Fall 12-13-2019

Expanding Magnetic Resonance Imaging Access for Patients with Cardiovascular Implantable Electronic Devices

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Fall 2019

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Table of Contents

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Abstract

Problem. Patients with non-conditional cardiovascular implantable electronic devices (CIEDs), which lack magnetic resonance imaging (MRI) components, are unable to undergo MRI.

Context. The Heart Rhythm Society guidelines for patient device management and Centers for Medicare and Medicaid Services requirements for persons with specific expertise in implanted permanent devices to manage CIEDs during MRI spurred policy, procedure and staffing changes.

Interventions. The evidence-based change-of-practice project comprised of workflow development, policy and procedure changes, implementation of required staffing support to manage the CIED during an MRI.

Measures: The outcome measure was to improve access to MRI for patients with CIEDs, measured through data extracted from the Clinical Business Analytics reporting tool. Three process measures determined the change in numbers of patients presenting for, excluded from, or receiving MRIs as a consequence of the intervention.

Results. CIED MRI workflows and the revised policy and procedure were finalized. Since implementation of extended hours of CIED support on October 7, 2019, the arrhythmia NP has supervised 18 MRIs after 5 pm.

Conclusions. The project expanded MRI access and CIED management support for all patients, ensuring high-quality care aligned with institutional standards and government regulations.

Keywords: *magnetic resonance imaging/MRI, cardiac implantable electronic devices/CIED, MRI safety, MRI adverse effects, CIED interference, pacemaker, implantable cardioverter defibrillator.*

Section II. Introduction

Problem Description

The healthcare organization selected for this project is a large academic medical center (AMC). The stakeholders for this project include the arrhythmia, neurology, and radiology leadership teams, medical directors, arrhythmia nurse practitioners (NPs), neurology, and radiology staff. The Doctorate in Nursing Practice (DNP) student is a member of the Cardiovascular Health (CVH) Service Line leadership team and is working with the stakeholders and department team members on this improvement project. The AMC was slow to adopt the 2017 Heart Rhythm Society (HRS) non-conditional device management guidelines. The AMC's CIED MRI policy and procedure addressed only the oversight of conditional CIEDs, therefore limiting the arrhythmia team's scope of service. The arrhythmia team was not assisting in the supervision of non-conditional CIEDs during magnetic resonance imaging (MRI). The AMC's arrhythmia physicians needed more evidence-based data demonstrating the safety of MRIs for patients with non-conditional CIEDs in order to agree to provide MRIs for these patients. The current arrhythmia staffing model could not support adding MRI services for patients even if the physicians agreed to do so.

In January 2018, the Centers for Medicare and Medicaid Services (CMS) proposed changes in the management and supervision of patients with CIEDs who require MRIs. CMS requires that a qualified physician, NP, or physician assistant (PA) with expertise in implanted permanent pacemakers (PM), implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy pacemakers (CRT-P), or cardiac resynchronization therapy defibrillators (CRT-D) must directly supervise patients with CIEDs during an MRI. Despite HRS's recent consensus statement and CMS's staffing requirements supporting the supervision

of non-conditional CIEDs, the AMC had not yet taken steps to provide device management for patients with non-conditional CIEDs.

In 2017, the neurology team conducted a retrospective chart review of patients 18 years or older who had received an inpatient neurology consultation for conditions warranting a brain MRI and who had a pre-existing non-conditional CIED. The neurology team concluded that on average 2.5 patients per month presented with an acute neurological condition and did not receive an MRI because of their non-conditional CIED. These patients were referred to other testing methods or sent to another facility to complete the MRI. The number of patients being deferred an MRI was reported to the arrhythmia and radiology leadership teams, where critical patient safety concerns were raised.

The AMC did not have standardized CIED MRI safety protocols and workflows in place. The DNP project included the development of CIED management workflows for MR non-conditional CIEDs, updating the device management policy and procedure, as well as defining and implementing safe staffing support to deliver CIED management during an MRI. After months of collaboration, the systematic workflows created by the arrhythmia team to support the management of non-conditional and urgent requests were approved by the arrhythmia, neurology, and radiology teams. Implementation of these workflows was dependent on the development of an arrhythmia team-staffing plan to facilitate and provide appropriate clinical support for these patients. The arrhythmia, neurology, and radiology teams worked collaboratively to assess and develop a staffing model to address the Centers for Medicare and Medicaid Services (CMS) requirements.

The importance of this improvement project is the promotion of safety protocols and adherence to CMS guidelines. Nurses play a critical role in ensuring safe patient practice,

understanding care processes and facilitating efficient workflows. This project was supported by the AMC and deemed one of significant scope (see Appendix A). The DNP project included the development of CIED management workflows for MR non-conditional CIEDs, updating the device management policy and procedure, as well as defining and implementing safe staffing support to deliver CIED management during an MRI.

Available Knowledge

PICOT question. For patients who need an MRI and have a CIED, how does the application of nationally recommended staffing standards compare to the current device management support improve patient access and throughput by October 7, 2019?

Literature review. The PICOT question guided a systematic search and a comprehensive review of the literature using the following search terms: *magnetic resonance imaging, cardiac implantable electronic devices, MRI, MRI safety, MRI adverse effects, CIED, CIED interference, pacemaker, and implantable cardioverter defibrillator*. The following databases were accessed to search for relevant literature: Cochrane, CINAHL, PubMed, Evidence-Based Journals, Scopus, Medscape, Heart Rhythm Society, and American Heart Association. The search yielded 30 articles from which 12 were selected. Articles were selected if they addressed CIEDs, MRIs, safety, safety concerns, were written in the English language, and were published between 2011 and 2018. Inclusion criteria were: MRI safety protocol, MRI magnetic strength, and conditional and non-conditional CIEDs. Articles were excluded if they were focused only on a product from one manufacturer.

Articles were critically appraised with the *Johns Hopkins Nursing Evidence-Based Practice Non-Research and Research Evidence Appraisal Tools* (Dang & Dearholt, 2018). These

tools provided a concise appraisal of the level and quality of the evidence. Articles were chosen based on the strength and quality of research evidence.

Two of the nine studies were prospective, single non-randomized studies. The study by Nazarian et al. (2017) and Bailey et al. (2016) reviewed conditional and non-conditional CIED interrogation results before and after the MRI with the utilization of a standardized device management protocol. Device interrogation with lead comparison was performed at enrollment, pre- and post-MRI scan, one-month post-MRI, and three-month post-MRI. Both studies compared the effects of thoracic and non-thoracic MRI on CIEDs. The results of these studies demonstrated no long-term clinically significant adverse events were associated with the MRIs. Limitations included small sample sizes and low number of cardiac MRIs. Based on the *Johns Hopkins Research Evidence Appraisal Tool*, both studies were rated II-A.

Two prospective, multicenter cohort studies by Jung, Sebastian, and Zvereva (2015) and Russo et al. (2017) analyzed CIED interrogation results before and after an MRI with the utilization of a standardized protocol. All studies were performed in a 1.5 tesla (T) MRI scanner. The study by Jung, Sebastian, and Zvereva (2015) identified the prospective adverse event rate and parameter changes in non-MRI CIEDs using a device registry and determined that the MRI risk was low. Russo et al. (2017) analyzed PM and ICD data and confirmed the safety of non-MRI conditional CIEDs who underwent clinically indicated non-thoracic MRI at 1.5T. Device or lead failure did not occur in both studies at 1.5T but was not predictive of findings with testing at higher magnetic strength, up to 3T. Both studies were rated III A/B using *the Johns Hopkins Research Evidence Appraisal Tool*.

In the studies chosen, the one retrospective cohort study by Dandamudi et al. (2016) reviewed the device assessment reports in the electronic medical records of patients with CIEDs

before and after an MRI performed according to a CIED safety protocol. When a comprehensive CIED MRI protocol was followed, the risk of performing 1.5T MRI with the device in the isocenter, including PM dependent patients was low. There were no significant changes in atrial and ventricular sensing impedance, and threshold measurements. There were no episodes of device mode changes, arrhythmias, therapies delivered, electrical reset, or battery depletion. This study is appraised as III A/B per the *Johns Hopkins Research Evidence Appraisal Tool*.

One prospective cohort study by Yadava et al. (2017) reviewed 277 patients who had undergone 293 scans. The CIEDs included 170 PMs and 71 ICDs. Devices were interrogated before and after the MRI with the use of a standardized protocol. The study demonstrated no changes in device settings during an MRI. Long-term follow-up device assessment confirmed no adverse effects from 1.5T MRI. According to the *Johns Hopkins Research Evidence Appraisal Tool*, both studies were rated III A/B.

Two randomized control trials (RCT) by Shenthar et al. (2015) and Wilkoff et al. (2011) analyzed CIEDs before, during, and after the MRI with the use of an MRI scan protocol. The study by Shenthar et al. (2015), evaluated MRI safety without positioning restrictions in patients with MR conditional PM with non-MR conditional leads. Two hundred sixty-six patients were sampled with a two to one ratio to the MRI group or control group. There were no related complications immediately post or at one-month post-MRI. The second RCT by Wilkoff et al. (2011) evaluated PM performance and pacing capture threshold nine to twelve weeks prior to the MRI, during the MRI, and immediately after the MRI. Four hundred sixty-four patients were randomized to undergo an MRI scan between nine to twelve weeks of post-CIED implantation. Patients were monitored for arrhythmias, symptoms, and PM system function during fourteen non-clinically indicated brain and lumbar MRI sequences. It was found that no

MRI related complications occurred during or after the MRI. Based on the *Johns Hopkins Research Evidence Appraisal Tool*, both studies were rated I-A.

One meta-analysis and systematic review performed by Shah et al. (2018) utilized a random-effects model for meta-analysis of continuous variables including device lead parameters such as capture threshold, sensing, and impedance; high-voltage ICD lead impedance, and battery voltage change. Safety outcomes were evaluated with descriptive analysis. Indexed articles from PubMed were queried between the years 1990-2017. The search yielded one thousand three hundred twenty-four records to review. Seventy studies were included for the systematic review, and five thousand ninety-nine patients were identified. The brain or cervical spine was imaged the most and thoracic imaging was completed in seven hundred seventy-three patients. The meta-analysis cohort included thirty-one studies. This analysis summarized the safety profile of five thousand nine-hundred eight MRI studies in five thousand ninety-nine patients with non-MRI conditional CIEDs in a span of twenty-five years. There were no reported deaths and three total lead failures. There were no relevant changes in lead, battery, or pulse generator performance. The observed changes were small, and inter-study variance was low. The findings suggested the need for ongoing monitoring. Per the *Johns Hopkins Research Evidence Appraisal Tool*, the study was rated III A/B.

Viera, Lazoura, Nicol, Rubens, and Padley (2013) analyzed data from a multicenter device registry. Devices were interrogated before and after an MRI with the use of a standardized protocol. The technical report confirmed the need for utilization of a comprehensive safety protocol and substantiated the development of new generation MRI conditional CIEDs. According to the *Johns Hopkins Research Evidence Appraisal Tool*, the study was rated III A/B.

A clinical review by Nordbeck, Ertl, and Ritter (2015) provided a better understanding of the structures responsible for life-threatening complications as well as technical advances supporting the safety of MRIs for CIEDs. Clinical trials were reviewed over the last twenty years, including fourteen PM and thirteen ICD studies. The studies assessed the outcome in 1.5T scanners and reported there were no adverse events. This was the only abstract found in the literature review that demonstrated CIED safety during an MRI with appropriate monitoring and application of a safety protocol. It attempted to offer an up-to-date and clinically useful summary for practicing cardiologists. Based on the *Johns Hopkins Research Evidence Appraisal Tool*, the study was rated III A/B.

In summary, the literature between 2011 and 2018 showed non-conditional CIEDs undergoing 1.5T MRI had been evaluated pre, intra, and post MRI and demonstrated minimal to no MRI-related complications or adverse effects. A CIED safety protocol was utilized in all the studies. Many of the studies reported CIED reprogramming before and after the MRI. The clinical review supported the utilization of appropriate monitoring and a safety protocol for CIEDs during an MRI.

Findings from all the studies support the safety of an MRI for patients with conditional as well as non-conditional CIEDs at the magnetic strength of 1.5T and validated the 2017 HRS consensus statement demonstrated in the evaluation table (see Appendix B). MRIs were performed with appropriate monitoring and the utilization of a safety protocol. Based on the literature, more research is needed to evaluate the safety of MRIs at higher magnetic strength, greater than 1.5T. Studies were limited due to the utilization of 1.5T magnetic strength. Several studies had small sample sizes. The studies by Yadava et al. (2017) and Nazarian et al. (2017)

could not accurately obtain follow-up device data because patients were referred by outside physicians or patients were lost to follow-up.

Rationale

Conceptual framework. The conceptual framework for this project was a combination of complexity theory and change theory. Complexity theory analyzes complex systems, strives to understand their structure and purpose, and recognizes the importance of inter-relationships and context (Litaker, Tomolo, Liberatore, Stange, & Aron, 2006). Complexity theory relates to organizational theory through understanding how organizations adapt to their environment and their coping mechanisms. In quality improvement, complexity theory thinking is utilized in understanding how individuals and organizations adapt to an uncertain environment while they respond to change-initiating events. Complexity theory asserts that people and organizations are non-linear and complex adaptive systems (Grossman & Valiga, 2013). This framework was suitable for the implementation of a comprehensive CIED MRI workflow algorithm and staffing model. The AMC can be treated as a complex adaptive system exhibiting emergence, complexity, chaos, self-organization, and interdependence.

