Perioperative Care of Patients with Cardiac Implantable Electronic Devices: A DNP Project

Caroline Flynn, BSN, SRNA

Travis Chabo, PhD, CRNA Project Chair

Nurse Anesthesia Program

College of Nursing, East Carolina University

Submitted in partial fulfillment of the

requirements for the degree of Doctor of Nursing Practice

Finalized December 7, 2023

Abstract

The current process for delivering perioperative care for patients with cardiac implantable electronic devices lacks standardization and creates the potential for unexecuted safety measures. The purpose of this quality improvement project was to assess anesthesia providers' perceptions of an educational handout summarizing current evidence-based practices as a tool to improve perioperative cardiac implantable electronic device management and patient safety. This project utilized a plan-do-study-act cycle conducted over a two-week period with a sample of 10 CRNAs working in the main operating room at the partnering organization. Data from these participants were gathered using pre- and post- intervention Qualtrics surveys and analyzed using Excel. After implementation of the handout, participants reported being more comfortable with professional guidelines regarding cardiac implantable electronic device management, managing high-risk electromagnetic interference cases, and spending less time searching for cardiac implantable electronic device management resources. The positive shift in CRNAs' perceived comfort caring for this population after the implementation period shows a potential utility for this educational handout. A significant limitation to this project was the differing number of pre- and post- survey responses. In the future, this project may be repeated with a larger sample size to obtain more conclusive results regarding CRNA perceptions of the efficacy of this tool.

Keywords: perioperative, cardiac implantable electronic device, nurse anesthetist.

Table of Contents

Section I. Introduction

Background

In the United States, more than three million people have a cardiac implantable electronic device (CIED; American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Implantable Electronic Devices [ASATF], 2020). The term CIED includes a permanent pacemaker (PPM), an automatic implantable cardioverter defibrillator (AICD), or a combination of the two devices. The perioperative care of these patients is vital to address as patient harms and mortality rates during the perioperative period have increased in this population (Samuels et al., 2021).

The perioperative period is used to describe the three phases surrounding an operation: the preoperative, intraoperative, and postoperative phases. During the preoperative period it is essential for the anesthesia team to have a comprehensive understanding of the patient, their history, and any implanted devices they may have in order to prevent harm. The ASATF (2020) has published clinical guidelines for best practice that should be followed during the preoperative period. The first step noted by these guidelines is to identify if a patient has a CIED. If the patient has a device, the medical team should determine the device's manufacturer, current settings, patient dependency on the device, and recent interrogation of the device. One barrier to these guidelines is that patients do not always know the manufacturer and settings of their devices, leading to delayed care. When a patient can provide this information about their CIED by presenting their manufacturer identification card, care can be facilitated in a more timely and cost-effective manner (Bryant et al., 2016).

In addition to verifying device information, the ASATF (2020) also acknowledges that when the device settings are altered or disabled (e.g., tachycardia therapies), it is essential that

the patient be in a monitored environment (Bryant et al., 2016). Remarkably, the ASATF acknowledges there is little evidence of patient harms when providers do not adhere to these guidelines in the preoperative stage. This acknowledgment does not signify these interventions are meaningless, however, as this lack of evidence stems more so from a substantial lack of research on the perioperative care of patients with CIEDs (ASATF, 2020; Bryant et al., 2016; Miller et al., 2019).

As the intraoperative phase is entered, there are increased risks to the patient. Samuels et al. (2021) investigated 43,759 reports of patients with CIEDs who had adverse events associated with their device while in the operating room (OR). Of these reports, electromagnetic interference (EMI) was identified as one of the major causes of CIED dysfunction. Sources of EMI included wireless devices such as infusion pumps, monitoring equipment, and ultrasound probes (Bryant et al., 2016). Experts also suggest caution with the use of cautery (bipolar and monopolar) as their high frequencies pose a particularly high risk of EMI, especially in locations above the umbilicus (ASATF, 2020; Bryant et al., 2016; Samuels et al., 2021). However, other sources, including Traczyk et al. (2021), state EMI can occur while operating in any location and medical teams should always be vigilant when providing care to these patients. The effects of EMI on CIEDs include inappropriate shocking or inhibition of pacing, resulting in arrhythmias including asystole, bradycardia, and ventricular tachycardia. In severe cases, EMI has resulted in complete failure of the device where explant or replacement was necessary.

Due to these complications, the ASATF (2020) recommended considering eliminating the device's ability to sense the patient's native rhythm by converting the device's settings to an asynchronous mode. Surgical teams using monopolar electrosurgical techniques (e.g., Bovie) historically have favored placing the device in asynchronous mode to limit the effect of EMI.

However, this practice can create additional problems as arrhythmias can occur and, depending on the patient's native rhythm, may lead to adverse outcomes (Bryant et al., 2016). The ASATF indicates current best practice is to verify a patient's hemodynamic stability with the programmed rate and capture amplitude, especially when utilizing this mode.

Furthermore, a significant threat to the safety of these patients in the intraoperative period is magnet placement over an implanted device (ASATF, 2020; Bryant et al., 2016). Despite magnets often being used to protect these devices, it is vital to stress that magnet placement on a CIED does not necessarily turn the device off or convert it to an asynchronous mode. Depending on the manufacturer, magnet application can cause a variety of changes, including conversion to asynchronous mode or even a diagnostic function test (Bryant et al., 2016). Arrhythmias can ensue after magnet removal due to resumption of the preprogrammed pacer settings (Samuels et al., 2021). In a study by Samuels et al. (2021), patient harm occurred in nearly half of cases when a magnet was utilized intraoperatively. If magnet application is necessary intraoperatively, it is best practice to identify the result of magnet application to the CIED from the manufacturer or the electrophysiology (EP) department. If magnet application is deemed appropriate, the magnet should be secured with medical grade surgical tape (Bryant et al., 2016). Also, utilizing an electrophysiologist can facilitate safe care by confirming optimal device settings (ASATF, 2020). Furthermore, whenever device settings are manipulated, it is essential for the patients' vital signs to be monitored, including continuous electrocardiogram analysis.

Another barrier to intraoperative care is that common anesthesia adjuncts (e.g., succinylcholine, positive and negative inotropes) can increase the risk of adverse events for patients with an AICD/PPM (Bryant et al., 2016). Due to this increased probability, it is vital for anesthesia teams to weigh the risks of utilizing these medications. In addition to medication

interference with the device, fluid shifts, hypoxemia, and acid-base balance can also alter the efficacy of the device (ASATF, 2020; Bryant et al., 2016; Traczyk et al., 2021). Because of these increased risks, it is essential that methods of external or transvenous pacing and defibrillation are immediately available.

As the patient transfers from the intraoperative period and moves into the postoperative phase, standards must be met to ensure safety. Postoperative patients, especially patients with a CIED, are at increased risk of arrhythmia due to electrolyte imbalance, acid-base imbalance, and fluid shifts (Bryant et al., 2016). Because of these risks, the ASATF (2020) states it is best practice for CIED patients to have continuous electrocardiogram (EKG) and peripheral pulse monitoring. Additionally, because device settings may have changed during the pre- and intraoperative periods, it is essential to evaluate the current settings and therapeutic functionality of the device prior to discharge (ASATF, 2020; Bryant et al., 2016). Along with this verification, if the patient had an emergency procedure, significant EMI exposure, delivery of a shock intraoperatively, or if there was any concern that the device malfunctioned, interrogation of the pacemaker is necessary (ASATF, 2020).

The complexity of CIED care, in addition to conflicting expert opinions and an overall lack of research, has created difficulties in providing care to patients with these devices. The American Society of Anesthesiologists (ASA) has acknowledged this shortcoming and has created guidelines to assist providers with recommendations aimed at each stage of the perioperative period (ASATF, 2020). The American Association of Nurse Anesthetists (AANA) has not published specific guidelines discussing perioperative care of CIEDs. This is an area with potential for improvement, as expansion of education and awareness of these devices is essential to forward progress of the nurse anesthetist profession.

Organizational Needs Statement

The anesthetic management of patients with CIEDs throughout the perioperative period is complex. With a variety of CIEDs and inconsistent practice guidelines, there is a lack of clarity regarding care for this patient population. At the partnering organization, there is an opportunity to increase knowledge and clinical skills which could improve outcomes for these patients. Compared to the rest of the state, eastern North Carolina, has an increased incidence of patients with heart disease, approximating 180 per 100,000 people (North Carolina Institute of Medicine, 2018). This increases the likelihood for health systems, including the partnering organization, to encounter a patient with a CIED. It is therefore imperative the anesthesia team has an organized, systematic way of caring for these patients.

Nurse anesthetists play a unique role in patients' surgical care as they are present throughout all phases of the perioperative period. This role places the nurse anesthetist in a key position to help mitigate the increased risks associated with care of this population. By implementing small, cost-effective interventions, such as an educational handout, the potential for patient harm and resulting costs and lawsuits, could be decreased. Not only does implementing further education decrease the potential for legal action, but it is in line with the AANA's Vision Statement, "to drive innovation and excellence in healthcare" (AANA, n.d., Vision Statement).

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 in relation to their implanted cardiac device.

Purpose Statement

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.

Section II. Evidence

Description of Search Strategies

To better understand the drivers behind increased harm among patients with CIEDs during the perioperative period, a literature review was conducted. The review evaluated articles concerning the anesthetic care of these patients published within the last seven years. Current guidelines and data suggest there are numerous barriers to safe, effective care of these patients during the perioperative period. To deliver excellent anesthesia care, it is vital to have up-to-date, clear, and concise guidelines which address the barriers and intricacies of these devices for providers.

To explore this topic effectively, a PICOT (problem, intervention, comparison, outcome, time) question was developed to guide the search strategy. The PICOT question used was: In the perioperative care of patients with CIEDs, how does implementation of an *AICD/PPM Handout* influence CRNA perceptions of caring for this patient population? In formulating this question, four concepts were identified to streamline inquiries into the existing data: pacemakers/ AICDs, perioperative, management, and nurse anesthetist. These concepts identified the target audience (nurse anesthetists), what action would be studied (management), the patient population to be studied (patients with AICD or PPM devices), as well as the setting in which these patients and anesthetists would be studied (perioperatively). See Appendix A for a Literature Concepts Table.

In exploring the literature, current evidence and recommendations regarding CIEDs were identified using the databases PubMed and Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the search engine Google Scholar. Boolean operators were used to combine keyword and concepts. The search strategy used to query PubMed was (nurse anesthetist OR anesthesia) AND (pacemaker OR implanted cardiac defibrillator) AND

(perioperative period). This search strategy pulled in the MeSH terms *nurse anesthetists; anesthesia; pacemaker, artificial; embryo implantation; heart; defibrillators; electric countershock;* and *perioperative period*. After limiting the search to the past seven years (2015-2022), 29 articles were identified, though only three were deemed pertinent to the topic upon title and abstract review.

To broaden the scope of this literature review, CINAHL was also searched using keywords and major headings. The search strategy used for CINAHL was ((MH "Defibrillators, Implantable") OR (MH "Pacemaker, Artificial") OR (MH "Cardiac Pacing, Artificial")) AND ((MH "Perioperative Care") OR (MH "Perioperative Nursing") OR (MH "Perioperative Medicine") OR (MH "Surgery, Operative")). This search was limited to the past five years (2017- 2022) and yielded 40 articles with four relevant articles identified after full-text review. Google Scholar was searched using the same search strategy as PubMed and was limited to the past five years (2017-2022). Four pages of Google Scholar results were searched, yielding nine relevant articles. See Appendix A for a list of keywords, MeSH terms, and subject terms utilized in searches. See Appendix B for search strategies and numbers of articles found and kept using structured searching. Additional evidence and information were identified by reviewing related and referenced articles as well as the websites and resources of anesthesia organizations.

Upon full-text review, and referencing Melnyk and Fineout-Overholt's (2019) levels of evidence hierarchy, evidence identified as pertinent to this Doctor of Nursing Practice (DNP) Project included two expert opinion papers (Level VII), one best practice advisory (Level VII), one quantitative descriptive study (Level VI), one quality improvement project (Level VI), one retrospective cohort study (Level V), one retrospective review (Level V), and one prospective observational study (Level IV). See Appendix C for a Literature Matrix.

Selected Literature Synthesis

This literature review synthesized the current data and expert recommendations, as well as highlighted conflicting information regarding the perioperative care of patients with CIEDs. As noted by experts and professional associations, there is a substantial lack of high-level, evidence-based studies focused on the perioperative care of patients with CIEDs (ASATF, 2020; Crossley et al., 2011; Neubauer et al., 2018). Due to the scarcity of, and at times even conflicting data, it can be difficult for providers to have a clear understanding of what current best practice suggestions and guidelines should be for this patient population (ASATF, 2020; Crossley et al., 2011). Because of this, providers often use manufacturer helplines inappropriately, often using them for specific directions for clinical interventions (Crossley et al., 2011). This should not be the case. The manufacturer consults should be used solely for technical support, not for clinical advice, as this is outside of their scope of practice (Crossley et al., 2011; Rooke et al., 2015). To prevent unfortunate situations, it is vital to continually update educational references, quick sheets, and handouts to make following current best practices easy and efficient for anesthesia providers.

Preoperatively, anesthesia providers are responsible for collecting data about the patient, the patient's CIED, and the planned procedure in order to identify risks and propose a perioperative strategy (ASATF, 2020; Crossley et al., 2011; Navas-Blanco et al., 2021; Neubauer et al., 2018). Experts agree on the importance of identifying if the patient has a CIED. Some literature has indicated that not identifying these devices can lead to adverse outcomes including, but not limited to, inappropriate discharge of a shock, inadvertently altering device settings to end-of-life mode, lead dysfunction, as well as device memory faults (ASATF, 2020).

Once a device is identified, patients should be interviewed preoperatively to confirm the team who manages their routine CIED care (Crossley et al., 2011). This team ideally should be included in discussions concerning CIED management, settings alterations, and magnet placement. If the patient cannot provide this information, the patient's pacemaker identification card, which lists the make and model of the device, would be the next best alternative (ASATF, 2020; Crossley et al., 2011). If a patient is unable to produce this information, a chest X-ray can be performed to identify the patient-specific pulse generator registration and manufacturer. This information can then be relayed to the manufacturer to obtain information on their last device implantation. To streamline this process, the Heart Rhythm Society (HRS)/ASA consensus statement suggests utilizing a CIED team (an institution-based team solely focused on CIED care) to create an individualized *prescription* for perioperative care (Crossley et al., 2011). This prescription would begin with an interprofessional discussion between the CIED, surgical, and anesthesia teams. By having this conversation, providers would have a uniform and comprehensive view of the patient's risk factors as well as potential adverse outcomes related to their planned procedure.

