Implementation of a Standardized Handout for Perioperative Care of Patients with Pacemakers and Automatic Implantable Cardioverter-Defibrillators: A Doctor of Nursing

Practice Project

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Abstract

Cardiac implantable electronic devices (CIEDs) are implanted in patients to treat life-threatening cardiac arrhythmias and other heart rhythm abnormalities. The current process for anesthesia providers delivering perioperative care for patients with CIEDs lacks standardization. The purpose of this quality improvement project was to assess anesthesia providers' perceptions of a standardized AICD/PPM Handout as a useful instrument to improve perioperative CIED management and patient safety. The tool was developed following a synthesis of literature and was distributed in person to CRNAs at a partnering facility. Both the handout and an educational PowerPoint with voiceover were also electronically delivered to participants for review. Participants utilized the handout for two weeks. The CRNAs responded to pre- and postintervention surveys regarding their perceptions of the usefulness of the intervention. Results indicated the anesthesia providers felt more comfortable assessing patients with CIEDs and identifying and managing high risk for EMI cases following the implementation period. There was also a decrease in the amount of time to find reference material to answer CIED questions after the intervention. This could positively impact the affiliate organization's workflow, supporting the rapid room turnover and fast-paced working environment. The primary limitation of this project was the limited sample size. Recommendations for future versions of this project include incorporating on-site and in-person educational sessions at the facility to increase awareness of both the project and resources.

Keywords: anesthesia, CRNA, education, perioperative, pacemaker

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Section I. Introduction

Background

Permanent pacemakers (PPMs) and automatic implantable cardioverter defibrillators (AICDs) are often referred to as CIEDs (cardiovascular implantable electronic devices). They are implanted in patients with known cardiac issues to treat life-threatening cardiac arrhythmias and other heart rhythm abnormalities. The prevalence of CIEDs continues to rise, meaning that more patients with CIEDs may present to the perioperative setting and need to undergo other unrelated operations after these devices are implanted (Neubauer et al., 2018). It is deemed safe for patients with CIEDs to have other non-cardiac surgical procedures, but there are certain protocols that should be followed to provide the safest perioperative care possible and to prevent electromechanical complications. Understanding the importance of providing comprehensive perioperative care to patients with PPMs and AICDs can help anesthesia providers identify the facilitators and barriers impacting delivery of appropriate care to these patients.

Burlingame (2020) discussed procedures and standards currently in place that perioperative nurses should follow to ensure the safety of patients with CIEDs undergoing surgical procedures. Current practice recommendations are that perioperative personnel take certain actions including "notifying the team managing the device, notifying the manufacturer, or consulting the health care organization's policy, procedure, or protocol" (Burlingame, 2020, p. 702). Before the start of the surgical procedure, consultation or discussion should be completed between the registered nurse, anesthesia provider, electrophysiologist, and surgeon, at a minimum, to ensure agreement amongst all team members of the patient's underlying health conditions and prior placement of CIEDs. Additional precautions should be completed before

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surgery, such as making backup temporary pacing systems or defibrillators, magnets as indicated, and monitoring devices available.

Organizations such as the American Society of Anesthesiologists (ASA) and the Anesthesia Patient Safety Foundation (APSF) have released practice advisories and newsletters, respectively, for perioperative management of CIED patients (ASA Task Force [ASATF], 2020; Neelankavil et al., 2013). The ASATF (2020) reviewed and synthesized current literature and expert opinion to develop an advisory for clinicians to reference. The APSF shared newsletters that place an emphasis on education of staff managing these devices to help mitigate adverse outcomes during the perioperative period (Neelankavil et al., 2013). Both organizations have identified using protocols and education as necessary for providing safe and effective perioperative care to these patients.

Following set algorithms, protocols, and checklists may help mitigate risks to both the patient and device. Feldman and Stone (2020) support this idea by recommending protocols where the anesthesia team is responsible for CIED patients. They suggest anesthesia staff can effectively care for these patients and prevent adverse outcomes with a minimum level of basic knowledge regarding CIED management during surgery. Possible adverse outcomes may include "damage to the device, inability of the device to deliver pacing or shocks, lead-tissue interface damage, changes in pacing behavior, electrical reset to the backup pacing mode, or inappropriate ICD therapies" (Feldman & Stone, 2020, p. 443). These adverse outcomes can result in significant clinical events including arrythmias, hypotension, and ultimately myocardial damage.

Lack of interprofessional communication and awareness of current protocols may act as a barrier to providing safe perioperative care to patients with CIEDs and may lead to possible adverse events. It is critical that all members of the healthcare team involved in these patients' surgeries are notified preoperatively and made aware of the CIED and protocols within the perioperative setting to decrease the potential for complications (Burlingame, 2020). Communication between the interprofessional team can help identify potential risks prior to surgery and help the healthcare team plan accordingly to ensure patient safety during the procedure. Effective communication and adherence to protocols by all professionals in the healthcare team are imperative to insure awareness of potential risks to patients with CIEDs, guide safe perioperative care, and prevent possible complications associated with electromechanical issues.

Organizational Needs Statement

The partnering facility for this quality improvement project is an outpatient surgical center affiliated with a hospital system in North Carolina that serves 29 rural counties as a level 1 trauma center. As the number of patients in the United States with CIEDs continues to rise, and considering the especially high rates of cardiovascular disease in this region, there are higher than national rates of patients with CIEDs undergoing surgical or cardiovascular procedures at this facility. Serving such a large population, the incidence of managing care for surgical patients with CIEDs at this hospital is high. There are no local or state statistics regarding the prevalence of CIEDs among surgical patients.

Although certain communication protocols have been implemented for handoffs between personnel, such as *situation, background, assessment, and recommendation* (SBAR), perioperative care staff have few established resources or guidelines for communicating about CIED care between the team. In view of inadequate communication being a potential barrier to best practice, a handout with next steps and guidelines addressing when, what, and with whom to communicate information regarding previously implanted CIEDs has the potential to improve delivery of care. Members of the preoperative and surgical teams, including Certified Registered Nurse Anesthetists (CRNAs), may be better equipped and prepared to ensure all recommendations are followed by referring to a designated handout. This quality improvement project, which consisted of an informative handout and a short, electronically delivered educational PowerPoint, aligned with the goals of the American Association of Nurse Anesthetists (AANA) to provide "safe and effective anesthesia care for every patient" (2022, AANA Motto section).

Problem Statement

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

Purpose Statement

The purpose of this quality improvement project was to assess anesthesia providers' perceptions of a standardized *AICD/PPM Handout* as a useful instrument to improve perioperative CIED management and patient safety.

Section II. Evidence

Description of Search Strategies

A structured literature review regarding perioperative care of patients with PPMs and AICDs was completed in September and October of 2022. To guide the literature search, a problem/patient, intervention, comparison, outcome, and time (PICOT) question was developed: *In the perioperative care of patients with cardiac implantable electronic devices (CIED), how does implementation of an AICD/PPM Handout influence CRNA perception of care for this patient population?* After determining the PICOT question, the main literature concepts identified for use in finding evidence addressing possible solutions or interventions were nurse anesthetist, pacemakers/AICDs, perioperative, and management. Based on these concepts, and as addressed in Appendix A, keywords for the literature search included, but were not limited to: nurse anesthetists, CRNA, pacemakers, cardiac implanted electronic devices, perioperative, surgical, patient safety, and disease management.

