers can establish more standardized care for these patients during the perioperative period.

Statistical data used to guide perioperative care for patients with CIEDs is severely lacking. During the search, most current literature to guide CIED management on EMI is primarily supported by expert opinion endorsed by associations and by minimal statistical data. Solomon-Adenola (2020) performed a single qualitative study. The author described most current evidence addressing the assessments of anesthesia providers on surgical patients with CIEDs as mostly low quality. They suggested that support is needed in order to improve perioperative safety for these patients. The authors also suggest that although recommendations

for perioperative CIED management may be consistent in many areas, the limited quality and amount of statistical data to guide practice may hinder care.

After reviewing the selected articles, it was clear that anesthesia providers face difficulties managing patients with CIEDs. While CRNAs are providing care, they must account for differences in device function and capabilities. Additionally, it is essential that they follow updated changes in new technology for both CIEDs and causes of EMI, all while ensuring their practices are following the most recent guidelines (Feldman and Stone, 2020). While some evidence focuses on particular obstacles (Arora & Inampudi, 2017), others broadly describe the challenges CRNAs face with CIED management from a holistic view (Solomon-Adenola, 2020). These obstacles are a possible contributing factor to the lack of standardization in care.

Many sources of literature highlight the technology that continues to change with time, warning anesthesia providers of the constant changes in the care they must make for patients with CIEDs (Solomon-Adenola, 2020). This is supported by the drastic changes in technology since the first pacemaker was introduced in 1958 by Dr. C. W. Lillhei and Earl Bakken (Arora & Inampudi, 2017). In fifty-eight years since the introduction of this technology, the healthcare community has seen frequent changes and improvements during its evolution. Within the last six years, newer technology has incorporated leadless technology that is unique to traditional models (Karuppiah et al., 2020). These same authors also noted that, as of 2020, two companies were providing this device in the United States. The technology is different in that the device is buried within the myocardium and will not respond to magnetic therapy as most previous devices do. In the work by Karuppiah et al. (2020), the anesthesia team was unfamiliar with the device, which ultimately led to a long delay in the scheduled surgery. Delays were described as a waste of hospital resources, ultimately leaving a financial strain on hospital finances.

As the variety of devices continues to grow, anesthesia providers may suffer from a lack of experience with particular models, potentially causing device mismanagement or even patient harm. An additional aspect of care related to changes in technology is surgical equipment causing EMI. Some of the information in current literature suggest that new surgical tools being implemented in the surgical area every year increase the risk of EMI (Neelankavil et al., 2013). Advances in technology have saved many lives, however, in CIED management, this potential benefit does not come without risk.

The selected literature supported the use of recent guidelines for directing care, though there were variations between which set of guidelines to be followed and how to address differences between recommendations. Feldman and Stone, (2020), described the different approaches between the published guidelines of the HRS and the ASA. For example, they described the HRS as recommending that anesthesiologists write specific CIED management plans for all patients with these devices undergoing surgeries, while the ASA only suggested a device interrogation if it had not been completed within the past 6 months. The authors also noted how the two associations' guidelines differed in their magnet use recommendations, with the HRS providing clear instructions for magnet use while the ASA provided limited support.

Another discussion evident within the literature corresponds with anesthesia providers' reluctance to change (Solomon-Adenola, 2020). This reluctance was found to be multifactorial and may be challenging to address if a permanent change is expected. These factors may include lack of time, poor communication, no mandates, and acceptance of mediocrity. Solomon-Adenola (2020) also stated that even though anesthesia providers are actively practicing with newer guidelines, constant reinforcement was required, writing "Continual reciprocal feedback

and communication between stakeholders and anesthesia staff on a change's success are necessary to make modifications" (Solomon-Adenola, 2020, pg. 8).

The identified literature primarily supports that anesthesia providers play a pivotal role in the safety of patients with CIEDs concerning the management of their devices (Solomon-Adenola, 2020). Time has proven that the proper management of CIEDs can only be achieved through awareness and adaptation. Constant growth in technology, patient demand, differences amongst guidelines, and providers' resistance to change lead to difficulty achieving standardization of care.

Project Framework

The plan-do-study-act (PDSA) cycle was utilized to complete this quality improvement project. The PDSA is an effective tool for documenting a test of change and has been used previously in hundreds of quality improvement projects within hospital organizations. (IHI, 2022). Developed in the 1920s by Andrew Shewhart, the model has four components: developing a plan, executing a test, learning from observation and consequences, and modifying components of the test for future use (Connelly, 2021). During the completion of this project, all components of the PDSA model were accomplished. First, a plan was developed for testing and collecting data to assess anesthesia providers' perceptions of a standardized "Cardiac Implanted Electronic Device Safety Tool" as a useful instrument for improving perioperative CIED management for patient safety. This plan included the development of the CIED Safety Tool along with formulating surveys to determine its value to CRNAs. After the plan was finalized, the test was implemented on a small scale within the organization. The test involved the delivery of the safety tool and an educational presentation, as well as pre-and post-surveys to obtain participant feedback. Following data collection, the study portion of the PDSA model was

implemented. Results were organized, analyzed, and displayed as visuals created using Excel. To complete the project, recommendations were considered for future use as the "act" portion of this model. By employing the PDSA model, this quality improvement project assessed anesthesia providers' perceptions of the newly developed AICD/PPM Handout as a useful instrument for improving perioperative CIED management by anesthesia providers, thus enhancing patient safety.

Ethical Considerations and Protection of Human Subjects

Ethical considerations were applied in all phases of this project. The intervention was shared with all interested participants within the target population of CRNAs as described. At no point during this project was any personal data gathered or presence for potential harm to the target population identified. The intervention was based on currently accepted standards already utilized in standard care delivery. To prepare for the formal approval process, Collaborative Institutional Training Initiative (CITI) modules focused on research ethics and compliance in human research were completed by the primary project lead (https://about.citiprogram.org/en/homepage/).

This quality improvement project met the criteria for approval as quality improvement through a special review process set up by East Carolina University (ECU) College of Nursing in conjunction with the University Medical Center Institutional Review Board (UMCIRB). It was therefore exempt from full IRB review. Additionally, facility approval was completed through the research office of the partnering facility in concurrence with the ECU UMCIRB. Local facility approval to collect data was obtained from a site contact person who signed the organizational approval form as part of the formal review process. See Appendix D.

Section III. Project Design

Project Setting

The setting for this project was in cardiovascular-designated operating rooms (OR) located within a Level 1 Trauma Center in North Carolina. This facility houses 37 ORs divided-between the main OR, cardiovascular OR, and outpatient surgicenter. Types of surgical procedures provided at this facility include general, minimally invasive, transplantation, pediatric, vascular, plastic, oncologic, thoracic, and trauma. Approximately 27,000 surgeries are conducted at this facility annually, all while serving over a million inpatient visits across the multi-hospital network each year.

One potential barrier related to the setting was that the introduction of new items is difficult to incorporate due to the operating rooms set up and the potential for the introduction of germs. The placement of printed handouts was confined to 3 areas. Those were break rooms, locker rooms, and documentation areas commonly used by the anesthesia staff. Access to mobile devices intra-operatively, to be used in the retrieval of the AICD/PPM Handout, is not well-supported which may have limited use of the intervention as well.

Project Population

The population of focus for this project included both full-time and part-time CRNAs employed by the participating facility who were assigned cases in the cardiovascular-designated ORs. As advanced practice registered nurses, CRNAs can deliver anesthesia in a variety of settings. Nurse anesthetists at the participating facility work autonomously, but also in collaboration with anesthesiologists, throughout the perioperative period. These CRNAs remain present during the duration of the surgical procedure to ensure patient safety. Travel CRNAs

were not included to ensure all participants would have access to the provided intervention and surveys throughout the entire allotted time of the study.

The most prominent barrier to participation by this population was lack of time. CRNAs typically have a heavy workload consisting of several procedures that vary in start times and duration. These procedures may last from minutes to hours, giving little predictability in daily schedules. Added to their schedule, production pressure for operating room efficiency makes CRNA availability and willingness to participate a difficult barrier to overcome. Aside from time constraints, another barrier identified was access to the handout for the CRNAs during their cases.