Although many recommendations made by the original HRS/ASA consensus (Crossley et al., 2011) are referenced and remain in recent guidelines, including the 2020 guidelines published by the ASATF, others disagree on aspects of this consensus statement. Feldman and Stone (2020) called the suggestion of utilizing a CIED team to create a *prescription* a vastly unusual idea. They suggested the intervention would be unlikely to be implemented in clinical practice due to its time-consuming nature. To evaluate the perceived lack of provider compliance with the HRS/ASA and ASATF guidelines, a retrospective cohort study was conducted (Navas-Blanco et al., 2021). This study evaluated provider compliance with the HRS/ASA and ASATF

guidelines and compared the groups of patients who had received these interventions to those who had not. Specifically, the researchers measured how implementing these guidelines affected preoperative holding times and CIED related postoperative adverse cardiac events. Of the patients in the study, 76% received preoperative interrogations of their CIED recommended by the HRS/ASA and ASATF. Those who did not have their devices interrogated experienced a significantly higher risk of interoperative and postoperative cardiac events (25% in the non-interrogated groups vs. 8% in the interrogated group), as well as increased preoperative holding times. Of patients with these prolonged holding times, 6% had a delay in OR time averaging 54 minutes due to issues related to their device. The authors concluded that preoperative device interrogation, as suggested by the ASATF and HRS/ASA, was a significant factor in preventing adverse outcomes.

Though the study by Navas-Blanco et al. (2021) indicated that preoperative device interrogation (meaning within the past 12 months for PPMs and every six months for patients with AICDs) correlated with fewer adverse events for patients with a CIED, the timing of this intervention is still in dispute amongst experts (ASATF, 2020; Crossley et al., 2011; Samuels et al., 2021). To give more generalizable advice for preoperative care of these implantable devices, the ASATF (2020) supports obtaining a recent interrogation of the device through patient records or conducting a new interrogation. The ASATF admits there is a lack of data supporting concrete timeframes for preoperative device interrogations. Because of this, an expert panel survey was conducted to evaluate current practice. This survey reflected a wide range of practices, with some providers requiring same-day interrogations and others opting to utilize any interrogation within the previous 12 months.

In addition to verifying the details of the patient's CIED, it is also necessary to identify the type and location of the upcoming procedure, cautery to be used, as well as the clinical setting in which the procedure is planned to take place (ASATF, 2020; Crossley et al., 2011; Neubauer et al., 2018). Electrocautery has been implicated as one of the major causes of EMI in patients with CIEDs (ASATF, 2020; Crossley et al., 2011; Feldman & Stone, 2020; Samuels et al., 2021). Monopolar cautery is associated with a high risk of EMI, inhibition of pacing, as well as incorrect interpretation of cautery by the device as a tachyarrhythmia resulting in a delivered shock (ASATF, 2020; Crossley et al., 2011). Because of these risks, it is preferred that bipolar cautery be utilized in CIED patients, especially if the surgery takes place above the umbilicus.

Even though there is a substantial risk of EMI with monopolar cautery, bipolar cautery is often not utilized by surgeons as it does not allow the cutting option that monopolar offers (Crossley et al., 2011). Keeping this in mind, a general rule has been formulated to gauge the risk of EMI related to location of surgery. In general, surgery above the umbilicus has an increased risk for EMI while surgery below the umbilicus poses a relatively low risk (ASATF, 2020; Crossley et al., 2011; Neubauer et al., 2018). Surgeries and procedures with increased risk of EMI include electrosurgery, radiofrequency ablation, lithotripsy, electroconvulsive therapy, magnetic resonance imaging, and nerve conduction studies (ASATF, 2020). Samuels et al. (2021) identified an increased use of radiofrequency, a significant source of EMI, in endoscopy. The authors state that this EMI risk is severe and has resulted in cardiac injury and programming changes, as well as inappropriate shock delivery to patients and staff.

To quantify the risk of EMI in place of the general *umbilicus rule*, the researchers in the Perioperative ICD Management study (PIM study) studied the risk of EMI associated with cautery techniques at different surgical sites (Neubauer et al., 2018). The study separated

subjects into three groups and interventions were assigned based on the ASATF and HRS/ASA guidelines, among others. Group 1 was comprised of patients having surgery above the umbilicus using monopolar electrocautery. These patients received device reprogramming preoperatively, with AICD tachytherapies inactivated and the device set to monitor mode with bradycardia therapies on. Group 2 utilized a magnet to inactivate the device in surgeries above the umbilicus using bipolar cautery or below the umbilicus using either monopolar or bipolar cautery. Group 3 subjects consisted of patients undergoing lower extremity surgery (identified as below the iliac crest) with the surgeon only using bipolar cautery. These patients received no inactivation via magnet or reprogramming.

After each surgery, a postoperative interrogation was conducted by a cardiologist to ensure no damage to the device's battery life, sensing abilities, or threshold occurred because of EMI during the case. Researchers indicated after reviewing the results that the interventions suggested by the ASATF and HRS/ASA were safe in all groups as there were no arrythmias, detected EMI, or damages to the AICD. Despite the ASATF endorsing these interventions, some clinical providers surveyed by the ASATF disagreed with reprogramming the device to an asynchronous mode when monopolar cautery is used in surgery below the umbilicus (ASATF, 2020).

Magnet placement is often preferred by anesthesia providers in the intraoperative setting (Neubauer et al., 2018). By placing the magnet, CIED tachyarrhythmia therapies are turned off, and if this function needs to be turned back on, it can be easily restored by removing the magnet. It is also important to emphasize that using a magnet turns off the tachyarrhythmia therapies but does not disable pacing abilities (Crossley et al., 2011). Additionally, applying a magnet on an AICD will convert the device to an asynchronous pacing mode, however this is not the case for

all PPMs. With magnet application, some PPMs (e.g., Medtronic AT500) will only turn off the tachyarrhythmia therapies but not convert the settings to an asynchronous pacing mode. Because of this variation among devices, it is necessary for providers to confirm which settings are altered by magnet placement.

Conversely, if settings are changed via reprogramming of the device, it may be extremely difficult to restore them in acute situations (e.g., intraoperative ventricular arrhythmias) unless a programming technician is immediately available. Furthermore, there is an increased risk of breaking sterility if external cardioversion or defibrillation is indicated due to inability to restore tachyarrhythmia therapies (ASATF, 2020; Crossley et al., 2011). However, a benefit of reprogramming a device is that the anesthesia team does not have to constantly ensure the correct application of the magnet during surgery. This could be especially beneficial in patients with a large body habitus, as the magnet's proximity to the CIED can shift with the patient's excess tissue.

Reprogramming also may prove to be beneficial in surgeries where changing patient positioning is indicated (ASATF, 2020; Crossley et al., 2011; Neubauer et al., 2018). If a patient is going to be prone during surgery, or if the surgical site is within six inches of the pulse generator, a magnet cannot be used (Neubauer et al., 2018). The magnet must not be used in the prone position because the anesthesia provider cannot verify the location of the magnet and soft tissue damage may occur from the patient laying on the magnet (Crossley et al., 2011; Neubauer et al., 2018). Experts recommend against indiscriminate use of a magnet, however, there is limited documented guidance on management strategy for magnet use (Feldman & Stone, 2020). The PIM study noted that not all AICDs can be inactivated through magnet placement and others may even become completely disabled if a magnet is applied (Neubauer et al., 2018). Others

identify that use of magnets still comes with an increased risk of EMI, with some studies noting that 30% of adverse events occur using the magnet application technique (Samuels et al., 2021).

In order to detect adverse events, including device malfunction or hemodynamic instability, five monitors should be used for patients with a CIED. An external defibrillator/ cardioverter and magnet should always be available when a CIED patient is in the operative period. It is important to note that the magnet should always be in reach of the anesthesia provider and never be placed in the surgical field as this increases the risk of breaking sterility. External defibrillating pads should always be placed on the patient intraoperatively (Crossley et al., 2011; Neubauer et al., 2018). In addition to this safety equipment, continuous cardiac monitoring with *pacing mode* activated should be used to monitor the patient's EKG (ASATF, 2020; Crossley et al., 2011). The *pacing mode* helps to differentiate pacing spikes from additional QRS complexes, falsely elevating the heart rate, or identifying pacing spikes as the QRS when the pacemaker has not captured (reading the pacer complex as a QRS when the patient could be in heart block or asystole), also falsely elevating the heart rate (Crossley et al., 2011). If this mode is not utilized there is an increased likelihood of inappropriate administration of medications, including chronotropic or anesthetic medications, by anesthesia providers. Because of this possibility it is not only recommended to use pacer mode, but to also use continuous peripheral pulse monitoring via a pulse oximeter or an arterial line as an additional method of verifying EKG data (ASATF, 2020; Crossley, et al., 2011). This is because the pulse oximeter and arterial line will help discern perfusing beats versus artifact, differentiating EKG artifact from an arrythmia.

Postoperatively, the patient should remain in a monitored environment with continuous EKG monitoring and external cardioverter/ defibrillator equipment should be available if the

device has been reprogrammed (ASATF, 2020; Crossley et al., 2011). Contrary to previous recommendations, a postoperative interrogation is no longer necessary unless there is a high likelihood of EMI resulting in subsequent reprogramming or damage to the device (ASATF, 2020; Crossley et al., 2011; Feldman & Stone, 2020). Unless emergent, timing of these interrogations is surgery-dependent based on EMI risk (Crossley et al., 2011). Some patients who have undergone procedures including electroconvulsive therapy, monopolar surgery, or lithotripsy can be seen by their provider within one month for a device interrogation. With very low risk EMI surgeries, including endoscopy and nerve conduction studies, the HRS/ASA recommends no postoperative interrogation. However, Samuels et al. (2021) advocate that patients undergoing endoscopy do have a high risk of EMI and should have standard postoperative device interrogation.

Though some researchers indicate that not every CIED patient requires a postoperative interrogation, insisting on postoperative interrogation may not be completely unwarranted. According to Neubauer et al. (2018), 8% of surgical cases in which devices have had settings changed or inactivated never were reverted to their previous settings. The study contributed this to human error. This was found to be especially common in large hospital settings with multiple providers caring for the patient. With several providers involved, there is a risk for miscommunication concerning what interventions a patient has, or has not, received. This creates the potential for a patient with a CIED to be discharged before the device is reprogrammed to its original settings. To prevent this, Crossley et al. (2011) recommend *tagging* patients with CIEDs to ensure these events don't happen.

In response to this, Traczyk et al. (2021) conducted a quality improvement (QI) project using a pre- and post-intervention observational design. The research team aimed to increase

CIED reprogramming postoperatively by instating electronic medical record (EMR) pop-up reminders for anesthesia providers. Instating this EMR reminder was a response to an identified issue concerning patients being discharged from the hospital without having their device reverted to its original settings. Traczyk et al. found that after the pop-up reminder was implemented, provider documentation of device setting changes increased. In addition to the reprogramming reminder, these pop-ups also allowed the team to identify and track patients who did not have these modifications documented. The results of the study indicated the postintervention group had a shorter length of stay, decreased device suspension times, and a higher rate of postoperative device reprogramming.

Rooke et al. (2015) observed similar shortcomings in CIED management and contributed these inadequacies to a lack of ownership over perioperative care of the devices by a specific specialty of providers. At the facility in the study conducted by Rooke et al., fellows in the Electrophysiology/Cardiology Service (EPCS) were solely responsible for device interrogations, pre- and postoperative evaluations of device, and intraoperative consults, as well as many other tasks around the hospital. Oftentimes, due to the EPCS's heavy workload, device assessments were often delayed or left incomplete. To improve the perioperative care for patients with CIEDs, five anesthesiologists given the title of Anesthesiology Device Service (ADS), completed 30 hours of education from manufacturer representatives about the intricacies of each device. The aim of this intervention was to evaluate if utilizing an anesthesia managed team would decrease OR delays due to CIED management, errors associated with device programming, as well as improve the workload for the EPCS caring for these devices.

The researchers found that both the ADS and the EPCS made errors in CIED care. The ADS group had an increased number of errors initially but improved over time. Even though the

ADS made initial mistakes, these providers improved care for patients with CIEDs in some respects. As compared to the EPCS, the ADS was more consistent in completing pre- and postoperative printouts of device settings. Due to the ADS's vigilance to this aspect of their care, many device programming alterations were discovered, which lead to the development of a new protocol requiring two providers evaluate these reports. Rooke et al. (2015) concluded that educating anesthesia providers and making a specialized team could be beneficial to patients with CIEDs, especially in high volume surgical centers.

Although there is continuing debate about specific treatment plans, multiple sources agree that using a *one size fits all* approach for patients with a CIED is unacceptable; the care needs are simply too diverse and complex (ASATF, 2020; Crossley et al., 2011). Although the data available on perioperative care of CIEDs consists largely of expert opinion, transforming the information into an educational handout should be helpful to anesthesia providers in predicting their patient's needs and streamlining their care. Several points could be especially helpful to anesthesia providers. One issue that is often unclear involves when to use a magnet versus when to use reprogramming based on location of surgery and cautery type. Presenting information derived from the PIM study (Neubauer et al., 2018) to convey this material in a streamlined manner, along with the guidelines from the HRS/ASA and ASATF (Crossley et al., 2011), could lead to an increase in anesthesia providers perceived comfort in caring for these patients. Additionally, reinforcing existing knowledge about using the *pacing mode* on the EKG monitor regarding pacemaker capture and the sensitivity of the EKG to pacer spikes would be of use. This is especially important to include as it can affect what drugs the anesthesia provider chooses to use during a case. Utilizing a streamlined educational handout could ease anesthesia

providers' burden of trying to stay up to date on best practice for patients with CIEDs as well as their confidence in caring for these patients.

Project Framework

For this project the plan-do-study-act (PDSA) cycle was utilized. This method best fits with the DNP Project as it is used to measure change incrementally (Institute for Healthcare Improvement, 2017). The aim of this project was to evaluate nurse anesthetists' perceptions of an *AICD/PPM Handout* as an educational tool to improve perioperative CIED management and patient safety. In the planning phase of this single PDSA cycle, the assessment of need, review of literature, creation of the *AICD/PPM Handout* and development of pre- and post- survey questions were accomplished. The *do* portion of the project extended over a period of two weeks and involved sharing the intervention (handout), answering questions from participants, and gathering data using Qualtrics pre- and post- surveys. The study aspect of the project involved analyzing data using Excel. This phase also involved developing suggested future changes and interventions. The act portion consisted of presenting the project, PowerPoint, intervention, and results with the students of the anesthesia program and the participants of the study. The project paper and poster were also posted in the university's digital repository for others to view.

Ethical Considerations and Protection of Human Subjects

Due to potential dangers associated with the current lack of standardization of perioperative care of patients with CIEDs, this QI project aimed to assess anesthesia providers' perceptions of an *AICD/PPM Handout* as an educational tool to improve perioperative management of these devices and patient safety. Since the goal of this handout was to provide a presentation of current CIED management strategies, it was vital to thoroughly evaluate the existing evidence and only include items which were best practice, not investigational. By doing

this, any potential risk of supplying incorrect information was limited. All information shared in the intervention fell within accepted practice standards utilized within the participating organization. Participation in the project was optional.

Before beginning this process, the primary investigator and project team completed the CITI modules (https://about.citiprogram.org/) focused on research standards and ethics. After generating the framework for the project, the project was classified by the team as QI. The project was then submitted for approval through a process established by the East Carolina University College of Nursing in conjunction with the University and Medical Center Institutional Review Board (UMCIRB). Additionally, the UMCIRB and the partnering organization approved the project as QI through a joint approval process, thus a full IRB review was not required. As part of the organizational review process, a signature of acknowledgement that the project would take place was obtained from the unit representative in the clinical setting. See Appendix D for the initial Quality Improvement Determination. See Appendix E for the organizational approval.