Databases and search engines utilized included Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, and Google Scholar. As noted in Appendix B, the CINAHL search strategy created was (MH "anesthesia") AND (MH "pacemaker, artificial") with 10 years (2012-2022) and written in English language as the limitations applied. The same limitations were applied to the PubMed search using the search strategy ((nurse anesthetist) OR (anesthesia)) AND ((pacemaker) OR (defibrillators)) AND (perioperative period). The Google Scholar search strategy read as (nurse anesthetist) AND ((pacemaker) OR (AICD)) AND (perioperative period) AND (surgical) AND (patient safety) with limitations of 5 years (2018-2022) and written in English language. Websites of anesthesia-related professional organizations were reviewed for desired keywords and to assess if included materials were pertinent to the topic of interest. Approximately nine articles were identified for full-text review through screening of titles and abstracts and after deletion of duplicate articles. Additionally, similar articles linked within the databases and references from highly pertinent articles were reviewed. Out of the total publications and articles identified and reviewed at a full-text level, 11 were found to provide evidence addressing possible solutions or interventions relevant to this project. See Appendix C for the complete literature matrix.

Melnyk and Fineout-Overholt (2019) break down levels of evidence into seven categories and suggest rating sources according to this hierarchy of evidence. The 11 articles provided in Appendix C were rated using this model. Upon full-text review, one systematic review (Level I), one controlled cohort study (Level IV), one quality improvement project (Level VI), and eight expert opinion articles (Level VII) were identified. The majority were published in nursing journals with guidelines and protocols written by healthcare professionals. There was a single systematic review, the highest level of evidence possible. Although the majority of sources identified were classified as lower level evidence, each contributed to understanding perioperative care for patients with PPMs and AICDs and served as evidence to support this project.

Selected Literature Synthesis

Current State of Knowledge: Perioperative Care of CIED Patients

With the incidence of patients with preexisting CIEDs who undergo surgical procedures on the rise, potential risks regarding perioperative CIED management must be identified and discussed to prevent adverse outcomes. Pavlovic et al. (2018) offered recommendations on reprogramming or inactivation of CIEDs to minimize risks during surgical procedures. According to these authors, the main risks encountered during surgeries performed on patients with existing CIEDs are inappropriate or inhibited pacing, accidental AICD shock, and device damage, all of which are normally related to electrocautery or magnet interference. For determining the best interventions for preventing complications, the device manufacturer and settings should be available and documented. Based on the site of surgery, the patient's underlying heart rhythm, and/or use of electrocautery, the CIED may need reprogramming, need to have a magnet applied, or need no intervention at all. One cohort study assessed safety of implantable cardioverter-defibrillator (ICD) management strategies by following 101 patients receiving either reprogramming, magnet application, or no intervention (Neubauer et al., 2018). When considering both the surgical site and the use of electrocautery, each intervention was deemed as a safe option for perioperative care in this study.

A recent quality improvement project provided additional understanding of effective ways to prevent adverse outcomes by investigating the use of a pre-procedure note completed within the electronic health record (EHR) for the perioperative and anesthesia team to review (Bonenberger et al., 2022). Bonenberger et al. (2022) found that implementation of a specific pre-procedure note in the EHR led to a more complete perioperative plan, and "the number of undocumented interventions that occurred with CIEDs in the intraoperative period (magnet use, preoperative programming, and postoperative reprogramming) was significantly reduced (P < .05)" (p. 312). Overall, the documentation of these interventions led to increased awareness and communication amongst the perioperative team.

Organizations such as the ASA have used task forces to develop practice advisories for anesthesia providers to use for management of care (ASATF, 2020). The ASATF advisory for the perioperative management of CIED patients from 2020 outlines care recommendations based on their analysis of existing evidence. One recommendation is performance of a comprehensive preoperative evaluation including:

(1) determining whether a patient has a cardiac implantable electronic device; (2) determining the cardiac implantable electronic device type, manufacturer, and primary indication for placement; (3) determining whether a patient is pacing-dependent; and (4) determining the cardiac implantable electronic device's current settings and that it is functioning properly by interrogating the cardiac implantable electronic device or obtaining the most recent interrogation report. (ASATF, 2020, p. 227)

Other techniques suggested for minimizing adverse outcomes include preoperative preparation, comprehensive intraoperative monitoring, and addressing electromagnetic interference (EMI).

The Heart Rhythm Society and the ASA also released an expert consensus statement on surgical management for CIED patients (Crossley et al., 2011). The expert panel consisted of cardiac electrophysiologists, anesthesiologists, a cardiothoracic surgeon, and an allied health professional. After reviewing the literature, receiving input from a designated reference group, and combining clinical experiences, they developed extensive recommendations. Their primary recommendation was that "the best prescription for the perioperative care of a patient with a CIED will be realized when that patient's CIED team is asked for advice and that advice is effectively communicated to the procedural team" (Crossley et al., 2011, p. 1116).

Current Approaches to Solving Patient Problem

The identified evidence suggests that there are facilitators to providing safe perioperative care for patients with CIEDs. Through effective communication and the incorporation of established protocols by healthcare organizations, risks and harm to these patients can be reduced. Burlingame (2020) reviewed current practice recommendations and emphasized the

importance of consultation amongst team members, preoperative preparation measures, and adherence to procedures and protocols. Existing literature also supports a focus on educating anesthesia providers to assure they receive adequate information regarding PPM and AICD management to better provide safe and effective anesthesia care (Cronin & Essandoh, 2018). These authors provided education on the different types of pacemaker settings and device recognition techniques, and ultimately advocated that anesthesia providers should seek out continual education regarding care of CIEDs to ensure preparedness to deliver safe, evidencebased patient care.

After identifying the pacemaker device and settings, it is important for anesthesia providers to be familiar with the different surgical instruments that can lead to EMI (Cronin & Essandoh, 2018). EMI can "result from any device that emits radiofrequency waves between 0 to 10 Hz" including devices used in ablation procedures, other surgical procedures requiring cautery, and external defibrillation (Cronin & Essandoh, 2018, p. 1875). Anesthesia providers, as well as the surgical team in general, can take precautions in the perioperative setting to decrease the risk of EMI by ensuring that the source of radiofrequency or electrocautery current is at least six inches away from the CIED or its leads. Electrocautery is believed to not interfere with CIEDs if used below the level of the umbilicus, and bipolar cautery is favored over monopolar.

If the provider chooses to deactivate the CIED with use of a magnet, external defibrillation devices should be immediately available. Schulman et al. (2013) outlined the preoperative, intraoperative, and postoperative considerations for patient management including documentation, reprogramming, magnet use, and reinterrogation following the end of the case. They suggest that further education and improvement of knowledge base, as well as "developing a systematic approach" can enhance CIED patient safety (Schulman et al., 2013, p. 1072).