Project Team

A collaborative team was necessary for the successful completion of this project. This team was comprised of a team lead, three Student Registered Nurse Anesthetist (SRNA) classmates, a project chair, a facility CRNA contact, a clinical instructor, a program director, and a course director. Some project team members were able to adopt multiple roles. Development of the safety tool and pre- and post-intervention questions was accomplished in coordination with the three additional SRNA classmates working on the same topic. The team lead independently performed literature searches, implemented the intervention, collected participant data, and synthesized results. The project chair, a CRNA faculty member and the program director, aided in constructing the outline of this project as well as transitioning the project into the clinical setting. The clinical director and facility contact, also a current CRNA, assisted with the implementation of the project through communication with the participating facility to help identify willing participants. The course director provided guidance in gathering existing literature, designing and conducting research, gaining IRB approval, and the writing process.

Methods and Measurement

This quality improvement project was constructed and performed to assess anesthesia providers' perceptions of a CIED handout as an educational tool to improve perioperative CIED management and patient safety. The goals of this project were to provide additional education and a useful resource to assist CRNAs in managing patient care with CIEDs. The intervention was a safety tool designed to be used as education and a brief perioperative guide for CRNAs. See Appendix G. In addition to the tool, a succinct presentation introduced the tool and the topic. For data collection, two Qualtrics surveys pre- and post-intervention, were used to measure the perceptions of CRNA participants toward the usefulness of the safety tool. The surveys were comprised of Likert-style questions which provided ordinal data for analysis. Both pre- and post-intervention surveys are displayed in Appendix E.

Methods Used

The plan, do, study, act (PDSA) cycle was utilized to guide each step of the project during its course. During the "Plan" phase, literature searches and IRB approval were completed. During this phase, the project team met several times. The team first defined the problem and purpose statements. Following meetings were used to designate tasks, discuss the outline of the project, make amendments, and collaborate. Prior to moving forward to other phases in the project, approval was gained from both the university and the partnering facility (see Appendix D).

The "Do" phase involved this SRNA sending electronic mail to potential participants that contained a Qualtrics link to the pre-survey as well as the constructed intervention. See Appendix F. The handout was a pdf-formatted document that could be used by participants as a

printout or retrieved on a mobile device See Appendix G. The educational presentation was also delivered as a handout and electronic copies sent via hyperlinks. In addition, participants were provided with instructions on how to use the tool as well as an overview of CIED management.

Data interpretation and analysis represent the "Study" phase of this cycle. The goal of this phase was to note any changes in the perceptions of the CRNAs regarding CIED management after using the tool. Trends were identified and the benefit of the intervention was weighed after comparing how much improvement was noted compared to the cost and time spent on the study.

Within the "Act" phase of the cycle, data was shared via poster presentation with other students and faculty of the ECU College of Nursing Nurse Anesthesia Program. Project participants were also invited. Upon completion of the project, upload of this paper to The Scholarship, ECU's digital repository, was also completed.

Timeline

In the fall of 2022, the project began with a thorough topic review, the creation of a tool to use as the intervention, and approval through a quality improvement project screening process with the UMCIRB. For topic research, multiple databases and a search engine were used to gather pertinent data on perioperative CIED management by anesthesia providers. During the literature review process, sources were gathered, and a synthesis of identified information was completed. After identification and synthesis of current evidence, the CIED safety tool and educational presentation were created to be used as the intervention for this project. The quality improvement screening approval process was completed, and the project was determined to meet criteria for this classification.

In the spring of 2023, the project was implemented, and data was gathered from participants. Before implementation began, approval to perform the project was obtained from the partnering facility. Attempts were made to reduce the exposure to COVID-19 and influenza viruses of both project members and participants during the course of the project, with interaction and communication between the project team designed to be primarily through electronic mail. Data collection was through Qualtrics surveys, with survey links shared through electronic mail. The project was completed as planned; however, changes were made after the second day of implementation regarding the size of electronic files to provide mobile access for participants. Data interpretation, analysis, and sharing occurred in the subsequent months in the summer and fall of 2023.

Section IV. Results and Findings

Results

Data was collected from participants, using pre-intervention and post-intervention Qualtrics surveys, to assess anesthesia providers' perceptions of an AICD/PPM Handout as an educational tool to improve perioperative CIED management and patient safety. The data was collected via Qualtrics and then analyzed using Microsoft Excel software. Ten participants were given access to the surveys through links sent via email. Pre-intervention survey participation included seven individuals, while post-intervention survey participation included five. Participants originally had a deadline of two weeks to complete the surveys, however, due to larger file sizes of the intervention causing access issues from mobile devices, the duration of the study was expanded to 4 weeks and 4 days. Online copies and compressed files were created to provide mobile access to all participants.

The pre-intervention survey consisted of questions that assessed the following: Any current standardized approaches, the frequency of difficulty obtaining device information, regularity of device malfunctions, length of time to gather pertinent device information, comfort in providing care, comfort in managing cases during high risk of EMI, use of the facility's current AICD/PPM policy, familiarity with current guidelines, involvement of poor outcomes related to AICD/PPM, and the need for an educational tool (see Appendix E). For the post-intervention survey, evaluation was made regarding the usefulness of the AICD/PPM Handout, frequency of use of the intervention, time reduction in gathering information, improved comfort in providing care, ability to identify and managing high-risk procedures, confidence in assessment, familiarity with current guidelines, and improvement in assessment efficacy (see Appendix E).

Data Presentation

Pre-intervention survey links were emailed to the ten CRNAs on April 16, 2023. Seven of the 10 individuals participated, with responses received between April 16-26, 2023. One question assessed the use of a standardized approach to care for patients with devices, for which three participants answered "no," while four participants answered "yes." The survey also asked how frequently CRNAs encountered difficulty obtaining all necessary information on a patient's AICD/PPM (such as manufacturer, type, last interrogation, etc.). One participant answered "sometimes," another "about half of the time," and the remaining five participants "most of the time."

The CRNAs' comfort levels in providing care for these patients and identification of high EMI risk were asked in two separate questions. All seven respondents had varying levels of agreement with the statement demonstrating adequacy in their level of comfort in providing care for patients with CIEDs. Specifically, six of these individuals responded they "strongly agreed." As for the statement in identifying level of comfort identifying high EMI risk instances, two respondents indicated adequate comfort as they "somewhat agreed", while the remaining five "strongly agreed." Of the seven respondents, three answered that they had experienced issues with AICD/PPMs during their career at some point within the perioperative period. In the assessment of awareness of the current policy within the facility, results alluded that a substantial majority of participants were unaware of or did not use the facility's policy (Figure 1). Despite the lack of a current hospital policy on perioperative management of CIEDs, participants responded that they are aware of and use current practice guidelines provided by the ASA and HRS. Conversely, the facility's current policy, favored CRNAs awareness and use for the majority. As seen in Figure 2, for the time needed to gather pertinent information on devices pre-

operatively, most responses indicated “5-10 minutes" though two answered ">15 minutes.” Although only one of the individuals answered that they knew of poor patient outcomes from improper AICD/PPM management peri-operatively, four of the seven agreed that further AICD/PPM education could reduce possible adverse outcomes.