Section III. Project Design

Project Setting

This QI project was implemented in a large, level I trauma center with 26 ORs. By implementing in a variety of OR suites (e.g., orthopedics, cardiac, etc.) the *AICD/PPM Handout* was evaluated in diverse scenarios. This helped the primary investigator gain a more comprehensive view of the *AICD/PPM Handout's* potential utility in the clinical setting. Though using this tool in a variety of different cases was beneficial to completeness of the project, there were some barriers to implementation. One of these barriers included strict time constraints faced by anesthesia providers. Another barrier was a consistently high patient capacity at the partnering organization during implementation. Generally, having a high patient capacity is coupled with increased OR cases and, as a result, increased workload for anesthesia providers. This increased workload coupled with the time constraints may have limited the ability of the CRNAs to apply the information in the tool within their practice.

Even though there were several barriers to project implementation, there were an equal number of facilitators. As one of the major medical centers in the eastern part of the state, the hospital has access to many experienced cardiac surgeons, electrophysiologists, and cardiologists. Because of this renown, the partnering organization also has numerous OR cases, many performed on patients with existing CIEDs. These factors increased the number of opportunities for the *AICD/PPM Handout* to be utilized. In addition to the opportunity to use the handout, participants had access to abundant resources, equipment, and expertly trained staff which increased the likelihood of the project's success. Also, the facility had an existing policy pertaining to the perioperative care of patients with CIEDs. Having this pre-existing policy was

beneficial as it was a foundation for participants and reinforced the importance and relevance of this topic.

Project Population

The population for this quality improvement project included nurse anesthetists who cared for patients with CIEDs in the perioperative setting. The CRNAs included in the project worked in various ORs within a single large level 1 trauma center. The goal of the project was to evaluate their perceptions of the newly designed *AICD/PPM Handout* as an educational tool to improve perioperative CIED management and patient safety. It was projected that their varying levels of experience could influence how each CRNA approached, perceived, and utilized the handout. Additionally, there was a possibility that CRNAs with fewer years of experience, or those who did not routinely care for CIEDs in their daily practice, might have been more open to utilizing the *AICD/PPM Handout*. Conversely, it was postulated that those with many years of experience, or those who frequently care for patients with CIEDs, may be less receptive to utilizing the handout.

Project Team

The project design team consisted of the primary investigator along with three other student registered nurse anesthetists (SRNAs) addressing the same issue. The project design team collaboratively designed the project and created the *AICD/PPM Handout*. Project implementation and project analysis were, however, performed solely by the primary investigator. The program director served as the project chair, acting as both a clinical expert and a guide to direct the team's attention to challenges of CIED care in the clinical area. The SRNAs, in conjunction with the project chair, were responsible for identifying key issues surrounding perioperative management of patients with CIEDs based on current literature. A handout was

then developed that aimed to assist CRNAs in tackling these difficulties by presenting a summary of current best practices. The project was implemented by the primary investigator at a large level I trauma center.

An additional member of the team was the course director who helped with navigation through the DNP Project process. They were responsible for ensuring the team met agreed upon deadlines to guarantee forward progress on the project. The final members of the team consisted of the clinical contact person and the site contact person. These affiliates were vital in ensuring smooth implementation of the project at each clinical site. In addition to answering inquiries about the project setting, the site contact person also provided approval for the team to collect data in the facility.

Methods and Measurement

This QI project addressed the lack of standardization of perioperative CIED care among anesthesia providers. The purpose was to assess CRNAs' perceptions of utilizing an educational tool, namely the *AICD/PPM Handout*, to improve perioperative CIED management and patient safety (see Appendix F for *AICD/PPM Handout*). The goal was to assess CRNAs' perceived level of comfort providing care to patients with CIEDs by providing a convenient, rapidly accessible handout containing current best practices. In addition to the handout, a supplemental PowerPoint was created to give additional background information and discuss the proper use of the handout (see Appendix G for supplemental PowerPoint). These educational materials were emailed to participants along with a link for a Qualtrics pre-survey (see Appendix H for emails sent to participants). This survey intended to gauge the CRNAs' current perceptions of caring for a patient with a CIED. After implementation of the project, the link to a post-intervention survey, aimed at gauging their perceptions of CIED care after utilization of the handouts, was emailed to

the invited participants (see Appendix I for Qualtrics pre- and post-intervention survey questions).

The *plan* phase of the PDSA cycle began in March 2022 as the team identified the topic of concern, *the perioperative care of patients with CIEDs*. To explore the topic, a literature review was conducted using PubMed, CINAHL, and Google Scholar, to collect data on clinical issues with CIED care and current best practices. The design team presented this information to the project chair and the course director in August 2022. It was decided that providing education through creating an *AICD/PPM Handout* may improve CRNAs' level of comfort caring for patients with CIEDs. The handout was organized by each phase of the perioperative period (preoperative, intraoperative, and postoperative). Each section included summaries of current best practices, common risks, and tips for evaluating EMI risk, as well as phone numbers for device manufacturers with the *healthcare provider option number* listed to streamline technical support phone calls. Although the handout summarized the current best practices for perioperative care of patients with CIEDs, the literature on the subject was variable and at times contraindicatory. To convey this inconsistency to the participants and ensure proper use of the handout, the DNP Team deemed it necessary to address this as part of a PowerPoint presentation. The handout and PowerPoint were finalized and approved in December 2022.

In addition to the handout and PowerPoint, pre- and post-intervention surveys were created in Qualtrics to gather CRNAs' perceptions surrounding CIED management. These surveys were brief, consisting of 10 pre-intervention questions and 9 post-intervention questions. The surveys included nominal, ordinal, and interval measures, with several of the same questions included in both the pre- and post-surveys to allow for direct comparison of the results. Some of these general outcome measures included participants' perceived comfort caring for CIEDs

(including managing EMI, locating information from the CIEDs, etc.), average time spent searching for resources related to CIED care, and if they or a coworker had experienced adverse patient outcomes due to mismanagement of a CIED. The post-intervention survey measured many of these same outcomes but was geared towards assessing if the *AICD/PPM Handout* increased the CRNAs' perceived comfort in CIED perioperative management. The last step of the planning phase involved gaining approval through the East Carolina University College of Nursing, the UMCIRB, and the partnering organization, which required a signature of approval from the designated unit representative. All entities approved the project as QI which concluded our planning phase in early March 2023.

The *do* phase of the PDSA cycle began in late March 2023 with the recruitment of participants for the QI project. The unit representative was key in initiating communication, through email, between the project team and the CRNAs at the implementation site. Potential participants were sent the Qualtrics pre-survey, educational materials (*AICD/PPM Handout* and PowerPoint), and the primary investigator's contact information. Participants were instructed to complete the survey prior to opening the educational material, with survey data collected confidentially through Qualtrics. Participants were asked to view the PowerPoint as well as the handout prior to using it in the clinical setting. They were instructed to refer to the handout, either utilizing the hard copies provided or a digital copy accessed on their mobile device, when caring for CIED patients during the two-week implementation period. The primary investigator was assigned to the project site for a clinical rotation during spring 2023 and was available at the site during the implementation period to ensure questions would be answered in a timely manner. After the two-week implementation period, the post-intervention survey link was sent, via email, to invited participants.

During the *study* phase of the PDSA cycle, in May 2023, the data from the Qualtrics surveys were evaluated. When designing the surveys, the team intentionally matched questions on the pre- and post-surveys to allow for direct comparison of results. The data from the surveys were analyzed using Excel. Additionally, during this phase the implementation timeframe was extended by an extra week in hopes of obtaining the same number of pre- and post- survey responses for data analysis. The final phase of the PDSA cycle, the *act* phase, consisted of discussing the findings and implications of the project with the DNP team and the participants. Participants were given the opportunity to share their suggestions regarding how the project could be modified and improved in the future. The primary investigator presented this information via a poster presentation to other SRNA students, faculty, and participants in November 2023. This paper and the poster were then uploaded to *The Scholarship*, the university's online data repository.

Section IV. Results and Findings

Results

The purpose of this QI project was to assess anesthesia providers' perceptions of an *AICD/PPM Handout* as an educational tool to improve perioperative CIED management and patient safety. To accomplish this task, 10 CRNAs from the partnering facility's main OR volunteered to participate in this QI project. Their perceptions of the *AICD/PPM Handout* were collected using Qualtrics pre-intervention and post-intervention surveys. The results of these surveys were then analyzed using Excel. The pre-intervention surveys were available three days prior to implementation and were available for one week after the implementation period. In total, there were 8 responses to the pre-intervention survey. The post-intervention survey was delivered two weeks after the implementation period began and was closed to the participants one week after the implementation period ended. There were 6 participants who responded to the post-intervention survey. The availability of these surveys was extended for one week to increase response rates. At the end of data collection, the responses were entered into Excel for analysis and generation of visual data representations.

Data Presentation and Discussion

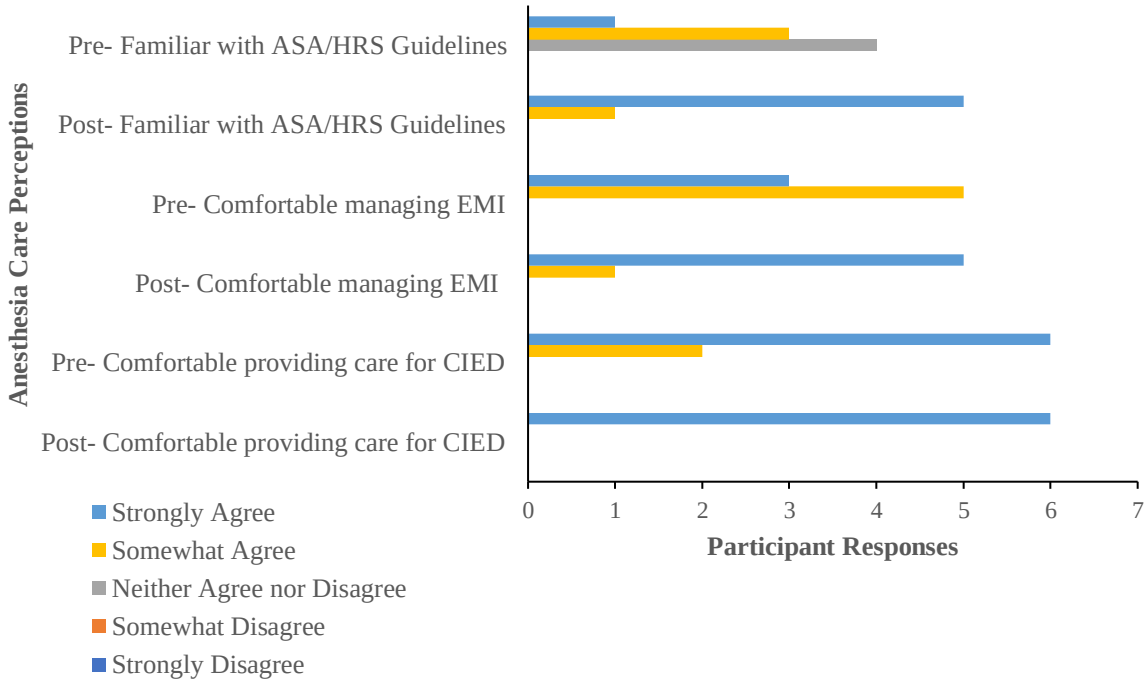
The pre-intervention survey responses presented interesting data concerning the utilization of a standardized approach to perioperative CIED care as well as providers' awareness of hospital policy and professional guidelines. Of the eight participating CRNAs, only half utilized a standardized approach to providing care to patients with CIEDs. Surprisingly, only two of these eight anesthesia providers were aware of, and used, their hospital's policy concerning perioperative care of patients with CIEDs. Additionally, of these eight respondents, only one

strongly agreed that they were familiar with the ASA/HRS guidelines for CIED management (see Figure 1).

The respondents also had a wide range of perceptions concerning the ease of obtaining information about a patient's CIED. Of the eight pre-survey respondents, only one reported to never having an issue locating information on their patient's device. The majority of the respondents indicated they sometimes (three participants) or half of the time (three participants) had an issue obtaining pertinent information on their patient's device. One respondent answered that they had problems most of the time when attempting to get information about their patient's CIED. The CRNAs' perceptions on how much time it would take to locate reference material on CIEDs also varied (see Figure 2). Even though finding resources and information was perceived to be a challenge for some CRNAs, most of the participants reported that they strongly felt they were comfortable providing care to patients with CIEDs. Even though most were confident in their management skills, many respondents only felt somewhat comfortable managing high-risk EMI cases (see Figure 1).

Figure 1

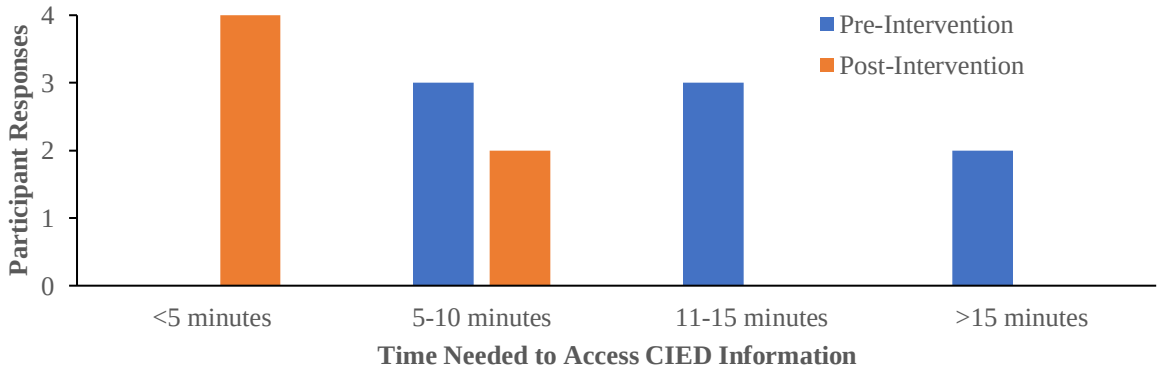
Comparison of CRNA Perceptions Regarding Care for CIED Patients



Note. Pre-Intervention n=8. Post-Intervention n=6.

Figure 2

Estimated Time to Access Evidence-Based AICD/ PPM Care References



Note. Pre-Intervention n=8. Post-Intervention n=6.

Although most respondents were not familiar with hospital policy or professional guidelines, and had difficulty obtaining information about their patients' CIEDs, none of the participants indicated that they experienced any issues with their patients' CIEDs. Additionally, all eight of the respondents denied being aware of a colleague's or their own personal involvement in a poor postoperative outcome related to CIED management during the perioperative period. However, the majority (six) of these anesthesia providers believed that further education on perioperative care of patients with CIEDs would be extremely helpful in preventing negative outcomes. The other respondents believed that further education would be somewhat helpful in preventing negative outcomes.