Evidence to Support the Intervention

Feldman and Stone (2020) recognized the importance of educated anesthesia teams to improve workflows and enhance patient care. To aid in mitigating adverse outcomes and improve care, each anesthesia provider "not only needs to have a basic fund of knowledge about CIEDs in general, but also needs to proactively ascertain specific information preoperatively about their patient's device in order to devise and implement a safe plan for perioperative management" (Feldman & Stone, 2020, p. 443). Arora and Inampudi (2017) stated that providing education on the basic functions of AICDs and PPMs may help improve collaboration amongst the interprofessional perioperative team. The editors and authors of the APSF newsletter encouraged anesthesia providers to take an active role in continual education on AICDs and PPMs, suggesting that "this needs to be accomplished through multiple sources such as local anesthesia training programs, web-based modules, simulation-based training, CIED workshop training by institutions and national societies, and national educational initiatives of multispecialty guideline development" (Neelankavil et al., 2013, p. 35).

Considering the evidence supporting education of anesthesia providers regarding hospital protocols and perioperative interventions, the goal of this quality improvement project was to assess anesthesia providers' perceptions of a standardized *AICD/PPM Handout* as a useful instrument to improve perioperative CIED management patient safety. This intervention was selected based on time and resource variables due to the supporting evidence of education through multidisciplinary, easily accessible platforms.

Project Framework

The model for improvement, utilized by the Institute for Healthcare Improvement (IHI), uses the plan, do, study, act (PDSA) cycle for implementation of interventions (2022). This

model can be utilized to guide work through a systematic process by enabling individuals or organizations to achieve improvement in multiple small steps. The PDSA cycle includes addressing the plan to test the change, how the test will be carried out, observing the study findings, and acting on or determining what should be done in the future. This process can then be repeated, leading to an acceleration in improvement.

The model for improvement and the PDSA cycle were effectively utilized to guide this quality improvement project. Foremost, the *plan* aspect of the cycle included identifying the problem, determining the objectives of the project, and planning for data collection. The second part of the PDSA cycle (*do*) included educating anesthesia staff through the use of the *AICD/PPM Handout* and administering the pre- and post-intervention surveys. The third part of the cycle (*study*) involved analyzing the data from the surveys, while the final stage (*act*) involved revising the *AICD/PPM Handout* based on findings, sharing findings, and providing suggestions for future investigation and change.

Ethical Considerations and Protection of Human Subjects

This quality improvement project involved implementation of an educational intervention focused on improving intraoperative CIED patient management and safety and assessment of participant perceptions of this intervention. Nurse anesthesia providers in the designated practice area were invited to participate at their discretion. No portions of the intervention fell outside of accepted practice standards within the partnering organization. No personal information was gathered, and results remained confidential. This quality improvement project presented participants no greater than usual risk encountered in their normal workday. No patients were involved, and no patient data was gathered. The primary investigator obtained research ethics training through the Collaborative Institutional Training Initiative (CITI; https://about.citiprogram.org) program by completing the Biomedical Investigators and Key Personnel and the Responsible Conduct of Research modules before performing this project. An initial approval was completed through a process set up between the East Carolina University (ECU) College of Nursing and the University and Medical Center Institutional Review Board (UMCIRB) through which the project was deemed quality improvement, thus not requiring full IRB review. Approval through the participating organization was obtained through a process involving both the organization and the UMCIRB. Local approval to collect data was obtained from a site contact person whose signature was required on the organization's approval form. See Appendix D for project approval processes.

Section III. Project Design

Project Setting

This quality improvement project was implemented at an outpatient surgical center, an affiliate of a local level 1 trauma center in eastern North Carolina. The same day surgical center offers various types of procedures and serves a complex patient population. The partnering organization, an affiliate of East Carolina University, acted as a facilitator throughout the project processes. The partnering facility has 10 operating rooms functioning with at least 10 CRNAs and two anesthesiologists on-site each day. The surgical center also provides a high volume of surgical procedures supported by CRNAs primarily designated to this location, increasing the opportunity for usage of the *AICD/PPM Handout* as well as the opportunity to work with a set anesthesia team. A barrier regarding this setting was time, as there are quick cases with rapid room turnover typical of a same day surgical center.

Project Population

The project population consisted of CRNAs from the core staff at this affiliated surgical center. While anesthesiologists also work and are available in this facility, the CRNAs are responsible for the primary patient care during the perioperative period, which served as a facilitator to increasing the utility of the *AICD/PPM Handout*. However, as the primary provider throughout surgical procedures, CRNAs may have limited time between each case to utilize the resource, which acted as a barrier to participation in this quality improvement project.

Project Team

The project team consisted of this Student Registered Nurse Anesthetist (SRNA) as the primary investigator, fellow program SRNAs, the project chair, the site contact person, the clinical contact person, the CRNA program director, and the course director. The primary

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investigator served as the team lead for implementation and data analysis of this project while collaborating with fellow students from the same cohort on this topic and developing the *AICD/PPM Handout*, the educational PowerPoint, and the Qualtrics surveys. The project chair, who is also the CRNA program director, was responsible for guiding the team of students addressing this topic. This team member also served as the clinical contact person to assist the primary investigator in working with the affiliate surgical center. The site contact person assisted with approval of conducting this project at the selected facility. The course director guided both the primary investigator and other SRNAs in the development and completion of this quality improvement project.

Methods and Measurement

The current process for anesthesia providers delivering perioperative care for patients with CIEDs lacks standardization and creates the potential for unexecuted safety measures. Focusing on this issue, the goal of this quality improvement project was to assess anesthesia providers' perceptions of a standardized *AICD/PPM Handout* (see Appendix E) as a useful instrument to improve perioperative CIED management and patient safety. A single PDSA cycle was utilized in implementation of this quality improvement project. The *plan* step included first setting aims and developing the project components. After determining the project components and creating both the *AICD/PPM Handout* and the companion educational PowerPoint (see Appendix F), the second part of the PDSA cycle, *do*, involved implementation of the project. Both the tool and an educational PowerPoint presentation were delivered to participants through email (see Appendix G). The third part of the cycle, *study*, involved analyzing data regarding participants' perceptions. The final stage of the cycle, *act*, involved sharing the findings, revising

the *AICD/PPM Handout* and providing suggestions for future investigation and change related to CIED patient care.

The *AICD/PPM Handout* is a tool developed to assist anesthesia providers with care of these patients, using current guidelines for patients with CIEDs. This tool was created based on the synthesis of literature, protocol and policy reviews, and identification of current guidelines from the literature review portion of this project. The educational PowerPoint with voiceover was created to provide further instruction regarding this tool.

Participants completed pre- and post-intervention surveys via Qualtrics electronic survey software. Data analysis was then completed based on the responses to the survey questions, including the anesthesia providers' reported perceptions of the usefulness of the intervention. Survey questions were created to assess anesthesia providers' perceptions using both nominal and ordinal levels of measurement, using Likert-style and dichotomous answers. See Appendix H for the Qualtrics survey questions.