Kurt Lewin developed the change theory of nursing and defined behavior as a dynamic balance of forces working in opposite directions (Batras, Duff, & Smith, 2014). Lewin's change theory allowed the evaluation of group behavior and involved understanding its complexity and influence on observed behaviors (Batras, Duff, & Smith, 2014). Health care providers facilitating change integrate this theory into the development of interventions. Lewin designed a three-step model for change: unfreezing, moving (change), and refreezing, Unfreezing involves creating uneasiness with the status quo, represented in the neurology study that concluded 2.5 patients per month did not receive an MRI because of their non-conditional CIED. It is also

demonstrated in the development of the NP staffing model based on CMS guidelines. Moving is the act of change, the implementation of the proposed workflows and NP staffing model. Refreezing is when change becomes the norm, demonstrated in the supervision and management for all patients with CIEDs during an MRI.

Specific Aims

The goal of this project was to maintain high-quality care and comply with CMS guidelines and national and institutional standards by extending NP service coverage to support CIED management during an MRI. The specific aim of the DNP led evidence-based project was to improve MRI access for all patients with CIEDs through the policy and procedure revision, creation of standardized workflows, and extension of hours for MRI by October 7, 2019.

Section III: Methods

Context

This quality improvement project promotes patient safety and throughput by providing access and the necessary care for all patients who have CIEDs and need MRIs. The key stakeholders for this project include arrhythmia, neurology, and radiology leadership teams, medical directors, arrhythmia NPs; and neurology, and radiology staff. All teams were aware of the need for change.

CMS provided clear guidelines in the supervision of the CIED during an MRI. To promote patient safety and align with best practices, it was necessary to support this endeavor. Non-compliance with the recommended guidelines poses risks to patient safety and potential liability. Per Wikman-Svahn and Lindblom (2018), the interpretation of risk magnifies ethical issues. Providing NP CIED management during an MRI minimizes the potential patient

safety risk concerns. The perspective of risks as probabilities and consequences is utilized in risk-benefit- analysis in healthcare organizations (Wikman-Svahn & Lindblom, 2018).

After the findings from the AMC's neurology retrospective, one-time chart review was brought to the arrhythmia and radiology teams, a collective decision involving all stakeholders was made to create a plan supporting the safe facilitation of MRIs for patients with CIEDs. The neurology team utilized a patient data analytics tool to identify patients with the diagnosis of stroke, transient ischemic attack (TIA), or acute neurological symptoms and had a CIED. Those patients were cross-referenced with a CIED database to determine the conditionality of their CIED. The outcome demonstrated that approximately 2.5 patients per month did not receive MRIs since they had non-conditional CIEDs. In January 2019, the radiology team requested a clinical and business analytics (CBA) report to identify all patients who needed MRIs and had CIEDs. The report demonstrated from January to October there were 350 conditional and non-conditional CIED MRI requests, 33% were patients with neurological conditions. This data further validated the need for CIED management during an MRI.

Adherence to the recommendations and staffing requirements of the 2018 CMS device management guidelines was necessary for reimbursement. The arrhythmia team expressed concerns that they could not adhere to the CIED management guidelines since they did not have enough NPs to support device management for all patients with conditional and non-conditional CIEDs. Although the MRI department has two suites that have the capacity to provide 1.5T magnetic strength, only one was being utilized for complex cardiac cases, thus impeding access. Extending weekly NP device management support for all CIEDs would enable imaging to accommodate three to four additional MRI cases per day (21-28 per week). Additional NP FTEs were necessary to implement extended hours of service. To reduce the direct cost of adding NPs

for the extended hours, the NPs would also assist in Catheterization Angiography Laboratory (Cath Lab) procedures and provide cardiovascular consultations throughout the hospital.

Intervention

The evidence-based change-of-practice project comprised of policy and procedure changes, standardization of workflows, maximizing equipment utilization and availability, modification of MRI scheduling, and implementation of required staffing support to manage the CIED during an MRI. Policy and procedure revisions were necessary to allow NPs to practice within their scope. Standardizing workflows for CIED MRI management was fundamental for consistent care. The utilization of a second MRI suite and access to CIED programmers was necessary to increase service capabilities. Creating a patient scheduling process was necessary to promote concise communication between the radiology and arrhythmia teams. Developing a staffing model was mandatory to comply with CMS requirements.

Study of the Intervention

Gap analysis. A gap analysis was conducted to identify inconsistencies. The MRI department had one dedicated day to schedule and perform one to two MRI studies for complex cardiology cases, which included patients with non-conditional CIEDs (see Appendix C). Prior to the intervention, the arrhythmia NP team did not have a standardized workflow or a staffing model to provide consistent CIED supervision during an MRI. The MRI department did not have the device management programmers conveniently stored in the department, creating an inefficient workflow for the arrhythmia team. The arrhythmia team had to find the programmer in the clinic and transport it to the MRI department. The MRI scheduling process specific to non-conditional CIEDs did not exist. Prior to the intervention, the state of this service was inefficient and inconsistent, creating delays in patient care.

Gantt chart. An action plan and timeline specific to this project are shown on the Gantt chart (see Appendix D). This tool defined the path necessary for the completion of the improvement activity, provided a foundation for scheduling tasks, and was useful in managing the project's activity schedule. The initial stages of the project began in early January 2018, when the project was identified. Once the proposed project was approved by the DNP chair, tasks such as creating an AIM statement, identification of stakeholders, and confirming baseline metrics to support the need of this improvement project were determined. The project plan, work breakdown structure, and the business plan were finalized in May 2018. In the fall of 2018, the business plan was presented in a situation, background, analysis or assessment, and recommendations (SBAR) format to our leadership teams and stakeholders (see Appendix E). The business plan was approved in January 2019. The development of the electronic document workflow and a screening tool was finalized in January 2019 (see Appendix F). In January 2019, the CIED MRI policy and procedure were finalized, and the NP staffing plan confirmed. Arrhythmia NP recruitment began in February, with three of the 4.5 NP FTEs hired by August 2019 (see Appendix G). The goal was to implement the extended NP coverage by early October 2019. During the fall and winter of 2019, the teams will continue to have touch point meetings to discuss any post-implementation issues with the new staffing model and conduct a plan, do, study, act (PDSA) to evaluate the intervention (see Appendix H). A similar retrospective chart review utilizing the CBA report to collect data on patients who require an MRI and have a CIED will continue to be performed. The DNP student will monitor, analyze, and evaluate the outcomes closely post-intervention to determine if the goal of having no patients turned away for an MRI is achieved. Mitigation plans will be discussed, developed, implemented, and evaluated. Once data is received, the outcomes will be presented to the teams and stakeholders.

Work breakdown structure. The work breakdown structure (WBS) for this project organized the deliverables into sections (see Appendix I). It was used as a communication tool to supplement the Gantt chart. It defined the scope of our project and allowed oversight of each task. The WBS had a hierarchical composition of the range of the project. There were three levels in this project's WBS. Planning and oversight involved developing the project plan, creating a project charter, and performing a gap analysis demonstrated in the four quadrant A3. The budget and business plan identified accountability, staffing needs, projected volumes, return on investment, and implementation costs. Education was associated with performing literature reviews and educational sessions with staff. Resources comprised of tasks such as reviewing HRS workflow recommendations and CMS staffing guidelines, comparing staffing and device management workflows from other organizations, and approval of the business plan. The staff category included the recruitment and hiring of NPs, proposal of a staffing plan and schedule, onboarding of NPs, and vetting schedules with the team and stakeholders. The implementation of intervention consisted of confirmation of NP extended hours' schedule, workflow review, monitoring of intervention, performing PDSA cycles if needed, and comparing data pre- and post-intervention.

Responsibility/Communication plan. As one of the team leaders of this project, the DNP student maintained oversight of the project and reported the progress of the intervention during scheduled meetings and via email. Maintaining accountability and communication was necessary to align with AMC's current organizational process and structure. The project improvement team included staff nurses, MRI technicians, NPs, department managers, medical directors, and department directors. Reporting of this project's findings and results to the team and stakeholders occurred after meetings and milestone completion (see Appendix J). Post-

implementation data reports were initiated on October 7, 2019 and will continue weekly for one month, monthly for three months, quarterly for one year, and then yearly thereafter.

SWOT analysis. The strengths, weaknesses, opportunities, and threats (SWOT) analysis (see Appendix K) enabled the DNP student to identify the challenges in meeting the specific project aim. The strengths of this project included the improvement of patient throughput and access, patient satisfaction, promoting patient safety, compliance with CMS staffing guidelines, creation of an updated CIED MRI policy and procedure, development of electronic documentation workflows, and providing a revenue-generating service. The only weakness identified was the MRI management support was only available for patients who presented with acute neurological conditions. Opportunities included serving the non-neurological patients who need an MRI and have a non-conditional CIED, and creating an extended hours plan. Threats included the rejection of 4.5 NP FTEs, business plan approval, and new hospital construction.

Intervention budget. The five-year financial analysis for the intervention is shown as Appendix L. Labor costs include the type of procedures, such as those performed in the Cath Lab by the NPs during the extended hours of service, including the provision of device management support at the time of the MRI. Also reviewed were non-labor costs, such as the amount of time spent by the staff, administrators, and the DNP student on planning this improvement project. Based on the financial analysis, 6.5 NPs are required to comply with CMS guidelines and support twenty-four hours, seven days per week, inpatient and outpatient cases. Two FTEs were previously approved for the new hospital activation in fall 2019; therefore, the net incremental request was for 4.5 NP FTEs. The first year anticipated a net loss of $347,396 is due to salaries and benefits, not fully ramping up with the projected number of procedures, as well as the frequent interdisciplinary team meetings needed for planning. Years two through five projects an

average annual net gain of $201,525. It was necessary to demonstrate a positive return on investment (ROI) to influence key stakeholders to support this quality improvement project.

Measures

The outcome measure was improved MRI access and throughput for patients with CIEDs, measured by all patients with CIEDs that have active MRI orders, ascertained through the CBA tool. Those patients were manually cross-referenced with completed procedure notes in the electronic medical record. The arrhythmia and radiology teams captured this discrete data through an electronically-generated report.

One process measure was the number of patients turned away from MRI due to a non-conditional CIED, determined through the CIED database, and confirmed by arrhythmia NPs that the reason for exclusion was due their non-conditional CIED (see Appendix M). A second process measure was the volume of all patients who have CIEDs and require an MRI. The AMC's CBA report and the patient's electronic medical record were the tools used to measure volume and determine the number of patients who were deferred an MRI. Through the CBA report and electronic medical records, the arrhythmia and radiology teams will perform post-implementation completion assessments weekly for one month, monthly for three months, quarterly for one year, and then yearly thereafter.

Analysis

In the initial assessment and planning of this quality improvement project, gaps in current practice were identified. Pre-intervention data was collected by performing a retrospective chart review of all patients who presented with acute neurological conditions, had a CIED, and required an MRI. Data was collected from the CBA report and the AMC's data management application by using diagnosis codes and keywords and a retrospective electronic chart review.

Microsoft Excel was utilized to capture and compare the data pre- and post-intervention. De-identified data were extracted from patient medical records and included in the spreadsheet. The final analysis will include the post-implementation data extracted during the scheduled monitoring period.

Ethical Considerations

Nursing is based on the foundation of compassion and benevolence for the health and respect of patients, families, and communities (American Nurses Association [ANA], 2015). This project supports the ANA code of ethics to formulate and maintain a standard for nurses to utilize ethical analysis and decision-making. The implementation of extended NP staffing coverage to manage CIEDs during an MRI demonstrates accountability and responsibility for nursing practice.

This evidence-based improvement project embodies the Jesuit value of *cura personalis*, suggestive of individualizing the care and attention to the whole being (McGinn, 2015). The goals of this quality-improvement project were to promote patient safety, improve patient throughput and access, and maintain high standards of care. As a non-research project, it did not require Institutional Review Board (IRB) approval for implementation. The project was evaluated and approved as a quality improvement endeavor through the University of San Francisco School of Nursing and Health Professionals (see Appendix N).

Section IV: Results

Hiring and training 4.5 NP FTEs was critical for the implementation of extended hours of CIED management support during an MRI, 24 hours per day, seven days per week. The arrhythmia team has successfully hired two NPs, both with limited cardiovascular health and CIED experience. Training for the two NPs is expected to be completed between November

2019 and January 2020. Recruitment continues for the remaining 2.5 NP FTEs. Support will be provided by extending the hours of service every Monday and Tuesday from 7 am until 11 pm starting October 7, 2019. Since implementation, the NP has supervised 18 MRIs after 5 pm. When all 4.5 NP FTEs are hired, the capacity to provide 24 hours per day, seven days per week accountability in CIED management during an MRI will have been achieved. Based on the CBA report identifying the volumes of patients with CIEDs requiring an MRI (see Appendix O), it is imperative that active NP recruitment is continued to fill the necessary positions in order to fully implement this improvement project and maintain adherence to CMS staffing requirements.

Section V: Discussion

Summary

The aim of the DNP led the evidence-based project in improving MRI access for all patients with CIEDs through the policy and procedure revision, creation of standardized workflows, and extension of hours for MRI was achieved. Key findings include the neurology team's retrospective chart review from 2017 that established the need for device management support for patients who present with acute neurological conditions, such as stroke and TIAs and have non-conditional CIEDs. The findings determined that 2.5 patients per month did not receive an MRI due to their non-conditional CIEDs. The review concluded that of the CIEDS, 75% were pacemakers, made by one specific vendor. We confirmed that patients with conditional CIEDs did not receive an MRI due to the misconception that the device was non-conditional. This data was concerning for the physician leaders from neurology, radiology, and arrhythmia teams and prompted an urgent need to find a solution to provide safe patient care (see Appendix P).

Stakeholder recognition of project implication on patient safety and interdisciplinary collaboration contributed most importantly to the successful changes. Leadership support and fostering team spirit were essential in achieving favorable outcomes. Integrating the best available evidence on quality of care, clinical outcomes, and patient satisfaction were necessary on the impact of advanced practice nursing. The implementation of the NPs in the CIED MRI management improved patient outcomes, thus impacting the advanced practice nursing role.