After implementing the *AICD/PPM Handout*, many of the outcome measures improved. However, although eight participants completed the pre-survey, only six responded to the post-survey. During the two-week implementation period, two participants utilized the handout in 3 to 5 procedures, while the remaining four participants referenced it in 2 or less procedures. After reviewing the handout, three respondents found the *AICD/PPM Handout* extremely useful, two found it very useful, and one found it moderately useful. Even though respondents found the handout at least moderately useful, only three were extremely likely to use the handout in the future and three believed they were somewhat likely to use the handout in the future.

After the implementation period, all responding participants strongly agreed they felt comfortable providing anesthesia care to patients with CIEDs (see Figure 1). All respondents also strongly agreed that the handout increased their efficiency in the preoperative period. Additionally, after participating in the QI project, the amount of time the participants believed it would take them to find reference material to answer a question concerning CIED care decreased (see Figure 2). In addition to finding references faster, participants also felt more confident that

their assessment of CIED patients was thorough and felt more comfortable managing high risk EMI cases. Finally, after implementing this QI project, the majority of respondents strongly agreed they were familiar with the HRS/ASA guidelines concerning perioperative care of patients with CIEDs (see Figure 1).

Analysis

It can be deduced from the pre- and post-intervention survey data that many of the participating CRNAs' perceptions changed after the implementation period. However, limitations to this analysis were that there was not the same number of respondents to both the pre- and post-intervention surveys and that the project sample size was small. Before the implementation period, only two of the eight pre-survey respondents strongly agreed that they felt comfortable providing anesthesia care to patients with a CIED. After reviewing the handout, all six post-survey respondents strongly agreed they were comfortable with providing perioperative care for a patient with a CIED (see Figure 1). Similarly, the pre-intervention survey responses indicated that only three of eight CRNAs felt comfortable managing high-risk EMI cases. However, after implementation, five of six CRNAs reported feeling comfortable managing high-risk EMI cases (see Figure 1). Additionally, only one CRNA in the pre-survey strongly agreed they were familiar with the ASA/HRS professional guidelines. By the end of the implementation period, as noted in the post-survey, five of six CRNAs strongly agreed they were familiar with these guidelines (see Figure 1). Although the number of pre- and post-survey responses differed, this positive shift in CRNAs' perceived confidence and comfort caring for this population post implementation shows potential utility for the *AICD/PPM Handout.*

Not only did the CRNAs report feeling more comfortable administering anesthesia to these patients, they also reported feeling more confident in their preoperative assessments of this

patient population. Additionally, the CRNAs felt that it took them less time to find resources to answer their questions about CIEDs after reviewing the *AICD/PPM Handout*. None of the CRNAs in the pre-survey believed they could find this information in less than five minutes. However, after the implementation period, four believed they could find the information in less than 5 minutes, while the remaining two respondents believed it would take them 5 to 10 minutes (see Figure 2).

Section V. Implications

Financial and Nonfinancial Analysis

Nurse anesthetists play a unique role in patients' surgical care as they are present throughout all phases of the perioperative period. This role places the nurse anesthetist in a key position to help mitigate the potential for adverse patient outcomes, especially for patients with CIEDs. By implementing small, cost-effective interventions, such as an educational handout for nurse anesthetists, the potential for patient harm, and resulting costs and lawsuits, could be decreased. This may be extremely beneficial for health systems, including the partnering organization, which encounter many patients with CIEDs.

One barrier health systems face when caring for patients with CIEDs is that the resources and guidelines regarding their care are sparse and difficult to access. Because of this, providers often spend valuable time sifting through the latest literature to find current best practices on CIED care. This can be detrimental to patient care as the provider's time must be devoted to finding this information, not to providing patient care. In addition to loss of time, there is also a financial loss for health systems when information is not easily accessible.

Considering an average nurse anesthetist salary of $206,450 per year (Incredible Health, 2023), a nurse anesthetist working 32 hours per week has an average hourly rate of approximately $124. If this nurse anesthetist spends 15 minutes per day searching for CIED resources, the health system forfeits $31 each day. This may seem like a miniscule amount of money, however, if multiple CRNAs spend this amount of time, or more, looking for this information on a repeated basis, it can create a significant cost for the health system. Additionally, if this information is not found in a timely manner, it may lead to delayed OR cases, creating a much greater financial loss for the hospital system. In addition to a potential

loss of revenue, these delays can cause confusion among providers regarding appropriate care, cause strife between anesthesia and surgical teams, and create scenarios that increase risk for patients.

An additional layer to the problem is the time-pressured work environment in which nurse anesthetists deliver care. These providers may be pressured by production constraints and may feel they do not have enough time to find these resources. Some may even choose to blindly accept other providers' suggestions, or rely on their own potentially uncertain knowledge in fear of repercussions for not keeping up with the fast-paced OR environment. The danger of this mentality is shortcomings in patient safety. Many times, these *almost events* are overlooked, especially when no harm is done to the patient. However, as proposed by James Reason in the *Swiss Cheese Model*, when there are enough shortcuts taken by multiple providers, the *holes* within the system can line up perfectly, creating the potential for major harm or death to a patient (Reason, 2000). This may also result in lawsuits involving the hospital and healthcare staff, thus creating a massive, avoidable, financial toll on the system.

One of these *Swiss Cheese Model* events may include improper safeguarding of the patient's CIED during a high-risk EMI case. In a retrospective analysis by Nichols et al. (2016), the authors analyzed the average cost of replacing a patient's CIED generator. The patients in the study had notable damage to their device due to EMI. This analysis found that the average cost of replacement was often associated with a hospital stay of three days. The average costs included this hospital stay and prices varied significantly depending on the type and manufacturer of the device. For a PPM generator replacement, the costs were lower, averaging $19,959. Prices were higher for ICD generator replacement, which averaged $24,885. A cost of

$46,229 was noted for implantable cardiac resynchronization therapy defibrillator generator replacement. These costs are significantly greater than the cost of implementing this QI project.

To quantify the cost of implementing this intervention in the partnering organization, including compensating for time spent on in-service training, the same annual CRNA salary of $206,450 can be used. If the hospital compensated 100 CRNAs for completing 30 minutes of training regarding the use of the *AICD/PPM Handout*, or a similar tool, it would cost the hospital $6,000. To have both printed and electronic copies in all the ORs, this would be a minor, one-time cost to the hospital. However, this intervention could be made more cost-effective if the handout was made available solely in an electronic format, as computers are already available to staff. By having these educational handouts available and providing training, there may be a significant cost reduction annually for the hospital. This is due to increasing provider knowledge and comfortability with CIEDs which may lead to fewer adverse events and decreased morbidity and mortality, as noted in the CIED generator replacement example.

Although financial implications of implementing an educational handout are worthy of discussion, non-financial resources also play a pivotal role. At the partnering organization, there are existing non-financial barriers and facilitators worth noting. One of these resources which acted as a facilitator to the success of the project included the presence of a pre-existing hospital policy on perioperative care for patients with CIEDs. This served as a platform for the project, as staff had already been introduced to the topic and its importance. An additional resource, though not utilized in the project, was the existing biweekly anesthesia staff meetings. These meetings serve as a forum for leadership and staff to address concerns and updates to practice, including initiation of new interventions. This platform could be utilized in future endeavors, as a staff

member or another primary investigator can discuss the intervention and provide updates on best practices for perioperative CIED management.

Although the partnering organization had non-financial resources which increased the success of this project, there were also notable barriers. For example, the partnering organization undertakes a high volume of surgical cases daily. Due to this volume, there is often limited time for providers to perform their tasks. These time constraints may have played a detrimental role in the success of this project as providers may not have had the time to adopt the intervention in practice. In addition to time pressures, this handout may have been more effective if the partnering organization's electrophysiologists had more time to act as a resource. Garnering support of the intervention from the EP department may have also increased anesthesia providers' confidence and comfortability accepting and utilizing a new tool.

By providing education on CIED management to anesthesia providers, there may be a resulting increased quality of care for these patients and improved efficiency through the perioperative period. If this project were to be sponsored by the organization and delivered on a larger scale, they could expect a good return on their investment. The intervention is low cost, has no expected negatives, and has high potential to improve patient care. Additionally, after implementation, the post-survey responses indicated the CRNAs had increased comfortability managing high-risk EMI cases. These providers also had increased awareness of the current best practices noted by the AHA/HRS. Increasing CRNAs' knowledge of and comfort caring for these devices has the potential to prevent negative outcomes, thus decreasing morbidity and mortality risks.

Implications of Project

One overarching theme in the ASA/HRS and ASATF guidelines is that not enough research has been conducted concerning the perioperative care of CIEDs. They have directly acknowledged these shortcomings and have called for more research to be conducted. While research is still scant, these organizations have created guidelines based on the existing evidence and expert opinions. These expert opinions are specific to each stage of the perioperative period and depict how other practitioners are providing care to these patients (ASATF, 2020). Unfortunately, the AANA has not published specific guidelines discussing perioperative care of CIEDs for anesthesia providers. This would be a significant area for improvement, as expansion of education and awareness of these devices is essential to forward progress of the nurse anesthetist profession. Not only does implementing further education decrease the potential for legal action, but it is in line with the AANA's Vision Statement, "to drive innovation and excellence in healthcare" (AANA, n.d., Vision Statement).

In order to continue to strive for excellence in anesthesia practice, this QI project aimed to assess anesthesia providers' perceptions of an educational handout to improve perioperative care for patients with CIEDs. This project, conducted in the main OR of the partnering organization, identified potential barriers to perioperative CIED care. According to pre-survey data, many CRNAs believed an educational handout would be extremely helpful to their practice. Additionally, in the pre-survey only two providers felt they strongly agreed that they were confident taking care of a patient with a CIED (see Figure 1), four providers used a standardized approach to their CIED care, and only three CRNAs felt they were comfortable managing high-risk EMI cases (see Figure 1). These responses may reflect what is noted in the ASA/HRS and the ASATF statements: that there is not much information on the subject, so

provider comfortability is decreased, and standardization of practice is inherently difficult. Increasing provider awareness of published best practice guidelines is necessary to increase safety and elevate provider practice. Unfortunately, only one participant in the pre-survey strongly agreed that they were familiar with the professional guidelines that the ASA/HRS published (see Figure 1).

Without conducting a thorough literature review it may be difficult for providers to readily obtain trusted information relating to CIED management, so perceived comfort caring for these patients was understandably low. By providing condensed best-practice guidelines from the ASATF and the ASA/HRS in the handout, participants increased their awareness of these guidelines (see Figure 1). In addition to increasing their knowledge on general best-practice guidelines for CIEDs, participants also became more comfortable managing EMI after reviewing the handout (see Figure 1). Presumably, due to this condensed, easily navigable tool, the participants were also able to decrease the amount of time they needed to find the CIED resources (see Figure 2).

Although the number of pre- and post-survey responses was different, the positive shift in participant responses shows potential utility for the *AICD/PPM Handout* for all parties involved. First, patients may benefit from this intervention as they may have increased margins of safety and decreased incidence of poor outcomes. Second, anesthesia providers may benefit as their practice improves through continuing education and increasing their comfort level managing CIEDs. These providers may also increase their satisfaction in their day-to-day workflow as they spend less time searching for CIED resources. By increasing their knowledge of best-practices, providers may also have a decrease the likelihood of legal repercussions. Third, the partnering organization may benefit from implementing this QI project as providing education to staff can

decrease their chances of litigation and not receiving full reimbursement by agencies such as Centers for Medicare and Medicaid Services. Also, due to the decreased time needed to find the CIED information they need, the partnering organization may also decrease costs related to OR delays. In future PDSA cycles, this handout could be individualized to the partnering organization's needs and could be of increased value to providers.

Sustainability

If the partnering organization were to adopt this quality improvement project, it would be an easy transition. Currently, the organization has all the resources to necessary to continue and improve on this intervention. For example, the organization has the ability to disperse the educational PowerPoint and has the physical space to conduct in-person training if desired. This rendition of the project could be continued until new guidelines are published and the education must be updated. At this point, the organization would have to find an individual to update the educational material and decide if the staff training would be compensated monetarily (estimated 6,000 dollars for 100 CRNAs). This project could be continually improved if the organization had a motivated individual that was dedicated to maintaining their knowledge of best practices and updating the *AICD/PPM Handout*. If they cannot find someone to adopt this task and keep the education updated, this would be a major barrier to sustainability.

In the future, it may be beneficial to directly assess CRNAs' perceptions on perioperative CIED management in a setting such as a staff meeting. This would offer a forum for departmental discussion on practical limitations faced by these providers that may have been missed in this QI project. One potential QI project that may be beneficial would be to create a manufacturer-specific trouble shooting guide. This may be worthwhile, as there are many different devices which require interventions specific to the device or manufacturer (e.g., magnet

placement). This may increase provider comfortability caring for CIED patients. Another subject of interest may also be implementing a standardized approach to CIED care. As the pre-survey indicated, only half of the respondents indicated that they currently used a standardized of approach to care for CIED patients. Additionally, another topic that may be worthy of consideration is the potential benefit of training a group of anesthesia providers to interrogate CIEDs. It may be beneficial to assess if this intervention increases perioperative efficiency and patient safety. It also may be beneficial to involve the EP department to increase providers' comfort with the intervention as well as increase resources available to them.

Dissemination Plan

For the dissemination aspect of this project, a poster was created summarizing this project's PDSA cycle, intervention, and its findings and implications and presented to East Carolina University nurse anesthesia program faculty and students, partnering organization department members, and project participants. Upon completion, this project and poster were posted in *The Scholarship,* the East Carolina University digital repository.

Section VI. Conclusion

Limitations

Limitations were met throughout the PDSA cycle for this QI project. These limitations began during the planning phase while reviewing the literature on this topic. The search results pulled in all databases expanded beyond the intended subject of interest. For example, as noted in the MeSH terms for PubMed, one of the terms the database considered pertinent to the research topic was *embryo implementation*. An additional difficulty while researching this topic was finding studies that had implemented tools such as algorithms and checklists. Originally, the primary interest of the DNP project team was to create an AICD/PPM algorithm to help simplify the decision-making process for patients with CIEDs during the perioperative period. However, due to the lack of data surrounding this topic, as well as the plethora of devices on the market, the DNP team decided it would not be prudent to create this type of tool. The team agreed that creating this intervention without ample supporting research risked creating *blanket statements* that may not represent best practice for all CIED manufacturers and devices. This led the project team to create an educational handout which summarized evidence-based practices for each phase of the perioperative period.

During the *do* phase of the project, there were also limitations. One of these was the small sample size, as there were only 10 CRNAs in the potential respondent pool. Unfortunately, not all of the CRNAs in the potential pool responded to the surveys which further limited the sample size. The implementation period was extended with no additional responses. Another limitation was data analysis, which was complicated by the difference in number of pre- and post-survey responses. These factors limited evaluation of the efficacy of the *AICD/PPM Handout*.