Prior to implementation of the intervention, approval was obtained through both the facility representative and the organization with the assistance of the site and clinical contact team members. The clinical contact person supported recruitment of participants at the facility and provided the team lead with names and email addresses of the potential participants. A pre-intervention Qualtrics survey was emailed to each of these potential participants. After obtaining all completed pre-survey questionnaires, the team lead dispersed laminated copies of the *AICD/PPM Handout* to the CRNAs at the participating facility. Additionally, an email was sent to all participants with an electronic copy of the handout and the informative PowerPoint presentation with voiceover for review.

The participants were asked to utilize the tool in the perioperative setting for patients with CIEDs during a two-week period, and assess its usefulness in the perioperative care and management of these patients. At the end of the two-week period, an email was sent containing the link to the Qualtrics post-intervention survey. Both pre- and post-intervention survey responses remained confidential as no identifying information was gathered. There were no identified issues that negatively impacted the implementation of the intervention or analysis of data collected during this project.

Timeline

This quality improvement project began in August of 2021 and was completed in November of 2023. Project initiation began by reviewing existing literature. After determining the project purpose and problem statements in September of 2022, a more structured literature review was completed. The *AICD/PPM Handout* and surveys were created in November of 2022, followed by project approvals in November of 2022 and March of 2023. The project was implemented in April and May of 2023. Data analysis took place in May of 2023, followed by poster creation in July of 2023. The findings were presented in November of 2023. See Appendix I for the project timeline.

Results

The purpose of this quality improvement project was to assess anesthesia providers' perceptions of a standardized *AICD/PPM Handout* as a useful instrument to improve perioperative CIED management and patient safety. The implementation of this project and data collection took place over an approximately four-week period. After two weeks of implementation, the data collection period was extended to provide additional opportunities for the anesthesia staff to participate in the surveys. Seven core anesthesia staff were emailed the pre-intervention survey. Of the seven emailed, six participated in the pre-intervention survey. After project implementation, five responses were received for the post-intervention survey. The pre- and post-survey data were collected with Qualtrics software and analyzed using Excel.

The pre-intervention survey provided insight into some of the perspectives of the anesthesia providers at this participating facility. Of the six participants, the majority (4) already used a standardized approach when providing perioperative anesthesia care to patients with an AICD/PPM. Despite using a standardized approach, however, some participants reported that finding reference material to answer their questions concerning AICD/PPM management may take a considerable amount of time at this high-turnover, fast-paced facility. See Figure 1 for these survey responses. When asked about having trouble obtaining information on a patient's AICD/PPM (such as manufacturer, type, last interrogation, etc.), one participant responded that they always have trouble; others reported most of the time (1), sometimes (2), about half the time (1), and never (1). Overall, anesthesia providers at this facility have not experienced an issue with an AICD/PPM during the perioperative period (5), and none of the participants (6) have either experienced themselves or know of a colleague that has been involved in the care of a

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patient with a poor postoperative outcome related to inadequate management of their AICD/PPM.

Figure 1







Note. Pre-intervention n=6. Post-intervention n=5.

When asked about their comfort providing anesthesia care to patients with AICD/PPMs, one participant somewhat disagreed with the statement that they felt comfortable. Other responses included neither agree nor disagree (1), somewhat agree (2), and strongly agree (2). The same responses were reported for the statement "I feel comfortable identifying and/or

managing cases that are high risk for electromagnetic interference (EMI) in patients with AICD/PPM."

Among five participant responses, four reported being aware of and having used the AICD/PPM policy at their facility, while one responded they were not aware and had not used the policy. To a question addressing their familiarity with the current best practice guidelines recommended by the ASA and the Heart Rhythm Society, one participant strongly agreed they were familiar, two somewhat agreed, one somewhat disagreed and two strongly disagreed. In regard to how helpful they perceived additional AICD/PPM education would be in preventing negative outcomes, two reported somewhat helpful while four of the six responded extremely helpful.

Following the two-week implementation of the *AICD/PPM Handout* and educational PowerPoint with voiceover, time to find reference material was less than 5 minutes as selected by two participants, and 5 to 10 minutes as selected by three participants, with one less participant in the post-intervention survey. See Figure 1. While all post-survey participants (n=5) reported referencing the *AICD/PPM Handout* for only between 0 and 2 procedures during the project duration, two reported they found the handout extremely useful for their anesthesia practice, one reported very useful, one moderately useful, and one slightly useful. See Figure 2 for these results.

Figure 2

Anesthesia Provider Perception of the Usefulness of the AICD/PPM Handout



Note. Post-intervention n=5.

Similar to the pre-intervention survey, two reported neither agree nor disagree with feeling comfortable providing anesthesia care for a patient with an AICD/PPM, two selected somewhat agree, and one strongly agree. See Figure 3. Three participants neither agreed nor disagreed with feeling comfortable identifying and managing cases that are high risk for EMI after the intervention, followed by one somewhat agree and one strongly agree response. When asked if using the handout increased their confidence in ensuring the assessment of their patient's

devices was thorough, two participants selected somewhat agree. Others (3) reported neither agree nor disagree to this statement. The same results were reported for the statement "using the *AICD/PPM Handout* improved my efficiency in assessing my AICD/PPM patient in the preoperative period."

Figure 3







Note. Pre-intervention n=6. Post-intervention n=5.

Somewhat agreeing with having familiarity with current best practice guidelines was reported by two participants, while there was one strongly agree reported, and two neither agree nor disagree results. Lastly, most of the participants were extremely likely (2) or somewhat likely (2) to use this *AICD/PPM Handout* in the future, with one final response of neither likely nor unlikely reported for this statement.

Analysis

Comparing the participant responses from both the pre- and post-intervention surveys provides insight into the perceived effectiveness of the intervention as a useful instrument to improve perioperative CIED management and patient safety. Overall, the *AICD/PPM Handout* was perceived to be a useful tool for anesthesia providers in the perioperative setting. Based on the results, as shown in Figure 1, improvements were made in the perceived time to find reference material to answer participants' questions concerning AICD/PPM management. While there was one less post-survey response as compared to pre-survey responses, all participants selected no greater than 10 minutes to find reference material to answer their AICD/PPM questions. This decreased from the pre-survey where some participants reported taking >15 minutes to find reference material.

Based on the data analysis, it was shown that participants are likely to use this *AICD/PPM Handout* again in their future practice. Many of the participants found the handout useful for their patient care, according to the results shown in Figure 2. As seen in Figure 3, anesthesia provider comfort with providing care to AICD/PPM patients increased when compared to the pre-survey responses. This is extremely important as increased provider comfort can help to identify risk factors and mitigate negative patient outcomes. Based on these results, the overall effectiveness of this intervention was positive, and it was deemed by participants to be a useful tool in their perioperative care of patients with AICD/PPMs.