Interpretation

The DNP project was guided by the published literature in combination with CMS requirements and clinical expertise. The findings from the studies were consistent with some of the literature review and validated the safety of MRI for non-conditional CIEDs at low magnetic strength. Implementation of the new CIED MRI workflows impacted patient throughput by providing safety guidelines for the non-conditional CIEDs. The AMC now has the capacity to provide MRIs for all patients regardless of the conditionality of their CIED.

Limitations

Since this is a non-research study, there are limitations to the generalizability of the results. Barriers to implementation were concentrated in recruitment, hiring, and training of the NPs. The arrhythmia team faced challenges to recruit the approved 4.5 NP FTEs. The number of interested NPs interested who have cardiovascular health experience is extremely limited. Hiring inexperienced NPs and providing the necessary training was the chosen alternative, although this strategy introduced additional challenges. The onboarding process, which includes credentialing, can take three months for each NP. Training inexperienced NPs could take up to nine months. With each new, inexperienced NP, it will take approximately one year to gain the competency to work independently. Considering these timelines, the arrhythmia

team was concerned it could take more than a year before full implementation of extended hours of service to 24 hours a day, seven days per week for CIED management can be achieved.

Since the arrhythmia team could not hire all the necessary NPs to fully implement the project, expectations were adjusted. Since March 2019, only three NPs were hired, two with minimal cardiac and CIED experience. After credentialing, the two NPs with limited experience will be fully trained between November 2019 and January 2020. Retention of NPs has also been challenging. One NP who had CIED experience recently resigned. These obstacles will not change the goal of improving MRI access for patients with CIEDs, but rather adjust how the arrhythmia team will be providing this service until all the necessary staff have been hired and trained.

Conclusions

The CVH service line's goal is to create a value-added framework for the CVH patient that spans the continuum of care by engaging teams in building a network of care programs thus improving access, capacity, quality, and patient experience. This quality improvement project supported the AMC's pillars of quality, service/patient experience, employee engagement, and financial strength. By implementing a national staffing model for patients who require an MRI and have a CIED, the AMC has provided the appropriate care for these patients, minimizing patient safety concerns, and improving patient service and experience. The collaborative effort between the arrhythmia, radiology, and neurology departments demonstrated meaningful development of a positive interdisciplinary working relationship. The arrhythmia NPs and radiology staff nurses view this project as a double benefit of adding value to patient care and streamlining workflows. By implementing the CMS national staffing model for patients who require an MRI and have a CIED, the AMC has provided the appropriate care for these patients,

minimizing patient safety concerns, and improving patient service and experience. Ensuring the sustainability of this project will require an ongoing commitment.

Section VI: Other Information

Funding

There were no special funding sources affiliated with this evidence-based quality improvement project. All resources and time associated with the investigation, development, implementation, and evaluation were included in the current pay structure and process.

SECTION VII: REFERENCES

American Nurses Association Code of Ethics with Interpretive Statements (2015). http://www.nursingworld.org/MainMenuCategories/EthicsStandards/CodeofEthicsforNurses/Code-of-Ethics-For-Nurses.html

Bailey, W., Mazur, A., McCotter, C., Woodard, P., Rosenthal, L., Johnson, W., & Mela, T. (2016). Clinical safety of the ProMRI pacemaker system in patients subjected to thoracic spine and cardiac 1.5T magnetic resonance imaging scanning conditions. *Heart Rhythm Society*, *13*, 464-471.

Batras, D., Duff, C., & Smith, B. J. (2014). Organizational change theory: Implications for health promotion practice. *Health Promotion International*, *31*(1), 231-241.

Centers for Medicare & Medicaid Services. (2018). https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=289

Dandamudi, S., Collins, J. D., Carr, J. C., Mongkolwat, P., Rahsepar, A. A., Tomson, T. T., ... Knight, B. P. (2017). The safety of cardiac and thoracic magnetic resonance imaging in patients with cardiac implantable electronic devices. *Academic Radiology*, *23*(12). http://dx.doi.org/10.1016/j.acra.2016.08.2016

Dang, D., & Dearholt, S. L. (2018). *John Hopkins evidence-based practice: Model and guidelines* (3rd ed.). Indianapolis, IN: Sigma Theta Tau International Honor Society of Nursing.

Grossman, S. C., & Valiga, T. M. (2013). *The new leadership challenge: Creating the future of nursing.* (4th ed.). Philadelphia, PA: F.A. Davis Company.

Indik, J. H., Gimbel, J., Abe, H., Alkmim-Teixeira, R., Birgersdotter-Green, U., Clarke, G. D., ... Woodard, P. K. (2017). 2017 HRS expert consensus statement on magnetic resonance

imaging and radiation exposure in patients with cardiovascular implantable electronic devices. *Heart Rhythm Society*, *14*(7). Retrieved from http://www.heartrhythmjournal.com/article/S1547-5271(17)30453-8/pdf

Jung, W., Sebastian, J., & Zvereva, V. (2015). MRI and implantable cardiac electronic devices. *Current Opinion Cardiology*, *30*, 65-73.

Litaker, D., Tomolo, A., Liberatore, V., Stange, K.C., & Aron, D. (2006). Using complexity theory to build interventions that improve health care delivery in primary care. *Journal of General Internal Medicine, 21*(2), S30-S34.

McGinn, A. (2015). Mission matters: What do Jesuits mean by Cura Personalis? *Conversations on Jesuit Higher Education, 47*(10).

Nazarian, S., Hansford, R., Rahsepar, A. A., Weltin, V., McVeigh, D., Ipek, E. G., ... Halperin, H. R. (2017). Safety of magnetic resonance imaging in patients with cardiac devices. *The New England Journal of Medicine*, *377*(26).

Nordbeck, P., Ertl, G., & Ritter, O. (2015). Magnetic resonance imaging safety in pacemaker and implantable cardioverter defibrillator patients: How far have we come?. *European Heart Journal*, *36*, 1505-1511. http://dx.doi.org/10.1093/eurheartj/ehv086

Russo, R. J., Costa, H. S., Silva, P. D., Anderson, J. L., Arshad, A., Biederman, R. W., ... Wolff, S. D. (2017). Assessing the risks associated with MRI in patients with a pacemaker or defibrillator. *New England Journal of Medicine*, *376*(8).

Shah, A. D., Morris, M. A., Hirsh, D. S., Warnock, M., Huang, Y., Mollerus, M., ... Lloyd, M. S. (2018). Magnetic resonance imaging safety in nonconditional pacemaker and defibrillator recipients: A meta-analysis and systematic review. *Heart Rhythm Society*, 1-8.

Shenthar, J., Milasinovic, G., Al Fagih, A., Gotte, M., Engel, G., Wolff, S., ... Nahle, C. (2015). MRI scanning in patients with new and existing CapSureFix Novus 5076 pacemaker leads: Randomized trial results. *Heart Rhythm Society*, *12*, 759-765.

Van der Graaf, A., Bhagirath, P., & Gotte, M. (2014). MRI and cardiac implantable electronic devices; current status and required safety conditions. *Netherlands Heart Journal*, *22*. http://dx.doi.org/10.1007/s12471-014-0544-x

Vieira, M., Lazoura, O., Nichol, E., Rubens, M., & Padley, S. (2013). MRI in patients with cardiovascular implantable electronic devices. *Clinical Radiology*, *68*(2013), 926-934. http://dx.doi.org/10.1016/j.crad.2013.04.003

Wikman-Svahn, P., & Lindblom, L. (2018, March 05). Toward a responsibility-catering prioritarian ethical theory of risk. *Science and Engineering Ethics*. http://dx.doi.org/10.1007/s11948-0018-0036-2

Wilkoff, B., Bello, D., Taborsky, M., Vymazal, J., Kanal, E., Heuer, H., ... Sommer, T. (2011). Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment. *Heart Rhythm Society*, *8*, 65-73.

Yadava, M., Nugent, M., Krebsbach, A., Minnier, J., Jessel, P., & Henrikson, C. A. (2017). Magnetic resonance imaging in patients with cardiac implantable electronic devices: a single-center prospective study. *Journal of Interventional Cardiac Electrophysiology*, *50*. http://dx.doi.org/10.1007/s10840-017-0262-6

SECTION VIII: APPENDICES

Appendix A – Letter of Support from the Organization

Stanford
HEALTH CARE
STANFORD MEDICINE

September 25, 2018

University of San Francisco, School of Nursing
2130 Fulton Street
San Francisco, CA 94117-1080

To who it may concern:

I am writing to express my support of Rosalie M. Geronimo to implement her Doctor of Nursing Practice Comprehensive Project at Stanford Health Care. Rosalie's project is of significant scope. She will be implementing a staffing plan to support magnetic resonance imaging for patients with conditional and non-conditional cardiovascular implantable devices.

This letter also verifies that Stanford Health Care has an existing contract with the University of San Francisco's School of Nursing.

Sincerely,

Charlene Kell, MBA, BSN, RN, CCRN, FACHE, NEA-BC
Administrative Director, Cardiovascular Health
Stanford Health Care