Recommendations for Future Implementation and/or Additional Study

If this project were to be replicated, there are a few aspects which could be improved for this topic to be studied more effectively. At the beginning of this project, the team had little background knowledge on CIEDs and therefore heavily relied on the literature. To increase time efficiency and to better direct literature reviews, it may be helpful to consult the health system's EP department as an additional resource. The DNP team did contact the EP department at the partnering organization during this PDSA cycle, however, the staff were unable to assist with the project. In the future, access to a provider in the EP department would be an excellent resource during the planning and implementation periods of the project. In fact, it may be beneficial to recruit an EP resident or fellow as part of the QI team, to assist in answering participant questions and targeting pertinent perioperative problems associated with CIEDs.

In addition to recruiting a CIED expert such as an electrophysiologist, it may be beneficial to talk to the participants face-to-face about the project to increase participant interest and participation. An in-person meeting could be an informal introduction to the project or a presentation of the educational PowerPoint. This is especially important as, even though the primary investigator gave contact information and was readily available at the site during implementation, many participants did not meet with the primary investigator, making asking questions in-person nearly impossible. In addition to an initial in-person meeting, a periodic check-in with participants may have been helpful to assess their perceptions of the handout. If an in-person check in was not possible, it may have been effective to add a free-response question to the post-survey to identify perceived strengths and weaknesses of the handout. This would have been helpful in analyzing the survey data and beneficial for improving future cycles of the project.

Future research or QI projects may involve further investigation into responses obtained from the surveys. For example, in the pre-survey, it was noted it took the CRNAs a longer time to find material about CIEDs than in the post-survey. In fact, seven out of eight participants identified that they had issues finding the CIED information they needed at least half of the time. Therefore, it may be beneficial to identify what CIED information was difficult for CRNAs to locate and what information the *AICD/PPM Handout* provided that allowed them to find the information faster. Another potential project would be to create a standardized approach for perioperative CIED care and assess for subsequent changes in the occurrence of patient safety issues, as only half of providers in this project's pre-survey indicated they used a standardized approach when caring for patients with CIEDs.

References

American Association of Nurse Anesthetists. (n.d.). *Who we are*. https://www.aana.com/about-us/who-we-are

American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Implantable Electronic Devices. (2020). Practice advisory for the perioperative management of patients with cardiac implantable electronic devices: Pacemakers and implantable cardioverter–defibrillators. *Anesthesiology*, *132*(2), 225–252. https://doi.org/10.1097/ALN.0000000000002821

Bryant, H. C., Roberts, P. R., & Diprose, P. (2016). Perioperative management of patients with cardiac implantable electronic devices. *British Journal of Anaesthesia Education*, *16*(11), 388–396. https://doi.org/10.1093/bjaed/mkw020

Crossley, G. H., Poole J. E., Rozner, M. A., Asiryatham, S. J., Cheng, A., Chung, M. K., Ferguson, T. B., Gallagher, J. D., Gold, M. R., Hoyt, R. H., Irefin, S., Kusumoto, F. M., Moorman, L. P., & Thompson, A. (2011). The Heart Rhythm Society (HRS)/ American Society of Anesthesiologists (ASA) expert consensus statement on the perioperative management of patients with implantable defibrillators, pacemakers and arrhythmia monitors: Facilities and patient management. *Heart Rhythm*, *8*(7), 1114-1115.

Feldman, J. B., & Stone, M. E. (2020). Anesthesia teams managing pacemakers and ICDs for the perioperative period: enhanced patient safety and improved workflows. *Current Opinion in Anaesthesiology*, *33*(3), 441-447.

Incredible Health. (2023). *Average nurse anesthetist salary in North Carolina.* https://www.incrediblehealth.com/salaries/crna/nc

Institute for Healthcare Improvement. (2017). *QI essentials toolkit: PDSA worksheet*. https://www.ihi.org/resources/Pages/Tools/PlanDoStudyActWorksheet.aspx

Miller, J. L., Thylen, I., Elayi, S. C., Etaee, F., Fleming, S., Czarapata, M. M., Lennie, T. A., & Moser, D. K. (2019). Multi-morbidity burden, psychological distress, and quality of life in implantable cardioverter defibrillator recipients: Results from a nationwide study. *Journal of Psychosomatics, 120*, 39-45. https://doi.org/10.1016/j.jpsychores.2019.03.006

Navas-Blanco J. R, Williams D. V., & Modak R. K. (2021). Analyzing the impact of preoperative interrogation of cardiac implantable electronic devices. *Annals of Cardiac Anaesthesia, 24*(4), 447-451.

Neubauer, H., Wellmann, M., Herzog-Niescery, J., Wutzler, A., Wber, T. P., Mugge, A., & Vogelsang, H. (2018). Comparison of perioperative strategies in ICD patients: The perioperative ICD management study (PIM study). *Pacing and Clinical Electrophysiology, 41*, 1536-1542.

Nichols, C., Vose, J., & Mittal, S. (2016). Incidence and costs related to lead damage occurring within the first year after a cardiac implantable electronic device replacement procedure. *Journal of the American Heart Association*, *5*(2). doi:10.1161/JAHA.115.002813

North Carolina Institute of Medicine. (2018). *North Carolina county health data*. https://nciom.org/nc-health-data/map/

Reason, K. (2000). Human error: models and management. *British Medical Journal*, 320(*7237)*, 768-770. doi: 10.1136/bmj.320.7237.768.

Rooke, G. A., Lombaard, S. A., Van Norman, G. A., Dziersk, J., Natrajan, K. M., Larson, L. W., & Poole, J. E. (2015). Initial experience of an anesthesiology-based service for

perioperative management of pacemakers and implantable cardioverter defibrillators. *Anesthesiology, 123*(5), 1024-1032. https://doi.org/10.1097/ALN.0000000000000838

Samuels, J. M., Overbey, D. M., Wikiel, K. J., Jones, T. S., Robinson, T. N., & Jones, E. L. (2021). Electromagnetic interference on cardiac pacemakers and implantable cardioverter defibrillators during endoscopy as reported to the US Federal Drug Administration. *Surgical Endoscopy, 35*, 3796–3801. https://doi.org/10.1007/s00464-020-07872-2

Traczyk, C., Rice, A. N., Thompson, A., Thompson, J., & Muckler, V. C. (2021). Implementation of a postoperative record alert for cardiac implantable electronic device patients. *Journal of Perianesthesia Nursing, 36*(4), 345-350. https://www.clinicalkey.com/nursing/#!/content/journal/1-s2.0-S1089947221002409

Appendix A

Literature Concepts Table

	Concept 1: Pacemakers/ AICD	Concept 2: Perioperative	Concept 3: Management	Concept 4: Nurse Anesthetist
Keywords (these are the "normal" words you would use anywhere)	Pacemakers, cardiac implanted electronic devices, permanent pacemakers, AICD/PPM	Perioperative, preoperative, postoperative, intraoperative, surgical	Disease management, patient safety, workflow	Nurse anesthetists, anesthesia, CRNA
PubMed MeSH (subject heading specific to PubMed)	Written for PubMed as "pacemaker, artificial"[MeSH Terms] OR "defibrillators" [MeSH Terms] OR AICD	Written for PubMed as "surgical procedures, operative"[MeSH Terms] OR "perioperative period"[MeSH Terms]	Written for PubMed as "workflow"[MeSH Terms] OR "patient safety"[MeSH Terms] OR "disease management"[MeSH Terms]	Written for PubMed as "anesthesia"[MeSH Terms] OR "nurse anesthetist" [MeSH Terms]
CINAHL Subject Terms (Subject headings specific to CINAHL)	(MH "Defibrillators, Implantable") OR (MH "Pacemaker, Artificial")	(MH "Surgery, Operative"))	-	Written for CINAHL as (MH "Anesthesia") OR (MH "Nurse Anesthetists")
Other (Google Scholar)	"Implantable Defibrillators" OR "Pacemaker Artificial" OR "AICD"	"Perioperative Period"	"Management"	"Anesthesia"

Appendix B

Literature Search Log

Database/ Search Engine	Search Strategy	Limits applied	Number of citations found/ kept	Rationale for inclusion/ exclusion
PubMed	(nurse anesthetist OR anesthesia) AND (pacemaker OR implanted cardiac defibrillator) AND (perioperative period) "nurse anaesthetist"[All Fields] OR "nurse anesthetists"[MeSH Terms] OR ("nurse"[All Fields] AND "anesthetists"[All Fields]) OR "nurse anesthetists"[All Fields] OR ("nurse"[All Fields] AND "anesthetist"[All Fields]) OR "nurse anesthetist"[All Fields] "anaesthesia"[All Fields] OR "anesthesia"[MeSH Terms] OR "anesthesia"[All Fields] OR "anaesthesias"[All Fields] OR "anesthesias"[All Fields] "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] ("embryo implantation"[MeSH Terms] OR ("embryo"[All Fields] AND "implantation"[All Fields]) OR "embryo implantation"[All Fields] OR "implantation"[All Fields] OR	7 years 2015-2022	29 found/ 3 kept	Perioperative management of AICD with focus on anesthesia personnel management and interventions/ not applicable

	"implant"[All Fields] OR "implant s"[All Fields] OR "implantability"[All Fields] OR "implantable"[All Fields] OR "implantables"[All Fields] OR "implantate"[All Fields] OR "implantated"[All Fields] OR "implantates"[All Fields] OR "implantations"[All Fields] OR "implanted"[All Fields] OR "implanter"[All Fields] OR "implanters"[All Fields] OR "implanting"[All Fields] OR "implantion"[All Fields] OR "implantitis"[All Fields] OR "implants"[All Fields]) AND ("cardiacs"[All Fields] OR "heart"[MeSH Terms] OR "heart"[All Fields] OR "cardiac"[All Fields]) AND ("defibrilator"[All Fields] OR "defibrillate"[All Fields] OR "defibrillated"[All Fields] OR "defibrillates"[All Fields] OR "defibrillating"[All Fields] OR "defibrillations"[All Fields] OR "defibrillator s"[All Fields] OR "defibrillators"[MeSH Terms] OR "defibrillators"[All Fields] OR "defibrillator"[All Fields] OR "electric countershock"[MeSH Terms] OR ("electric"[All Fields] AND "countershock"[All Fields]) OR "electric countershock"[All Fields] OR "defibrillation"[All Fields]) "perioperative period"[MeSH Terms] OR ("perioperative"[All Fields] AND "period"[All Fields]) OR "perioperative period"[All Fields]			

Search Date	Database/ Search Engine	Search Strategy	Limits applied	Number of citations found/ kept	Rationale for inclusion/ exclusion
9/7	CINAHL	((MH "Defibrillators, Implantable") OR (MH "Pacemaker, Artificial") OR (MH "Cardiac Pacing, Artificial")) AND ((MH "Perioperative Care") OR (MH "Perioperative Nursing") OR (MH "Perioperative Medicine") OR (MH "Surgery, Operative"))	5 years 2017-2022	40 found/ 4 kept	Anesthetic focus of AICD perioperative care/ not applicable
9/7	Google Scholar	((nurse anesthetist OR anesthesia) AND (pacemaker OR (implanted cardiac defibrillator) AND (perioperative period)) AND (Anesthesia)	5 years 2017-2022	4 pages searched/ 9 kept	Focus on intervention (e.g., algorithms) and “gap closing” interventions/ not applicable

Appendix C

Literature Matrix

Year	Author, Title, Journal	Purpose & Conceptual Framework or Model	Design and Level of Evidence	Setting	Sample	Tool/s and/or Intervention/s	Results
2011	Crossley, G. H., Poole J. E., Rozner, M. A., Asiryatham, S. J., Cheng, A., Chung, M. K., Ferguson, T. B., Gallagher, J. D., Gold, M. R., Hoyt, R. H., Irefin, S., Kusumoto, F. M., Moorman, L. P., & Thompson, A. (2021). The Heart Rhythm Society (HRS)/ American Society of Anesthesiologists (ASA) expert consensus statement on the perioperative management of patients with implantable defibrillators, pacemakers and arrhythmia monitors: Facilities and patient management. *Heart Rhythm*, *8*(7), 1114-1115.	The purpose of this article is to guide anesthesia providers in their care for patients with CIED during the perioperative period. The authors indicated that there were no randomized control trials or meta-analyses used for this consensus due to the lack of research on the subject. So, the purpose was to provide an expert opinion in the face of a lack of evidence to guide providers care for these patients. No framework or model noted.	Level VII: Expert Opinion.	Intended for use in procedural and surgical areas.	14 experts in CIED care. Statements only published if a minimum of 85% of the panel's agreement on each recommen-dation.	Of the many recommendations and guidelines suggested by this committee, only one tool was supplied. This tool was an emergency operation protocol for a patient with a CIED and an algorithm to follow to provide optimum care.	Many recommendations were noted. These included consulting the CIED team, or, if unavailable, each patient's individual CIED team (e.g., their cardiologist) to decrease unnecessary, extensive preoperative device workups during each perioperative visit. This team would provide a perioperative "prescription" for the patient. The experts also cautioned to not rely on manufacturer representatives in perioperative management of

							devices. They reminded providers to take the representatives' recommendations as technical support of the device not clinical support of the patient. This article also touches on all phases of perioperative care including evaluation techniques, effects of EMI, and other common difficulties faced in the perioperative period. Additionally, the panel clarified what patients should have a mandatory post-operative device interrogation. This statement was used heavily as a resource for the 2020 ASTAF guidelines.