Figure 1

Pre-intervention Awareness and Use of the Facility's Current Policy (n=7)

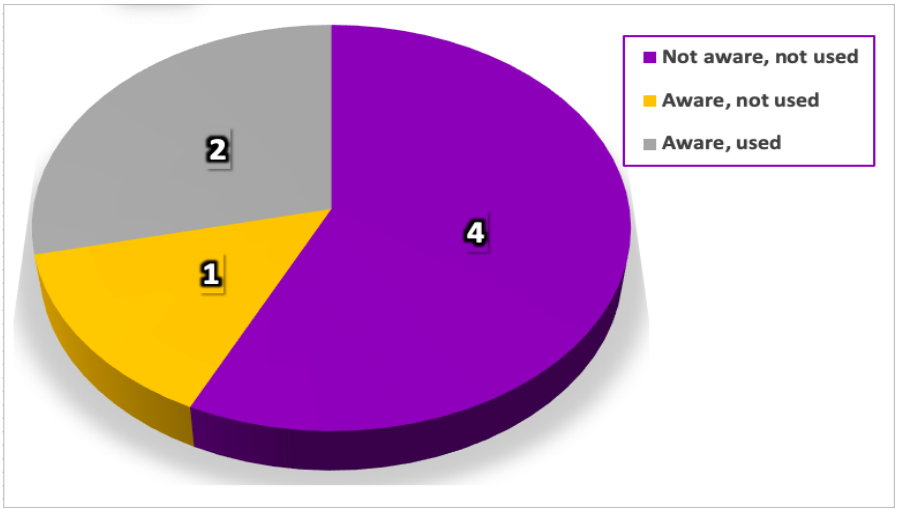
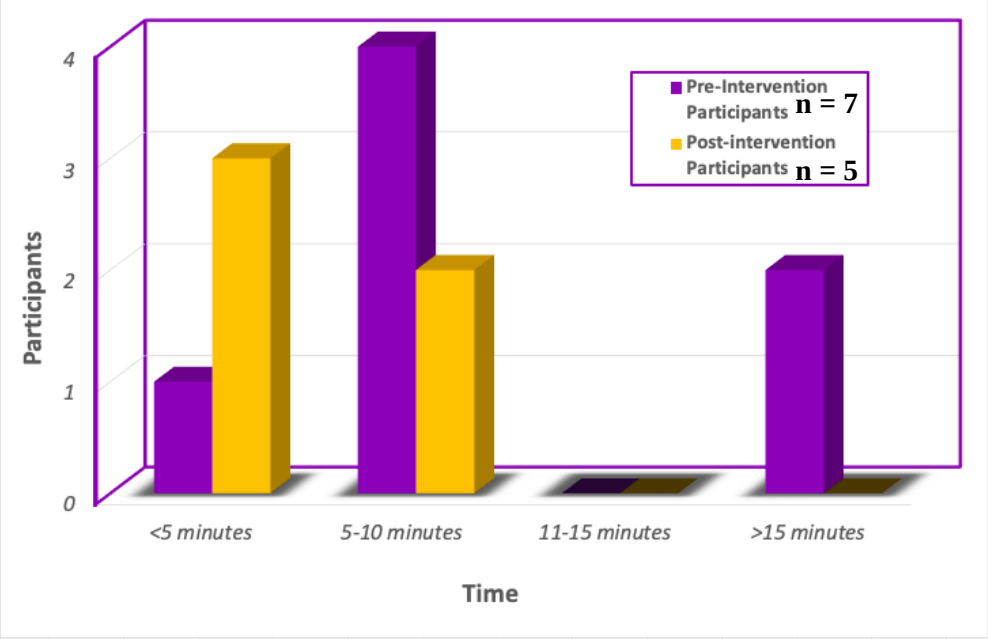


Figure 2

Estimated time to gather pertinent AICD/PPM information.



Post-intervention survey links were emailed to the ten CRNAs on April 26, 2023. Five of the ten potential participants completed the survey, with responses received between April 16-26, 2023. All respondents answered that the intervention was practical, two of which reported it being either “extremely” and “very useful,” while the remaining three reported it as “slightly useful.” Although the participants reported they found benefits in using the AICD/PPM Handout, all respondents reported only using it in a maximum of two procedures apiece due to their case load and patient assignments. As shown previously in Figure 2, after utilizing the AICD PPM Handout, no participants selected an option above "5-10 minutes" when responding regarding how long it took them to find necessary device information. Although results varied regarding perceived efficiency with patient assessment, four individuals reported it was “likely” they would be using the AICD/PPM Handout in the future.

Analysis

While analyzing differences between the pre- and post-intervention survey results, several inferences were drawn that support the need for open communication and education regarding perioperative care for patients with AICDs/PPM. It is a concern that few respondents were aware of either the facility’s policy or the current ASA and HRS guidelines. The point could be raised that potentially harmful gaps in patient care due to lack of awareness of current practice standards could result from this deficit. Additionally, all participants responded that they thought more education on AICD/PPM care would be beneficial in reducing adverse outcomes. This supports a recognized need for education, and additionally the potential benefits that CRNAs have for educational interventions. This idea can be further supported by the fact that the

interventional tool was perceived to be useful in some degree by all respondents, specifically one respondent answering, “extremely useful” and another “very useful.”

Aside from education, it was evident that most CRNAs encounter problems in attaining pertinent device information, which can consume time, affecting delivery of cares and delays in procedures. Fortunately, with a guide such as an AICD/PPM Handout, the amount of time wasted gathering device information can be decreased, as supported by comparison of pre- and post-intervention results. Before using the intervention, two of seven participants responded that they took at least 15 minutes to gather patient/device information. In contrast, all participants attained the necessary information in under 10 minutes following use of the AICD/PPM Handout. Majority the respondents “strongly agreed” that they had confidence in managing patients with AICD/PPM, however, despite their confidence, all believed, in varying strength, that additional education could prevent negative outcomes.

Section V. Implications

Financial and Nonfinancial Analysis

The main costs of this project can be found in the time taken to organize and produce the intervention and the printing of the physical copies needed for distribution within the facility. Both, however, come at low costs compared to potential adverse patient outcomes and prolonged OR times. If the leadership personnel in the facilities decided to include this project within the annual education curriculum required for anesthesia providers, they could reduce the compensation and time needed for instructors and participants. Depending on the number of CRNA staff and the size of the facility, the number of physical copies of the intervention needed to sustain this project could be anywhere from 20 to 60 single-sheet copies. With the average black and white copy costing 5 to 8 cents per sheet and colored copies costing an average of 8 to12 cents per sheet (Errera, 2023), a facility could expect to spend anywhere from $1 to $7.20 on printing costs. To further reduce costs, physical copies could be replaced by providing access to digital copies on computers facility-wide.

The cost of facilitating this project is outweighed in comparison to the potential costs of adverse patient outcomes. As indicated by Feldman and Stone (2020), clinical risks associated with improper patient management could result in device malfunction leading to sustained hypotension, arrhythmias, and myocardial tissue damage. These risks may ultimately result in extended hospital stays, ICU admissions, cancellation of surgery, and additional hospital resource utilization. For example, the average daily cost of a hospital bed on a general unit is $1,772, and an ICU bed $2,902 (Ohsfeldt et al., 2021). Organizations that decide to make a small financial investment in enrolling the AICD/PPM Handout could prevent large expenses that heavily outweigh the benefits related to cost.

It should also be considered that prolonged time spent on data collection for pertinent device information can be costly to the patient and an unnecessary waste of resources for the facility. According to Childers and Maggard-Gibbons (2018), $36 to $37 can be charged to a patient with each minute spent in the OR, on average. Poor patient satisfaction rates, lower hospital ratings, lawsuits, and reduced reimbursement are also negative consequences that may result from the negative patient outcomes previously mentioned. Aside from financial implications, it is also important to note that post-survey results indicated that most CRNAs perceived using an education guide, such as the AICD/PPM Handout, could improve quality by reducing poor patient outcomes.

Implications of Project

As previously mentioned, improper patient care and AICD/PPM management in the perioperative phase could lead to severe cardiac harm, ultimately leading to other negative outcomes. The rates of device-induced cardiac-related harm such as sustained hypotension, myocardial tissue damage, and arrhythmias have the potential to be reduced when using tools such as the AICD/PPM Handout. The HRS and ASA routinely provide updated practice guidelines to assist anesthesia providers in delivering safe and efficient care to patients with AICD/PPM devices. These guidelines were developed on the sole premise of reducing patient harm by the reduction of preventable device-induced injuries through education.

The use of the AICD/PPM Handout would make hospital policy and current practice guidelines more available to CRNAs and would likely increase its application with the ultimate goal of reducing patient harm. In addition to reducing patient harm and providing quality improvement, this or a similar tool could help educate CRNAs and improve their time efficiency.

Sustainability

Considering the low cost to implement this project and the potentially high cost of adverse patient outcomes associated with improper AICD/PPM management, along with possible reduction in procedural delays, the participating organization should find this intervention to be cost-effective during consideration for future use. The sustainability of this project could depend upon the facility's willingness to maintain physical copies of project materials in work areas, email frequent reminders to possible participants, update materials, motivate employees, and continue access to project materials on computers facility-wide. It should also be noted that any new hires could be educated on the implementation project during their orientation period. The long-term sustainability of this project would heavily depend on these factors.