Appendix B - Evaluation Table

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Russo, R.R., Costa, H.S., Silva, P.D., Anderson, J.L., Arshad, A., Biederman, R.W.W., … Wolff, S.D. (2017). Assessing the risks associated with MRI in patients with a pacemaker or defibrillator. New England Journal of Medicine, 376(8), 755-764.	None	Prospective, multicenter study	N= 1500 1000 cases in which patients had a pacemaker and in 500 cases in which patients had an ICD	Devices were interrogated before and after MRI with the use of a standardized protocol and were appropriately reprogrammed before the scanning.	All studies were performed in a 1.5-tesla MRI	Data were analyzed separately for the pacemaker and ICD cohorts with the use of R statistical software, version 3.2.3.16. The Wilson score method without continuity correction was used to calculate 95% confidence intervals for single proportions for primary end-point events.	Device or lead failure did not occur in any patient with a non–MRI conditional pacemaker or ICD who underwent clinically indicated nonthoracic MRI at 1.5 tesla	**Strengths:** Data from both pacemakers and ICDs. Multicenter study. **Limitations:** The results are not predictive of findings with all device lead combinations or higher MRI field strengths. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Yadava, M., Nugent, M., Krebsbach, A., Minnier, J., Jessel, P., & Henrikson, C.A. (2017). Magnetic resonance imaging in patients with cardiac implantable electronic devices. *Journal of Interventional Cardiac Electrophysiology* ,50, 95-104.	None	Prospective Cohort Study	N = 277 patients underwent 293 scans. The devices included 170 pacemakers and 71 ICDs	Devices were interrogated before and after MRI with the use of a standardized protocol and were appropriately reprogrammed before the scanning.	All studies were performed in a 1.5-tesla MRI scanner. Statistical analysis was performed with the R programming language. The comparison of normally distributed variables between device groups was performed with two sample t tests and non-normally distributed variables were compared with two-sample Wilcoxon tests	Patients with permanent pacemakers (PPM) or implantable cardioverter-defibrillator (ICD) and a clinical indication for an MRI were considered. Exclusion criteria included newly implanted devices (<4 weeks), PPMs manufactured before 1996 and ICDs before 2000, epicardial and abandoned leads, and pacemaker dependent ICD patients. Pacemaker dependent patients were programmed to asynchronous pacing. Tachycardia detection and therapies were disabled for ICDs. Devices were interrogated pre and post-scan and at follow up 1-6 weeks later. Defibrillation threshold testing (DFT) was not completed post-scan. Patients were followed to monitor device therapies.	The devices included 170 pacemakers and 71 ICDs. Thirteen scans were aborted due to subjective complaints or artifact on imaging. Post-scan and follow-up interrogations showed no changes in device settings requiring reprogramming or revision. Long-term follow-up demonstrated that nine ICD patients had appropriate device shocks and one had four inappropriate shocks for atrial fibrillation.	**Strengths:** Data from both pacemakers and ICDs. **Limitations:** Follow-up data was not available for some of their patients due to the large number of them being referred from outside physicians. It was difficult to accurately obtain information about device parameters. Device malfunction could not be ruled out in those patients who were lost to follow-up. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool,* III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Dandamudi, S., Collins, J.D., Carr, J.C., Mongkolwat, P., Rahsepar, A.A., Tomson, T.T., … Knight, B.P. (2016). The safety of cardiac and thoracic magnetic resonance imaging in patients with cardiac implantable electronic devices. *Academic Radiology*, *23* (12), 1485-1505.	None	Retrospective cohort study	N = 58 patients underwent 51 cardiac and 11 thoracic spine MRI exams.	The cardiac device information was acquired from interrogation reports in the electronic medical record, which included a mandatory device assessment pre- and post-MRI scanning, per the prespecified CIED safety protocol.	Devices were interrogated before and after imaging with reprogramming to asynchronous pacing in pacemaker dependent patients. The clinical interpretability of the MRI and peak and average specific absorption rates (SARs, W/kg) achieved were determined.	Twenty-nine patients had a pacemakers and 29 patients had ICDs. Ten patients were pacemaker dependent. Fifty-one patients had non-MRI conditional devices. There were no significant changes in atrial and ventricular sensing impedance, and threshold measurements. There were no episodes of device mode changes, arrhythmias, therapies delivered, electrical reset, or battery depletion. One study was discontinued because the patient experienced chest pain (not related to the exam).	When a comprehen-sive CIED MRI safety protocol is followed, the risk of performing 1.5T magnetic resonance studies with the device in the magnet isocenter, including pacemaker dependent patients is low.	**Strengths:** Data from both pacemakers and ICDs. Utilization of thoracic scans. **Limitations:** The study had a small sample size in addition to the small number of patients with repeat MRI exams.The retrospective nature of the study did not allow for control of all confounding variables, did not allow for control of all confounding variables. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool*, III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Jung,W., Sebastian, J., Zvereva, V. (2015). MRI and implantable cardiac electronic devices. *Current Opinion in Cardiology* , 30(1), 65-73.	None	Prospective Study, Multicenter	N= 34 prospective studies from1998-2014.	The MagnaSafe registry determined prospectively the adverse event rate and device parameter changes in patients with non-MRI-conditional cardiac devices (pacemakers or ICDs) implanted after 2001, undergoing clinically indicated nonthoracic MRI at 1.5 T.	Data from MagnaSafe registry.	Data was extracted from 1.5T MRI scans.	Development of MRI conditional devices has improved the risk benefit. Risks have been low; however, minor risks have significant effects.	**Strengths:** Data from both pacemakers and ICDs. Studies from 1998-2014. Data extracted from all studies. **Limitations:** Data from all studies only used 1.5T magnetic field. Should test at higher magnetic strength. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Viera, M.S., Lazoura, O., Nicol, E., Rubens, M. & Padley, S. (2013). MRI in patients with cardiovascular implantable electronic devices. *Clinical Radiology* , 68(2013), 928-934.	None	Technical Report	Interim analysis of the multicentre MagnaSafe Registry	Devices were interrogated before and after MRI with the use of a standardized protocol and were appropriately reprogrammed before the scanning.	Analysis of the multicentre MagnaSafe Registry	Risks were identified, need for comprehensive safety protocol.	New generation of MRI conditional pacemakers developed. Higher risk with ICD and CRT devices.	**Strengths:** Identification of risks, need for safety protocols. **Limitations:** Data from all studies only used 1.5T magnetic field. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Shenthar, J., Milasinovic, G., Al Fagih, A., Gotte, M., Engel, G., Wolff, S., …..Nahle, C. (2015). MRI scanning in patients with new and existing CapSureFix Novus 5076 pacemaker leads: Randomized trial results. *Heart Rhythm Society* , 12(4), 759-765.	None	Randomized Control Trial	N = 266; 2:1 ratio to the MRI group (177 patients) or to the control group (89 patients)	Devices were interrogated before and after MRI. The MRI scan protocol was modeled after the Advisa MRI safety and effectiveness trial using 1.5-T cylindrical MRI systems7.	Evaluate the safety of MRI without positioning restrictions in patients with an MR conditional pacemaker and currently a non–MR-conditional Medtronic CapSureFix Novus 5076 lead(s).	At 9-12 weeks post implant, the MRI group underwent MRI at 1.5T. Primary end-points were MRI-related complication-free rate and non-inferiority of the MRI group compared to the control group with the regard to the proportion of patients with increase of <0.5V in the right atrial and right ventricular pacing capture thresholds from immediately before MRI to 1 month post MRI.	No MRI-related complications occurred in 156 MRI scanned patients who were followed through 1 month post MRI. MRI scans can be performed safely.	**Strengths:** RCT. **Limitations:** Data from all studies only used 1.5T magnetic field. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , I A.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Shah, A.D., Morris, M.A., Hirsh, D.S., Warnock, M., Huang, Y., Mollerus, M., …..Lloyd,, M.S. (2018). Magnetic resonance imaging safety in nonconditional pacemaker and defibrillator recipients: A meta-analysis and systematic review. *Heart Rhythm Society* , 1-8.	None	Meta-analysis and systematic review.	Queried indexed articles from PubMed and CINAHL from 1990-2017. The search yielded 1324 records to review. 70 studies were included for the systematic review. 5099 patients.	A random effects model was used for meta-analysis of continuous variables. Safety outcomes were evaluated with descriptive analysis.	For the primary safety objective, a 1-sided, 1-proportion binomial exact test was used, and the corresponding 1-sided 97.5% lower confidence bound was calculated.	70 studies on non-MRI conditional devices undergoing MRI were identified, allowing analysis of 5099 patients who underwent 5908 MRI studies. All lead characteristics and battery voltage showed minimal changes. Electrical resets were only found in older devices. Defibrillator function was unchanged and inappropriate were avoided.	This review demonstrated low lead failure and clinical event rates in non-MRI conditional pacemaker and ICD undergoing MRI. Observed changes were small and interstudy variance was low suggesting that the composite event rates offer a reasonable estimate of true effect. The observed adverse events reinforce the need for ongoing monitoring and caution.	**Strengths:** Large number of studies and significant number of patients. **Limitations:** Previously published, largely observational data. Unknown number of patients were implanted with Medtronic model 4076 and 5076 leads which may have lowered the clinical risk observed because these leads are MRI compatible. The data did not allow for review of all possible device, lead, and MR combinations to determine safety. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Wilkoff, B.L., Bello, D., Taborsky, M., Vymazal, J., Kanal, E., Heuer, H., …..Sommer, T. (2011). Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment. *Heart Rhythm Society* , 8, 65-73.	None	Prospective Randomized Control Trial	N= 464 were randomized to undergo an MRI scan between 9-12 weeks post implant. MRI group n = 258 or not undergo an MRI (control group n = 206) after successful implantation of specially designed dual chamber pacemaker and leads.	Pacemaker performance, pacing capture threshold, evaluation 9-12 weeks prior to MRI, during MRI, and immediately after MRI. Technical observations and adverse events were evaluated.	Sequences were performed at 1.5T and included scans with high radiofrequency power deposition and/or high gradient dB/dt exposure.	Patients were monitored for arrhythmias, symptoms, and pacemaker system function during 14 non-clinically indicated relevant brain and lumbar MRI sequences.	No MRI related complications occurred during or after the MRI.	**Strengths:** This trial documented the ability of the pacemaker to be exposed in a controlled fashion to MRI in a 1.5T scanner without adverse impact on patient outcomes or pacemaker function. **Limitations:** Data only from 1.5T magnetic field. Use of MRI scanners on pacemaker patients was specifically limited to well-defined conditions in the trial and safe use outside of these conditions was not demonstrated. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , I A.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Bailey, W.M., Mazur, A., McCotter, C., Woodard, P.K., Rosenthal, L., Johnson, W., & Mela, T. (2016). Clinical safety of the ProMRI pacemaker system in patients subjected to thoracic spine and cardiac 1.5T magnetic resonance imaging scanning conditions. *Heart Rhythm Society* , 13, 464-471.	None	Prospective Single, Non-randomized study	N = 245 with stable baseline pacing indices implanted with a Biotronik Entovis pacemaker and Sertox leads.	Pre-MRI, atrial and ventricular sensing and thresholds. Using investigational software.	Device interrogation was performed at enrollment, pre and post MRI scan, and 1 and 3 months post MRI.	216 patients completed the MRI and 1-month post-MRI follow up. Statistical analysis was based on the proportion of the leads or patients satisfying end-point criteria. Two-sided 95% CIs for the parameters were given.	One adverse event possibly related to the implanted system and the MRI procedure occurred, adverse device effect-free rate of 99.6%. The study demonstrated the clinical safety and efficacy of the ProMRI pacemaker system.	**Strengths:** This study demonstrated the safety and function of the ProMRI pacemaker. **Limitations:** Sample size was insufficient to observe rare adverse effects of MRI on the patient population. The number of cardiac MRI was lower than thoracic MRI and could underestimate the risk of cardiac MRI. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , II A.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Nazarian, S., Hansford, R., Rahsepar, A.A., Weltin,V., McVeigh, D., Ipek, E.G.,….. Halperin, H.R. (2017). Safety of magnetic resonance imaging in patients with cardiac devices. *The New England Journal of Medicin* e, 377(26), 2555-2564.	None	Prospective, Single, Non-randomized study	N = 1509 who underwent 2103 thoracic and non-thoracic MRIs	Evaluated the safety of MRI, performed with the use of a prespecified safety protocol. Lead parameters were compared with the use of the Wilcoxon signed-rank test, with MRI examination as the unit of analysis.	The pacing mode was changed to asynchronous mode for pacing dependent patients and to demand mode for other patients.	In 9 MRI exams, 95% CI was reported. The most common notable change in device parameters immediately after MRI was a decrease in the P wave amplitude, which occurred in 1% of the patients. Lead parameters were compared with the use of the Wilcoxon signed rank test with MRI examination as the unit of analysis.	Lead parameters were compared with the use of the Wilcoxon signed rank test with MRI examination as the unit of analysis.	**Strengths:** This study demonstrated the MRI safety of pacemakers and ICDs. **Limitations:** Data was acquired at a single center and may not be generalizable to other clinical settings and MRI facilities. Unable to obtain long-term follow up information from 302 patients. The study did not perform defibrillation testing in patients who had an ICD. The numbers of each individual devices were small. Interactions of future systems cannot be ruled out. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool*, II A.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Van der Graaf, A.W.M., Bhagirath, P., & Gotte, M.J.W. (2014). MRI and cardiac implantable electronic devices; current status and required safety conditions. *Netherlands Heart Journal* , 22, 269-276. Retrieved from http://dx.doi.org/10.1007/s12471-014-0544-x	None	Abstract	This review paper provides an overview of the currently available data related to CIEDs and MRI and attempts to offer an up-to date and clinically useful summary for the practicing cardiologist. Six studies and four clinical trials were reviewed.	6 studies and 4 clinical trials were reviewed.	Reviewed clinical trials and numerous literature to study the safety of MRIs and CIEDs.	An overview of all available MRI conditional devices and their individual restrictions was given.	With appropriate monitoring and application of a safety protocol, MRI can be safely performed in patients with CIEDs.	**Strengths:** This abstract demonstrated the MRI safety of pacemakers and ICDs. **Limitations:** Data was limited to the 6 studies and 4clinical trials. Studies with use of higher magnetic strength should have been included. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , III A/B.

Citation	Conceptual Framework	Design/Method	Sample/Setting	Variable Studied and Their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
Nordbeck, P., Ertl, G., & Ritter, O. (2015). Magnetic resonance imaging safety in pacemaker and implantable cardioverter defibrillator patients: How far have we come? *European Heart Journa* l, 36, 1501-1511.	None	Clinical Review and Update	This clinical review provides a better understanding of the mechanisms responsible for life-threatening complications as well as technical advances allowing an increasing number of pacemakers and ICDs to safely undergo MRIs.	Reviewed clinical trials over the last 20 years.	14 pacemaker studies and 13 ICD studies.	14 pacemaker studies and 13 ICD studies assessed the outcome in 1.5T MR scanners. There were no adverse events reported.	Appropriate monitoring and application of a safety protocol, MRIs can be safely performed in patients with CIEDs.	**Strengths:** This review demonstrated the MRI safety of pacemakers and ICDs. **Limitations:** Data was limited to 14 pacemaker studies and 13 ICD studies. Studies with use of higher magnetic strength (>1.5T) should have been included. **Critical Appraisal Tool & Rating:** John Hopkins *Research Evidence Appraisal Tool* , III A/B.

Studies **Author & Year**	Russo et al. (2017)	Yadava et al. (2017)	Dandamudi et al. (2016)	Jung,W., Sebastian, J., Zvereva, V. (2015)	Viera, M.S., Lazoura, O., Nicol, E., Rubens, M. & Padley, S. (2013)	Shenthar et al. (2015)	Shah et al. (2018)	Wilkoff et al. (2011)	Bailey et al. (2016)	Nazarian et al. (2017)	Van der Graaf, A.W.M., Bhagirath, P., & Gotte, M.J.W. (2014)	Nordbeck, P., Ertl, G., & Ritter, O. (2015)
Types of Magnetic Resonance Imaging (MRI)												
Thoracic 1.5Tesla		X	X			X			X			
Spinal 1.5 Tesla		X	X					X	X			
Non-thoracic 1.5 Tesla	X	X	X			X	X	X				
Full body 1.5 Tesla				X	X					X	X	
Utilization of CIED MRI Protocol	X	X	X		X	X	X	X	X	X	X	X
Type of Cardiovascular Implantable Electronic Device (CIED)												
MRI Conditional CIED		X	X	X	X	X		X	X	X	X	
MRI Non-conditional CIED	X	X	X	X			X					
CIED Reprogramming	X	X	X		X	X	X	X	X	X	X	X
Single Vendor Specific						X		X	X	X		
Multi-vendor Specific		X		X	X		X				X	
Outcomes												
Low to No MRI Related Complications/Adverse Effects	X	X	X		X	X	X	X	X	X	X	X

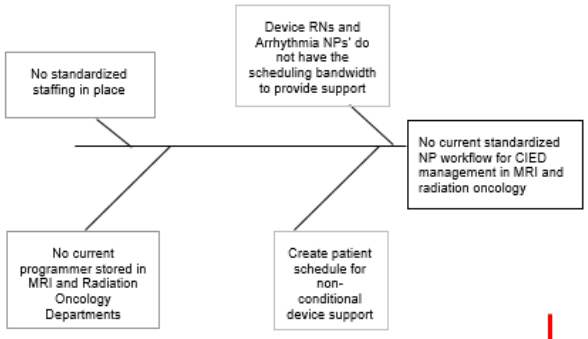
Appendix C – Gap Analysis

Expanding Access to MRI

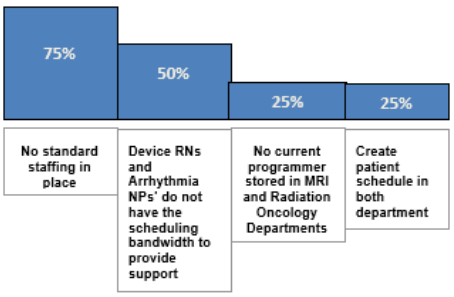
Rose Geronimo

1. Currently, no standardized staffing model to support the management of the CIED during an MRI.
2. Delay of patient care.