2015	Rooke, G. A., Lombaard, S. A., Van Norman, G. A., Dziersk, J., Natrajan, K. M., Larson, L. W., & Poole, J. E. (2015). Initial experience of an anesthesiology-based service for perioperative management of pacemakers and implantable cardioverter defibrillators. *Anesthesiology, 123*(5), 1024-1032.	The aim of this study was to identify if increasing the number of anesthesiologists trained to manage, interrogate, and create strategies for perioperative management of patients with AICDs/ PPMs altered workload of EPCS, errors associated with device programming, and OR delays due to AICD/PPM management. Numbers of devices cared by EPCS versus the ADS was also evaluated. No framework or model noted.	Level V: Retrospective review.	WMC	Five anesthesio-logists trained as part of the ADS. 662 patients under-going 1,025 procedures.	Descriptive statistics- Two group Fisher exact test utilized $p<0.05$ using OpenEpi.	Both ADS and EPCS groups made errors in CIED management. ADS group initially made more errors than the EPCS group but improved with practice. The investigators found that restoring the AICD/PPM settings were more challenging and had more error in both groups than originally expected. The authors determined that utilizing an ADS team and educating more providers would likely only be of use in a high-volume surgical center/ hospital. They also found that increasing the number of trained anesthesia providers may prove to be helpful.
2018	Neubauer, H., Wellmann, M., Herzog-Niescery, J., Wutzler, A., Wber, T. P., Mugge, A., & Vogelsang, H.	The purpose of this study was to compare different ICD perioperative	Level IV: Prospective observational study.	University Hospital.	N=101, n=42 ICD reprogram-med	Intervention: PIM Study Protocol. Compared three groups of	This study found that all three strategies were safe considering the electrocautery and

	(2018). Comparison of perioperative strategies in ICD patients: The perioperative ICD management study (PIM study). *Pacing and Clinical Electrophysiology*, *41*, 1536-1542.	strategies with surgery location and electrocautery used. No framework or model noted.			preopera-tively, n= 45 magnet used to inactivate pacemaker n=11 received no pacemaker inactivatio n.	perioperative CIED strategies depending on location of surgery. and electrocautery used. Each group had a corresponding suggested intervention for the patient's CIED.	surgery location. Results indicate that the use of a magnet or choosing to not inactivate the device could both be safe options for patients with CIED undergoing surgery. Using the PIM Protocol may be able to simplify perioperative care of CIEDs.
2020	American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Implantable Electronic Devices. (2020). Practice advisory for the perioperative management of patients with cardiac implantable electronic devices: Pacemakers and implantable cardioverter–defibrillators. *Anesthesiology*, *132*(2), 225–252.	Preoperative best practice (BP): Confirm device, settings, dependency, consult electrophysiologist if needed Intraoperative BP: Ensure EMI is mitigated, continuously monitor the patient's peripheral pulse and ECG Have emergency defibrillator/ cardioverter/ pacer available. Postoperative BP	Level VII: BP Advisory-Combined a systematic review of the literature as well as an expert opinion survey.	N/A (BP guidelines-no setting indicated).	N=32, some participant s did not answer all data-some questions on survey were only answered by 27/32 responses. Random sampling within members of the	Expert Survey=Likert Style- no survey name included.	Guidelines for perioperative management of CIEDs was presented based on 2011 HRS Expert Consensus statements, current literature, and an additional expert survey. These guidelines aimed at clarifying confusing and at times contradictory statements across anesthesia providers regarding the proper care of these devices.

		continuously monitor the patient's peripheral pulse and ECG. Have emergency defibrillator/ cardioverter/ pacer available; reprogram device and interrogate as needed. No framework or model noted.			ASATF. 85% of responden ts were anesthesio logists. 15% were Cardiac Electroph ysiologists		In this advisory, the authors admitted that there is a lack of evidence due to lack of overall research in this area.
2020	Samuels, J. M., Overbey, D. M., Wikiel, K. J., Jones, T. S., Robinson, T. N., & Jones, E. L. (2021). Electromagnetic interference on cardiac pacemakers and implantable cardioverter defibrillators during endoscopy as reported to the US Federal Drug Administration. *Surgical Endoscopy, 35,* 3796–3801.	Purpose was to identify if the use of a magnet in endoscopic surgical cases with high risk of electromagnetic interference (EMI) would affect patient outcomes. In addition, use and benefit of device interrogations was also evaluated. No framework or model noted.	Level VI: Quantitative Descriptive.	N/A (Not noted: search of database of all U.S. endoscopic surgical events).	N=311; used convenien ce sampling from MAUDE database, for seven cardiac implantabl e device fault codes from the years 2009-2019 that were related to	Database search of Manufacturer and User Facility Device Experience (MAUDE) was utilized to identify risks of EMI for patients with CIEDs.	Electricity used during endoscopic surgeries can cause faults in implanted cardiac devices. Patients need pre and post evaluations of their devices to ensure proper function.

					endoscopic procedures.		
2020	Feldman, J. B., & Stone, M. E. (2020). Anesthesia teams managing pacemakers and ICDs for the perioperative period: enhanced patient safety and improved workflows. *Current Opinion in Anaesthesiology*, *33*(3), 441-447.	The purpose of this article was to synthesis the available recommendations and literature pertaining to perioperative care of CIED patients. The article aimed at targeting each phase of the perioperative period to clarify the conflicting perioperative strategies proposed by various experts. No framework or model noted.	Level VII: Synthesis of Expert Opinions.	N/A (synthesis of opinions and BP from literature).	N/A	Provided a decision-making algorithm for the perioperative care of CIED patients.	Avoidance of problems in the perioperative period was the focus of these recommendations. This article focused on the anesthesia team's contribution to CIED patient safety and noted the need for proactive care and a high level of competency on the devices. The authors indicated education as well as implementation of algorithms would be beneficial to anesthesia providers to validate their decision making in caring for these patients. By avoiding common stumbling blocks in providing care, workflows of the surgical and

							anesthesia teams improve.
2021	Traczyk, C., Rice, A. N., Thompson, A., Thompson, J., & Muckler, V. C. (2021). Implementation of a postoperative record alert for cardiac implantable electronic device patients. *Journal of Perianesthesia Nursing*, *36*(4), 345-350.	The purpose was to identify if implementing a postoperative alert in the electronic medical record would prevent adverse outcomes in patients with AICD/ PPM undergoing surgery. The goal was to evaluate if implementing this reminder would reduce patient's length of stay and device inactivity time while also facilitating postoperative reprogramming of these devices. No framework or model noted.	Level VI: QI Project using the IOWA model: pre and post observational design.	A large university medical center in the southeast.	N=404; Post Implementation group: n=272 Pre-implementation group: n=132. The study used convenience sampling method. All participants had an AICD/ PPM and were 18 years old or older. Included patients having emergent or planned	Intervention: Pop up reminders intra-operatively and post operatively to reprogram devices. This study observed effects of the intervention on length of stay, and adverse patient events.	Utilizing post-operative pop-up reminders for anesthesia providers, the post-intervention group had fewer adverse events for patients, shorter lengths of stay, decrease in device suspension time, and an overall increase in device reprogramming in the post operative period. The authors identified postoperative programming risks and barriers to successful reprogramming.

					operations.		
2021	Navas-Blanco J. R, Williams D. V., & Modak R. K. (2021). Analyzing the impact of preoperative interrogation of cardiac implantable electronic devices. *Annals of Cardiac Anaesthesia*, *24*(4), 447-451.	To evaluate if patients were undergoing the HRS/ ASA recommended preoperative interrogation and how this intervention, if received, affected operating room delays as well as intraoperative/ post-operative cardiac events. No framework or model noted.	Level V: Retrospect-ive cohort.	Single-center tertiary teaching medical center.	N=151 patients with CIED having elective and emergent surgeries between November 2013-December 2016 Used electronic medical records and the Internatio nal Classificat ion of Disease Code (code ICD- 10) to identify patients.	Fisher's exact test, two-sample *t*-test and chi-square were used to determine average differences between groups. $P < 0.05$ denoted statistical significance.	In this study, 76% of patients received preoperative interrogations of their CIED. Those who did not receive this intervention had a significantly higher risk of interoperative and postoperative cardiac events (25% in the non-interrogated groups vs. 8% in the interrogated group). Regarding preoperative holding times, 6% of these patients had an CIED-related delay in OR start times averaging 54 minutes. Study also noted providers do not consistently utilize the ASA/ HRS recommendations.

Note. ASA= American Society of Anesthesiologists; ASATF= American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Implantable Electronic Devices; HRS= Heart Rhythm Society; CIED= Cardiac Implanted Electronic Device (includes both AICD and permanent pacemaker categories); EMI= electromagnetic interference; BP= Best Practice; EPCS= Electrophysiology/ Cardiology Services; ADS= Anesthesiology Device Service; WMC= Washington Medical Center; QI= quality improvement. 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.

Appendix D

ECU CON Quality Improvement Determination

Click "download PDF" to save a copy of this page for your records.
Note: The IRB Office does not maintain copies of your responses.

Below is a summary of your responses

Download PDF

Quality Improvement/Program Evaluation Self-Certification Tool

Purpose:
Projects that do not meet the federal definition of human research pursuant to 45 CFR 46 do not require IRB review. This tool was developed to assist in the determination of when a project falls outside of the IRB's purview.

Instructions:
Please complete the requested project information, as this document may be used for documentation that IRB review is not required. Select the appropriate answers to each question in the order they appear below. Additional questions may appear based on your answers. If you do not receive a STOP HERE message, the form may be printed as certification that the project is "not research", and does not require IRB review. The IRB will not review your responses as part of the self-certification process. For projects being done at Vidant Health, site support will be required. Please email [redacted] to obtain site support from [redacted]

Name of Project Leader:

Caroline Flynn

Project Title:

Perioperative Care of Patients with Cardiac Implanted Electronic Devices: A DNP Project

Brief description of Project/Goals:

The purpose of this quality improvement project is to assess anesthesia providers' perceptions of adequacy of a newly developed AICD/ PPM Handout. Process: A quick-reference perioperative Automatic Implantable Cardioverter-Defibrillator/ Permanent Pacemaker Handout (AICD/ PPM Handout), based on accepted national guidelines, will be developed. Anesthesia providers at [redacted] or an affiliate facility will be asked several questions (through Qualtrics) about their perceptions of the adequacy of their currently used resources relating to AICD/ PPM care in a pre-intervention survey. Then, the AICD/ PPM Handout and an educational PowerPoint discussing the newly developed resource will be made available to participants. Participants will be asked to use the AICD/ PPM Handout for two weeks. Upon completion of the two-week utilization period, they will be asked to complete a questionnaire (through Qualtrics) about their perceptions of the adequacy of the AICD/ PPM Handout and their current practice. No patient information will be recorded or maintained during this project.

Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?

- ○ Yes
- ● No

Has the project received funding (e.g. federal, industry) to be conducted as a human subject research study?

- ○ Yes
- ● No

Is this a multi-site project (e.g. there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)?

- ○ Yes
- ● No

Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?

- ○ Yes
- ● No

Will the results of the project be published, presented or disseminated outside of the institution or program conducting it?

- ● Yes
- ○ No

Would the project occur regardless of whether individuals conducting it may benefit professionally from it?

- (●) Yes
- ( ) No

Does the project involve "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)?

- (●) Yes
- ( ) No

Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program, and falls under well-accepted care practices/guidelines?

- (●) Yes
- ( ) No

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. 11/26/2022

Appendix E

Research Department Letter

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] 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: Perioperative Care of Patients with Cardiac Implanted Electronic Devices: A DNP Project		
Funding Source: None		
Project Leader Name: Caroline Flynn, 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:** [redacted]
	Primary Contact (If different from Project Leader):	
	Phone: [redacted]	**Email:** [redacted]

Key Personnel/ Project Team members:

Name and Degree:	**Department:** (Affiliation if other than ECU Health)	**Email:**
Caroline Flynn	ECU Nurse Anesthesia Program	[redacted]
Travis Chabo	ECU Nurse Anesthesia Program	[redacted]

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:

The purpose of this quality improvement project is to assess anesthesia providers' perceptions of adequacy of a newly developed *Automatic Implantable Cardioverter- Defibrillator/ Permanent Pacemaker (AICD/ PPM) Handout*. A quick-reference AICD/ PPM educational guide, based upon accepted national guidelines, will be developed. Anesthesia providers at [redacted] Main Operating Room will be asked several questions (through Qualtrics) about their perceptions of the adequacy of the/their currently used AICD/PPM resources and preparedness for providing anesthesia care for these patients. An educational PowerPoint about the use of the newly developed *AICD/ PPM Handout* will be made available to them, and they will be asked to use the guide for two weeks. Upon completion of the two-week 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 acceptability and adequacy of the intervention prior to and post implementation of the project. No patient information will be recorded or maintained during this project.

a) **The project's primary purpose.** 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.
b) **The project design.** The project will consist of a single Plan, Do, Study, Act cycle using a pre- and postintervention survey design.
c) **Any interaction or intervention with humans.** CRNA participants will be contacted via email and asked to complete a pre-survey and then utilize an informational tool, the *AICD/ PPM Handout,* which is based on current evidence and that aligns with practices currently accepted within the facility to support their practice regarding perioperative AICD/PPM management. After two weeks, they will then be asked to complete a post-survey 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.
d) **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 anesthetic care of patients with an AICD/

PPM. The handout information is based on current evidence and falls within current accepted practice standards within the facility.

e) **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.

f) **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 email and IP addresses, no identifiable data will be gathered. Data of interest is participant opinions and perceptions of practice and regarding the newly developed informational tool.

g) **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 will be email and IP addresses. Qualtrics survey software is accessed through ECU and involves multifactorial password protection. Data in Excel will be on a password protected personal laptop. Email addresses will be deleted from Excel files after both surveys are completed and analysis of results begins.

h) **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.

i) **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.** The deidentified data will be analyzed with results shared via a poster presentation to the ECU Nurse Anesthesia Program students and faculty, 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. Caroline Flynn will be responsible for de-identification of all data prior to dissemination.

2. 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]

DocuSigned by: [redacted] 3/1/2023 | 11:14 PM EST

0704EC6E5DCA423...

[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]"
- 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 [redacted] 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 [redacted] 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

Identified [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] ealthcare 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.

DocuSigned by:
FF91C00F3FCB4CC...
3/6/2023 | 7:20 PM EST

Caroline Flynn **2/11/23**

Project Leader Signature **Date**

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

NHSR vs. HSR Determination:

☑ **Not Human Subject Research:** T[redacted] 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] 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] **Reviewer:** [redacted] **Date:** 3/7/2023

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

Appendix F

AICD/PPM Handout

AICD/ PPM Education

Phone Numbers

Biotronik: 1-(800)-547-0394
Medtronic: 1-(800)-929-4043, (option #2)
Abbott Laboratories: 1-(800)-722-3774
Boston Scientific: 1-(866)-484-3268, (option #2)

Preoperative

- Review medical record device identification card (if unavailable chest X-ray):
  - Manufacturer, Type, Indication, Settings
  - Ensure interrogation performed within 6 months, if not obtain preoperative interrogation
- Optimize settings according EMI Risk:
  - Permanent Pacemaker
    - Consider disabling special algorithms (i.e., rate response, antitachycardia functions)
    - *Dependent only*- Reprogram to asynchronous mode if surgery site is above umbilicus with high-risk EMI (i.e., monopolar electrosurgery, lithotripsy)
  - AICD
    - Suspend antitachyarrhythmia function regardless of surgical location
    - Turn off rate-response abilities with monopolar cautery (by reprogramming only)
  - Prone: Do NOT use magnet; must reprogram

Intraoperative

- Monitoring: Continuous EKG (with pacing mode), SPO2, and peripheral pulse
- Reduce EMI:
  - If unexpected EMI occurs, stop surgery until EMI eliminated
- Emergency
  - Terminate EMI and remove magnet to allow ICD antitachycardia therapies to resume if this fails follow ACLS