Dissemination Plan

A poster and presentation of the results of this quality improvement project were shared with CRNA department members, project participants, fellow SRNAs, and members of the project team. Individuals were notified and encouraged to attend this presentation but were not required to participate. In addition, this paper and poster were uploaded to The Scholarship, an online digital archive of work by East Carolina University’s faculty, staff, and students. This archive will provide ongoing access to these materials for any individual interested in learning about this project.

Section VI. Conclusion

Limitations

The primary limitations of this project included varying numbers of pre-intervention to post-intervention survey participants, short length of study, a small sample size, issues with technology, and ambiguous responses. The pre-intervention survey was completed by seven individuals, as compared to five for the post-intervention survey. This discrepancy potentially limited the efficiency assessment of the AICD/PPM Handout as shown in the survey questions. The length of time taken to complete the survey may have also been a limitation within the project. The duration of this project was four weeks and four days but could have been extended to compensate for participants spending less time in the heart institute compared to the main OR and for those individuals taking time off work. An additional limitation of the project was the inability of individuals to download digital copies of the intervention and PowerPoint during the first week of the project due to large file size, a problem corrected in the following weeks. Participants who experienced difficulty with access may have chosen not to participate despite correction of this issue. Ambiguity could also be considered a limitation, considering direct comparisons could not be made between pre- and post-intervention survey responses.

Recommendations for Future Implementation and/or Additional Study

Recommendations for adjusting this project for future study include: producing a larger sample size, creating individualized survey links, assessing the staff schedule, decreasing digital file sizes, incorporating a third-party observer, and providing direct access to project materials (intervention and PowerPoint) throughout the facility's computers. Larger sample sizes could be achieved by implementing the project in a larger portion of the facility, or more than one facility, and encouraging travel and contract CRNAs to also participate. Travel and contract CRNAs may

be less likely to participate due to varying schedules and less organizational buy-in, and it should be noted that some facilities currently employee large numbers of this category of employees. Individualized survey links could allow for more direct comparisons of pre- and post-intervention survey results and better follow-up communication should the participant fail to complete a post-intervention survey. Prior to implementation, it would also be advisable to assess the staffing schedule and plan implementation during a period that avoids federal holidays and employee vacations, as procedure numbers and available participants may be limited.

Future studies may also find benefit in reducing the sizes of digital files to be accessed by participants, should they be used. Mobile access to materials used in future projects may encourage participation, however, this access could be hindered by larger file sizes that require long download times or unable to be downloaded completely. An additional recommendation would be to incorporate an unbiased third-party observer. A third-party observer present during the intervention could provide more accurate data collection, such as time spent looking up pertinent AICD/PPM information and duration of procedural delay, should one arise. Observers could also encourage use of the intervention to enhance the number of participants. Providing direct access to project materials on the main desktop screen of all computers throughout the facility may limit access issues for participants. It could also serve as a reminder to participate in the project. These recommendations may support a more thorough data-collection process.

The final suggestion for future studies would be to assess the usefulness of a specific decision-based algorithm for perioperative management of CIEDs, rather than a generic educational handout or tool. Many national healthcare protocols, such as BLS and ACLS, are commonly presented in algorithm-based formats. These algorithms are frequently seen throughout patient care areas and could attract more attention from healthcare providers. Due to

their prevalence, healthcare providers may find more comfort and ease of use with this style of format for an intervention.

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Appendix A

Literature Concepts Table

	Concept 1: Anesthesia	***Concept 2: Pacemaker***	***Concept 3: Perioperative***	***Concept 4: Management***
Keywords	Nurse Anesthetists, Anesthesia team, CRNA, Anesthesiologist	Pacemakers, cardiac implanted electronic devices, permanent pacemakers, AICD/PPM	Perioperative, preoperative, postoperative, intraoperative, surgical	Device management, patient safety, interventions
PubMed	"anesthesia" [MeSH Terms] OR “nurse anesthetist” [MeSH Terms]	"pacemaker, artificial" [MeSH Terms] OR “defibrillators” [MeSH Terms] OR “AICD”	"surgical procedures, operative" [MeSH Terms] OR "perioperative period" [MeSH Terms]	"workflow" [MeSH Terms] OR "patient safety" [MeSH Terms] OR "disease management" [MeSH Terms] OR "organization and administration"[MeSH Terms]
CINAHL	(MH “Anesthesia”)	(MH “Defibrillators, Implantable”) OR (MH “Pacemaker, Artificial”)	**Didn’t use** too few results	**Didn’t use** too few results
Google Scholar	“Anesthesia”	“Defibrillators” OR “Pacemaker” OR “AICD”	“Perioperative”	“Management”

Appendix B

Literature Search Log

Search Date	*Database or Search Engine*	*Search Strategy*	*Limits Applied*	*Number of Citations Found/Kept*	*Rationale for Inclusion/ Exclusion*
9/7/22 9/8/22	PubMed	Anesthesia AND Pacemaker AND Perioperative AND Management (("anaesthesia"[All Fields] OR "anesthesia"[MeSH Terms] OR "anesthesia"[All Fields] OR "anaesthesias"[All Fields] OR "anesthesias"[All Fields]) AND ("pacemaker s"[All Fields] OR "pacemaker, artificial"[MeSH Terms] OR ("pacemaker"[All Fields] AND "artificial"[All Fields]) OR "artificial pacemaker"[All Fields] OR "pacemaker"[All Fields] OR "pacemakers"[All Fields] OR "pacemaking"[All Fields]) AND ("perioperative"[All Fields] OR "perioperatively"[All Fields]) AND ("manage"[All Fields] OR "managed"[All Fields] OR "managements"[All Fields] OR "managements"[All Fields] OR "manager"[All Fields] OR "manager s"[All Fields] OR "managers"[All Fields] OR "manages"[All	Date: 2002-2022 English	74 found/14 kept	Exclusion: Diaphragmatic pacing not relevant/temporary transvenous pacemaker not adequate/ duplicates

		Fields] OR "managing"[All Fields] OR "managment"[All Fields] OR "organization and administration"[MeSH Terms] OR ("organization"[All Fields] AND "administration"[All Fields]) OR "organization and administration"[All Fields] OR "management"[All Fields] OR "disease management"[MeSH Terms] OR ("disease"[All Fields] AND "management"[All Fields]) OR "disease management"[All Fields])) AND (english[Filter])			
9/7/22 9/8/22	CINAHL	(MH "Anesthesia") AND (MH "Pacemaker, Artificial")	Date: 2002-2022 English	21 found, 4 kept (2 New, 2 Duplicates)	Exclusion: Duplicates, non-relatable surgical interventions
9/7/22 9/8/22	Google Scholar	Anesthesia AND Pacemaker AND Perioperative AND Management	Date: 2017-2022 English	10 pages searched, 8 kept (2 New, 6 were duplicates)	Exclusion: Duplicates, device brand specific, surgery specific, animal studies, non-cardiac electronic devices