2. What causes are preventing us from meeting our target(s)? What are the "root" causes?



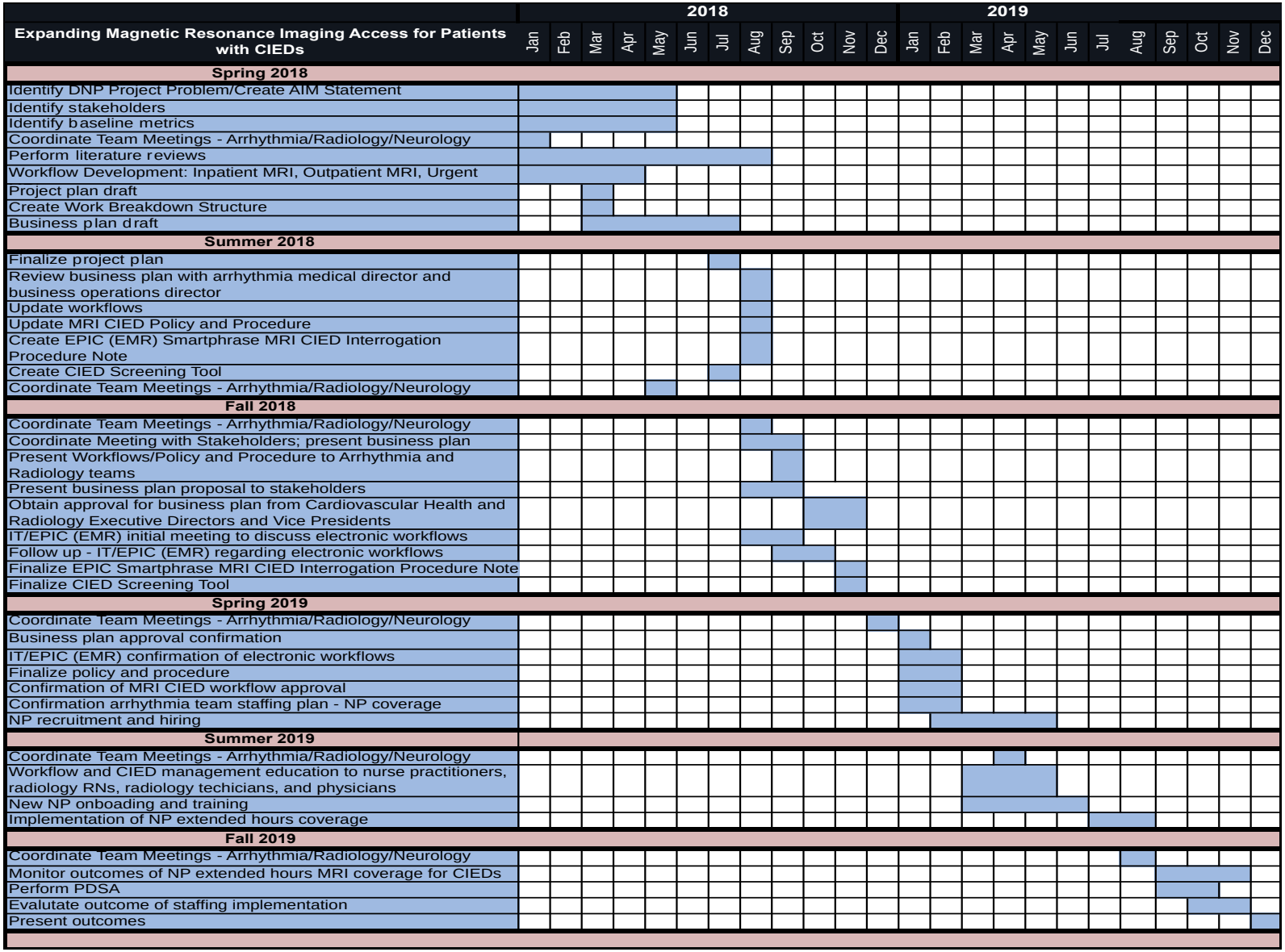
3. Based on data, what are the causes in order of importance?



4. Which actions will address the most important causes?

Goal (Cause)	Actions	By When/By Who
No standardized staffing for MRI CIED in place	Create standardized staffing; create business plan	1/30/2019 – Rose Geronimo and AT
Device RNs and Arrhythmia NPs' do not have the scheduling bandwidth to provide support	Create a schedule to provide Arrhythmia NP and MRI RN support	1/30/2019 – Rose Geronimo and AT
No current programmer stored in MRI and Radiation Oncology Departments	Create plan for equipment support	12/31/2018 – Rose Geronimo and AT
Create patient schedule in both departments that correlate with Device RN/Arrhythmia NP schedule	Work with MRI and Radiation Oncology team to create staffing support for MRI/Rad Onc CIED patients	1/30/2019 – Rose Geronimo, AT, PW, MRI/Radiation Oncology Department

Appendix D – Gantt Chart



Appendix E – SBAR

Situation:

SHC is not able to facilitate MRIs for patients with Cardiovascular Implantable Electronic Devices (CIEDs) to meet national standards and CMS guidelines.

Reference CMS Decision Memo:
https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=289

Background:

- Over 2 million patients in the United States have CIEDs
- 50% of these patients will require magnetic resonance imaging (MRI) after device implantation
- In 2017, HRS (Heart Rhythm Society) came out with recommendations for Management of the patient with an MR conditional and nonconditional CIED who is to have an MRI scan.
    - For patients undergoing MRI, personnel with the skill to program the CIED should be in attendance.
- Device management during an MRI can be provided based on EP staff availability and leads to increased hospital stay as well as inability to provide standard of care imaging for patients with CIEDs.
- The number of urgent referrals for inpatient ILR implantation for cryptogenic stroke from the Stanford neurology service will increase at least 3-fold due the paradigm shift in practice.

Analysis:

Inpatient Coverage Responsibilities

During the day shift:

- Improve patient flow in the pre-procedure area by consenting patients for procedures, entering orders, and discharging patients in a timely manner to avoid unnecessary delays and maximize preop and post op bed utilization.
- Assist in the cath lab during EP procedures (getting access, making device pocket, suturing the pocket, assist during ablation procedures).
- Meet unmet demand for Cardioversion resulting an increase in volumes.
- Provide evaluation for appropriateness of MRI procedure and device management during MRI for patients with CIEDs undergoing MRI scan.

During the night and weekend shift:

- Will assist with late cases and add on cases (getting access, making device pocket, suturing the pocket, assist during ablation procedures).

- Consenting patients for procedures, entering orders, and discharging patients in a timely manner to avoid unnecessary delays and maximize preop and post op bed utilization.
- Take calls for EP service (patient calls, urgent calls from monitoring companies, urgent device transmissions)
- Interrogate CIED for urgent patients (including ED)
- Provide evaluation for appropriateness of MRI procedure and device management during MRI for patients with CIEDs undergoing MRI

Financial Impact:

Incremental demand is estimated to be 8 additional Cardioversions and 22 additional MRI per week. We expect to reach full demand by year 2. Expanded service will be rolled out in 2 phases. Phase 1 will cover Mon-Fri from 6 AM until 10 PM. Phase 2 will extend this schedule to Sat-Sun. To provide this level of coverage and comply with CMS guidelines, 4.6 CVH APP FTEs, 1.7 Radiology RN FTEs and 1.7 MRI Tech FTEs are required at full ramp up (in phase II).

	Year 1	Year 2	Year 3	Year 4	Year 5
	Phase-I	Phase-2			
Cardioversion (8 /week)		*Ramp Up*			
Target Volume at Full Ramp Up = **416**	*208*	*416*	*416*	*416*	*416*
Charge	$2,031,083	$4,346,517	$4,650,773	$4,976,327	$5,324,670
NetRev *(19% reimbursement)*	$430,134	$886,076	$912,658	$940,038	$968,239
Direct Cost	$318,600	$443,833	$463,995	$485,103	$507,205
Contribution Margin	$111,534	$442,243	$448,663	$454,935	$461,034
Operating Margin	$89,039	$395,903	$400,933	$405,772	$410,397
MRI (22 conditional & non-conditional/week)					
Target Volume at Full Ramp Up = **1144**	*572*	*1,144*	*1,144*	*1,144*	*1,144*
Charge	$9,758,978	$20,884,212	$22,346,107	$23,910,335	$25,584,058
NetRev *(19% reimbursement)*	$2,066,714	$4,257,432	$4,385,155	$4,516,709	$4,652,210
Direct Cost	$2,031,104	$3,456,229	$3,591,150	$3,731,680	$3,878,066
Contribution Margin	$35,611	$801,202	$794,004	$785,029	$774,145
Operating Margin	($423,934)	($145,460)	($181,058)	($219,285)	($260,299)
Total Operating Margin	**($334,896)**	**$250,442**	**$219,875**	**$186,487**	**$150,098**
Total Incremental FTEs	**6.00**	**8.00**	**8.00**	**8.00**	**8.00**

Recommendations:

To maintain high quality of patient care and comply with CMS, national and institutional standards we propose adding total of 8.0 FTEs (APPs, RNs, MRI Tech) with the estimated additional incremental cost of $1.7M. At full ramp-up this service will produce an operating margin of $250K.

Appendix F – Electronic Order Sets and Workflows

	Cardiology CIED screening form for patients undergoing MRI	**Please fax completed form to MRI Scheduling (650) 723-6036**
Ordering Physician Name (please print):		**Date and Time:**
Patient Name:	**MR #**	**DOB:**

The patient should be evaluated and reviewed for the following:

Device Name and Model_____

Lead(s) Model: Atrial:_____ RV:_____ LV:_____

Date of device implantation _____

Is this MRI conditional system: yes: o no: o

- o No abandoned leads or wires, lead extenders, or lead adapters are present (confirmed with CXR within 2 weeks)
- ☐ No broken leads or leads with intermittent electrical contact as confirmed by lead impedance history
- ☐ For patients who have multiple MR-Conditional devices, the MR labeling conditions for all implants are satisfied
- ☐ Pace polarity parameters set to Bipolar
- ☐ The device is operating normally and within the projected service life and/or pulse generator has sufficient battery, not at ERI or EOL
- ☐ In patients whose device will be programmed to an asynchronous pacing mode when MRI scan mode is On: no diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms
- ☐ All Lead impedance values ≥ 200 ohms and ≤ 1500 ohms
- ☐ For Medtronic ICDs: SureScan ICD system: pacing lead impedance value: >200 ohms and <3000 ohms
- ☐ All Lead capture thresholds: <2V @0.4 msec in devices programmed to asynchronous pacing mode
- ☐ In BiV devices LV lead pacing impedance of ≥ 200 ohms and ≤ 3000 ohms;
- ☐ Defibrillation lead impedances between 20 and 200 ohms
- ☐ For Boston Scientific: Patient does not have an elevated body temperature or compromised thermoregulation at the time of the scan

Patient's intrinsic rhythm is:_____

Patient is pacemaker-dependent: Yes o Noo

Recommendation for MRI:

Based on the information documented above patient can proceed to have MRI:

Yes o Noo

Name of the EP RN/CNS/NP completing the form:_____

Date: _____

For patients with MRI non-conditional CIEDs:

"Patient informed about the potential adverse interactions between the CIED and MRI that may include the inhibition of pacing, CIED warming, vibration, skin or soft tissue burns, asynchronous pacing, induction of atrial fibrillation, induction of ventricular fibrillation, switch mode malfunction, rapid atrial stimulation, rapid ventricular stimulation, and alteration in the CIED programming with potential damage to CIED circuit or system dislocation leading to potential CIED malfunction resulting in potentially life-threatening arrhythmias, heart block, and death"

Provider Name_____

Date_____

	Cardiology Order Set for Pacemaker/ICD programing for MRI	**Please fax completed form to MRI Scheduling (650) 723-6036**
Ordering Physician Name (please print):		**Date and Time:**
Patient Name:	**MR #**	**DOB:**
Home Phone:	**Work/Cell Phone:**	

All fields MUST be completed to clear patient for MRI. ***Incomplete forms will be rejected and sent back.***

The Patient was reviewed for the following:

- o Device Name and Model_____ Lead(s) Model_____
- o An MR Conditional pacing device has been implanted a **minimum of 6 weeks** in the left or right pectoral region post the lead maturation period. Date of device implantation _____
- o No abandoned leads or wires, lead extenders, or lead adapters are present
- ☐ No broken leads or leads with intermittent electrical contact as confirmed by lead impedance history
- ☐ For patients who have multiple MR-Conditional devices, the MR labeling conditions for all implants are satisfied
- ☐ Pace polarity parameters set to Bipolar
- ☐ The device is operating normally and within the projected service life and/or pulse generator has sufficient battery, not at ERI or EOL
- ☐ No diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI scan mode is On
- ☐ All Lead impedance value ≥ 200 ohms and ≤ 1500 ohms
- ☐ For Medtronic ICDs : SureScan ICD system: pacing lead impedance value: >200 ohms and <3,000
- ☐ All Lead capture thresholds: <2V @0.4 msec.
- ☐ In BiV devices LV lead pacing impedance of ≥ 200 ohms and ≤ 3000 ohms;
- ☐ Defibrillation lead impedances between 20 and 200 ohms
- ☐ For Boston Scientific: Patient does not have an elevated body temperature or compromised thermoregulation at the time of the scan

Patient can proceed to have MRI: Yes o Noo

Cardiology orders for device programming:

Prior to MRI:

For MRI conditional Devices:

Medtronic: SureScan mode ON o

St Jude: Confirmed MRI Setting status and the programmed MRI Mode settings o

Boston Scientific: MRI protection Mode ON o

For non-MRI conditional devices:

o Deactivate monitoring and tachyarrhythmia therapies
o Deactivate magnet response, rate response, PVC response, noise response, ventricular sense response and conducted AF response

Is the patient pacemaker dependent?

o Yes: Program to**:** DOO oVOO Pacing Rate: _____bpm

o No: Program to**:** DDI oVVI

During MRI:

oMonitor blood pressure, EKG, O2 and symptoms during MRI

Post MRI:

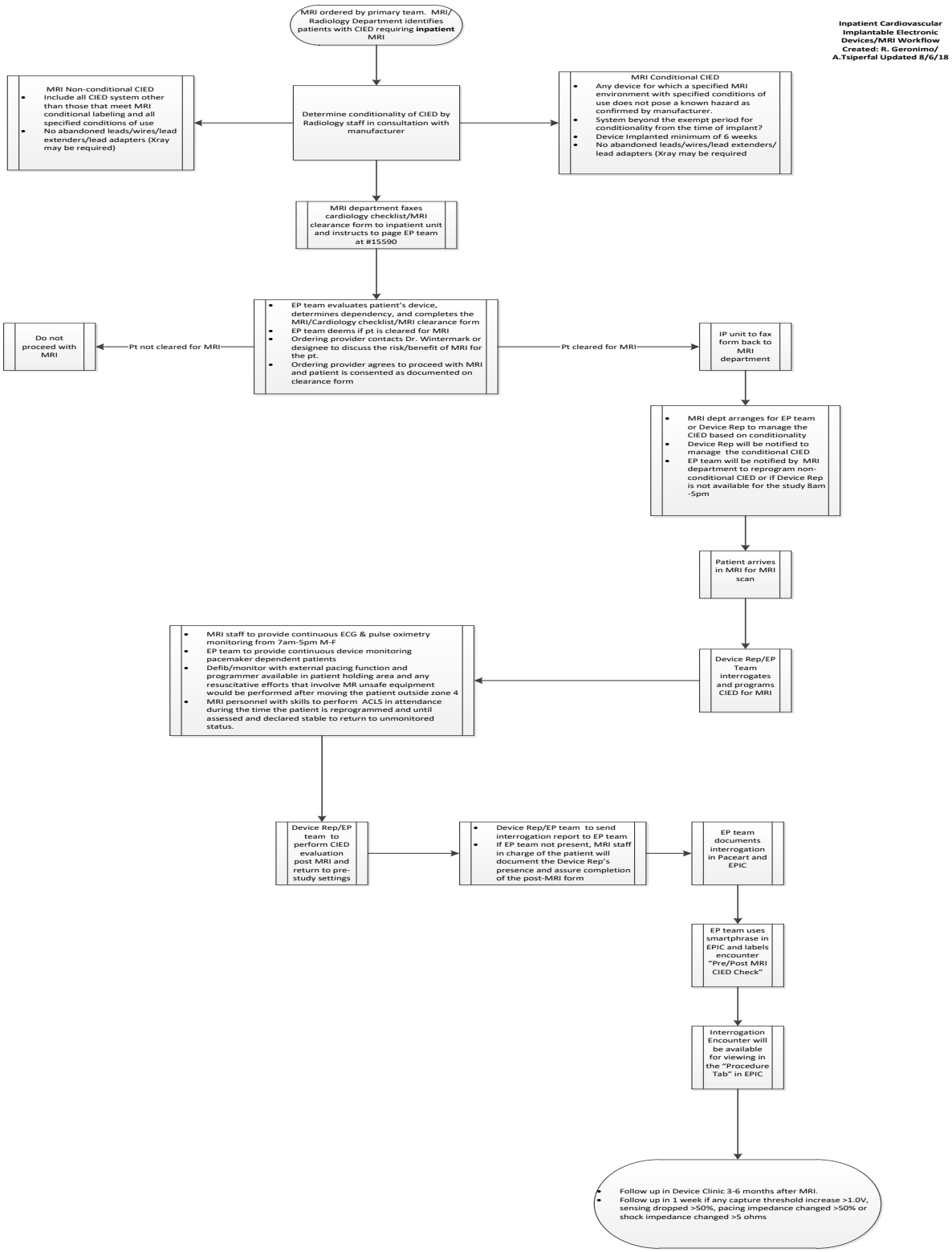
oRecheck sensing, impedance and pacing thresholds and compare with baseline
o Restore original programming.
oPost-scan program MRI scan mode to OFF.

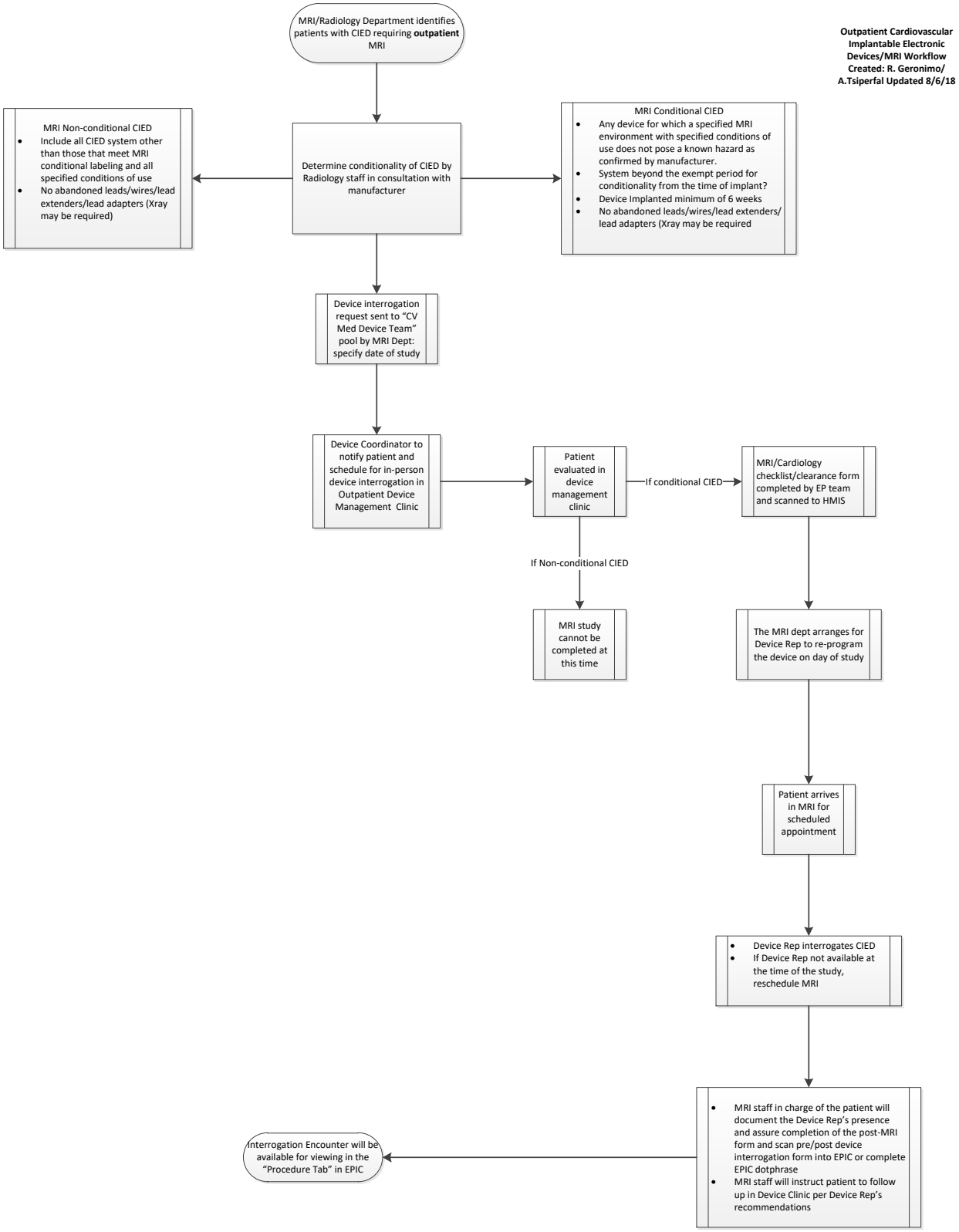
oComplete device interrogation documentation in EPIC

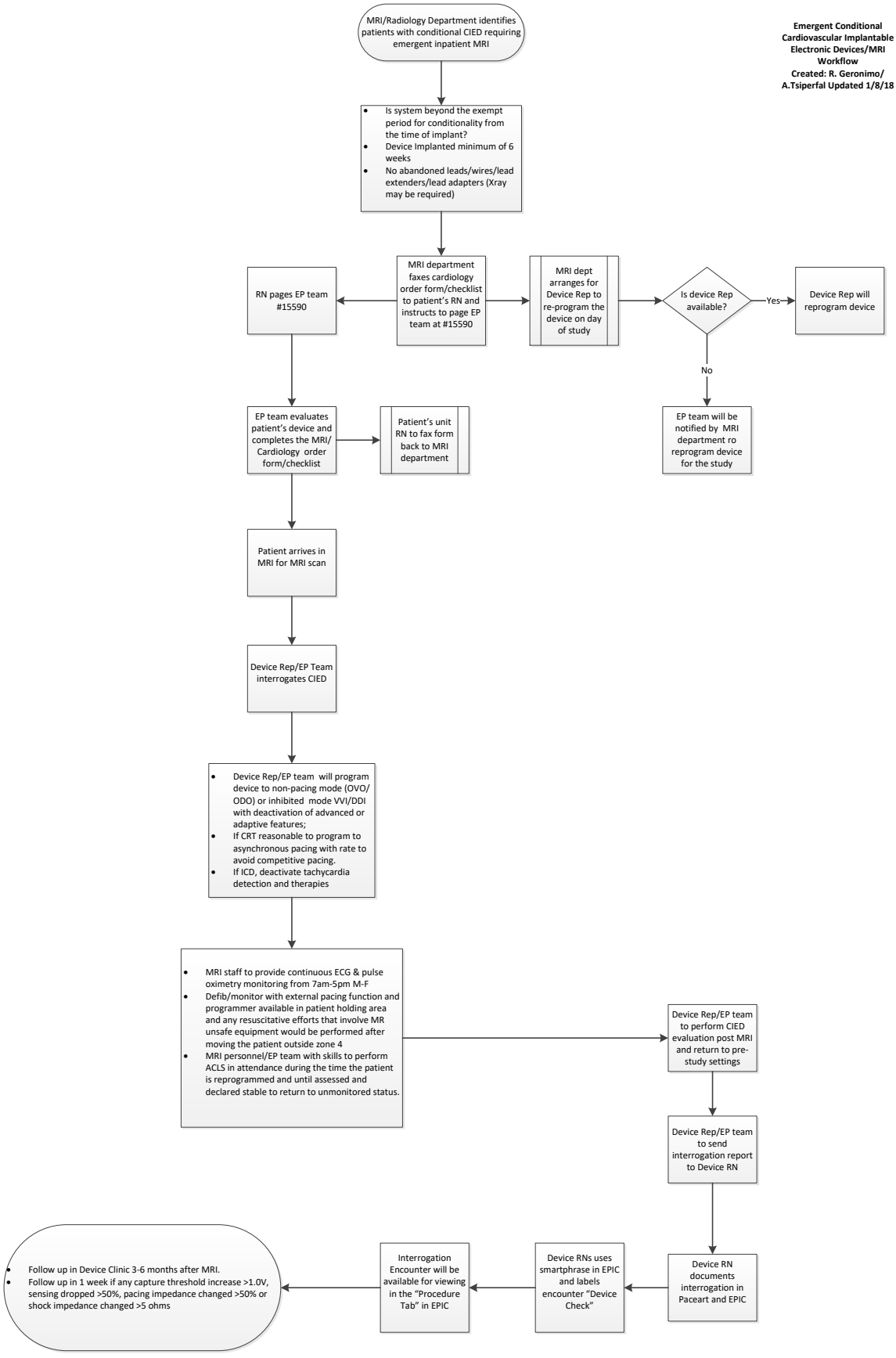
Physician/Provider signature_____ Date_____

Print name:_____ Pager_____

CIED MRI Workflows (Inpatient/Outpatient/Urgent)




MRI/Radiology Department identifies patients with CIED requiring **outpatient** MRI
Outpatient Cardiovascular Implantable Electronic Devices/MRI Workflow Created: R. Geronimo/ A.Tsiperfal Updated 8/6/18
MRI Non-conditional CIED
Include all CIED system other than those that meet MRI conditional labeling and all specified conditions of use
No abandoned leads/wires/lead extenders/lead adapters (Xray may be required)
Determine conditionality of CIED by Radiology staff in consultation with manufacturer
MRI Conditional CIED
Any device for which a specified MRI environment with specified conditions of use does not pose a known hazard as confirmed by manufacturer.
System beyond the exempt period for conditionality from the time of implant?
Device Implanted minimum of 6 weeks
No abandoned leads/wires/lead extenders/ lead adapters (Xray may be required
Device interrogation request sent to "CV Med Device Team" pool by MRI Dept: specify date of study
Device Coordinator to notify patient and schedule for in-person device interrogation in Outpatient Device Management Clinic
Patient evaluated in device management clinic
If conditional CIED
MRI/Cardiology checklist/clearance form completed by EP team and scanned to HMIS
If Non-conditional CIED
MRI study cannot be completed at this time
The MRI dept arranges for Device Rep to re-program the device on day of study
Patient arrives in MRI for scheduled appointment
Device Rep interrogates CIED
If Device Rep not available at the time of the study, reschedule MRI
MRI staff in charge of the patient will document the Device Rep's presence and assure completion of the post-MRI form and scan pre/post device interrogation form into EPIC or complete EPIC dotphrase
MRI staff will instruct patient to follow up in Device Clinic per Device Rep's recommendations
Interrogation Encounter will be available for viewing in the "Procedure Tab" in EPIC


Emergent Conditional Cardiovascular Implantable Electronic Devices/MRI Workflow
Created: R. Geronimo/ A.Tsiperfal Updated 1/8/18
MRI/Radiology Department identifies patients with conditional CIED requiring emergent inpatient MRI
Is system beyond the exempt period for conditionality from the time of implant?
Device Implanted minimum of 6 weeks
No abandoned leads/wires/lead extenders/lead adapters (Xray may be required)
MRI department faxes cardiology order form/checklist to patient's RN and instructs to page EP team at #15590
RN pages EP team #15590
MRI dept arranges for Device Rep to re-program the device on day of study
Is device Rep available?
Yes
Device Rep will reprogram device
No
EP team will be notified by MRI department ro reprogram device for the study
EP team evaluates patient's device and completes the MRI/ Cardiology order form/checklist
Patient's unit RN to fax form back to MRI department
Patient arrives in MRI for MRI scan
Device Rep/EP Team interrogates CIED
Device Rep/EP team will program device to non-pacing mode (OVO/ ODO) or inhibited mode VVI/DDI with deactivation of advanced or adaptive features;
If CRT reasonable to program to asynchronous pacing with rate to avoid competitive pacing.
If ICD, deactivate tachycardia detection and therapies
MRI staff to provide continuous ECG & pulse oximetry monitoring from 7am-5pm M-F
Defib/monitor with external pacing function and programmer available in patient holding area and any resuscitative efforts that involve MR unsafe equipment would be performed after moving the patient outside zone 4
MRI personnel/EP team with skills to perform ACLS in attendance during the time the patient is reprogrammed and until assessed and declared stable to return to unmonitored status.
Device Rep/EP team to perform CIED evaluation post MRI and return to pre-study settings
Device Rep/EP team to send interrogation report to Device RN
Device RN documents interrogation in Paceart and EPIC
Device RNs uses smartphrase in EPIC and labels encounter "Device Check"
Interrogation Encounter will be available for viewing in the "Procedure Tab" in EPIC
Follow up in Device Clinic 3-6 months after MRI.
Follow up in 1 week if any capture threshold increase >1.0V, sensing dropped >50%, pacing impedance changed >50% or shock impedance changed >5 ohms

Appendix G – EP Nurse Practitioner Job Description

ELECTROPHYSIOLOGY NP JOB DESCRIPTION

Our fast-growing Cardiology EP department is currently seeking a Nurse Practitioner or Physician Assistant to join its prestigious team. The overall responsibility of this EP NP/PA is to provide high-quality care to the arrhythmia patients under the supervision of the EP attending.