Section V. Implications

Financial and Nonfinancial Analysis

This quality improvement project would be cost effective for the partnering organization due to the low cost of the implementation and distribution of the *AICD/PPM Handout*. The upfront cost of this project was approximately \$27 and consisted of printing and laminating hard copies of the tool to hand out at the facility. An additional cost that the organization would need to consider is employee time for holding training and educational sessions. Further education for anesthesia providers at the organization has the potential, however, to decrease additional costs associated with negative patient outcomes due to non-ideal perioperative care of patients with AICD/PPMs. Having core anesthesia staff is a great benefit in that it enables the organization to target and monitor which staff have received additional educational sessions.

Prolonged hospital stays may be needed for heart rhythm monitoring or AICD/PPM interrogation due to improper perioperative care. According to the Kaiser Family Foundation, data from 2021 suggests that the average cost of a single overnight hospital stay in North Carolina is approximately \$2,573 (2023). Eliminating some of these additional hospital stays has the potential to be highly cost effective and is a good return on their investment. Mitigation of these costs is possible by providing education to staff on where to find AICD/PPM information in a timely manner.

Implications of Project

This quality improvement project addresses several of the current guidelines and recommendations and the intervention serves as a source for healthcare professionals to use as a guide to ensure all protocols are followed and communicated to the appropriate personnel. By following this handout for care of surgical patients with AICD/PPMs, members of the interprofessional team will be more aware of their roles and responsibilities for their patients as well as who to communicate with during each stage of the perioperative period. This enables the anesthesia providers to deliver the safest perioperative care possible.

The ASATF recommendations consist of a comprehensive preoperative evaluation including information such as determining if a patient has a CIED, the type, the manufacturer, indications for the device, pacing-dependence, as well as the device's current settings (2020). The *AICD/PPM Handout* directly aligns with these guidelines by providing information on how and where to find each assessment piece. As identified in the presentation of post-intervention survey results, the majority of the participants reported they were likely to use the handout in the future. It was also indicated that the anesthesia providers felt more comfortable overall with assessing patients with CIEDs and in identifying and managing cases that are high risk for EMI after the intervention period. Decreasing the amount of time to find reference material to answer CIED questions has the potential to positively impact the affiliate organization's workflow, supporting rapid room turnover and fast-paced working environment.

Ongoing education is essential to increasing confidence in anesthesia providers taking care of patients with CIEDs and is essential to mitigating adverse patient outcomes. CIED patients could be greatly impacted by the outcomes of this intervention as their anesthesia providers may feel more comfortable and better equipped to provide their care. This ultimately impacts the organization and the health care system by decreasing costs, both for extended stays and additional testing and procedures that may be utilized if issues arise when ineffective care is provided.

Sustainability

Considering the low cost of conducting and implementing this quality improvement project, the partnering organization could afford, and may greatly benefit from, using this pilot to implement a larger quality improvement project. As previously discussed, the low cost of this project makes it a sustainable option for increasing education of anesthesia providers regarding perioperative CIED care. This intervention has the potential to ultimately lead to a decrease in negative patient outcomes that may result from less effective care. Additional quality improvement projects could be performed to validate and verify that most anesthesia providers are likely to use this *AICD/PPM Handout* in the future, and if it does indeed improve provider comfort with assessing and caring for CIED patients. Factors to consider are usability and functionality of the handout and the likelihood that anesthesia providers will refer to the handout for future perioperative questions. Additionally, the developed tool could be imbedded in the EHR, and open as a notification option for those caring for patients with these devices. EHR systems could have automatic pop-up windows to alert providers of best management strategies.

Dissemination Plan

Dissemination of the results and findings from this quality improvement project included two components. A poster was created and presented, in person and virtually, to current CRNA program SRNAs, faculty, staff, and special guests. Project participants were provided a link to attend the virtual presentation, but their attendance was not required. Both the project poster and this paper will be made electronically available in The Scholarship, the East Carolina University digital repository.

Section VI. Conclusion

Limitations

One limitation of this quality improvement project was the limited sample size, based on the number of anesthesia providers routinely practicing in this specific area of the affiliated organization. Additionally, the project was of short duration. Lengthening the timeframe of the project may have provided more opportunities for the participants to care for patients with CIEDs and to directly utilize the tool. Extension of the study to a 4-to-6-week or longer period may have been beneficial.

Recommendations for Future Implementation and/or Additional Study

Recommendations for further implementation of this project include planning on-site and in person educational sessions at the facility to increase awareness of both the project and resources. Implementing this quality improvement project at a larger facility with more daily anesthesia staff is recommended to validate and verify the usefulness and impact of the *AICD/PPM Handout*.

An additional consideration is that the presence of an on-site AICD/PPM representative may be helpful as a resource for anesthesia providers to answer any questions that arise in real time during the perioperative period. Further investigation should also be conducted on how to improve the awareness of hospital policies and procedures to be used in the daily practice of anesthesia providers. Including free response questions on future survey questionnaires may also be beneficial in gaining more perspective about the anesthesia providers' perceptions.

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Appendix A

Literature Concepts Table

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

Appendix B

Literature Search Log

Search date	Database or search engine	Search strategy	Limits applied	Number of citations found/kept	Rationale for inclusion/exclusion of items
9/29/22	PubMed	((nurse anesthetist) OR (anesthesia)) AND ((pacemaker) OR (defibrillators)) AND (perioperative period)	10 years (2012- 2022) English	52 found/2 kept	Perioperative focus, patient safety and improved workflow discussed/not applicable
		<pre>(("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]) OR "nurse anesthetist"[All Fields] OR ("anaesthesia"[All Fields] OR "anesthesia"[All Fields] OR "anesthesias"[All Fields] OR "pacemaker, artificial"[MeSH Terms] OR ("pacemaker"[All Fields] OR "artificial"[All Fields] OR "pacemaker"[All Fields] OR "pacemaker"[All Fields] OR "pacemaker"[All Fields] OR</pre>			

		"pacemaking" [All Fields] OR ("defibrilator" [All Fields] OR "defibrillate" [All Fields] OR "defibrillated" [All Fields] OR "defibrillates" [All Fields] OR "defibrillating" [All Fields] OR "defibrillators" [All Fields] OR "defibrillator s" [All Fields] OR "defibrillators" [MeSH Terms] OR "defibrillators" [All Fields] OR "defibrillator" [All Fields] OR "countershock" [All Fields]) OR "electric countershock" [All Fields]) OR "defibrillation" [All Fields]) OR "defibrillation" [All Fields])) AND ("perioperative period" [MeSH Terms] OR ("perioperative" [All Fields] AND "period" [All Fields]) OR "perioperative period" [All Fields])) AND ((y_10[Filter]) AND (english[Filter]))			
9/29/22	CINAHL	(MH "anesthesia") AND (MH "pacemaker, artificial")	10 years (2012- 2022) English	9 found/1 kept	Surgical focus, cardiac electronic devices discussed/not applicable
9/24/22	Google Scholar	(nurse anesthetist) AND ((pacemaker) OR (AICD)) AND (perioperative period) AND (surgical) AND (patient safety)	5 years (2018- 2022) English	3,360 found/ reviewed 5 pages of results/6 kept	Surgical safety focus/duplicate from previous searches, not applicable