Appendix C

Literature Matrix

Author, Title, Journal	*Year*	*Purpose & Conceptual Framework or Model*	*Design and Level of Evidence (Melnyk)*	*Setting*	*Sample*	*Tool/s and/or Interventions*	*Results*
Arora, L., & Inampudi, C. (2017). Perioperative management of cardiac rhythm assist devices in ambulatory surgery and non-operating room anesthesia. *Current Opinion in Anesthesiology*, *30*(6), 676-681.	2017	Review existing data and to provide education of the anesthesia team regarding perioperative management and need education on such devices. No conceptual framework/ model.	Level VII: Expert opinion	Hospital/ Operating Room	N/A	N/A	Demonstrates lack of data on Perioperative CIED management. Majority of information provided by expert opinion endorsed by societies. Table presented on generic code for understanding anti-bradycardia pacing mode abbreviations Expert opinion provided based on recent advancements in CIED expansion of use, and new considerations according to existing guidelines.
Chakravarthy, M., Prabhakumar, D., & George, A. (2017). Anaesthetic consideration in patients with cardiac implantable electronic	2017	Provide basic understanding of pathophysiology, device characteristics and troubleshooting before embarking on anesthetizing	Level VII: Expert Opinion	Hospital/ Operating Room	N/A	N/A	Anesthesiologists irrespective of the subspecialty of their practice may make an effort to understand equipment

devices scheduled for surgery. *Indian Journal of Anaesthesia, 61(*9), 736.		patients with implantable cardiac electronic devices. No conceptual framework/ model.					characteristics, troubleshooting, and bail out of catastrophic complications. The number of CIED implants will increase with increasing number of patients having indications for placement of the same; thus, the need to understand them becomes all the more important.
Chia, P. L., & Foo, D. (2015). A practical approach to perioperative management of cardiac implantable electronic devices. *Singapore Medical Journal*, *56*(10), 538.	2015	To discuss and presents a practical approach to perioperative CIED management in Singapore. No conceptual framework/ model.	Level VII: Expert Opinion	Singapore Hospitals	N/A	N/A	Flowchart of proposed algorithms for the perioperative management of patients with cardiac implantable electronic devices (CIED) in an emergency and non-emergency settings. -Expert opinion provided based on collaboration of several guidelines.
Feldman, J. B., & Stone, M. E. (2020). Anesthesia teams managing pacemakers and ICDs for	2020	To determine whether current practice guidelines align with the newer CIED's and the	Level VII: Expert Opinion	Hospital/ Operating Room	N/A	N/A	Current practice recommendations now acknowledge that not every patient requires a

the perioperative period: enhanced patient safety and improved workflows. *Current Opinion in Anesthesiology, 33(*3), 441-447.		necessity of old guidelines/ recommendations. No conceptual framework/ model.					formal interrogation of their CIED before and after surgery (as was previously suggested).
Karuppiah, S., Prielipp, R., & Banik, R. K. (2020). Anesthetic consideration for patients with micra leadless pacemaker. *Annals of Cardiac Anaesthesia, 23(*4), 493.	2020	To highlight perioperative challenges due to the devices' novelty, paucity of report, and guidelines. To reduce patient danger and delays in care. No conceptual framework/ model.	Level VI: Single Case Report	Hospital/ Operating Room	1 patient – single case report	N/A	With Medtronic Leadless Pacemakers if a concern for EMI, Medtronic recommends programming to asynchronous mode and to restore device parameters postoperatively. In emergent situations where preoperative reprogramming is not possible, follow hospital procedures.
Neelankavil, J. P., Thompson, A., & Mahajan, A. (2013). Managing cardiovascular implantable electronic devices (CIEDs) during perioperative care. *Anesthesia Patient Safety Foundation*	2013	To review the contents of The 2011 Heart Rhythm Society /American Society of Anesthesiologists Expert Consensus statement in addition to an overview of the management of CIEDs.	Level VII: Expert Opinion	Hospital/ Operating Room	N/A	N/A	Expert opinions provided by anesthesiologists endorsed by the Anesthesia Patient Safety Foundation.

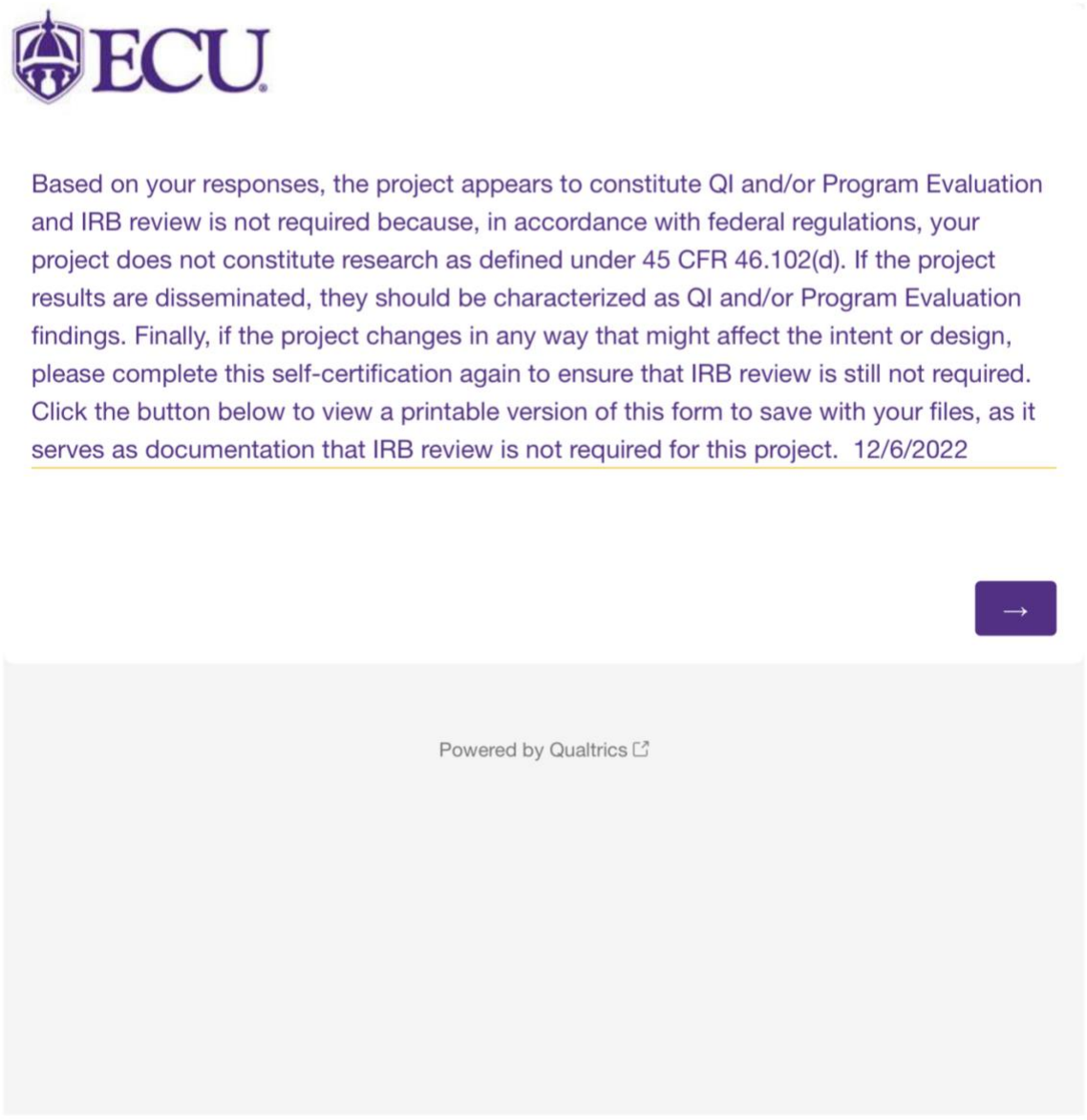
*Newsletter, 28(*2), 29-35.		No conceptual framework/ model.					
Solomon-Adenola, O. (2020). *Perioperative anesthesia management of surgical patients with cardiac implantable electronic devices*. [Doctoral dissertation, University of Baltimore Maryland]. UMB Digital Archive.	2020	"The purpose of this Doctor of Nursing Practice project was to develop an evidence-based clinical practice guideline for standardizing the preoperative and postoperative anesthesia management of surgical patients with CIEDs at a large, teaching, level two trauma hospital in Baltimore, Maryland. Currently, there is no existing evidence-based practice for anesthesia management of these patient populations at this facility which provided an educational opportunity to improve patient safety". – page 2 No conceptual framework/ model.	Level VI: Single Descriptive or Qualitative Study	Hospital/ Operating Room in Baltimore, Maryland	Expert panel with 2 CRNAs, 1 anesthesiologist, 1 interventional cardiologist, and 1 chief information officer. Appraisal of Guidelines for Research & Evaluation II (AGREE II) Tool was utilized to assess quality of the CPG. After CPG shared via an educational PowerPoint to anesthesia providers feedback questionnaire (PFQ) was completed (3 point Likest-scale used to assess the accuracy and transparency of developme	"Overall, 94% of the anesthesia providers agreed that the guideline should be approved for practice and it would be applied in their practice. The Appraisal of Guidelines for Research & Evaluation II (AGREE II) Tool was utilized by the expert panels to assess the quality of the CPG." —Page 2	"This CPG impacted the knowledge deficit among anesthesia providers at this facility to increase awareness and improve patient safety of surgical patients with CIEDs. Even though this CPG was designed based on the need of this institution's anesthesia providers, stakeholders permitted the application and usability of this CPG at other sister hospitals under this facility's health system." —Page 2

					nt of the CPG.		