SUMMARY:

Primary responsibility of this position is to support inpatient hospital services including electrophysiology patient admissions, rounding, discharges, and EP coverage including admissions, education, discharge process, and discharge when needed, peri-operative management of patents undergoing EP procedures, evaluation and management of patients with cardiac arrhythmias, pacemakers, CRT-D, and defibrillators, and their devices, management of patients with CIEDs during MRI, engage in a consultative care of hospitalized patients and to collaborate with physicians, fellow, residents, and medical /APP students, assisting EP MD during device implant procedures and ablation procedures. This position requires excellent communication skills and the ability to multi-task. Must have a professional, efficient, and caring attitude and be a cooperative team member, while maintaining and endorsing high clinical standards in both the outpatient and inpatient settings.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

➢ Performs evaluation and problem identification of patients.

➢ Performs history and physical examination of patients.

➢ Consents patients for electrophysiology procedures.

➢ Writes orders and interprets laboratory data and radiological tests.

➢ Monitors patient status and response to treatments.

➢ Documents findings in the medical record.

➢ Recommends and orders appropriate therapeutic interventions and writes prescriptions for recommended pharmacologic treatments.

➢ Interacts with consultants as appropriate.

➢ Directs patient and/or family to agencies dealing with specific illnesses/diseases.

➢ Participates in departmental quality assurance, risk management, and compliance efforts.

➢ Discharges patients who require an overnight observation period after electrophysiological device placements or ablations.

➢ Venous and arterial sheath removal

ELECTROPHYSIOLOGY NP JOB DESCRIPTION:

➢ Participates in daily team rounding, periodic M&M sessions and department conferences/teaching opportunities.

➢ Perform ICD/PPM interrogations and programming during these clinics and as needed on inpatients.

➢ Perform patient education during clinic for the patients and families of the aforementioned Physicians.

➢ Make appropriate referrals.

➢ Identify patients for research protocols and notify the PI and research coordinator of potential subjects.

EDUCATION:

A master's degree in nursing and completion of an approved course of study as a nurse practitioner. Current ANCC certification and CA licensure as an NP is necessary.

PREFERRED:

Two years of Cardiology experience
One year critical care experience
Cardiac experience as an NP Computer Proficiency
Employment Type: Full-Time

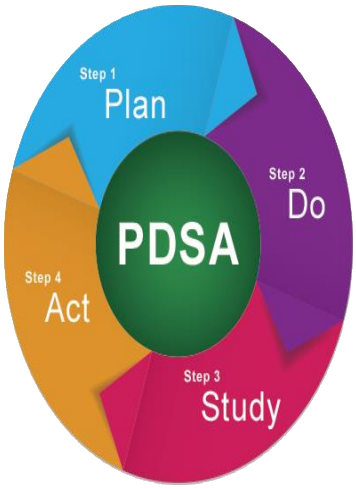
Appendix H – PDSA Process

Plan

1. Observe implementation of MRI CIED workflows.
2. Observe implementation of NP extended staffing model.

Do

1. Create backup staffing plan.



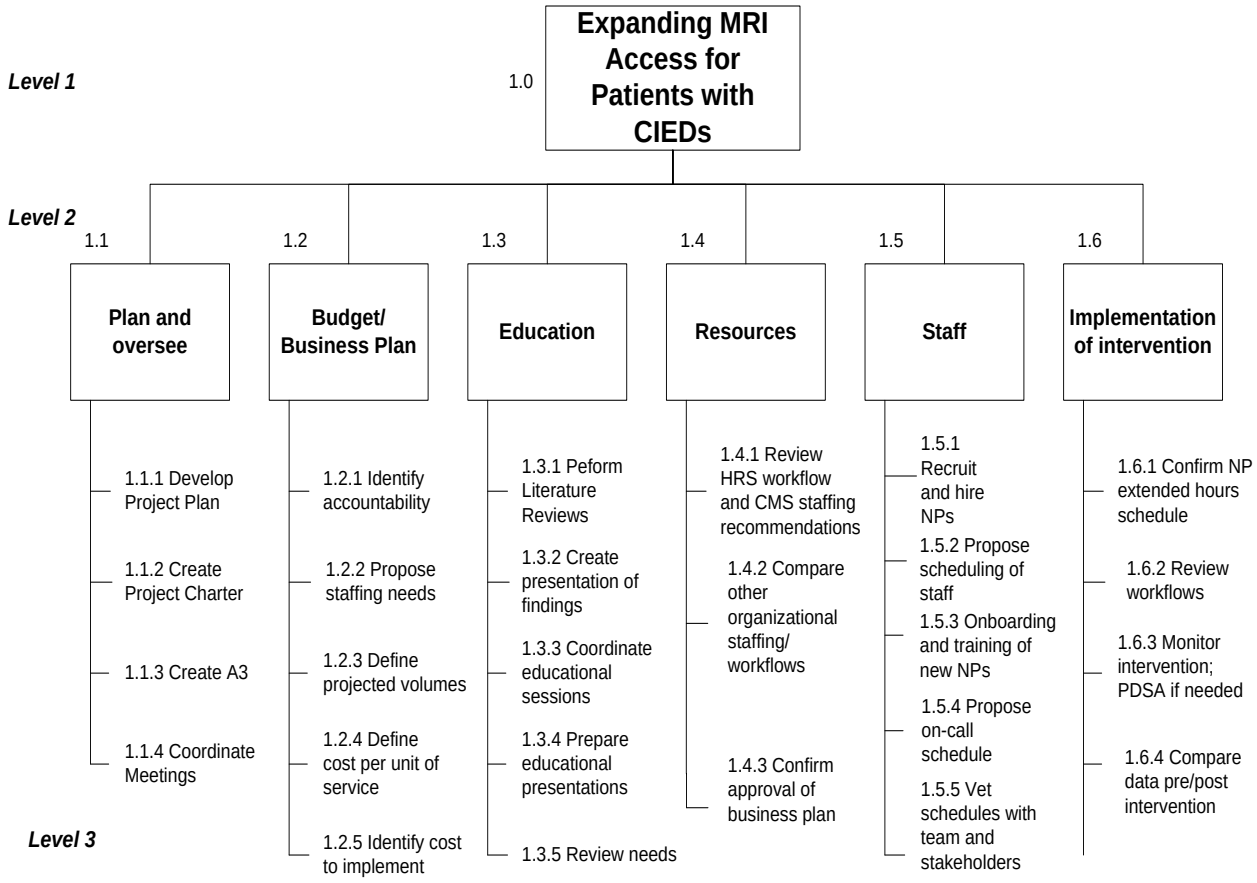
Act

1. Confirm patient data and identify gap(s).
2. Implement new staffing plan.

Study

1. Monitor patients turned away for MRIs
2. Identify patients with CIEDs

Appendix I - Work Breakdown Structure



Appendix J – Responsibility/Communication Matrix

Project Charter						
Project Name	Expand MRI Access for Patients with CIEDs					
Problem Statement	Arrhythmia Service would like to partner with the Radiology and Neurology Services to improve MRI access for patients with CIEDs.					
Project Scope	Create standardized workflows for conditional and non-conditional CIEDs. Create business plan to support the CMS staffing standards for CIED management during MRIs. Obtain physician support to implement the standardized workflows. Create policy and procedure for MRI CIED management					
Metrics	**#**	**Description**		**Target**	**Current**	**Accountability**
	1	Identify patients who presented with acute neurological conditions who have non-conditional CIEDs.		0%	2.5/month	Neuro team
	2	Create standardized workflows for conditional and non-conditional CIEDs.		100%	100%	Rose G/Angela T
	3	Create business plan to support the CMS staffing standards for CIED management during MRIs.		100%	90%	Rose G/Angela T
	4	Create policy and procedure for MRI CIED management		100%	80%	Rose G/Angela T
Project Benefits	Improved staff engagement Improved health outcomes Improved transitions of care Improved patient satisfaction					
Team Members	Sponsor(s), Team Leader, Performance Excellence Lead		Team Members:			
	Team Sponsors: S.S.; S.W.; C.K.; D.K.; P.W.; M.W. Team Leader: Rose Geronimo		A.T. T.N. R.R.			
Potential Barriers/Risks	No budget - competing priorities (new hospital construction Physician support					

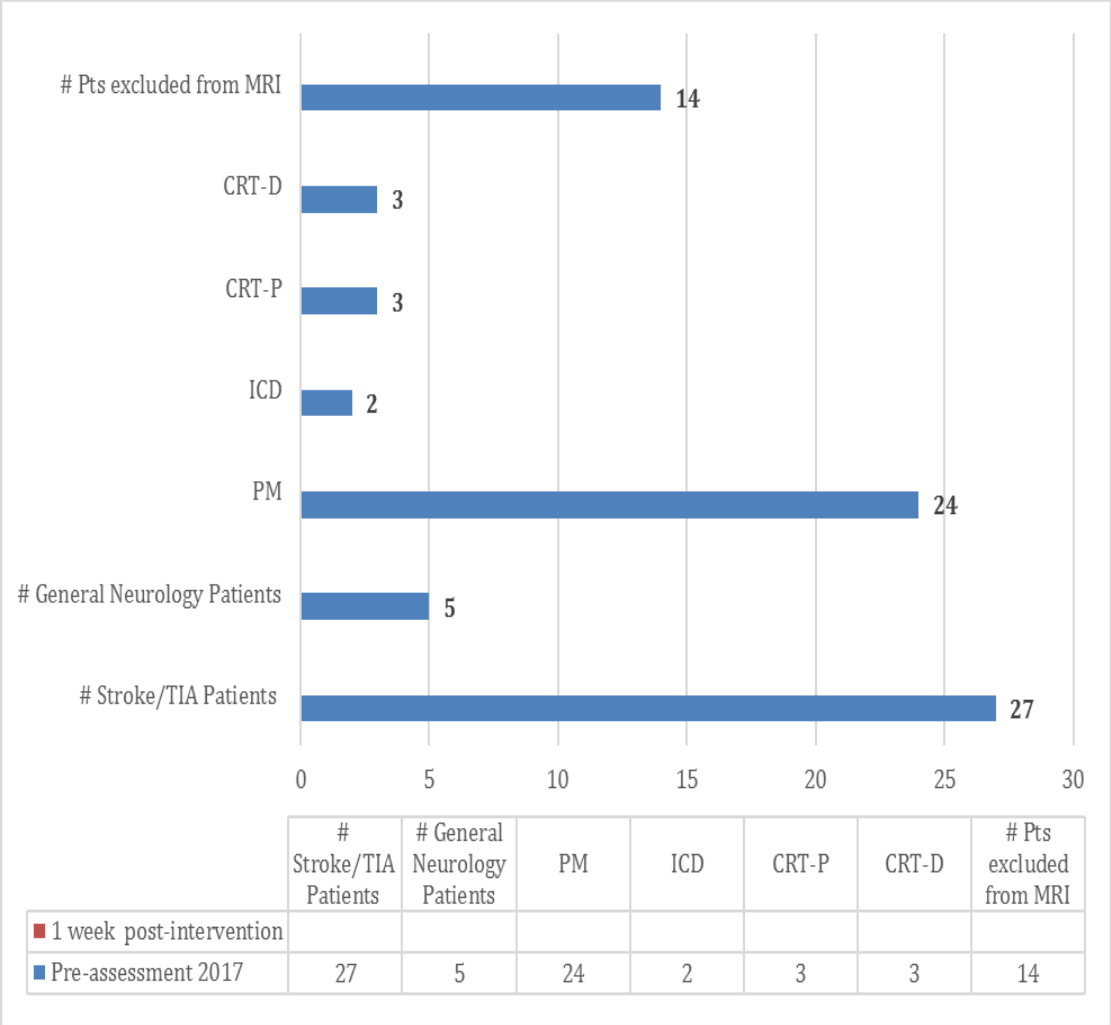
Appendix K – SWOT Analysis

Expanding Access to Magnetic Resonance Imaging for Patients with CIEDs SWOT Analysis	
Strengths	
Improve patient throughput	Creation of policy and procedure
Improve patient satisfaction	Development of staffing plan to improve patient flow
NPs will provide evaluation of appropriateness of the MRI procedure	NPs will provide device management for patients with CIEDs undergoing an MRI
Promote patient safety	Compliance with CMS guidelines
Revenue generating	Development of electronic documentation workflows
Weaknesses	
Serving only neurological patients	
Opportunities	
Expand service for all patients with CIEDs	Creation of extended hours plan versus 24 hours/7 days per week coverage plan
Threats	
Nurse Practitioner FTE approval	Organization competing priorities (i.e.: new hospital construction)
Budget approval	