Appendix C

Literature Matrix

	•	Designana	Setting	Sample	rool/s and/or	Results
	Conceptual	Level of			Intervention/s	
	Framework or Model	Evidence				
onenberger, M., Rice, A. N., hompson, A., Thompson, J., & immons, V. C. (2022). tandardized perioperative note o improve perioperative nanagement of patients with ardiac implantable electronic evices. <i>Journal of PeriAnesthesia</i> <i>Jursing</i> , <i>37</i> (3), 312–316. ttps://doi.org/10.1016/j.jopan.2 21.06.100	Refine the standardized approach to perioperative management of CIED patients No framework or model noted	QI (Level VI)	Large academic medical center (Duke University Hospital)	405 CIED patients 132 pre- implement- ation cohort 272 post- implement- ation cohort	Pre-post implementation design with two independent groups Non-directional statistical tests with SPSS	Use of a pre- procedure note led to improved perioperative patient management, decreased case cancellations, and improvement in documentation of intraoperative interventions (such as magnet use or pre- and postoperative reprogramming
				1 exclusion		
merican Society of nesthesiologists Task Force on erioperative Management of atients with Cardiac Implantable lectronic Devices. (2020). ractice advisory for the erioperative management of	To facilitate safe and effective care to CIED patients and reduce adverse outcomes by completing a review and creating a new practice advisory	Systematic Review (Level I)	N/A	N/A	N/A	Individuals who deliver anesthesia care should use this advisory Preoperative
ine eri ati lec rac eri ati	erican Society of esthesiologists Task Force on ioperative Management of ients with Cardiac Implantable stronic Devices. (2020). ctice advisory for the ioperative management of ients with cardiac implantable	erican Society of esthesiologists Task Force on ioperative Management of eents with Cardiac Implantable ctronic Devices. (2020).To facilitate safe and effective care to CIED patients and reduce adverse outcomes by completing a review and creating a new practice advisorycompleting a review and creating a new practice advisoryand creating a new practice advisory	erican Society of To facilitate safe and effective care to CIED patients and reduce adverse outcomes by completing a review and creating a new practice advisory for the inters with cardiac implantable inters with cardiac i	erican Society of esthesiologists Task Force on ioperative Management of ents with Cardiac Implantable ctronic Devices. (2020).To facilitate safe and effective care to CIED patients and reduce adverse outcomes by completing a review and creating a new practice advisorySystematic N/AN/A Review (Level I)N/A Review (Level I)	erican Society of To facilitate safe and effective care to CIED patients and reduce adverse outcomes by ctronic Devices. (2020). completing a review and creating a new ioperative management of practice advisory for the inters with cardiac implantable ioperative management of practice advisory ion the ioperative	erican Society of To facilitate safe and effective care to CIED patients and reduce patients and reduce adverse outcomes by ctronic Devices. (2020). completing a review and creating a new practice advisory for the practice advisory for the practice advisory for the ients with cardiac implantable ients with ca

	electronic devices: Pacemakers and implantable cardioverter- defibrillators 2020. <i>Anesthesiology, 132</i> (2), 225-252. <u>https://doi.org/10.1097/ALN.000</u> 000000002821	Evidence Model used to guide systematic review					preoperative preparation, intraoperative monitoring, & managing sources of EMI are areas addressed in the advisory
2020	Burlingame, B. L. (2020). Surgical patients with cardiac implanted electronic devices. <i>AORN</i> <i>Journal, 112</i> (6), 702-704.	Discuss interventions and provide guidelines to ensure safety of patients with cardiac implanted electronic devices undergoing monopolar electrosurgery No framework or model noted	Expert opinion (Level VII)	N/A	N/A	N/A	Hospital protocols Provides guidelines for perioperative surgery that nurses should follow to provide safe care to these patients with cardiac implanted electronic devices (temporary pacing or defibrillators, magnets, notifying the manufacturer, and following the protocol set by the organization)
2020	Feldman, J. & Stone, M. (2020).	Provide guidelines	Expert	N/A	N/A	N/A	Providing adequate
	Anesthesia teams managing	for how anesthesia	opinion				care prior to surgery
	pacemakers and ICDs for the	teams can help	(Level VII)				for these patients
	perioperative period: Enhanced	manage CIEDs to					avoids complications

	patient safety and improved	enhance patient					in the perioperative
	workflows. Current Opinion in	safety; interventions					period
	Anesthesiology, 33(3), 441-	before surgery with					
	447. <u>https://doi.org/10.1097/ACO</u>	anesthesia					
	.00000000000856	involvement in care					Anesthesiologists
		such as CIED decision					should be involved
		making algorithm					with the perioperative
							care to improve
							preoperative and
		No framework or					postoperative
		model noted					workflows on the day
							of surgery
							Consistent with much
							of the literature
							addressing this topic,
							places primary
							emphasis on
							anesthesiologists
							rather than nurses
2018	Cronin, B., & Essandoh, M. K.	To provide	Expert	N/A	N/A	N/A	Reviews the current
	(2018). Update on cardiovascular	background	opinion				recommendations set
	implantable electronic devices for	information required	(Level VII)				by the ASA and HRS
	anesthesiologists. <i>Journal of</i>	for the anesthesia					and addresses
	Cardiothoracic and Vascular	team to provide					alternative protocols
	Anesthesia, 32(4), 1871–1884.	successful					for management of
	https://doi.org/10.1053/j.jvca.201	perioperative					these devices (device
	7.09.007	management for					recognition,
		CIEDs					assessment,

		No framework or model noted					reprogramming, and magnet use)
2018	Neubauer, H., Wellmann, M., Herzog-Niescery, J., Wutzler, A., Weber, T., Mügge, A., & Vogelsang, H. (2018). Comparison of perioperative strategies in ICD patients: The perioperative ICD management study (PIM study). <i>Pacing and Clinical</i> <i>Electrophysiology, 41</i> (11), 1536- 1542. <u>https://doi.org/10.1111/pa</u> <u>ce.13514</u>	To compare different perioperative strategies in patients with ICDs to evaluate if these are practicable and safe No framework or model noted	Prospective Observatio nal/ Cohort Study (Level IV)	Hospital OR	101 patients	Observed & compared patients with ICDs undergoing three interventions: 1. 42 patients with ICD Reprogramming 2. 45 patients with magnetic inactivation, 3. 14 patients no intervention	The authors found that all three management strategies proved safe during surgery while keeping in mind the location of surgery, electrocautery, & magnets Limitations: non- randomized study design Usefulness: stresses importance of surgical location
2018	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	To review and set standardized guidelines and hospital protocols for patients undergoing surgery with cardiac	Expert opinion (Level VII)	N/A	N/A	N/A	Risks of surgery for patients with pacemakers and AICDs depends upon site of surgery, basic cardiac rhythm, type and way of programming CIEDs,