Note: Key to abbreviations: CPG = clinical practice guideline *;* CIED = Cardiac implanted electronic device *;* EMI = Electromagnetic Interference*;* MHRA = Medicines and Healthcare Products Regulatory Agency. Key to Levels of Evidence: I: Systematic review/meta-analysis of randomized controlled trials (RCTs); II: RCTs; III: Nonrandomized controlled trials; IV: Controlled cohort studies; V: Uncontrolled cohort studies; VI: Descriptive or qualitative study, case studies, EBP implementation and QI; VII: Expert opinion from individuals or groups. Adapted from *Evidence-based practice in nursing and healthcare: A guide to best practice* (4th ed.), by B. M. Melnyk and E. Fineout-Overholt, 2019, p. 131. Copyright 2019 by Wolters Kluwer.

Appendix D

Forms of Approval



ECU

Based on your responses, the project appears to constitute QI and/or Program Evaluation and IRB review is not required because, in accordance with federal regulations, your project does not constitute research as defined under 45 CFR 46.102(d). If the project results are disseminated, they should be characterized as QI and/or Program Evaluation findings. Finally, if the project changes in any way that might affect the intent or design, please complete this self-certification again to ensure that IRB review is still not required. Click the button below to view a printable version of this form to save with your files, as it serves as documentation that IRB review is not required for this project. 12/6/2022

→

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Center for Research and Grants

[redacted]

Quality Improvement Project vs. Human Research Study Determination Form

This worksheet is a guide to help the submitter to determine if a project or study is a quality improvement (QI) project or research study, is involving human subjects or their individually identifiable information, and if IRB approval as defined by the Health and Human Services (HHS) or Food and Drug Administration (FDA) is required. (For more guidance about whether the activity meets the definition of Human Subjects Research see the IRB FAQs or the Human Subject Research Decision Chart)

Please use Microsoft Word to complete this form providing answers below. For signatures, please hand sign or convert into a PDF file and electronically sign. Once completed and signed please email the form to the [redacted] Center for Research and Grants [redacted] A CRG team member will contact you with the results of their review and may request additional information to assist with their determination. The determination will be made in conjunction with the UMCIRB office.

Project Title: Quality Improvement Project: Perioperative Care for Patients with Cardiac Implantable Devices		
Funding Source: None		
Project Leader Name: Coley Mizell, BSN, SRNA / Travis Chabo, PhD, CRNA ☐ **Ed.D.** ☐ **J.D.** ☐ **M.D.** ☐ **Ph.D.** ☐ **Pharm.D.** ☒ **R.N.** ☐ **Other(specify):**		
Job Title: ECU SRNA / ECU CRNA Faculty	**Phone:** [redacted]	**Email:** chabot14@ecu.edu
	Primary Contact (If different from Project Leader):	
	Phone: [redacted]	**Email:** mizellc15@students.ecu.edu

Key Personnel/ Project Team members:

Name and Degree:	**Department:** (Affiliation if other than ECU Health)	**Email:**
Coley Mizell BSN	ECU Nurse Anesthesia Program	mizellc15@students.ecu.edu
Travis Chabo PhD	ECU Nurse Anesthesia Program	chabo14@ecu.edu

QI/QA Assessment Checklist:

Consideration	Question	Yes	No
PURPOSE	Is the PRIMARY purpose of the project/study to: • IMPROVE care right now for the next patient? OR • IMPROVE operations outcomes, efficiency, cost, patient/staff satisfaction, etc.?	☒	☐
RATIONALE 1	The project/study falls under well-accepted care practices/guidelines or is there sufficient evidence for this mode or approach to support implementing this activity or to create practice change, based on: • literature • consensus statements, or consensus among clinician team	☒	☐
RATIONALE 2	The project/study would be carried out even if there was no possibility of publication in a journal or presentation at an academic meeting. (**Please note that answering "Yes" to this statement does not preclude publication of a quality activity.) **Of note, quality must not be published as if it is research!**	☒	☐
METHODS 1	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes?	☒	☐
METHODS 2	Are patients/subjects randomized into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection? (Control group, Randomization, Fixed protocol Methods)	☐	☒
METHODS 3	Will there be delayed or ineffective feedback of data from monitoring the implementation of changes? (For example to avoid biasing the interpretation of data)	☐	☒
METHODS 4	Is the Protocol fixed with fixed goal, methodology, population, and time period?	☐	☒
RISK	The project/study involves no more than minimal risk procedures meaning the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.	☒	☐
PARTICIPANTS	Will the project/study only involve patients/subjects who are ordinarily seen, cared for, or work in the setting where the activity will take place?	☒	☐

FUNDING	Is the project/study funded by any of the following? • An outside organization with an interest in the results • A manufacturer with an interest in the outcome of the project relevant to its products • A non-profit foundation that typically funds research, or by internal research accounts	☐	☒

If all of the check marks are inside the shaded gray boxes, then the project/study is very likely QI and not human subject research. Projects that are not human subject research do not need review by the IRB.

In order to assess whether your project meets the definition of human subject research requiring IRB review or may qualify as a quality improvement/assurance activity, please provide the following information:

1. Project or Study Summary:

Please provide a **summary of the purpose and procedures** as well address all of the following:

- The purpose of this quality improvement project was to assess anesthesia providers' perceptions of an Automated Implantable Defibrillator-Cardioverter/Permanent Pacemaker (AID/PPM) Handout as an educational tool to improve perioperative CIED management and patient safety. A quick-reference AID/PPM handout guide, based upon accepted national guidelines, will be developed. Anesthesia providers at the [redacted] will be asked several questions (through Qualtrics) about their perceptions of the adequacy of their currently used policy and preparedness for caring for patients with cardiac implantable devices. An educational video about the use of the newly developed Automated Implantable Defibrillator-Cardioverter/Permanent Pacemaker (AID/PPM) handout will be made available to them, and they will be asked to use the guide for two weeks. Upon completion of the twoweek utilization period, they will be asked to complete a questionnaire about their perceptions of the adequacy of the guide. Qualtrics survey software will be used to gather participant perceptions of their current practice prior to implementation of the intervention and then the acceptability and adequacy of the intervention (the guide and a short educational presentation) post implementation. No patient information will be recorded or maintained during this project.

b) The project's primary purpose. • The purpose of this quality improvement project was to assess anesthesia providers' perceptions of an Automated Implantable Defibrillator-Cardioverter/Permanent Pacemaker (AID/PPM) Handout as an educational tool to improve perioperative CIED management and patient safety.

c) The project design.

- The project will consist of a single Plan, Do, Study, Act cycle using a pre- and postintervention survey design.

d) Any interaction or intervention with humans.

- CRNA participants will be contacted via email and asked to complete a pre-survey and then utilize an AID/PPM Handout, developed based on current evidence and which aligns with practices currently accepted within the facility, regarding perioperative care of patients with cardiac implantable devices. After two weeks they will then be asked to complete a postsurvey addressing their perceptions of the intervention and their own practice. The primary researcher will be available electronically, by phone, or in person to consult with participants as needed.

e) A description of the methods that will be used and if they are standard or untested.

- The intervention for this project will be a newly created informational tool focused on perioperative care for patients with AID/PPM which is based on current evidence and falls within current accepted practice standards within the facility.

f) Specify where the data will come from and your methods for obtaining this data -please specify who/where (i.e., CRG will provide you with the data, or someone from a specific department will provide you with the data, or you will pull it yourself).