Postoperative

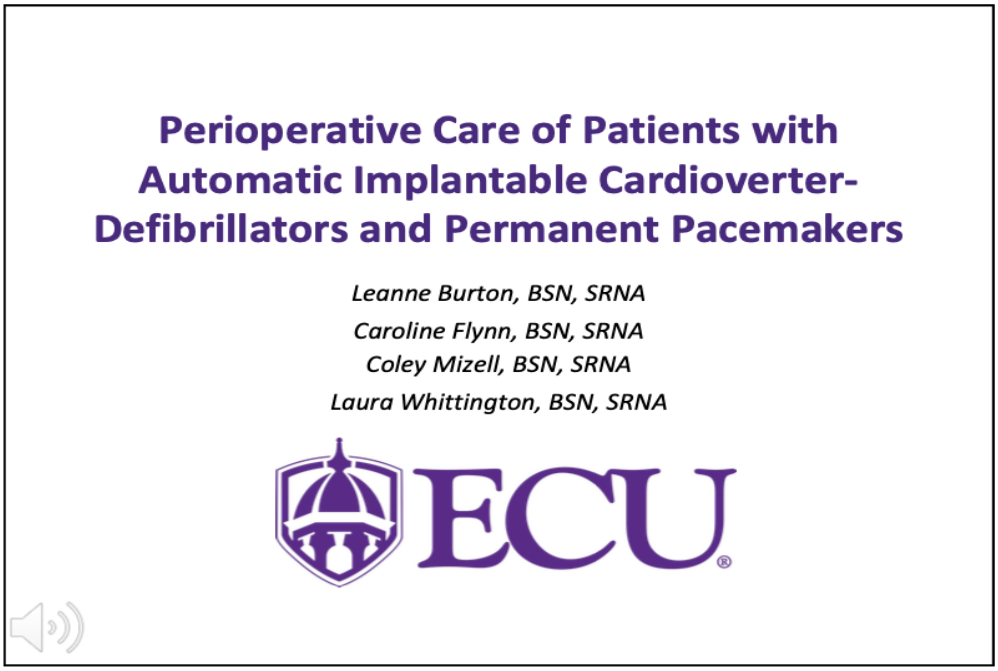
- Continuous monitoring of EKG
- Restore preoperative settings before leaving the monitored environment
- Ensure backup pacing and emergency equipment available
- Postoperative Interrogation for:
  - Emergency surgery/ no preoperative interrogation
  - If settings were adjusted
  - Suspected or known EMI interference
  - Shock occurred (external or internal)
  - Concern for device malfunction

How to decrease EMI Risk:

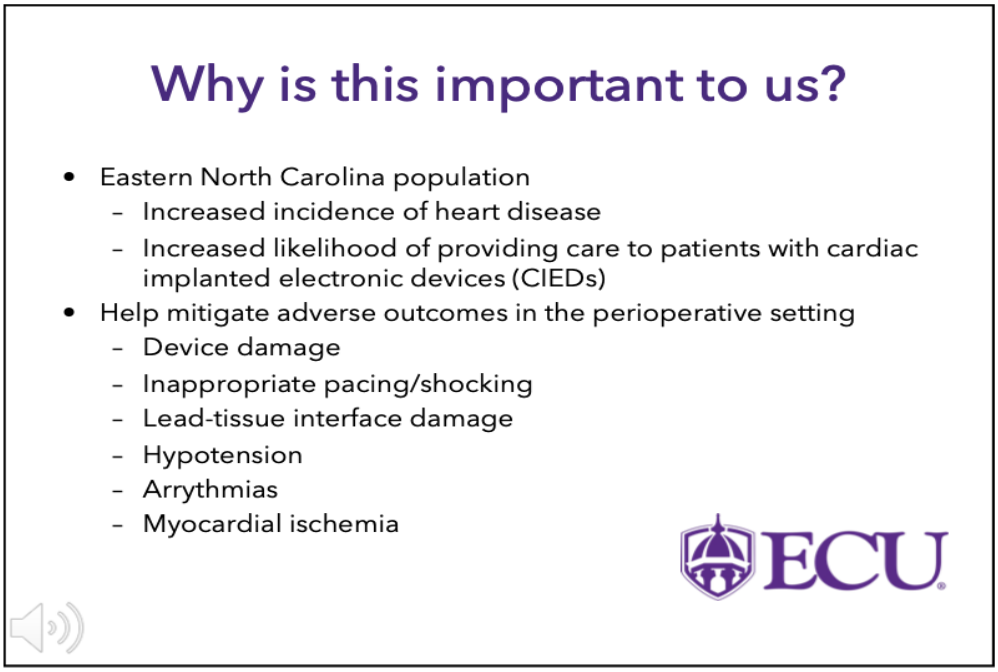
- Suggest ultrasonic scalpel and bipolar electrosurgery if possible
- Limit cautery: Encourage short, intermittent, irregular bursts of cautery at lowest energy
- Do NOT wave activated electrode of electrosurgery instrument near device
- Avoid close proximity of radiofrequency identification wands to CIED
- Avoid contacting device with ablation catheter
- Ensure current path does not pass through or near CIED generator or leads (i.e. Bovie pads and/or radiofrequency)

Appendix G

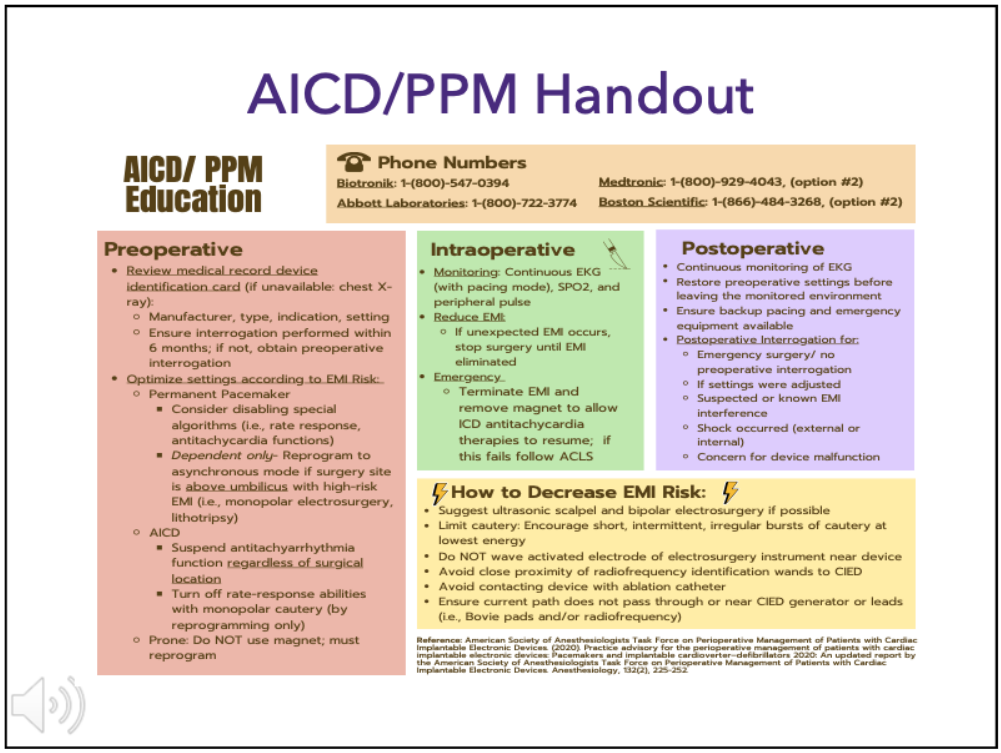
Supplemental PowerPoint



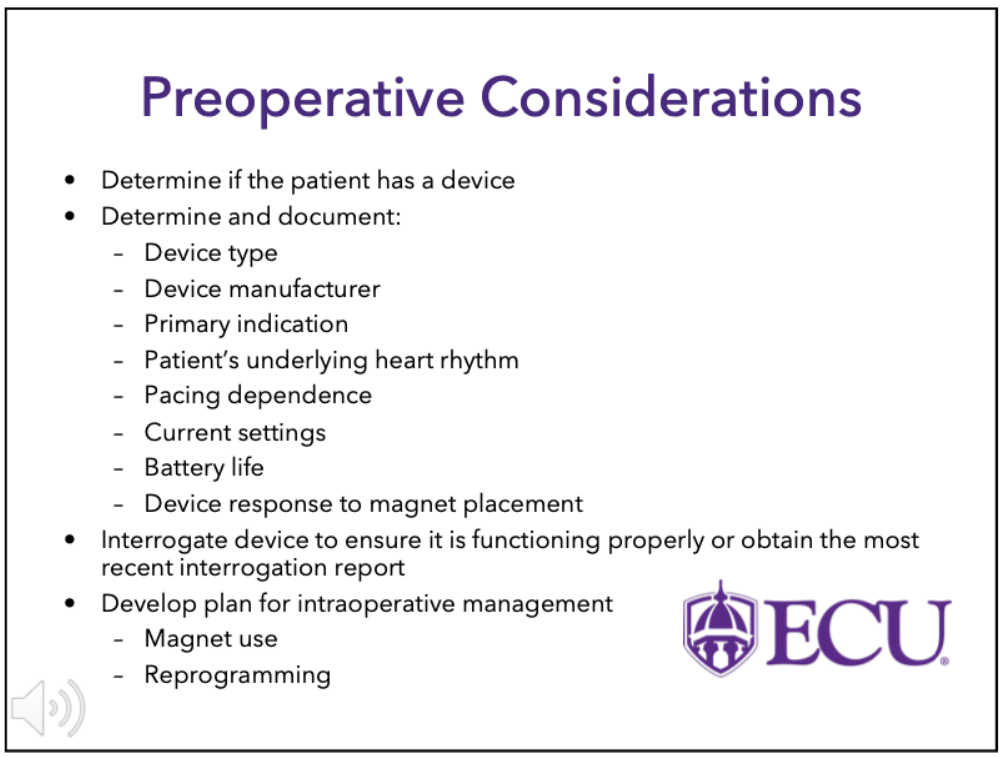
1



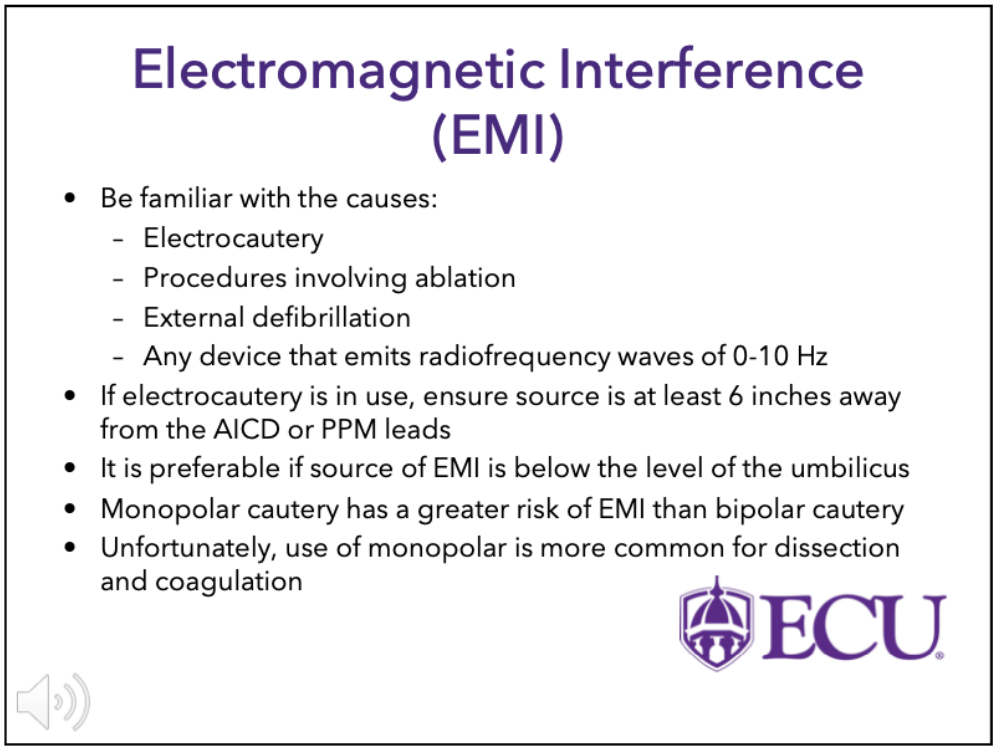
2

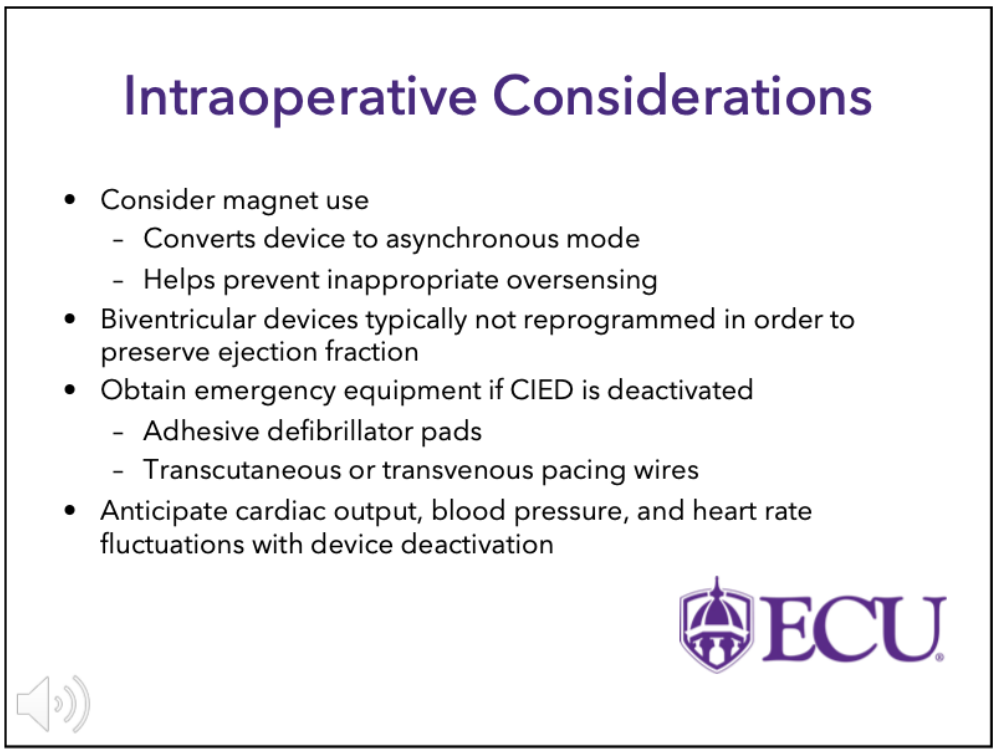

AICD/PPM Handout
AICD/ PPM Education
Phone Numbers
Biotronik: 1-(800)-547-0394
Abbott Laboratories: 1-(800)-722-3774
Medtronic: 1-(800)-929-4043, (option #2)
Boston Scientific: 1-(866)-484-3268, (option #2)
Preoperative
Review medical record device identification card (if unavailable: chest X-ray):
Manufacturer, type, indication, setting
Ensure interrogation performed within 6 months; if not, obtain preoperative interrogation
Optimize settings according to EMI Risk:
Permanent Pacemaker
Consider disabling special algorithms (i.e., rate response, antitachycardia functions)
Dependent only- Reprogram to asynchronous mode if surgery site is above umbilicus with high-risk EMI (i.e., monopolar electrosurgery, lithotripsy)
AICD
Suspend antitachyarrhythmia function regardless of surgical location
Turn off rate-response abilities with monopolar cautery (by reprogramming only)
Prone: Do NOT use magnet; must reprogram
Intraoperative
Monitoring: Continuous EKG (with pacing mode), SPO2, and peripheral pulse
Reduce EMI:
If unexpected EMI occurs, stop surgery until EMI eliminated
Emergency
Terminate EMI and remove magnet to allow ICD antitachycardia therapies to resume; if this fails follow ACLS
Postoperative
Continuous monitoring of EKG
Restore preoperative settings before leaving the monitored environment
Ensure backup pacing and emergency equipment available
Postoperative Interrogation for:
Emergency surgery/ no preoperative interrogation
If settings were adjusted
Suspected or known EMI interference
Shock occurred (external or internal)
Concern for device malfunction
How to Decrease EMI Risk:
Suggest ultrasonic scalpel and bipolar electrosurgery if possible
Limit cautery: Encourage short, intermittent, irregular bursts of cautery at lowest energy
Do NOT wave activated electrode of electrosurgery instrument near device
Avoid close proximity of radiofrequency identification wands to CIED
Avoid contacting device with ablation catheter
Ensure current path does not pass through or near CIED generator or leads (i.e., Bovie pads and/or radiofrequency)
Reference: American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Implantable Electronic Devices. (2020). Practice advisory for the perioperative management of patients with cardiac implantable electronic devices: Pacemakers and implantable cardioverter–defibrillators 2020: An updated report by the American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Implantable Electronic Devices. Anesthesiology, 132(2), 225-252.