	electronic devices. <i>Acta Clinica</i> <i>Croatica (Tisak), 57</i> (2), 383. <u>https://doi.org/10.20471/acc</u> .2018.57.02.22	implanted electronic devices No framework or model noted					and type of cautery being used
2017	Arora, L., & Inampudi, C. (2017). Perioperative management of cardiac rhythm assist devices in ambulatory surgery and nonoperating room anesthesia. <i>Current Opinion in</i> <i>Anesthesiology</i> , <i>30</i> (6), 676–681. https://doi.org/10.1097/ACO.000 000000000532	Review of literature to discuss the newly developed features of CIEDs and their interactions with OR equipment; importance of knowledge among anesthesia staff No framework or model noted	Expert opinion (Level VII)	N/A	N/A	N/A	Collaboration is important amongst the surgical team; providers should have a basic understanding of CIEDs, indications, and perioperative needs
2013	Neelankavil, J., Thompson, A., & Mahajan, A. (2013). Managing cardiovascular implantable electronic devices (CIEDs) during perioperative care. <i>Anesthesia</i> <i>Patient Safety Foundation</i> <i>Newsletter, 28</i> (2), 29, 32-35.	To address the consensus of the current practice recommendations and provide an overview for management of CIED patients	Expert opinion (Level VII)	N/A	N/A	N/A	Anesthesia providers should take active roles in education on these devices Education should include training programs, web-based modules, simulations, and workshops

		No framework or model noted					
2013	Schulman, P., Rozner, M., Sera, V., & Stecker, E. (2013). Patients with pacemaker or implantable cardioverter-defibrillator. <i>The</i> <i>Medical Clinics of North</i> <i>America</i> , <i>97</i> (6), 1051–1075. https://doi.org/10.1016/j.mcna.2 013.05.004	model noted To familiarize anesthesia providers with the proper techniques for perioperative care of patients with pacemakers and AICDs; and to develop the systems to manage these patients efficiently	Expert opinion (Level VII)	N/A	N/A	N/A	Outlines the preoperative, intraoperative, and postoperative considerations for management of these patients (documentation, reprogramming, magnet use, and reinterrogation)
		No framework or model noted					
2011	Crossley, G., Poole, J., Rozner, M., Asirvatham, S., Cheng, A., Chung, M., Ferguson, T., Gallagher, J., Gold, M., Hoyt, R., Irefin, S., Kusumoto, F., Moorman, L., & 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	To provide an expert consensus on surgical management of patients with CIEDs No framework or model noted	Expert opinion (Level VII)	N/A	N/A	N/A	Expert consensus provided from 14 healthcare professionals from various backgrounds; recommendations based on review of literature, clinical experience, and reference group input

and patient management. Heart			Primary	
Rhythm, 8(7), 1114-			recommended	
1154. https://doi.org/10.1016/j.hr			approach is	
thm.2010.12.023			consultation between	
			the CIED team and	
			procedural team	

Note: Key to abbreviations used in chart: AICD: Automatic Implantable Cardioverter Defibrillator; ASA: American Society of Anesthesiologists; CIED: Cardiovascular Implantable Electronic Device; EMI: Electromagnetic Interference; HRS: Heart Rhythm Society; ICD: Implantable Cardioverter Defibrillator; N/A: Not Applicable; OR: Operating Room; 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. Copyright 2019 by Wolters Kluwer.

Appendix D

Project Approval Processes

East Carolina University College of Nursing Approval

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. 11/30/2022 Partnering Facility Approval



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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:		
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.) <u>Of note, quality</u> <u>must not be published as if it is research!</u>		
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.

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

1. Project or Study Summary:

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

The purpose of this quality improvement project is to assess anesthesia providers' perceptions of adequacy of a newly developed

AICD/PPM Handout (Automatic Implantable Cardioverter-Defibrillators and Permanent Pacemakers). A quick-reference

AICD/PPM Handout, based upon accepted national guidelines, will be developed. Anesthesia providers at will be asked several questions (through Qualtrics) about their perceptions of the adequacy of their current perioperative care for patients with Automatic Implantable Cardioverter-Defibrillators and Permanent Pacemakers and preparedness for management of these devices. An educational PowerPoint with voiceover about the use of the newly developed handout will be made available to them, and they will be asked to use the handout (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 handout (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 is to assess anesthesia providers' perceptions of a standardized AICD/PPM Handout as a useful instrument 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 handout based on current evidence that aligns with practices currently accepted within the facility to support their practice regarding perioperative care of patients with AICD/PPMs. 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 handout focused on perioperative care for patients with

AICD/PPMs which is based on current evidence and falls within current accepted practice standards within the facility.

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 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 the newly developed informational handout.

- 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 connected to responses will be the IP address of the computer used for completing each Qualtrics survey. No individually identifiable information will be collected or connected to responses. Qualtrics survey software is accessed through ECU and involves multifactorial password protection. Data in Excel will be on a password protected personal laptop. IP 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 (deidentified) 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. Laura Whittington will be responsible for de-identification of all data prior to dissemination.

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

2. If the Primary purpose of your project is for QI, have you obtained approval from the primary 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]

Operationa	l Mgr/Leader Name:	
DocuSigned by:		
5AB2E7BD53674F0	3/2/2023	· · · · · · · · · · · · · · · · · · ·
	5:58 AM EST	
Operationa	l 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 **Example in** Center for Research and Grants."
- If you are submitting a Poster to Media Services, you will also need to submit this Quality Determination Form or IRB Approval to Media Services for printing.
- If the CRG determines the activity is <u>not</u> human subject research, then any presentation, publication, etc. should <u>not</u> refer to the activity as "human subject research," "exempt research," or "expedited research."

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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, **and the set of the minimum necessary to accomplish the purpose of the use, disclosure or request.**

Under HIPAA, a Covered Entity **Constitution 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 **and the appropriate manner as a quality initiative, not resembling research in any context.**

Luma Whitting to

02/21/23

Project Leader Signature

Date

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

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for	CRG Use Only
NHSR vs. HSR Determination:	
Not Human Subject Research: The CRG haproject/study, approval by the IRB is not necessary. A discussed with the CRG at that time to ensure research that would need IRB approval.	s determined that based on the description of the Any changes or modifications to this project may be those changes do not elevate the project to human
□ Human Subject Research: This project/study req the electronic IRB submission system should be subr	uires review by the IRB prior to initiation. An application in nitted.
<u>Approval</u> <u>Signatures:</u>	
CRG Reviewer:	Date: 3/7/2023
UMCIRB Office Staff Reviewer:	Date: <u>3/8/23</u>

Appendix E

AICD/PPM Handout



Phone Numbers

Biotronik: 1-(800)-547-0394

Abbott Laboratories: 1-(800)-722-3774

Preoperative

- <u>Review medical record device</u> <u>identification card</u> (if unavailable: chest Xray):
 - 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 <u>above umbilicus</u> with high-risk EMI (i.e., monopolar electrosurgery, lithotripsy)
 - AICD
 - Suspend antitachyarrhythmia function <u>regardless of surgical</u> <u>location</u>
 - Turn off rate-response abilities with monopolar cautery (by reprogramming only)
 - Prone: Do NOT use magnet; must reprogram

Intraoperative

- <u>Monitoring</u>: 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

Boston Scientific: 1-(866)-484-3268, (option #2)

Medtronic: 1-(800)-929-4043, (option #2)

Postoperative

- Continuous monitoring of EKGRestore preoperative settings before
- leaving the monitored environment
- Ensure backup pacing and emergency equipment available
- <u>Postoperative Interrogation for;</u>
 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.