Appendix L – Budget/Financial Analysis

Nurse Practitioner Procedures	Year 1	Year 2	Year 3	Year 4	Year 5
	Phase 1	Phase 2			
Cardioversion (8/week)		***Ramp Up***			
Target Volume at Full Ramp Up = **416**	*208*	*416*	*416*	*416*	*416*
Charge	$2,031,083	$4,346,517	$4,650,773	$4,976,327	$5,324,670
Net Revenue (19% reiumbursement)	$430,134	$886,076	$912,658	$940,038	$968,239
Direct Cost (Including salaries and benefits)	$318,600	$443,833	$463,995	$485,103	$507,205
Contribution Margin	$111,534	$442,243	$448,663	$454,935	$461,034
Operating Margin	$89,039	$395,903	$400,933	$405,772	$410,397
MRI (22 conditional & non-conditional/week)					
Target Volume at Full Ramp Up = **1144**	*572*	*1144*	*1144*	*1144*	*1144*
Charge	$9,758,978	$20,884,212	$22,346,107	$23,910,335	$25,584,058
Net Revenue (19% reiumbursement)	$2,066,714	$4,257,432	$4,385,155	$4,516,709	$4,652,210
Direct Cost (Including salaries and benefits)	$2,031,104	$3,456,229	$3,591,150	$3,731,680	$3,878,066
Contribution Margin	$35,611	$801,202	$794,004	$785,029	$774,145
Operating Margin	($423,934)	($145,460)	($181,058)	($219,285)	($260,299)
Total Operating Margin	**($334,896)**	**$250,442**	**$219,875**	**$186,487**	**$150,098**
Total Incremental FTEs	**6**	**8**	**8**	**8**	**8**
Cost of Meetings					
Executive Leaders - VPs and Executive Directors (2 VPs/2 ED/4 qaurterly meetings) = $200/hr	$3,200	0	0	0	0
Physician Leaders (3 MDs/6 meetings) = $250/hr	$4,500		0	0	0
Managers/Nurse Practitioners (3 Managers/1 NP/12 meetings for 1st year; 2 meetings 2nd year) = $100/hr	$4,800	$800	0	0	0
Equipment - CIED Programmers (2) - Provided by vendor	0	0	0	0	0
Net Gain (Loss)	**($347,396)**	**$249,642**	**$219,875**	**$186,487**	**$150,098**

Appendix M – Outcome Measures



	# Stroke/TIA Patients	# General Neurology Patients	PM	ICD	CRT-P	CRT-D	# Pts excluded from MRI
1 week post-intervention							
Pre-assessment 2017	27	5	24	2	3	3	14

Appendix N – Statement of Non-Research Determination Form

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DNP Statement of Non-Research Determination Form

Student Name: Rosalie M. Geronimo

Title of Project: Expanding Access for Magnetic Resonance Imaging (MRI) for Patients with Cardiovascular Implantable Electronic Devices (CIEDs).

Brief Description of Project:

A) Aim Statement: The aim of this project is to decrease the number of patients with non-conditional CIEDs who present with acute neurological conditions, such as stroke or transient ischemic attack (TIA) and do not receive an MRI by 50% by October 2019.

B) Description of Intervention: The arrhythmia team will implement the recommended CIED MRI protocols for conditional and non-conditional CIEDs. We are proposing 24 hour/7 day a week Nurse Practitioner (NP) staffing coverage for the management of all CIEDs during an MRI.

C) How will this intervention change practice? Current state is an inefficient process with limited coverage. The assigned Device NP is only available Monday through Friday from 7:30am until 5:30pm. The NP will only manage the CIED during the MRI if it is scheduled, urgent requests may not be prioritized if there are competing priorities. Manufacturer clinical engineers provide management support as a back-up if the NP is not available, but their availability is not guaranteed. This intervention will create standardized staffing and device management support for all patients with CIEDs.

D) Outcome measurements: With the utilization of data analytics (Vizient and Paceart), we determined that in 2017, approximately 2.5 patients per month presented with an acute neurological condition, mostly stroke or TIA, but did not receive an MRI because of their non-conditional CIED. We will use the same data analytics to measure the outcome of the intervention.

To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used: (http://answers.hhs.gov/ohrp/categories/1569)

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X This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). Student may proceed with implementation.

☐ This project involves research with human subjects and must be submitted for IRB approval before project activity can commence.

Comments:

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST *

Instructions: Answer YES or NO to each of the following statements:

Project Title:	**YES**	**NO**
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	**X**	
The specific aim is to improve performance on a specific service or program and **is a part of usual care**. ALL participants will receive standard of care.	**X**	
The project is **NOT** designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does **NOT** follow a protocol that overrides clinical decision-making.	**X**	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	**X**	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	**X**	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	**X**	
The project has **NO** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	**X**	
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., **not** a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.	**X**	
If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: *"This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board."*	**X**	

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research.

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IRB review is not required. Keep a copy of this checklist in your files. If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

STUDENT NAME (Please print): Rosalie M. Geronimo

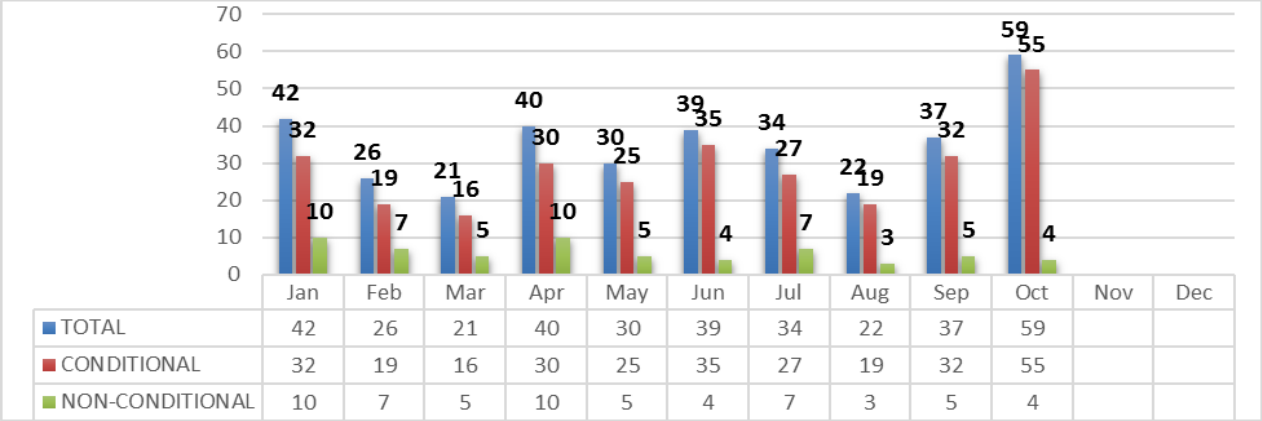
Signature of Student: _____ **DATE** 7/26/18

SUPERVISING FACULTY MEMBER (CHAIR) NAME (Please print): ELENA CAPELLA

Signature of Supervising Faculty Member (Chair): _____ **DATE** 10/13/18

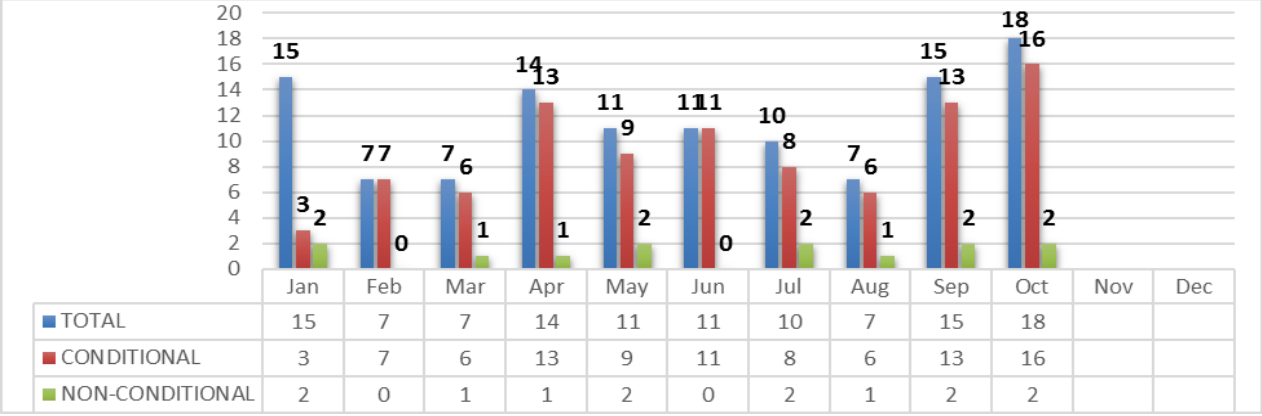
Appendix O – Clinical Business Analytics Report – CIED MRI Volumes

2019 ALL CIED MRI VOLUMES



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
TOTAL	42	26	21	40	30	39	34	22	37	59		
CONDITIONAL	32	19	16	30	25	35	27	19	32	55		
NON-CONDITIONAL	10	7	5	10	5	4	7	3	5	4		

2019 NEURO CIED MRI VOLUMES



	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
TOTAL	15	7	7	14	11	11	10	7	15	18		
CONDITIONAL	3	7	6	13	9	11	8	6	13	16		
NON-CONDITIONAL	2	0	1	1	2	0	2	1	2	2		

Appendix P – Neurology Study

Creating an Institutional Protocol for MRI in Patients with Legacy Cardiac Rhythm Devices

Collin J. Culbertson, MD[1]; Max Wintermark, MD[2]; Paul Wang, MD[3]; Angela Tsiperfal, MS, RN, ACNP, CNS[3]; Rosalie Geronimo, MSN, RN, CNL[3]; Teresa Nelson[2]; Connie Lund[2]; Carl A. Gold, MD, MS[1]

Stanford Health Care, Departments of Neurology[1], Neuroradiology[2], and Cardiovascular Medicine[3]

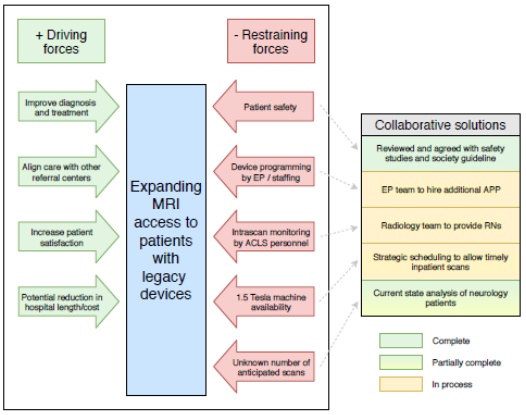
Problem Statement

Patients of Stanford Health Care (SHC) with older pacemakers or implantable cardioverter defibrillators (ICDs) could not have MRI scans, leading to delay in diagnosis and treatment.

Background

- MRI is invaluable for diagnosing and managing medical conditions, especially neurological disorders.
- Patients with pacemakers or ICDs could not have MRI unless their device was "MR-conditional" (first approved in 2011; only ~25% of active devices[1-2]).
- However, recent studies showed patients with non-conditional or "legacy" devices can undergo MRI safely[3-4].
- Despite this data, many referral centers including SHC have not developed protocols to accommodate this practice.

Force Field Analysis



SMART Goal / Intervention

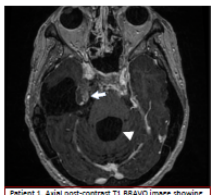
To improve timely diagnosis and treatment of patients with neurological disorders and legacy devices by launching a protocol for inpatient MRI starting July 2019.

Planned Data Analysis

- We will create a prospective database of inpatients with legacy devices undergoing MRI.
- Outcome measures:
  - Primary: change in diagnosis/treatment based on MRI
  - Secondary: change in device parameters (main safety outcome), time from order to scan, length of stay

Pilot Data

Age/ Sex	Diagnosis	Device	# of MRIs	Δ in dx/tx?	Δ in device parameters?
48M	Clival chordoma, hydrocephalus	Medtronic ICD	3	Yes	No
82F	Cerebral dural AV fistula	Boston Scientific PM	1	Yes	No
69M	SCC w/ perineural spread	Medtronic CRT-D	3	Yes	No



Patient 1. Axial post-contrast T1 BRAVO image showing residual clival chordoma with adjacent resection cavity (arrow) and ventriculomegaly (arrowhead).

Patient 3. Axial post-contrast T1 BRAVO image showing perineural spread of SCC along left cisternal trigeminal nerve extending into Meckel's cave (arrow).

Current State

- Our 2017 analysis of neurology patients showed ~2-3 patients per month present with legacy device and indication for inpatient MRI[5].
- Figures for other disorders requiring neuro MRI (such as CNS malignancy or spine disease) are unknown.

References

1. "Product performance report 2017, 2nd edition." Medtronic.
2. "Product performance report 2017, 2nd edition." Abbott (St. Jude Medical).
3. Russo RJ et al. N Engl J Med. 2017;376(8):755-764.
4. Nazarian S et al. N Engl J Med. 2017;377(26):2555-2564.
5. Culbertson CJ, Gold CA. Expanding access to MRI... Stanford QI Symposium 2018.

Sustain Plan

- Results will be used to further revise and improve the protocol and workflow as necessary, especially scheduling and staffing issues.
- Ideally, the policy can eventually be extended to outpatient settings.