Data will be gathered directly from participants through completion of Qualtrics pre- and post-surveys delivered and completed electronically.

g) Specify what data will be used and any dates associated with when that data was originally collected (i.e., Patient Name, Diagnosis, Age, Sex), *If applicable, please attach your data collection sheet.*

- Aside from participant emails and IP addresses, no identifiable data will be gathered. Data of interest is participant opinions and perceptions of their practice and of the newly developed informational tool.

h) **Where will the data (paper and electronic) for your project be stored? Please specify how it will be secured to protect privacy and maintain confidentiality. For paper data, please provide physical location such as building name and room number and that it will be kept behind double lock and key. For electronic data, please provide the file path and folder name network drive where data will be stored and specify that it is secure/encrypted/password protected. If using other storage location, please provide specific details**.

- All data will be gathered using Qualtrics survey software then transferred to Excel for analysis. The only identifying information gathered will be email and IP addresses. Qualtrics survey software is accessed through ECU and involves multifactorial password protection. Data in Excel will be located on a password protected personal laptop. Email and IP addresses will be deleted from Excel files after both surveys are completed and analysis of results begins.

i) Please specify how long data will be stored after the study is complete? (Keep in mind that data collected/generated during the course of the project that includes protected health information (PHI) should have identifiers removed at the earliest opportunity.) • No PHI will be collected for this project. Data will be stored in Qualtrics and in Excel files (de-identified) until student graduation, anticipated to be spring of 2024.

j) Please specify how the collected data will be used (internal/external reports, publishing, posters, etc.) and list name(s) of person responsible for de-identification of data before dissemination.

- After removing patient identifiers, data will be analyzed, with results shared via a poster presentation to the ECU Nurse Anesthesia Program students and faculty, and with participants invited to view the presentation remotely. If requested, a presentation of results to the participating department will be provided. Additionally, analysis of results will be addressed in a DNP Project Paper, completion of which is required for program graduation. This paper will

be posted in the ECU digital repository, The Scholarship. Coley Mizell will be responsible for de-identification of all data prior to dissemination.

Please use this space above or **attach a** separate **summary and/or any other additional documentation describing your project**.

1. **If the Primary purpose of your project is for QI, have you obtained approval from the [redacted] operational leader within your department or health system:**

   ☐ **No [STOP. Please contact the appropriate operational leader for approval before proceeding.]**

   ☒ **Yes** [Please specify here whom and obtain their signature in the signature section below]

[redacted] **Operational Mgr/Leader Name:** _____

[redacted] 3/1/2023 | 11:13 PM EST

[redacted] **Operational Mgr/Leader Signature Date**

(Part 11 Compliant Electronic Signatures Acceptable-i.e. AdobeSign or DocuSign)

Please note:

- By submitting your proposed project/study for QI determination you are certifying that if the project/study is established to qualify as QI project, you and your Department would be comfortable with the following statement in any publications regarding this project: "This project was reviewed and determined to qualify as quality improvement by the [redacted] for Research and Grants."
- If you are submitting a Poster to Media Services, you will also need to submit this Quality Determination Form or IRB Approval to Media Services for printing.
- If the ECUH CRG determines the activity is not human subject research, then any presentation, publication, etc. should not refer to the activity as "human subject research," "exempt research," or "expedited research."

Attestation of Understanding

My signature below indicates that I fully understand that HIPAA Privacy standards as they apply to Quality Projects involving Protected Health Information and patient medical records as outlined below.

Under HIPAA's minimum necessary provisions, [redacted] must make reasonable efforts to limit PHI to the minimum necessary to accomplish the purpose of the use, disclosure or request.

Under HIPAA, a Covered Entity (i.e. [redacted] can disclose PHI to another CE (i.e. BSOM) for the following subset of health care operations activities of the recipient CE without needing patient consent:

- Conducting quality assessment and improvement activities
- Developing clinical guidelines
- Conducting patient safety activities as defined in applicable regulations
- Conducting population-based activities relating to improving health or reducing health care cost

Identifie[redacted] healthcare data utilized in this project should not be shared outside of the CE without a fully executed data use/sharing agreement.[redacted] leadership reserves the opportunity to review all articles for dissemination/ publication for which [redacted] healthcare data has been utilized and that the content is being disseminated in the appropriate manner as a quality initiative, not resembling research in any context.

[redacted] 2/10/23

Project Leader Signature **Date**

(Part 11 Compliant Electronic Signatures Acceptable-i.e. AdobeSign or DocuSign)

----------for [redacted] CRG Use Only----------

NHSR vs. HSR Determination:

☑ **Not Human Subject Research:** The [redacted] CRG has determined that based on the description of the project/study, approval by the IRB is not necessary. Any changes or modifications to this project may be discussed with the [redacted] CRG at that time to ensure those changes do not elevate the project to human research that would need IRB approval.

☐ **Human Subject Research:** This project/study requires review by the IRB prior to initiation. An application in the electronic IRB submission system should be submitted.

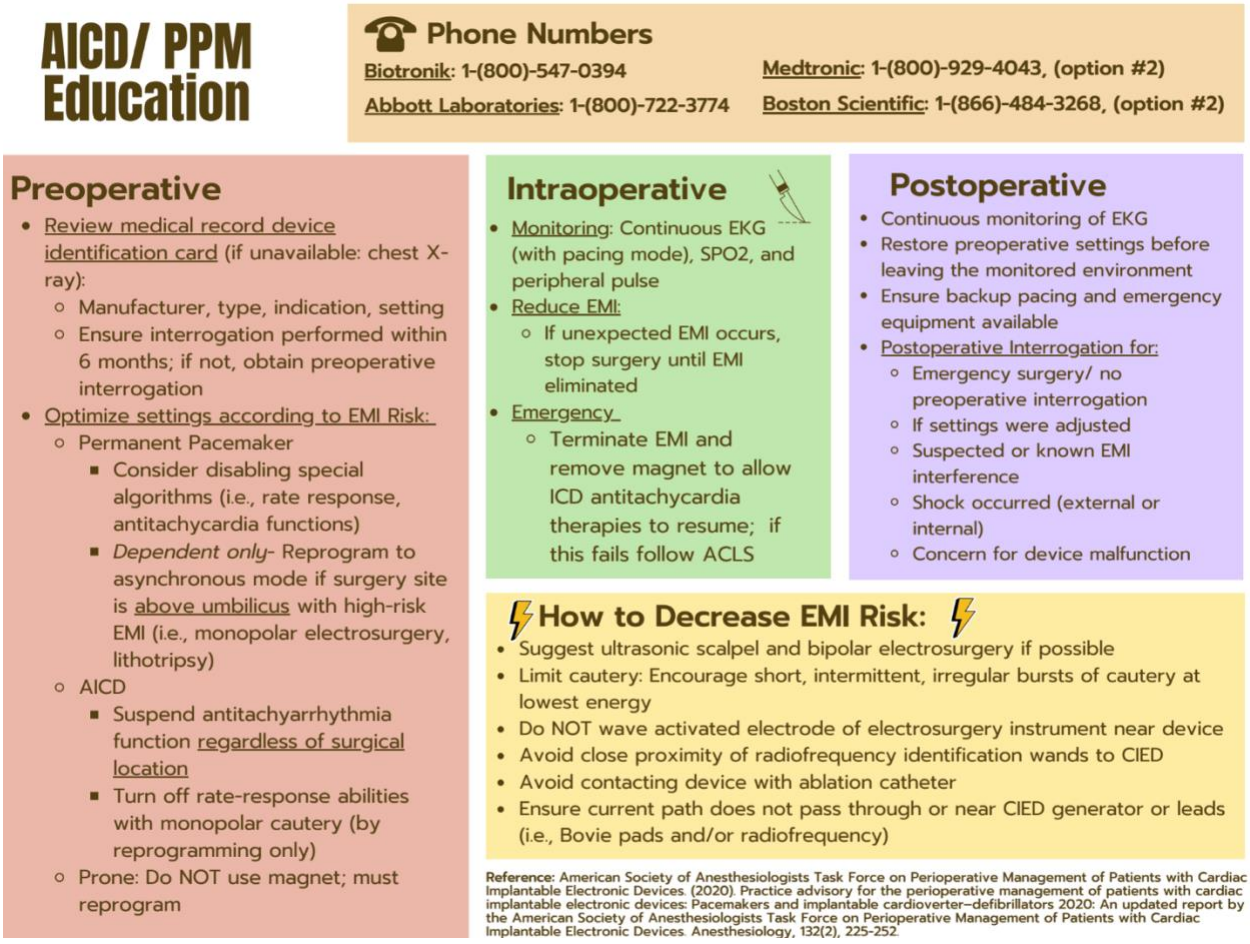
Approval Signatures:

[redacted] **CRG Reviewer:** [redacted] **Date:** 3/7/2023

UMCIRB Office Staff Reviewer: [redacted] **Date:** 3/8/23

Appendix E

AICD/PPM Handout



Appendix F

Pre-Intervention Survey Questions

1. Do you currently use a standardized approach for providing perioperative care to patients with AICD/Permanent Pacemakers (PPM)?
   Yes
   No

2. Are you aware, and have you used the AICD/PPM policy where you work?
   Not aware, not used Aware, not used Aware, used

3. Have you experienced an issue with an AICD/PPM during any perioperative stage (preoperative, intraoperative, postoperative)?
   Yes
   No

4. If you had a question concerning AICD/PPM management, how long do you think it would take to find reference material to answer your question?
   <5 minutes 5-10 minutes 11-15 minutes >15 minutes

5. I feel comfortable providing anesthesia care to a patient with an AICD/PPM.
   Strongly disagree Somewhat disagree Neutral Somewhat agree Strongly agree

6. I feel comfortable identifying and/or managing cases that are high risk for electromagnetic interference (EMI) in patients with an AICD/PPM.
   Strongly disagree Somewhat disagree Neutral Somewhat agree Strongly agree

7. How often do you have trouble obtaining all necessary information on a patient's AICD/PPM (such as manufacturer, type, last interrogation, etc.)?
   Never Infrequently Neutral Somewhat Frequently Commonly

8. I am familiar with the current best practice guidelines recommended by the American Society of Anesthesiologist and the Heart Rhythm Society.
   Strongly disagree Somewhat disagree Neutral Somewhat agree Strongly agree

9. Have you or do you know of a colleague that has personally been involved in the care of a patient who had poor postoperative outcomes related to inadequate management of their AICD/PPM?
   Yes
   No

10. Do you believe additional AICD/PPM education would help prevent negative outcomes?
    Yes
    No
    N/A

Post-Intervention Survey Questions

1. What is your perception on the usefulness of the AICD/PPM Handout for your anesthesia practice?
   Not useful Neutral Somewhat useful Very useful

2. While participating in this quality improvement project, approximately how many procedures did you reference the AICD/PPM Handout?
   0-2 procedures 3-5 procedures 6-8 procedures More than 8 procedures

3. After reviewing the AICD/PPM Handout, I feel comfortable providing anesthesia care for a patient with an AICD/PPM.
   Strongly disagree Somewhat disagree Neutral Somewhat agree Strongly agree

4. After utilizing the AICD/PPM Handout, how long do you think it would take to find reference material to answer your question concerning AICD/PPM management?
   <5 minutes 5-10 minutes 11-15 minutes >15 minutes

5. After using the AICD/PPM Handout, I feel comfortable identifying and managing cases that are high risk for electromagnetic interference (EMI) in patients with an AICD/PPM?
   Strongly disagree Somewhat disagree Neutral Somewhat agree Strongly agree

6. Using the AICD/PPM Handout increased my confidence in ensuring the assessment of my patient's device was thorough.
   Strongly disagree Somewhat disagree Neutral Somewhat agree Strongly agree

7. I am familiar with the current best practice guidelines recommended by the American Society of Anesthesiologist and the Heart Rhythm Society.
   Strongly disagree Somewhat disagree Neutral Somewhat agree Strongly agree

8. Using the AICD/PPM Handout improved my efficiency in assessing my AICD/PPM patient in the preoperative period.
   Strongly disagree Somewhat disagree Neutral Somewhat agree Strongly agree

9. How likely are you to use this AICD/PPM Handout in the future?
   Never Not likely Neutral Likely Very likely

Appendix G

Emails to Participants

Initial Pre-Survey and Video Email to Participants (1 of 4)

Dear [redacted] CRNAs,

Thank you for considering participating in a quality improvement project titled "Perioperative Care for Patients with Cardiac Implantable Electronic Devices." The purpose of this project is to assess anesthesia providers' perceptions of an AICD/PPM Handout as an educational tool to improve perioperative CIED management and patient safety at [redacted].

Participation is voluntary and will involve completing a short pre-intervention survey, viewing a brief PowerPoint presentation with voiceover, utilizing a AICD/PPM Handout in your CRNA practice for two weeks (at your discretion), and completing a short post-intervention survey when the two-week implementation period is over.

Completing each survey and viewing the PowerPoint presentation should take less than 2-4 minutes to complete. The surveys were created and are completed using Qualtrics® survey software. The use of the AICD/PPM Handout falls within currently accepted practice in your work area. Your participation is voluntary and confidential. We will share the results of this QI study with you upon completion.

First, complete the pre-intervention survey: ****INDIVIDUAL LINK****

Following completion of the survey, view the brief introductory presentation on Perioperative Care for Patients with CIEDs. AICD/PPM Handouts will be attached to this email and are also available in the anesthesia lounge and locker rooms to be used during the duration of the study.

Again, thank you for your participation in our quality improvement project. If you have any questions, I will be at [redacted] from June 5th until July 5th and you may also reach out to me or Dr. Travis Chabo PhD, CRNA by email at any time.

Sincerely,

Coley Mizell, SRNA, mizellc15@students.ecu.edu
Travis Chabo PhD, CRNA chabot14@ecu.edu

Pre-Survey and Video Reminder Email to Participants (2 of 4)

Hello [redacted] CRNAs,

I just wanted to send a quick reminder about the ongoing DNP Project on Perioperative Care for Patients with Cardiac Implantable Electronic Devices (original email below). If you've already filled out the pre-survey and viewed the PowerPoint presentation, thank you. If you haven't had a chance to do so yet, it's not too late and would be very helpful and much appreciated. For participants that still need access to the presentation and or handout, I have pasted a link for the presentation and attached a copy of the AICD/PPM handout below. Additional copies of the AICD/PPM Handouts are also located in the Anesthesia lounge and locker rooms as well. You may use these at your discretion. After the end of next week, I will begin sending out the post-surveys.

Links:
Pre-survey:**INDIVIDUAL LINK**
Presentation: Perioperative Care of Patients with CIEDs.pptx

Please let me know if you have any questions and thank you again for your participation.

Sincerely,
Coley Mizell, SRNA
ECU Nurse Anesthesia Program
Class of 2024

Post-Survey Email to Participants (3 of 4)

Dear [redacted] CRNAs,

Thank you to everyone who has already completed my pre-survey and viewed the video. It's now time to complete the brief post-survey.

If you have not filled out a pre-survey, I would really and truly appreciate your participation (it's just surveys and a PowerPoint presentation!). The link to the pre-survey is **INDIVIDUAL LINK*** and you can follow it up by watching the introductory PPT here (Perioperative Care of Patients with CIEDs.pptx). Additional AICD/PPM handouts are available in the Anesthesia Lounge and locker rooms if you would like to use them in the future or if you wanted to share with fellow anesthesia providers.

If you've already completed the first survey, please complete the post-survey at ***INDIVIDUAL LINK. It should take less than 2 minutes.

If anyone has questions or issues with any of these links please let me know. Again, thank you to everyone for your help and for being excellent preceptors. I look forward to coming back to [redacted] Medical Center soon.

Sincerely,
Coley Mizell, SRNA
ECU Nurse Anesthesia Program
Class of 2024

Final Thank You Email to Participants (4 of 4)

Dear [redacted] CRNAs,

I just wanted to say thank you so much to everyone for helping me out with my DNP Project! I have collected all of the data I need to proceed with data analysis and plan to finalize my paper soon. Once it's complete you all will be able to read it if you'd like. And if you liked the AICD/PPM Handout and found it useful, you are welcome to continue to use it.

Thank you again! I hope to work with you more in the future.

Take care,
Coley Mizell, SRNA
ECU Nurse Anesthesia Program
Class of 2024