Appendix F

Educational PowerPoint

















Appendix G

Emails to Participants

Email 1

Dear SurgiCenter CRNAs,

My name is Laura Whittington, and I am a junior SRNA in the East Carolina University Nurse Anesthesia Program. I have had the great privilege of meeting most of you when I was on my first SurgiCenter rotation in February and am looking forward to coming back to your facility next week.

Thank you for considering participating in our quality improvement project titled "Implementation of a Standardized Handout for Perioperative Care of Patients with Pacemakers and Automatic Implantable Cardioverter-Defibrillators: A Doctor of Nursing Practice Project." The purpose of this project is to assess anesthesia providers' perceptions of a standardized *AICD/PPM Handout* as an educational tool to improve perioperative AICD/PPM management and patient safety at SurgiCenter.

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

Each survey and the voiceover PowerPoint 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 https://ecu.az1.qualtrics.com/jfe/form/SV_4Pzzi1D8TiLBmn4

Following completion of the survey, view the *AICD/PPM Handout* and the supplemental brief PowerPoint with voiceover. Both items are attached to this email and hard copies of the handout will be available at your facility next week.

Again, thank you for your participation in our quality improvement project. I will be at the SurgiCenter from April 17th until April 27th. If you have any questions, you may reach out to me or Dr. Travis Chabo by email at any time.

Sincerely,

Laura Whittington, SRNA

Dr. Travis Chabo, PhD, CRNA

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Email 2

Hello SurgiCenter CRNAs,

I just wanted to send a quick reminder about the ongoing DNP Project on perioperative care of patients with AICDs and PPMs (original email below). If you've already filled out the pre-survey and viewed the PowerPoint with voiceover, 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. The AICD/PPM PowerPoint with voiceover and the *AICD/PPM Handout* are attached files in this email thread. There are still copies of the *AICD/PPM Handout* 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.

Link: https://ecu.az1.qualtrics.com/jfe/form/SV_4Pzzi1D8TiLBmn4

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

Sincerely,

Laura Whittington, SRNA ECU Nurse Anesthesia Program Class of 2024

DNP PROJECT TEMPLATE CRNA WORKING

Email 3

Dear SurgiCenter CRNAs,

Thank you to those who have already completed the pre-survey, reviewed the handout, and viewed the PowerPoint. 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

<u>https://ecu.az1.qualtrics.com/jfe/form/SV_4Pzzi1D8TiLBmn4</u>, and you can follow it up by listening to the introductory PowerPoint with voiceover attached to this email. The *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 <u>https://ecu.az1.qualtrics.com/jfe/form/SV_b2fqx5ormfVCKFg</u>. 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 the SurgiCenter soon.

Sincerely,

Laura Whittington, SRNA ECU Nurse Anesthesia Program Class of 2024 Email 4

Dear SurgiCenter CRNAs,

I just wanted to say thank you so much to everyone for helping by participating in my DNP Project! I have collected the pre-survey data I need to proceed with data analysis and will soon be finishing my paper. Once it's complete, you all will be able to access it online if you'd like. If you found the AICD/PPM Handout useful, you can continue to use the printed copies or access the online version in my previous email.

If anyone has not yet completed the post-survey and would still like to, please complete the post-survey here: <u>https://ecu.az1.qualtrics.com/jfe/form/SV_b2fqx5ormfVCKFg</u>

Thank you again! I look forward to working with you all more in the future.

Take care,

Laura Whittington, SRNA ECU Nurse Anesthesia Program Class of 2024

Appendix H

Qualtrics Survey Questions

Pre-Intervention Survey Questions

 Do you currently use a standardized approach for providing perioperative care to patients with AICD/Permanent Pacemakers (PPM)? Yes

No

- 2. Are you aware, and have you used the AICD/PPM policy where you work? Not aware, not used Aware, not used Aware, used
- 3. Have you experienced an issue with an AICD/PPM during any perioperative stage (preoperative, intraoperative, postoperative)?
 Yes

No

- 4. If you had a question concerning AICD/PPM management, how long do you think it would take to find reference material to answer your question?
 <5 minutes
 5-10 minutes
 11-15 minutes
 >15 minutes
- 5. I feel comfortable providing anesthesia care to a patient with an AICD/PPM. Strongly disagree Somewhat disagree Neutral Somewhat agree Strongly agree
- 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
- How often do you have trouble obtaining all necessary information on a patient's AICD/PPM (such as manufacturer, type, last interrogation, etc.)? Never Infrequently Neutral Somewhat Frequently Commonly
- I am familiar with the current best practice guidelines recommended by the American Society of Anesthesiologist and the Heart Rhythm Society.
 Strongly disagree Somewhat disagree Neutral Somewhat agree Strongly agree
- 9. Have you or do you know of a colleague that has personally been involved in the care of a patient who had poor postoperative outcomes related to inadequate management of their AICD/PPM?

Yes

No

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

Post-Intervention Survey Questions

- What is your perception on the usefulness of the AICD/PPM Handout for your anesthesia practice?
 Not useful
 Neutral
 Somewhat useful
 Very useful
- 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
- 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
- After utilizing the AICD/PPM Handout, how long do you think it would take to find reference material to answer your question concerning AICD/PPM management?
 <5 minutes
 5-10 minutes
 11-15 minutes
 >15 minutes
- 5. After using the AICD/PPM Handout, I feel comfortable identifying and managing cases that are high risk for electromagnetic interference (EMI) in patients with an AICD/PPM? Strongly disagree Somewhat disagree Neutral Somewhat agree Strongly agree
- 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
- 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
- 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?

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Never Not likely Neutral	Likely	Very likely
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Appendix I

Project Timeline

Date	Task
May 2021	Begin exploring literature
September 2022	Develop PICOT question & begin search strategies
September 2022	Submit Project Paper Section I draft
October 2022	Complete CITI Modules
October 2022	Complete literature review & submit literature matrix
October 2022	Develop Qualtrics Survey questions
October 2022	Submit Project Paper Section I revisions & Section II draft
October 2022	Complete IHI Worksheet
November 2022	Submit Project Paper Section I & II revisions & Section III draft
November 2022	Submit College of Nursing/IRB Exemption Approval
January 2023	Submit Project Paper Section I, II, & III for feedback
January 2023	Finalize Qualtrics Surveys
February 2023	Finalize Handout & PowerPoint with Voiceover
February 2023	Submit Partnering Facility Approval
March 2023	Submit edited Project Paper Sections I, II, & III
April 2023	Initiation of Project Implementation
May 2023	Completion of Project Implementation
May 2023	Complete Data Analysis
July 2023	Submit edited Project Paper Sections I-VI for feedback
July 2023	Submit initial Poster Presentation for feedback
September 2023	Submit edited Project Paper Sections I-VI with Abstract
October 2023	Submit revised Project Paper and Poster
November 2023	Project and Poster Presentation