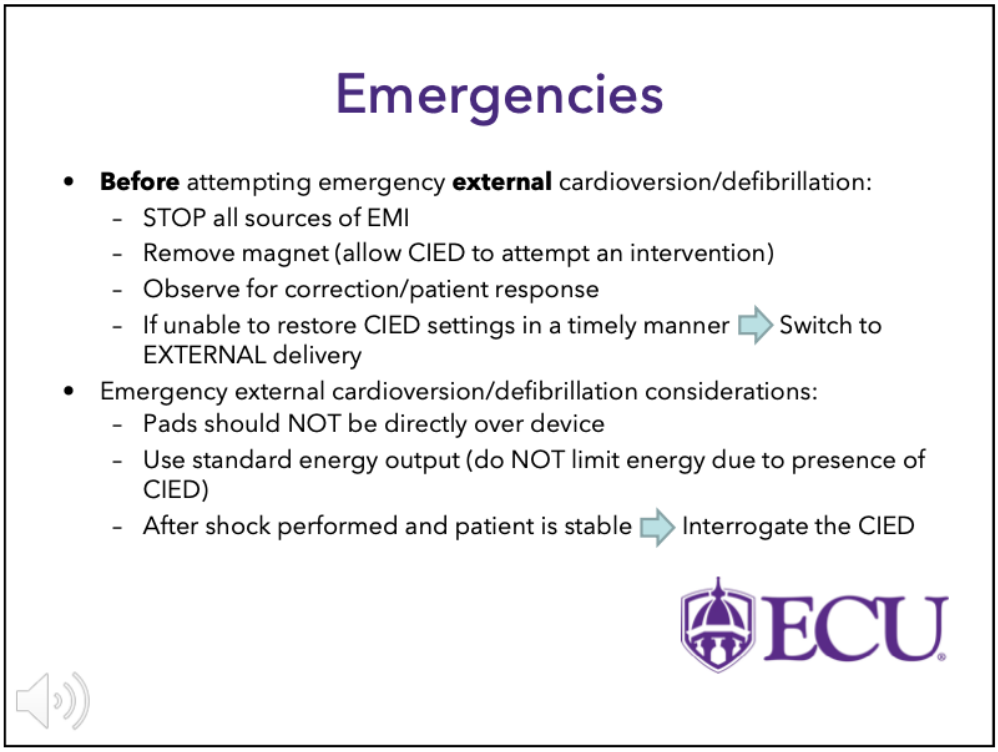
3


Preoperative Considerations
Determine if the patient has a device
Determine and document:
Device type
Device manufacturer
Primary indication
Patient's underlying heart rhythm
Pacing dependence
Current settings
Battery life
Device response to magnet placement
Interrogate device to ensure it is functioning properly or obtain the most recent interrogation report
Develop plan for intraoperative management
Magnet use
Reprogramming
ECU

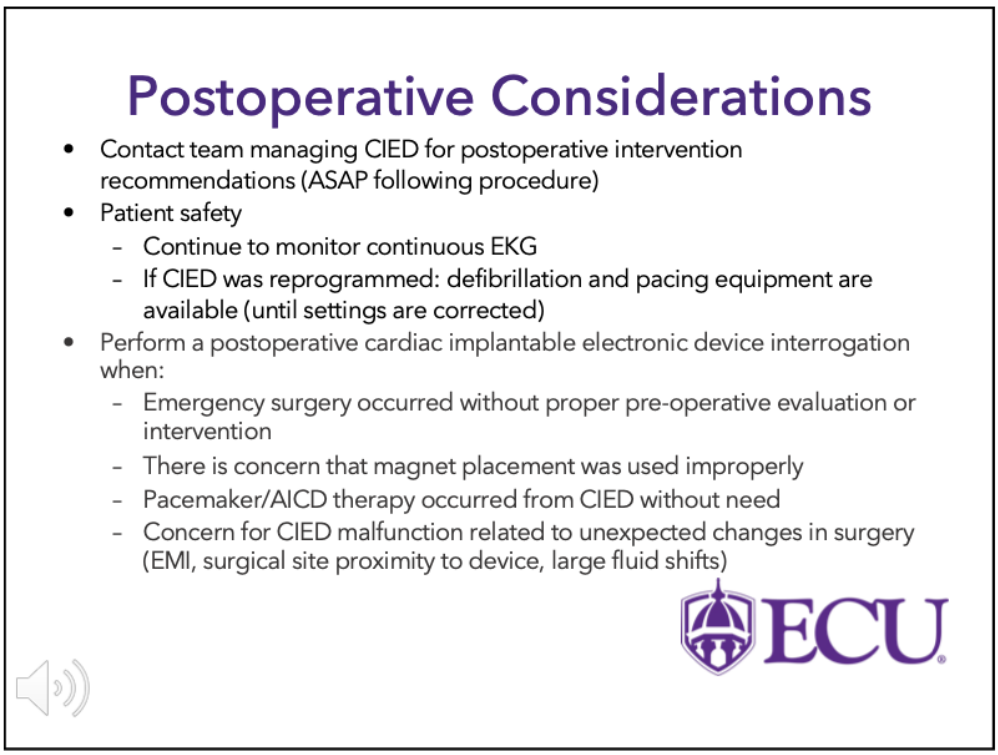
4


Electromagnetic Interference (EMI)
• Be familiar with the causes:
– Electrocautery
– Procedures involving ablation
– External defibrillation
– Any device that emits radiofrequency waves of 0-10 Hz
• If electrocautery is in use, ensure source is at least 6 inches away from the AICD or PPM leads
• It is preferable if source of EMI is below the level of the umbilicus
• Monopolar cautery has a greater risk of EMI than bipolar cautery
• Unfortunately, use of monopolar is more common for dissection and coagulation
ECU
5


Intraoperative Considerations
• Consider magnet use
– Converts device to asynchronous mode
– Helps prevent inappropriate oversensing
• Biventricular devices typically not reprogrammed in order to preserve ejection fraction
• Obtain emergency equipment if CIED is deactivated
– Adhesive defibrillator pads
– Transcutaneous or transvenous pacing wires
• Anticipate cardiac output, blood pressure, and heart rate fluctuations with device deactivation
ECU
6


Emergencies
• Before attempting emergency external cardioversion/defibrillation:
– STOP all sources of EMI
– Remove magnet (allow CIED to attempt an intervention)
– Observe for correction/patient response
– If unable to restore CIED settings in a timely manner Switch to EXTERNAL delivery
• Emergency external cardioversion/defibrillation considerations:
– Pads should NOT be directly over device
– Use standard energy output (do NOT limit energy due to presence of CIED)
– After shock performed and patient is stable Interrogate the CIED
ECU

7


Postoperative Considerations
• Contact team managing CIED for postoperative intervention recommendations (ASAP following procedure)
• Patient safety
– Continue to monitor continuous EKG
– If CIED was reprogrammed: defibrillation and pacing equipment are available (until settings are corrected)
• Perform a postoperative cardiac implantable electronic device interrogation when:
– Emergency surgery occurred without proper pre-operative evaluation or intervention
– There is concern that magnet placement was used improperly
– Pacemaker/AICD therapy occurred from CIED without need
– Concern for CIED malfunction related to unexpected changes in surgery (EMI, surgical site proximity to device, large fluid shifts)
ECU

8

Current Policy

- Title: "Implanted Electronic Devices, VH-PS16"
- How to access it: (Click Direct Link Here)
  - 1) myvidant.org
  - 2) Under "Resources", click "Policies" to enter Policy Stat
  - 3) Search "CIED" and open first result
- What does it cover?
  - Preoperative and postoperative communication
  - Non-emergent versus emergent situations
  - High risk situations
  - Interventions to consider

ECU

9

Highlights of Current Policy

- Communication
  - Anesthesia team and perioperative RN will contact team managing device for recommended intraoperative care
    - If team not available or emergency, the manufacturer of the device should be contacted
  - Information to communicate: dependence, ability for reprogramming, procedure and operative site, cardioversion/defibrillation anticipation
- If pacemaker or CIED is inactivated, an armband indicating so will be placed on the patient.
- Patient Safety:
  - EKG preoperative and postoperative continuous beat-to-beat indicator (at least pulse oximeter), pacing equipment readily available, magnet available
  - If CIED reprogrammed, continuous EKG required

ECU

10

Additional Resources

- Current Guidelines
  - American Heart Association (AHA)
    - https://www.ahajournals.org/doi/10.1161/circulationaha.109.192665
  - American Nurses Association (ANA)
    - https://pubs.asahq.org/anesthesiology/article-abstract/132/2/225/108844/Practice-Advisory-for-the-Perioperative-Management/
- Recorded Lecture: Basic Management of Perioperative Pacemakers
  - By UK College of Medicine
    - https://www.youtube.com/watch?v=lqbMiNesFSE

ECU

11

References

- American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Implantable Electronic Devices. (2020). Practice advisory for the perioperative management of patients with cardiac implantable electronic devices: Pacemakers and implantable cardioverter-defibrillators 2020. *Anesthesiology, 132*(2), 225-252. https://doi.org/10.1097/ALN.0000000000002821
- Cronin, B., & Essandoh, M. K. (2018). Update on cardiovascular implantable electronic devices for anesthesiologists. *Journal of Cardiothoracic and Vascular Anesthesia*, *32*(4), 1871–1884. https://doi.org/10.1053/j.jvca.2017.09.007
- Feldman, J. & Stone, M. (2020). Anesthesia teams managing pacemakers and ICDs for the perioperative period: Enhanced patient safety and improved workflows. *Current Opinion in Anesthesiology, 33*(3), 441-447. https://doi.org/10.1097/ACO.0000000000000856
- Pavlovic, N., Manola, S., Vrazic, H., Vucic, M., Brusich, S., Radeljic, V., Zeljkovic, I., Matasic, R., Anic, A., Benko, I., Gavranovic, Z., & Glogoski, M. (2018). Recommendations for perioperative management of patients with cardiac implantable electronic devices. *Acta Clinica Croatica* (Tisak), *57*(2), 383. https://doi.org/10.20471/acc.2018.57.02.22

ECU

12

Appendix H

Emails to Participants

Initial Pre-Survey and Email to Participants

Dear [redacted] CRNAs,

Thank you for participating in our quality improvement project titled, "Perioperative Care of Patients with Cardiac Implantable Electronic Devices: A DNP Project". The purpose of this project is to assess CRNAs' 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, utilizing an *AICD/PPM Handout* in your practice for two weeks, and completing a short post-intervention survey when the two-week implementation period is over.

Each survey and the video 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 the project with you upon completion.

First, complete the pre-intervention survey through the link provided here: https://ecu.az1.qualtrics.com/jfe/form/SV_d4OLrxZi177u2KG

Following completion of the survey, view the *AICD/PPM Handout* and the supplemental brief voiceover PowerPoint attached to this email. Physical copies of the handout will be made available in my mailbox in the anesthesia workroom on Monday, April 17th. Again, thank you for your participation in our quality improvement project. I will be at [redacted] Main OR from April 17th until April 27th if you have any questions. You may also reach out to me or Dr. Chabo by email at any time.

Sincerely,

Caroline Flynn, SRNA
flynnc14@students.ecu.edu

Dr. Travis Chabo, PhD, CRNA
chabot14@ecu.edu

Pre-Survey and Reminder Email to Participants (2)

Hello [redacted] CRNAs,

I just wanted to send a quick reminder about the ongoing DNP Project on the perioperative care of patients with cardiac implantable electronic devices. If you've already filled out the pre-survey and viewed the PowerPoint, 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.

Pre-survey:
https://ecu.az1.qualtrics.com/jfe/form/SV_d4OLrxZi177u2KG

There are still hard copies of the AICD/PPM Handout in my mailbox in the anesthesia workroom if you haven't already received one. You may use these at your discretion. After the end of next week, I will begin sending out the post-surveys.

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

Sincerely,
Caroline Flynn, SRNA
ECU Nurse Anesthesia Program Class of 2024
flynnc14@students.ecu.edu

Post-Survey Email to Participants (3)
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. The link to the pre-survey is https://ecu.az1.qualtrics.com/jfe/form/SV_d4OLrxZi177u2KG, and you can follow it up by watching the introductory PPT. AICD/PPM Handouts are available for your use if you would like them, but their use is not mandatory for participation in this project.

If you've already completed the first survey, please complete the post-survey by using the following link, https://ecu.az1.qualtrics.com/jfe/form/SV_01HTOEaOeePVgQS. 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] soon.

Sincerely,
Caroline Flynn, SRNA
ECU Nurse Anesthesia Program Class of 2024
flynnc14@students.ecu.edu

Final Thank You Email to Participants (4)
Dear [redacted] CRNAs,

Thank you so much for helping me with my DNP Project! I have collected all of the pre-survey data. If you have not already, please fill out the post-survey as it would be very helpful for my data analysis (access post-survey
here: https://ecu.az1.qualtrics.com/jfe/form/SV_01HTOEaOeePVgQS).
I will be finishing my paper soon, once it's complete you will be able to read it if you'd like.

If you liked the AICD/PPM Handout and found it useful, you can continue to use the mobile version of the handout. If you prefer a hard copy, there will be additional copies in my mailbox in the anesthesia workroom. I look forward to continuing to work with you. Thank you again!

Take care,
Caroline Flynn, SRNA
ECU Nurse Anesthesia Program Class of 2024
flynnc14@students.ecu.edu

Appendix I

Pre- and Post- Intervention Survey Questions

Pre-Intervention Survey Questions

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

2. How often do you have trouble obtaining all necessary information on a patient's AICD/PPM (such as manufacturer, type, last interrogation, etc.)?
   - Never
   - Sometimes
   - About half of the time
   - Most of the time
   - Always

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

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

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?
    No
    Yes

10. Do you believe additional AICD/PPM education would help prevent negative outcomes?
    I do not believe it would be helpful
    I believe it would be somewhat helpful
    I believe it would be extremely helpful

Post-Intervention Survey Questions

1. What is your perception on the usefulness of the AICD/PPM Handout for your anesthesia practice?
    - Not at all useful
    - Slightly useful
    - Moderately useful
    - Very useful
    - Extremely 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 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

4. 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

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?
    Extremely Unlikely
    Somewhat Unlikely
    Neither Likely nor Unlikely
    Somewhat Likely
    Extremely Likely